United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-99-010 November 1999

EPA

Reregistration Eligibility Decision (RED)

CAPTAN

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA-738-F99-015
September 1999

EPA R.E.D. FACTS

CAPTAN

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act of 1996 (FQPA), EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0120, captan.

Use Profile

Captan is a fungicide used to control diseases on orchard crops, seed treatments, ornamentals, lawns and turf, and is also used as an in-can preservative in adhesives and paint. Formulations include dust, emulsifiable concentrate, flowable concentrate, water dispersible granules, wettable powder, and a variety of others.

Captan is applied by sprayers, chemigation equipment, power duster, liquid seed treater, paintbrush, tank-type sprayers, and other application methods. Captan is also applied as a post-harvest dip to apples, cherries and pears.

Regulatory History

Captan was first registered as a pesticide in the U.S. in 1951. EPA published the August 18, 1980 Notice of Rebuttable Presumption Against Reregistration (RPAR) because it had determined that captan exceeded certain risk criteria. The RPAR Notice was triggered by the Agency's receipt of data demonstrating that captan could induce oncogenic effects in experimental mammals (mice and rats).

The Agency issued a Registration Standard for captan in March 1986. The captan Registration Standard identified the data gaps required to be satisfied in order to continue the existing registration. A 1988 Data Call-In Notice required the submission of additional toxicity data.

EPA published the Position Document (PD4) "Captan; Intent To Cancel Registrations; Conclusion of Special Review" (54FR8116) on February 24, 1989. This notice announced the conclusion of EPA's Special Review and risk/benefit analysis of captan registrations. EPA evaluated additional data received and issues raised received during the Special Review process and decided to allow the continued registration of the following uses: all non-food uses, seed treatments, and certain food uses listed in the PD4 (almonds, apples, apricots, blackberries, blueberries, celery plant-beds, cherries, dewberries, eggplant plant-beds, grapes, green onions, lettuce, mangoes, nectarines, peaches, post-harvest pears, pepper plant-beds, pimento plant-beds, plums/prunes, raspberries, spinach plant-beds, strawberries, taro and tomato plant-beds). The Notice canceled all other uses.

Currently, 158 captan products are registered, of which nine are manufacturing-use products. Two technical registrants, Tomen Agro, Inc. and Makhteshim-Agan of North America, are members of the Captan Stewardship Task Force.

Human Health Assessment

Toxicity

The human health risk assessment evaluated toxicological and exposure data to develop dietary, drinking water, residential, aggregate and occupational exposure analyses, and to assess the adequacy of existing tolerances. Because the available studies demonstrated no indication of increased sensitivity of animals to *in utero* or postnatal exposure to captan and the database is complete, the Agency determined that there is no evidence of special sensitivity to infants and children. Therefore, the FQPA Safety Factor was removed (reduced to 1X) for captan and the RfD equals the PAD.

The developmental endpoint in rabbits, with a NOAEL of 10 mg/kg/day, was selected for the acute Reference Dose and the

short- and intermediate-term dermal risk assessments. A three-generation reproduction study in rats is the basis for the chronic RfD. The NOAEL in the study was 12.5 mg/kg/day. Captan is severely irritating to the eyes and is classified in the Toxicity Category I.

Captan is severely irritating to the eyes, and classified in Toxicity Category I based on corneal opacity in a rabbit study. Captan has been classified as a B2 probable human carcinogen, based on increased incidence of intestinal tumors in mice and rats. To estimate human cancer risks, the Agency used a linear, low dose extrapolation approach for captan. Based on intestinal tumors in mice, a Q1* of 2.4×10^{-3} $(mg/kg/day)^{-1}$ was calculated.

Dietary Exposure

EPA has assessed the acute and chronic dietary risk posed by captan, considering food and water sources of potential residues. Residues of captan plus the metabolite THPI were included in the anticipated residues for chronic (non-cancer) exposure and acute exposure in meat and milk.

To determine the risk from captan in foods, the Agency conducted acute, chronic (non-cancer) and chronic (cancer) dietary analyses. The acute analysis used a probabilistic dietary risk assessment estimated and the chronic dietary exposure was assessed using refinements such as anticipated residues and percent crop treated information. Since THPI is not considered carcinogenic, the cancer risk assessment considered only the residues of captan ***per se.***

The Agency has reassessed captan food and feed tolerances under the standards of FQPA. Crop group tolerances are being established for various groups of related vegetables. Many of these tolerances support seed treatment only, as the foliar applications have not been permitted since the PD4 was issued in 1989. The crop subgroup tolerance for caneberries (raspberries and blackberries) is being established to support Special Local Needs registrations in Oregon, Ohio, Pennsylvania, South Carolina, and Washington.

Occupational and Residential Exposure

For occupational risk, different routes of exposures are considered. As mentioned previously, captan is severely irritating to the eyes, and for dermal exposure, a dermal absorption rate of 0.4%/hour was selected. The assessments also assume that captan is taken up through the inhalation pathway to the same degree as oral ingestion.

Residential exposure to captan residues can occur by dermal and inhalation routes. Also, postapplication residential dermal exposure is expected from gardening and lawn activities on captan treated areas. The Agency is concerned about postapplication exposure to toddlers hand-to-mouth activity on treated lawns. The registrant has agreed to voluntarily cancel this use. Captan is also incorporated in paints and adhesives. Homeowner use of captan containing paints and adhesives do not result in a risk concern to the Agency.

Human Risk Assessment

The human health risk assessment evaluated toxicological and residue data, and included dietary, drinking water, aggregate, residential, and occupational exposure, as required by FQPA. The FQPA Safety Factor was removed as there is no evidence that there is increased sensitivity to infants and children from exposure to captan, and the database is complete for evaluating FQPA concerns.

An acute probabilistic dietary risk assessment estimated that acute dietary exposure to be 36% of the acute population adjusted dose (aPAD) at the 99.9th percentile. The chronic non-cancer dietary risk from exposure to captan is <2% of the chronic population adjusted dose (cPAD). The upper bound dietary cancer risk for the U.S. population is 1.3×10^{-7}, which is below the Agency's level of concern for lifetime excess cancer risk. The Agency has also determined that there is no risk concern from the consumption of captan residues in drinking water.

The Agency has also examined aggregate risk. These assessments take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information including pesticide residues in drinking water, exposure from pesticides uses in and around the home, and exposure in non-residential settings such as, parks and schools.

Residential exposure to captan may occur either during or after a captan application to home gardens, ornamental flowers, shrubs, or seeds. Exposure may also occur to golfers from treated golf courses. Because of concern about toddlers exposed to treated lawns, the technical registrants have agreed to voluntarily cancel these uses. For all other residential uses, exposure and risks do not exceed the Agency's level of concern.

The Agency has determined that acute and chronic dietary (food and water) and cancer aggregate risks are not of concern. Residential exposure from the use of captan around the home does not exceed the Agency's level of concern when aggregated with food and drinking water exposure.

For occupational scenarios, most risk estimates were well above 100 (values below 100 are a concern for captan) with cancer risks ranging from 1.3×10^{-5} to 1.7×10^{-9}. No additional mitigation is required to address occupational cancer risks. There is a concern for mixers and loaders of wettable powder for the aerial application of captan. The Agency believes that this risk will be adequately mitigated by requiring water soluble bags or a suitable reduction in application rate. Reentry Intervals were also reevaluated during the RED process and new REIs are being established ranging from 12-hours for seed treatment uses to 4-days for ornamentals.

The Agency is aware of a proposed common mechanism of carcinogenicity between captan and folpet, which implicates their common metabolite, thiophosgene. Because thiophosgene is so highly reactive in animal systems, its residues cannot be scientifically quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the rate of thiophosgene formation may be different for both compounds. The Agency has conducted a conservative aggregate assessment for thiophosgene, assuming that it may cause cancer through both captan and folpet, and has determined that this conservative risk is not of concern.

The FQPA also directed the Agency to develop an Endocrine Disruptor Screening Program, which was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of captan and end-use products for endocrine effects may be required.

Environmental Assessment

Environmental Fate

Captan dissipates rapidly in the environment, with a half-life of less than 1 day, based on the results of hydrolysis and aerobic soil studies. Parent captan is slightly mobile to relatively immobile in various soils. The major degradates, THPI and THPAm, appear to be mobile in soil. Though these degradates have the potential to reach ground and surface water, they are not expected to be persistent.

Ecological Effects

For ecological risk, only acute toxicity to freshwater fish is of concern. There are no reported fish kills. Additionally, the Agency has determined that captan is: practically nontoxic to avian species, both on an acute and subacute basis; not acutely toxic to mammals,

and relatively nontoxic to insects. Terrestrial and aquatic plant toxicity is not a concern. Both THPI and THPAm were found to be non-toxic to fish species tested. The Agency is requiring a 96-hour oyster shell deposition study, however, these data are considered confirmatory and are not expected to change the conclusions of this risk assessment.

Risk Mitigation

To reduce the risks posed by captan, the Agency is requiring the following mitigation measures for captan-containing products:

- Voluntary cancellation of the residential turf use;
- Water-soluble packaging for the wettable powder formulation used aerially
- Various Personal Protective Equipment, including chemical-resistant gloves, aprons/coveralls, eye protection, and dust/mist respirators;
- Revised labeling to reduce the risks to non-target aquatic organisms;
- Eye wash stations for occupational field workers; and
- Double notification for workers entering treated fields.

Additional Data Required

EPA is requiring the following additional generic studies for captan to confirm its regulatory assessments and conclusions: the 96-hour oyster shell deposition study,72-3(b), Acute Estuarine/Marine Toxicity - Mollusk; 81-1 Acute Oral Toxicity (rat); 81-2 Acute Dermal Toxicity (rat/rabbit); 81-3 Acute Inhalation Toxicity (rat); 875.2400 Dermal Exposure; 875.2500 Inhalation Exposure; product-specific data including product chemistry, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration. These data are considered to be confirmatory and are not expected to change the conclusions of this RED.

Product Labeling Changes Required

All captan end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see Section V of the captan RED document.

Regulatory Conclusion

EPA has determined that products containing captan are eligible for reregistration, except for those with uses on turf and aerially-applied wettable powder formulations. Products applied to turf at sod farms or golf courses are eligible for reregistration; uses at all other turf sites are being voluntarily canceled. Wettable powder

formulations that are applied aerially are eligible for reregistration, provided either: 1) the products are packaged in water soluble packaging; or 2) the application rates are reduced to a level that is no higher than 1.2 lb ai/A. The use of eligible captan products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to captan will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for captan during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

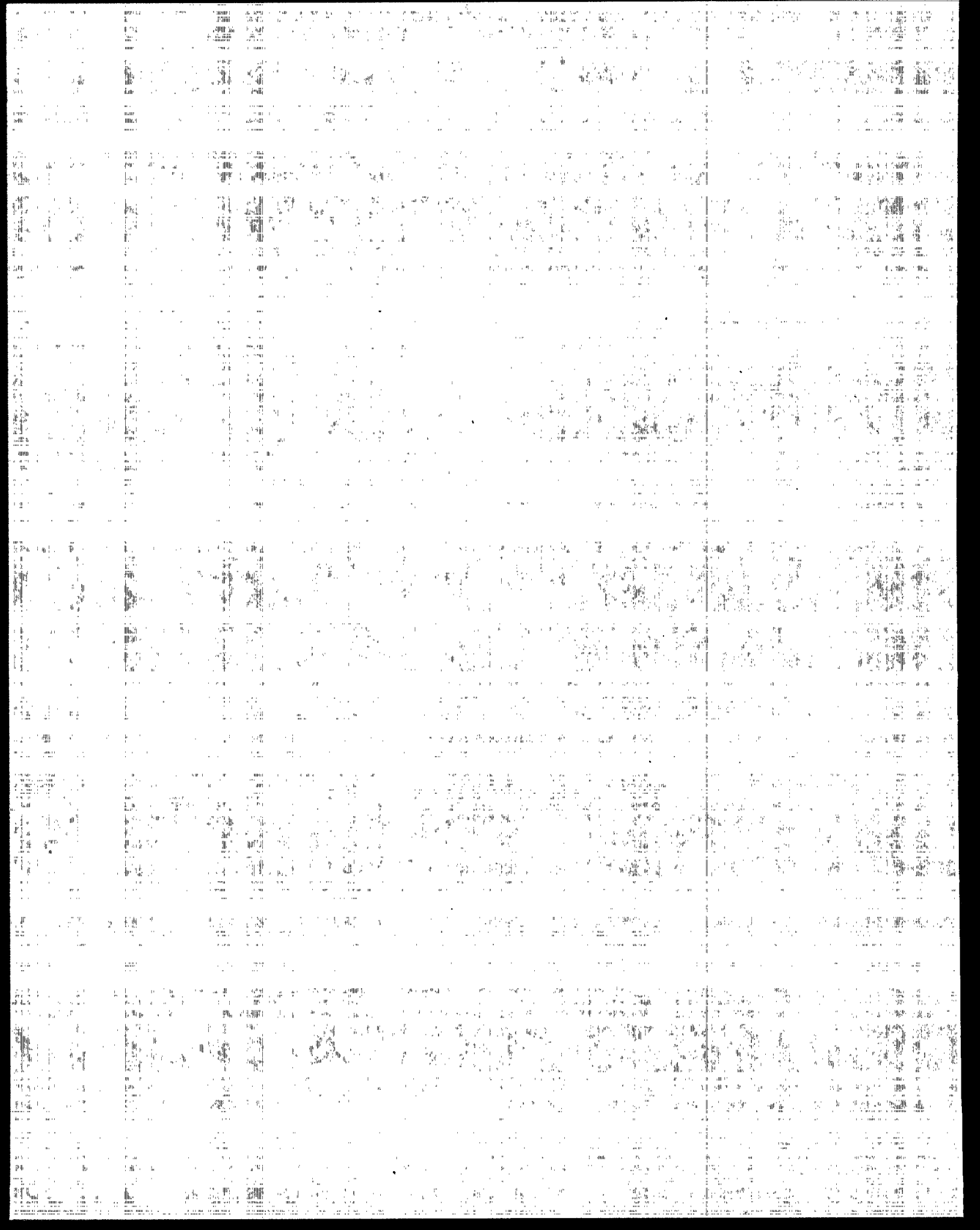
Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the captan RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-605-6000.

For more information about EPA's pesticide reregistration program, the captan RED, or reregistration of individual products containing captan, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN) toll-free at 1-800-858-7378. Their Internet address is ace.orst.edu/info/nptn.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

NOV - 2 1999

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case #0120 which includes the active ingredient captan. The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1999, and contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 (FQPA) became effective on August 3, 1996, amending portions of both pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the required generic data requirements or wish to meet with the Agency on specific decisions made in the RED, please contact the Special Review and Reregistration Division representative Kylie Rothwell at 703-308-8055. Address any questions on product specific data requirements or specific changes required to the Special Review and Reregistration Division representative Karen Jones at 703-308-8047.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-605-6000).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must

comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration.** You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Citation of Data**. Complete and sign EPA form 8570-34 and 8570-35 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

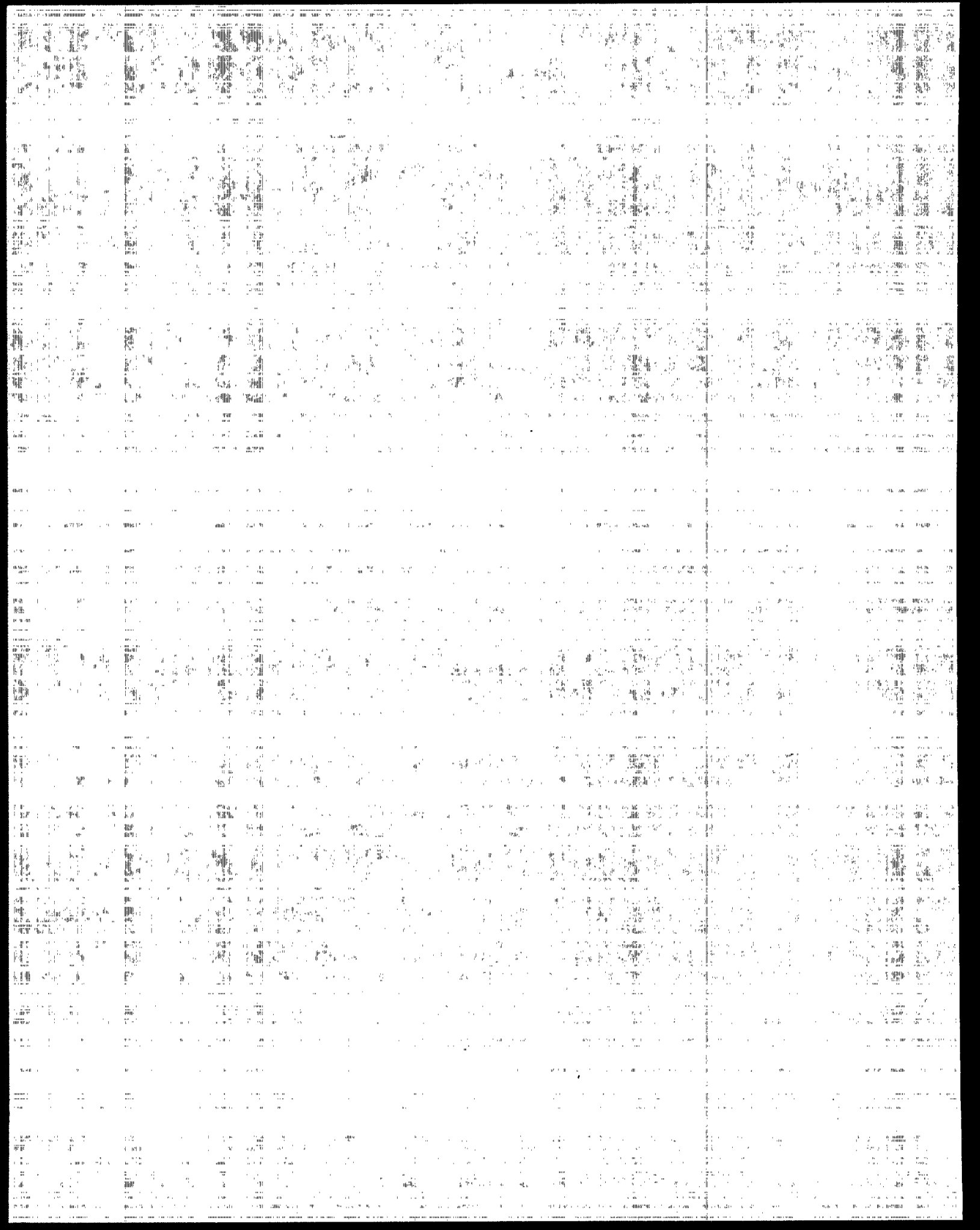
6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

CAPTAN

LIST A

CASE 120



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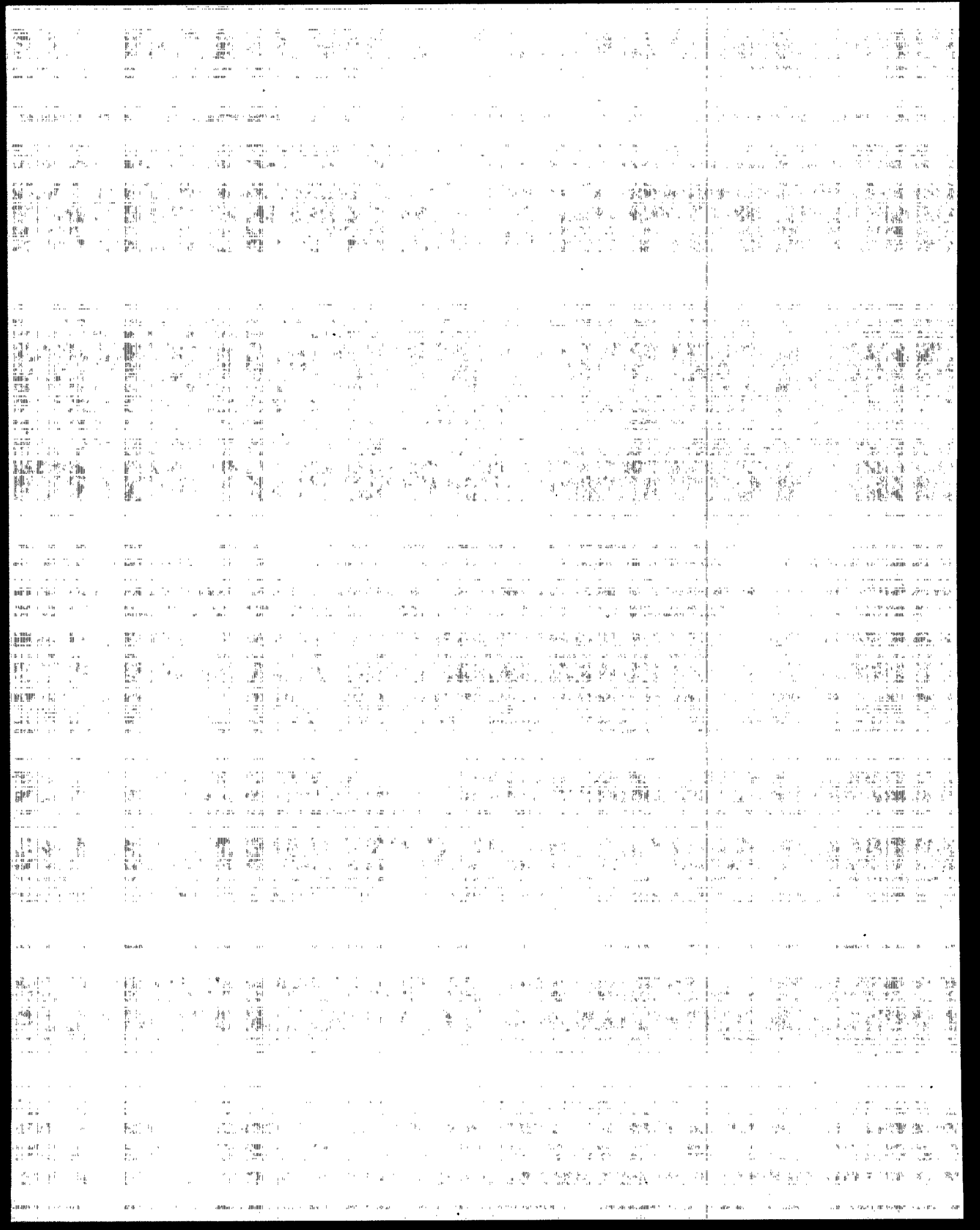


CAPTAN REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis

John Faulkner	Economic Analysis Branch
Steve Jarboe	Biological Analysis Branch
Rich Michell	Biological Analysis Branch

Environmental Fate and Effects Assessment

Iwona Mayer	Environmental Risk Branch I
Kevin Costello	Environmental Risk Branch I
Harry Craven	Environmental Risk Branch III
Richard Mahler	Environmental Risk Branch I
Norman Birchfield	Environmental Risk Branch I

Health Effects Risk Assessment

David Hrdy	Reregistration Branch IV
Thurston Morton	Reregistration Branch IV
Sanju Diwan	Reregistration Branch IV
Paula Deschamp	Reregistration Branch II
Shiela Piper	Chemistry and Exposure Branch I

Registration Support

Cynthia Giles-Parker	Fungicide Herbicide Branch

Risk Management

Kylie Rothwell	Reregistration Branch III
Kathryn Boyle	Reregistration Branch III
Susan Jennings	Reregistration Branch III

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWLOC	Drinking Water Level of Comparison
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observational Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
µg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level

GLOSSARY OF TERMS AND ABBREVIATIONS

NOAEL	No Observed Adverse Effect Level
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose, the Reference Dose adjusted to include the FQPA Safety Factor
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RTU	Ready to Use Pesticide
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 © of FIFRA)
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The US Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide captan (N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide).The Agency has considered generic data to support the reregistration of captan and determined that these data are sufficient to support reregistration of products containing captan, except for those with uses on turf and aerially-applied wettable powder formulations. Products applied to turf at sod farms or golf courses are eligible for reregistration; uses at all other turf sites are being voluntarily canceled. Wettable powder formulations that are applied aerially are eligible for reregistration, provided either: 1) the products are packaged in water soluble packaging; or 2) the application rates are reduced to a level that is no higher than 1.2 lb ai/A.

This reregistration decision also considered the requirements of the "Food Quality Protection Act of 1996" (FQPA) which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon enactment on August 3, 1996 and the new REDs are being evaluated under the new standards imposed by FPQA. The Act directs EPA to consider the potential for increased susceptibility of infants and children, to evaluate the toxic effects of pesticide residues, and to develop a screening program to determine whether pesticides produce endocrine disrupting effects.

Captan is a non-systemic fungicide used to control diseases in orchard crops, berries, seeds, turf, and ornamentals. Captan is also incorporated into paint and adhesives as an in-can preservative. The pesticide has several formulations and is applied by various methods, including aerial, airblast, and groundboom. Captan is also applied as a postharvest dip to apples, cherries and pears. Captan's technical registrants are Tomen Agro, Incorporated, and Makhteshim-Agan of North America, who are both members of the Captan Stewardship Task Force.

Reregistration Eligibility

The Agency has concluded, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that captan products, when labeled and used as specified in this document, will not cause unreasonable adverse effects on human health or the environment and are, therefore, eligible for reregistration. The Agency has conducted both human health and ecological risk assessments for captan, and has also evaluated data on its major degradates, THPI and THPAm. The Agency has determined that THPAm has no toxicological significance. However, THPI does have toxicological significance and was included in the dietary risk assessment. For captan, the carcinogenic process is thought to be triggered by the highly reactive but short-lived metabolite thiophosgene. The Agency has classified parent captan as a B2 (probable human) carcinogen. Since THPI is not believed to contribute to the carcinogenicity of captan, it is not factored into the cancer risk assessment.

Human Health Effects

The human health risk assessment evaluated toxicological and exposure data to develop dietary, drinking water, residential, aggregate and occupational exposure analyses, and to assess the adequacy of existing tolerances. Because the available studies demonstrated no indication of increased sensitivity of animals to *in utero* or postnatal exposure to captan and the database is complete, the Agency determined that there is no evidence of special sensitivity to infants and children. Therefore, the FQPA Safety Factor was removed (reduced to 1X) for captan and the RfD equals the PAD.

The developmental endpoint in rabbits, with a NOAEL of 10 mg/kg/day, was selected for the acute Reference Dose and the short- and intermediate-term dermal risk assessments. A three-generation reproduction study in rats is the basis for the chronic RfD. The NOAEL in the study was 12.5 mg/kg/day. Captan is severely irritating to the eyes and is classified in the Toxicity Category I.

The Agency is aware of a proposed common mechanism of carcinogenicity between captan and folpet, which implicates their common metabolite, thiophosgene. Because thiophosgene is so highly reactive in animal systems, its residues cannot be scientifically quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the rate of thiophosgene formation may be different for both compounds. The Agency has conducted a conservative aggregate assessment for thiophosgene, assuming that it may cause cancer through both captan and folpet, and has determined that this conservative risk is not of concern.

To determine the risk from captan in foods, the Agency conducted acute and chronic dietary analyses. An acute probabilistic dietary risk assessment estimated that acute dietary exposure to be 36% of the acute population adjusted dose (aPAD) at the 99.9th percentile. Chronic dietary exposure was assessed using refinements such as anticipated residues and percent crop treated information. The chronic non-cancer dietary risk from exposure to captan is <2% of the chronic population adjusted dose (cPAD). The upper bound dietary cancer risk for the U.S. population is 1.3×10^{-7}, which is below the Agency's level of concern for lifetime excess cancer risk. The Agency has also determined that there is no risk concern from the consumption of captan residues in drinking water.

Residential exposure to captan may occur either during or after a captan application to home gardens, ornamental flowers, shrubs, or seeds. Exposure may also occur to golfers from treated golf courses. Because of concern about toddlers exposed to treated lawns, the technical registrants have agreed to voluntarily cancel these uses. For all other residential uses, exposure and risks do not exceed the Agency's level of concern.

The Agency has determined that acute and chronic dietary (food and water) and cancer aggregate risks are not of concern. Residential exposure from the use of captan around the home

does not exceed the Agency's level of concern when aggregated with food and drinking water exposure.

For occupational scenarios, most risk estimates were well above 100 (values below 100 are a concern for captan) with cancer risks ranging from 1.3×10^{-5} to 1.7×10^{-9}. There is a concern for mixers and loaders of wettable powder for the aerial application of captan. The Agency believes that this risk will be adequately mitigated by requiring water soluble bags or a suitable reduction in application rate. Reentry Intervals were also reevaluated during the RED process and new REIs are being established ranging from 12- hours for seed treatment uses to 4-days for ornamentals.

The Agency has reassessed captan food and feed tolerances under the standards of FQPA. Because THPI was detected in plant metabolism studies at less than 10% of total residues, the tolerance expression for plant commodities should remain as captan *per se*. Because captan is extensively metabolized to THPI in animal tissues, the tolerance expression for captan residues in animal commodities should include THPI as well as captan. Crop group tolerances are being established for various groups of related vegetables. Many of these tolerances support seed treatment only, as the foliar applications have not been permitted since the PD4 was issued in 1989. The crop subgroup tolerance for caneberries (raspberries and blackberries) is being established to support Special Local Needs registrations in Oregon, Ohio, Pennsylvania, South Carolina, and Washington.

Ecological Risks

For ecological risk, only acute toxicity to freshwater fish is of concern. The Agency is requiring label modifications, including updated spray drift language, that are expected to mitigate this risk. There are no reported fish kills. Additionally, the Agency has determined that captan is: practically nontoxic to avian species, both on an acute and subacute basis; not acutely toxic to mammals, and relatively nontoxic to insects. Terrestrial and aquatic plant toxicity is not a concern. Both THPI and THPAm were found to be non-toxic to fish species tested. The Agency is requiring a 96 - hour oyster shell deposition study, however, these data are considered confirmatory and are not expected to change the conclusions of this risk assessment.

For environmental fate concerns, captan dissipates rapidly, with a half-life of less than 1 day, determined by hydrolysis and soil aerobic studies. THPI and THPAm are not expected to persist in ground and surface water.

Risk Mitigation

To reduce the risks posed by captan, the Agency is requiring the following mitigation measures for captan-containing products:

- Voluntary cancellation of the residential turf use;

- Water-soluble packaging for the wettable powder formulation used aerially
- Various Personal Protective Equipment, including chemical-resistant gloves, aprons/coveralls, eye protection, and dust/mist respirators;
- Revised labeling to reduce the risks to non-target aquatic organisms;
- Eye wash stations for occupational field workers; and
- Double notification for workers entering treated fields.

Before reregistering the products containing captan, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and the submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "The Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately and EPA initiated an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food use pesticides. The FQPA does not, however, amend any of the existing reregistration deadlines set forth in §4 of FIFRA. Therefore, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of captan including the risk to infants and children for any potential dietary, drinking water, dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes captan, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for captan. Section V discusses the reregistration requirements for captan. Finally, Section VI contains the Appendices that support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available upon request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Captan
- **Chemical Name:** N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide
- **Chemical Family:** Dicarboximides
- **CAS Registry Number:** 133-06-2
- **OPP Chemical Code:** 081301
- **Empirical Formula:** $C_9H_8Cl_3NO_2S$
- **Trade and Other Names:** Merpan, Orthocide, Vondcaptan, Vancide-89, SR-46
- **Basic Manufacturer:** Gustafson, LLC; Makhteshim-Agan of North America; Drexel Chemical Co.; and Tomen Agro, Inc.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods.

Type of Pesticide: Fungicide or antimicrobial pesticide

Use Sites: Variety of terrestrial food/feed crops, greenhouse food crops, indoor food (fruit dips), indoor non-food (e.g., paints, adhesives, etc.), seed treatments and ornamental sites

Target Pests: Numerous fungi and microbials

Formulation Types: Dust (5 to 75%), emulsifiable concentrate (6 to 29%), flowable concentrate (10 to 75%), ready-to-use liquid (14 to 30%), liquid soluble concentrate (12%), solid (62 to

90%), water dispersible granules (75%), wettable powder (6 to 80%), wettable powder/dust (5 to 50%)

Application Techniques: Applied at all phases of crop growth including: seed, foliage, blossom, soil, fruit, dormant, dip, and post-harvest commodity treatment. Also used in industrial applications as a bacteriostat.

Methods: Broadcast treatment, chemigation, dust, dip, and seed treatment to soil and spot treatments

Equipment: Aerial equipment; airblast; chemigation equipment; dip tank; drill box; duster; hand held duster; liquid seed treater; paintbrush; paper bag; planter/seed box; power duster; seed treater; slurry-type seed treater; spray-dip machine; sprayers; squeeze applicator; tank; and tank-type sprayer

C. Estimated Usage of Pesticide

The table below summarizes the best available estimates for the pesticide uses of captan. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Domestic Foliar Usage of Captan

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Avg Rate of Application		States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	#app /yr	lb ai/ A/app	(state and % ai used)
Almonds	429	80	112	19%	26%	300	382	1.2	3.2	CA 100%
Apples	572	270	376	47%	66%	2,000	3,600	4.3	1.7	MI NY PA NC VT VA 59%
Apricots	19	4	8	18%	42%	13	30	1.0	3.7	
Blackberries	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Blueberries (huckleberries)	59	36	41	61%	69%	250	495	3.7	1.9	MI ME NJ 88%
Cherries, Sweet	64	8	12	12%	19%	18	40	1.9	1.2	MI OR 90%
Cherries, Tart	64	18	28	28%	44%	62	120	3.2	1.1	NY MI 86%
Dewberries	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Grapes	825	40	100	5%	12%	100	250	2.1	1.2	CA NY AZ MO AR VA 83%
Nectarines	29	3	8	10%	27%	13	29	1.3	3.2	CA 100%
Peaches	212	86	118	41%	56%	550	692	3.6	1.8	SC AL MI NJ PA AR 57%
Plums	64	8	16	13%	25%	32	61	1.0	3.8	MI CA 92%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Avg Rate of Application		States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	#app /yr	lb ai/ A/app	(state and % ai used)
Prunes	80	25	44	31%	55%	93	164	1.2	3.2	CA 100%
Raspberries	11	7	8	62%	68%	36	53	3.1	1.6	WA OR 93%
Strawberries	50	31	45	63%	89%	540	1,086	8.2	2.1	FL CA PA 83%
Total		**616**	**915**			**4006**	**7000**			
Post Harvest										
Apples	-	-	-	11%	22%	3	-	-	-	
Cherries	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Pears	-	-	-	20%	40%	0.2	-	-	-	

SOURCES: EPA data (1987-97), USDA (1990-97), and National Center for Food and Agricultural Policy (1992 data)Tables exclude all uses that have been cancelled as a result of the 1989 Special Review Decision.

COLUMN HEADINGS:

Weighted average is based on the most recent years, with more reliable data weighted more heavily
Estimated Maximum is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA - Calculated numbers may not agree due to rounding to nearest 1000 for acres treated (0 acres =< 500) and to nearest whole percentage for % of crop treated (0% = < 0.5%). Dash (-) indicates NOT available or insufficient data in EPA sources.

Seed Treatment - Usage of Captan in 1990

Seed Treated	% Seeds Treated	Seed Treated (million lbs)	App Rate lb ai/1000 lb seed	Applied lb ai (000)	Seeding Rate Lb seed/Acre	lb ai/Acre on Seeds	Acres Planted (000)
Corn	100%	1,020	0.7	714	14	0.01	72,857
Sweet corn	80%	18	1.0	18	16	0.02	1,100
Beans	80%	144	1.0	144	60	0.06	2,384
Peas	90%	99	1.0	99	220	0.22	451
Potatoes	11%	290	0.8	246	2,000	1.70	145
Soybeans	5%	141	0.7	98	60	0.04	2,342
Sorghum	100%	77	1.6	123	7	0.01	10,694
Peanuts	60%	106	1.6	170	102	0.16	1,040
Cotton	50%	147	1.4	206	24	0.03	6,133
Rice	0%			-	-	0.00	-
Total Seed		2,042		1,818			97,147

SOURCES: EPA data (1991)

D. Data Requirements

The Agency required the registrants to submit studies as specified in 40 CFR Section 158. Data from these studies are sufficient to characterize the risks associated with the uses described in this document. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Captan was first registered as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act in 1951 for the control of fungal diseases of fruit crops. Prior to 1980, there were many use-patterns registered and tolerances established for this broad spectrum fungicide. Currently, there are 159 registered products (including 17 State and Local Needs) containing captan.

In 1980, EPA published a Notice of Rebuttable Presumption because it had concluded that there were adequate data to determine that captan could induce oncogenic effects in experimental mammals (mice and rats). In addition, mutagenicity studies demonstrated that captan could cause gene mutations in bacteria, in eukaryotic microorganisms and in mammalian cells in culture. The public notice requested that registrants and other interested persons submit rebuttals and other information on the presumption and to submit any other data on the risks and benefits of captan.

A DCI issued April 29, 1985 required the submission of residue chemistry and toxicology studies. Subsequently, a proposed-decision was published (50 FR 25884), which was quickly followed by a supporting document entitled, "Captan Special Review Position Document 2/3." Based on cancer risks, it was proposed that all food-uses of captan be canceled and that all seed treatments be retained. The proposal allowed time for additional residue chemistry data to be submitted to refine the amount of residues used in the dietary assessments. The proposal also: allowed the continued feeding of detreated corn seed to cattle and hogs, if fed at least fourteen days prior to slaughter; required workers to wear dust masks and impermeable gloves when applying, mixing or loading captan formulations; and required harvesters and weedpickers to wear water-resistant gloves when working in fields or nurseries in which ornamentals have been treated with captan formulations. For non-agricultural uses of captan, the Agency proposed that: persons incorporating captan into products such as adhesives, plastics and paints wear impermeable gloves, respirators and protective clothing; and labels be amended to require impermeable gloves when applying oil-based paints for home or professional use.

In March, 1986, the Agency issued a Registration Standard for captan. The Registration Standard summarized the data that had been submitted in support of the captan registration and identified data gaps that needed to be addressed in order to reregister all captan pesticide products. A 1988 Data Call-In Notice required the submission of a 90-day rat inhalation study and a 90-day dermal study in rats.

In 1989, the Agency published the Position Document (PD4) to conclude the Special Review of captan (54 FR 8116). This notice announced the conclusion of the Agency's Special Review and risk/benefit analysis of captan registrations. EPA evaluated the issues raised in the PD 2/3 and additional data received during the Special Review process. With this notice, the Agency determined that the following uses of captan could remain: all non-food uses, seed treatments, and a subset of the existing food uses (almonds, apples, apricots, blackberries, blueberries, plant-bed for celery, cherries, dewberries, plant-bed for eggplant, grapes, lettuce,

mangoes, nectarines, green onions, peaches, post-harvest on pears, plant-bed for peppers, plant-bed for pimentos, plums/prunes, raspberries, plant-bed for spinach, taro, and plant-bed for tomatoes). Some of these uses have been subsequently canceled by the registrants. The notice also disallowed the use of captan on: avocados, beans, beets, broccoli, Brussels sprouts, cabbage, canteloupes, carrots, cauliflower, celery (foliar), collards, corn (sweet), cotton, crabapples, cranberries, cucumbers, eggplant (foliar), grapefruit, honeydew, kale, leeks, lemons, limes, muskmelon, mustard greens, onions (dry bulb), oranges, pears (pre-harvest), peas, peppers (foliar), pimentos (foliar), pineapple, potatoes, pumpkin, quince, rhubarb, rutabagas, shallots, soybeans, squash, tangerines/tangelos, tomatoes (foliar), turnips, and watermelon.

Later in 1989, the Agency issued a proposed rule (54 FR 35891) to revoke the feed additive regulation (40 CFR 186.500). The final rule revoking the tolerances was published on August 4, 1993 (58 CFR 1430-2). Additional tolerances were revoked on January 25, 1999 (63 FR 57067-77)

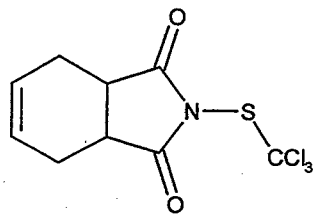
III. SCIENCE ASSESSMENT

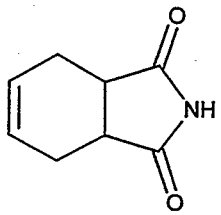
A. Physical Chemistry Assessment

The product chemistry data base for captan is incomplete. To maintain continued registration of captan following issuance of the RED, the product chemistry data gaps identified in Appendix B must be fulfilled. These data are considered confirmatory and are not expected to change the conclusions of this risk assessment.

1. Identification of the Active Ingredient

Captan [(N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide)(trade names: Merpan, Orthocide, Vondcaptan, Vancide-89 and SR-46)] belongs to the chemical class of dicarboximides or chlorinated organosulfur compounds.





Captan		THPI (Captan metabolite)	
Empirical Formula:	$C_9H_8Cl_3NO_2S$	Molecular Weight:	151.16
Molecular Weight:	300.61	Empirical Formula:	$C_8N_9O_2$
CAS Registry No.:	133-06-2		
PC Code:	081301		
IUPAC Name:	1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide		

Pure captan is a colorless crystalline solid with a melting point of 178°C; a vapor pressure of <1.3 mPa at 25°C; and an octanol/water partition coefficient of 610 at 25°C. Solubility of captan in water is 3.3 mg/l at 25°C and it is soluble in acetone, ethyl alcohol, kerosene, xylene, chloroform, and benzene.

2. Manufacturing-Use Products

There are nine manufacturing-use products registered at this time: an 88% formulation intermediate and an 88% technical (19713-258, 19713-500) registered to Drexel Chemical Company; an 88% technical registered to Gustafson, Inc. (7501-24); an 88% technical registered to Makhteshim-Agan of North America Inc. (11678-1); three 88% technicals and an 87% formulation intermediate registered to Tomen Agro, Inc. (66330-31, 66330-32, 66330-33 and 66330-34, respectively), and an 88% formulation intermediate registered to Sostram (72304-3). Both Tomen Agro, Inc. and Makhteshim-Agan are members of the Captan Stewardship Task Force.

B. Human Health Assessment

1. Toxicology Assessment

The toxicology database is adequate to assess health hazards resulting from exposure to captan. In acute toxicity studies, captan is not toxic via the oral route, and has low toxicity via the dermal and inhalation routes. Captan is severely irritating to the eyes. Repeated dose toxicity studies (e.g. 21-day dermal, 90-day subchronic inhalation and chronic oral) indicate that thiophosgene causes local irritation of the skin, larynx or lining of the gastrointestinal (GI) tract depending upon the site where it is generated.

In chronic studies, captan causes cancer in mice and rats. The Agency has classified captan as a B2 (probable human) carcinogen, based on an increased incidence of intestinal tumors in mice. It also caused an increased incidence of renal neoplasms in male Charles River CD rats and an increased incidence of uterine sarcomas in Wistar rats. A Q_1^* approach is used for cancer risk assessment.

Captan is a member of the N-trihalomethylthio group of compounds (including folpet) which metabolize to the highly reactive species thiophosgene. Much of the observed toxicity of captan can be explained by the release of thiophosgene, which is a highly reactive, short-lived metabolite. Thiophosgene is likely responsible for the irritant properties of captan and may be responsible for the intestinal tumors in mice, although its exact mode of action is unclear. Because of rapid metabolism of captan and high reactivity of its thiophosgene metabolite, these chemicals are unlikely to accumulate in the body.

At doses that are maternally toxic, captan causes developmental effects in experimental animals producing delayed ossification and post-implantation loss in hamsters, and increases in skeletal defects in rabbits. At doses that are toxic to the parent, captan causes decreased pup litter weights in a reproduction study.

a. Toxicology Endpoint Selection

The Agency has established toxicological endpoints for acute and chronic dietary, as well as occupational and residential (dermal and inhalation) exposure risk assessments for captan. The selection of these toxicological endpoints is based on a comprehensive evaluation of the available toxicology data as well as the use pattern/exposure profile for captan.

For deriving the acute Reference Dose (RfD), the Agency selected the developmental NOAEL of 10 mg/kg/day from the prenatal developmental toxicity study in rabbits. This endpoint was selected because it is thought that the observed developmental effects could occur following a single exposure, however, since these effects can occur only *in utero,* they are applicable only to the acute risk assessment for females (ages 13-50). Following a review of the available toxicology database, the Agency did not identify any other *ex utero* toxicological endpoint that could be attributed to a single exposure of captan. This review included consideration of the maternal effects noted in the developmental toxicity studies; however, the maternal effects noted in these studies (mortality, decreased body weight and food consumption) were not attributed to a single dose of captan. Therefore, no separate acute endpoint was selected for the general population, which includes infants and children. Thus, a risk assessment was conducted only for the females (13 - 50).

The developmental endpoint in rabbits, with a NOAEL of 10 mg/kg/day, was also selected for the short- and intermediate-term dermal risk assessments. The 21-day dermal toxicity study in rabbits was not selected for these risk assessments, even though it is the most appropriate route of exposure. In this study, repeated dermal application of captan caused dermal irritation, but only

minimal systemic effects (reductions in body weight, body weight gain, and food consumption) at a dermal dose of 1000 mg/kg/day, with a systemic NOAEL of 110 mg/kg/day. However, effects on fetuses are not investigated in a guideline 21-day dermal toxicity study. Thus, because of the potential for occupational or residential dermal exposure to pregnant women, the more conservative NOAEL from the oral developmental toxicity study in rabbits was considered appropriate for the short- and intermediate-term dermal risk assessments.

Summary of Doses and Endpoints Selected for Captan Risk Assessments

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study
Acute Dietary Female 13+	NOAEL=10 UF = 100 FQPA = 1	30 mg/kg/day based on increased skeletal defects (27 pre-sacral vertebrae) in fetuses. Applies to females 13+ only; no appropriate endpoint for general population.	Developmental Toxicity Study in Rabbits
	Acute RfD=aPAD = 0.1 mg/kg/day		
Chronic Dietary	NOAEL=12.5 UF = 100 FQPA = 1	25 mg/kg/day based on decreased pup body weight	One- and three-generation repro Studies-Rat
	Chronic RfD = cPAD = 0.13 mg/kg/day		
Correction for oral to dermal exposure necessary (0.4% per hour; dermal absorption factor)			
Short- and Intermediate-Term (Dermal)	Oral NOAEL=10 UF = 100	30 mg/kg/day based on increased skeletal defects (27 pre-sacral vertebrae)	Developmental Toxicity Study in Rabbits
Long-Term (Dermal)	None	Use pattern and exposure indicate no need for long-term risk assessment	
Use 100% lung absorption relative to oral absorption			
All Durations (Inhalation)	Oral NOAEL=10 UF = 100	30 mg/kg/day based on increased skeletal defects (27 pre-sacral vertebrae)	Developmental Toxicity Study in Rabbits
Q_1^*	2.4×10^{-3}	Based on findings of intestinal tumors in mice	Mouse Oncogenicity

(1) Reference and Population Adjusted Doses

As indicated earlier, the Agency is establishing an acute Reference Dose (RfD) of 0.1 mg/kg/day, based on a NOAEL of 10 mg/kg/day from a developmental study in rabbits. In this study, post-implantation loss, reduced mean fetal weight, and increased skeletal defects in fetuses were observed at 30 mg/kg/day. This dose reflects application to the NOAEL of an uncertainty factor of 100x to account for interspecies extrapolation and intraspecies variability. The acute

RfD is appropriate for assessing acute dietary risk for females 13-50 years only. No acute RfD is needed to assess dietary risks for other population subgroups, as no other acute dosing toxicity study showed any other effects.

A three-generation reproduction study in rats is the basis for the chronic RfD. The NOAEL in the study was 12.5 mg/kg/day, based on decreased mean litter weights at the next higher dose level of 25 mg/kg/day. The chronic RfD of 0.13 mg/kg/day is obtained by application of an uncertainty factor of 100 for interspecies and intraspecies variability.

Although the NOAEL chosen for the chronic RfD is slightly greater than the NOAEL chosen for the acute RfD; the endpoints are similar when considering the spacing of the dosages of the two studies and the fact that the two studies used different species. For practical purposes, the numbers (10 versus 12.5 mg/kg/day) are considered numerically equivalent; therefore, no attempt was made to adjust either the acute or chronic RfD to accommodate differences in exposure duration.

The population adjusted dose (PAD) refers to an RfD which has been adjusted to take into account the FQPA safety factor. The RfD is calculated by dividing the NOAEL by the uncertainty factors. Numerically, the PAD is defined as the RfD divided by the FQPA safety factor. For captan, the RfD equals the PAD, since the safety factor is 1X.

To estimate human cancer risks, the Agency recommended a linear, low dose extrapolation approach for captan. Based on intestinal tumors in mice and using a (body weight)$^{3/4}$ scaling factor, a Q1* of 2.4×10^{-3} (mg/kg/day)$^{-1}$ was calculated.

(2) Studies Used to Support the Endpoint Selection

Developmental Toxicity in Rabbits (MRID 41826901)

In a developmental toxicity study, 20 New Zealand White rabbits per dose group received either 10, 30, or 100 mg captan/kg/day by oral gavage from gestation days 7 through 19. Maternal NOAEL/LOAEL were considered to be 10 and 30 mg/kg/day, based upon reduced body weight gain, decreased food consumption and anorexia. Developmental NOAEL/LOAEL were considered to be 10 and 30 mg/kg/day, based upon increased skeletal defects (27 pre-sacral vertebrae) in fetuses at 30 mg/kg/day. There was increased post-implantation loss, reduced mean fetal weight, and altered growth at 100 mg/kg/day.

The endpoints selected are based on the developmental toxicity NOAEL of 10 mg/kg/day with increased skeletal defects observed at 30 mg/kg/day.

One- and Three-generation Reproductive Studies in Rats (MRIDs 00120315 and 00125293)

In both studies, captan was tested in COBS CD rats. In the one-generation study, captan was tested at 6, 12.5 or 25 mg/kg/day. This study showed no effects on parents or pups at 6, 12.5 or 25 mg/kg/day. The NOAEL for pups was determined to be 12.5 mg/kg/day as a more protective endpoint for pups.

In the three-generation study, captan was tested at 25, 100, 250 or 500 mg/kg/day. The maternal toxicity NOAEL and LOAEL were considered to be 12.5 and 25 mg/kg/day, respectively, based on decreased body weight gain and food consumption. The offspring toxicity NOAEL and LOAEL were considered to be 12.5 and 25 mg/kg/day, respectively, based on decreased pup and litter weights. Pup survival was reduced at 250 mg/kg/day and higher dose levels. Parental toxicity was observed at 100, 250 and 500 mg/kg/day, which indicated a NOAEL of 25 mg/kg/day.

The endpoints selected are based on the NOAEL of 12.5 mg/kg/day with decreased mean litter weights observed at the next higher dose level of 25 mg/kg/day. The one- and three-generation studies are acceptable together and the two studies also show that pups and parents are equally sensitive.

Oncogenicity Rat (MRIDs 00120316, 00129157, 00129163, 00129164, 00153207)

Two carcinogenicity studies were performed on rats. In the first study, Charles River CD strain rats were fed diets containing 0, 25, 100 or 250 mg/kg/day of captan for 2 years. The NOAEL for systemic effects was 25 mg/kg/day. At the LOAEL of 100 mg/kg/day, males displayed: hepatocellular hypertrophy; increased relative organ weight for kidneys (males and females); increased relative organ weight for heart, brain, liver and thyroid/parathyroid (males) and decreased body weight. At the same dosage, females displayed: increased relative organ weight for kidneys and decreased body weight. There was a significant increasing trend in males for the combined adenomas and carcinomas of the kidney in male rats. There was no increased incidence of renal cortical/tubular cell neoplasia in females.

In another carcinogenicity feeding study, Wistar rats were fed diets containing 0, 6.25, 24 or 98 mg/kg/day of captan for 30 months. The NOAEL/LOAEL for systemic toxicity were at least 98 mg/kg/day. There was no increase in the incidence of renal cortical/tubular cell neoplasms. There was a slight but statistically significant increase in uterine sarcomas in the high dose group.

Oncogenicity Mouse (MRIDs None and 00068076)

Three carcinogenicity studies were performed on mice. In the first study, B6C3F1 mice were fed diets containing 0, 900, and 2,400 mg/kg/day of captan for 80 weeks followed by no treatment for 33 weeks. The NOAEL for systemic toxicity was 900 mg/kg/day and the LOAEL for systemic toxicity was 2400 mg/kg/day based on decreased mean body weight. Male and female mice had an increased incidence of combined duodenal adenoma/polyps or adenocarcinomas at 2400 mg/kg/day, with the first reported tumor at 91 weeks. There was a minimal increase in hyperplasia of the duodenal mucosa noted in the high dose males (National Cancer Institute, 1977. Bioassay of Captan for Possible Carcinogenicity. Technical Report Series No. 15).

In a second study, ICR derived CD-1 Charles River mice were initially fed diets containing 0, 2000, 6000 or 10000 ppm of captan for 4 weeks. Subsequently captan concentrations were increased to 0, 6000, 10000 or 16000 ppm (900, 1500 or 2400 mg/kg/day for females and 900, 1000 or 2400 mg/kg/day for males) for the remainder of the study. The NOAEL for systemic toxicity was not established. The LOAEL for systemic toxicity was 6000 ppm, the lowest dose tested, based on decreased body weight gain and food consumption (no quantitative information was available). There was an increased incidence of small intestinal (primarily duodenal) adenomas/polyps and carcinomas at all dose levels. A positive dose-related trend for an increased incidence of duodenal tumors in both sexes was also observed. Proliferative duodenal changes appeared to occur earlier in the high-dose males. There was also a statistically significant increase in gastric and duodenal hyperplasia in both sexes and in jejunal hyperplasia in females. This study satisfies the toxicological data requirement for a carcinogenicity study [83-2 (b)] in mice.

In a third study, Charles River CD-1 mice were fed diets containing 0, 15, 60, 120, or 900 mg/kg/day and the study was terminated at 22 months due to increased mortality in the high-dose males. The NOAEL for systemic toxicity was 120 mg/kg/day and the LOAEL for systemic toxicity was 900 mg/kg/day based on increased mortality in males and reduced weight gain throughout the study in both sexes. There was a small increase in small intestinal tumors (benign and malignant) in the male and female high-dose groups. The results of an Agency audit of this study suggested that there was a problem with achieving and maintaining the appropriate dose levels throughout the study. (MRID 00126845)

Using Oral Studies to Approximate Dermal and Inhalation Dosing

Oral endpoints are used for all risk assessments. These assessments assume that captan is absorbed through the skin at 0.4% per hour of the dosage that would be absorbed orally during the same time period. The assessments also assume that captan is taken up through the inhalation pathway to the same degree as oral ingestion; i.e., this standard assumption indicates that absorption by the inhalation and oral routes are considered to be equivalent.

b. Acute Toxicity

Acute toxicity values and categories for captan are summarized in the following table:

Overview of Acute Toxicity

Guideline	Test	MRID	Results	Category
81-1	Oral LD_{50} - rat	00054789**	LD_{50} = 9 g/kg (M)	IV
81-2	Dermal LD_{50} - rat	40021401**	LD_{50} > 2 g/kg	III
81-3	Inhalation LC_{50} - rat	00148070**	LC_{50} = 0.72 mg/L (M) LC_{50} = 0.87 mg/L (F)	III
81-4*	Eye Irritation - rabbit	00128621	Irreversible corneal opacity at 21 days in unwashed eyes	I
81-5*	Dermal Irritation - rabbit	40021401	Not an irritant at 3 days	IV
81-6*	Dermal Sensitization - guinea pig	00054791	Moderate skin sensitizer	N/A

* Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support reregistration of the active ingredient. Data are presented for information purposes.

** The acute toxicity endpoints, listed above, are for informational purposes only. The data supporting these endpoints do not meet current acceptability criteria. The acceptability status of these data may be reassessed during product reregistration.

c. Chronic Toxicity/Carcinogenicity

For human cancer risk assessment, the Agency recommended a linear, low dose extrapolation approach for captan. Based on intestinal tumors in mice, a Q_1^* of 2.4×10^{-3} $(mg/kg/day)^{-1}$ was calculated.

The Agency has classified captan as a B2 (probable human) carcinogen based on an increased incidence of intestinal tumors in mice. Captan was also found to have caused an increased incidence of renal neoplasms in male Charles River CD rats and an increased incidence of uterine sarcomas in Wistar rats.

The Captan Task Force has submitted several mechanism studies for captan. The Agency has reviewed these studies and determined that they do not contribute any additional information to the mode of action nor have any bearing on the cancer risk assessment. Similar mechanistic type studies have been reviewed and considered by the Agency for folpet which has a common metabolite, thiophosgene, with captan. Following review of these data, the Agency reaffirmed its decision and that the linear low dose extrapolation model should continue to be used for risk

assessment. Therefore, a reconsideration for captan according to the 1996 Draft Cancer Risk Assessment guidelines was not required.

d. Metabolism

The Agency evaluated the metabolism of captan based on several studies. A rat metabolism study evaluated the breakdown of captan in mammalian species. Two plant, one lettuce and one tomato, metabolism studies determined how parent captan is metabolized by crops. In addition, two animal metabolism studies, one poultry and one ruminant, determined what metabolites may be present in animals that have consumed captan-treated forage and feed products.

The first step in the metabolism of captan is the cleavage of captan's N-S bond to form tetrahydrophthalimide (THPI) and a derivative of the trichloromethylthio side chain. This cleavage frequently occurs in the GI tract, though it may also occur in the blood. THPI and the trichloromethylthio side chain are each further metabolized through independent pathways.

For the pathway involving the trichloromethylthio side chain group, four metabolites are formed, including the highly reactive species thiophosgene. Although much of the toxicity of captan is attributed to thiophosgene, this moiety is not likely to be found in tissues due to its short half-life, and therefore, captan is regulated as the parent compound itself.

For the THPI pathway, a total of 7 metabolites are formed. Unlike thiophosgene, THPI is stable enough to be found in total captan residues. Heretofore, the tolerance expression for captan for all commodities has included only the parent compound. Because captan is extensively metabolized to THPI in animal tissues, the tolerance expression for captan residues in animal commodities should include THPI as well as captan. Since THPI comprises less than 10% of the total captan residue for plants (based on metabolism studies), the tolerance expression in plant RACs and processed commodities should remain as captan *per se*.

For purposes of non-cancer dietary risk assessment, the combined residues of captan and THPI are considered to comprise the residue of concern. For purposes of carcinogenic risk assessment, only parent captan is considered since the carcinogenicity of captan is believed to be associated with the reactive thiophosgene moiety.

2. Dose Response Assessment

a. Special Sensitivity of Infants and Children (FQPA Safety Factor)

FQPA directs the Agency to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue in setting and reassessing tolerances. The law further states that in the case of threshold effects, for

purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

In determining what safety factor is appropriate for assessing risks to infants and children, EPA considers all available reliable data and makes a decision using a weight-of-evidence approach. This approach takes into account the completeness and adequacy of the toxicity and exposure data bases, the nature and severity of the effects observed in pre- and post-natal studies, and other information such as epidemiological data.

There are no data gaps for the assessment of the effects of captan following *in utero* and/or postnatal exposure. Prenatal developmental toxicity studies in hamsters and rabbits, and two reproduction studies in rats (a one-generation and a three-generation study considered together) were submitted in support of captan reregistration and were judged to be acceptable. The Agency has determined, based on a weight-of-the-evidence review of the available data, a developmental neurotoxicity study is not required for captan.

The available studies demonstrated no indication of increased quantitative or qualitative sensitivity of rats, rabbits or hamsters to in utero and/or postnatal exposure to captan. In the prenatal developmental toxicity study in hamsters, delayed ossification and postimplantation loss occurred at 400 mg/kg/day (the developmental LOAEL), while in dams, decreased body weight and mortality were observed at a LOAEL of 200 mg/kg/day. The developmental NOAELs for maternal and developmental toxicity in the prenatal developmental hamster study were 50 and 200 mg/kg/day, respectively. In the prenatal developmental toxicity study in rabbits, the maternal and developmental NOAELs were equivalent (10 mg/kg/day). Fetal findings (an increase in 27th presacral vertebrae, a skeletal variation) were observed at the same dose level (30 mg/kg/day) which caused maternal anorexia and decreased food consumption and a decrease of over 128g in mean maternal body weight. In combined results of the one- and three-generation reproduction studies in rats, both parental and offspring LOAELs were established based upon decreased body weight at 25 mg/kg/day.

The selection of a developmental endpoint for risk assessment, has no bearing on the conclusion that captain does not cause an increased susceptibility in the developmental studies. Assessment of increased susceptibility is based on the evaluation of both the quantitative and qualitative aspects of the effects seen in the fetuses in relation to those seen in the dams (i.e., whether the developmental findings were seen in the presence or absence of maternal toxicity, and whether the observations in dams and fetuses indicate, for example, differential severity of toxicity or the potential for long-term consequences). The acute nature of developmental effects observed

at a maternally toxic dose are attributable to the life stage of the organism; i.e., that the fetus is undergoing a unique period of rapid cellular differentiation, proliferation, and organization.

In summary, the results of these studies demonstrated that toxicity to the offspring occurred at equivalent or higher doses than parental toxicity, indicating that there is no quantitative susceptibility. Additionally, a comparison of the treatment-related findings in the adult animals and in their offspring, as described, did not indicate a qualitative difference in the relative severity of the response to treatment by the offspring following perinatal exposure at the LOAELs. Therefore, the Agency has determined that the 10X factor for enhanced sensitivity to infants and children (as required by FQPA) for captan should be removed (reduced to 1X).

Exposure methodologies were not found to indicate a concern for potential risk to infants and children. This determination was based on the following information: 1) the dietary exposure assessment for captan is a refined, realistic estimate of what is likely to be consumed; 2) captan residues are primarily surface residues and are likely to be removed by peeling, washing, and cooking; 3) the models used to assess drinking water exposure to captan are considered to provide realistic but somewhat conservative estimates; and 4) although some assumptions used in the residential exposure models are modified to better reflect the use patterns of captan in the home, the result is likely an over-estimate of exposure.

3. Dietary Risk and Exposure From Food

a. Summary of Residue Data Requirements

All data requirements for magnitude of the residue in plants have been evaluated. All data are adequate to reassess captan tolerances in light of canceled and revised uses. Field data on fruit and nut orchard crops and grapes are available reflecting multiple foliar applications of wettable powder, flowable concentrate, or dry flowable formulations with appropriate PHIs and geographic representation. Data on postharvest fruit dip are available for apples, cherries, and pears. Data from seed treatments using the wettable powder, flowable concentrate and dust formulations on representative crop seed and potato seed-pieces indicate that these uses will not result in detectable residues of captan in/on edible commodities.

All magnitude of the residue in processed food/feed data have been evaluated and deemed adequate to determine the extent to which residues concentrate in food/feed items upon processing of the raw agricultural commodity. Data pertaining to reduction of captan residues on plant commodities were submitted in response to the Special Review of captan. Studies conducted on apples, cantaloupe, cucumbers, grapefruit, lemons, lettuce, oranges, squash, strawberries, and spinach indicate that residues are substantially reduced by washing and are almost non-detectable after peeling. Cooking studies on celery, cucumbers, squash, and spinach indicate that residues of captan are almost non-detectable after cooking, with a corresponding increase in the THPI residues.

Adequate methodology is available for enforcement of tolerance residues of captan *per se* in/on plant commodities. A GC/electron capture detection (EC) method included in PAM, Vol. II as Method I is the preferred enforcement method. Other methods in PAM Vol. II that use colorimetry to analyze surface residues from plant tissues are not acceptable. THPI is completely recovered through Protocol D, but not through Protocol E (PESTDATA, PAM, Vol. 1, Appendix, 8/93).

b. Summary of Risks from Food

The Agency has conducted three separate dietary analyses to determine the risk from captan in foods on an acute, chronic (non-cancer), and chronic (cancer) basis. Commodities with canceled registrations or for registrations for which tolerances have been recommended for revocation were not included in any of the analyses. Residues of captan plus the metabolite THPI were included in the anticipated residues for chronic (non-cancer) exposure and acute exposure in meat and milk. Because the metabolite THPI is not considered carcinogenic, the cancer risk assessment was conducted using only the residues of captan *per se.*

To assess acute dietary exposure, the Agency conducted an acute probabilistic dietary (food) exposure analysis using the Dietary Exposure Evaluation Model (DEEM™). Residues in food items were estimated using residue field trials, USDA/PDP and FDA pesticide monitoring data, and reduction/concentration factors when available. The acute analysis evaluated the dietary exposure based on individual consumption data from USDA's 1989-1992 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII). For acute assessment, exposure was compared to the acute population adjusted dose (aPAD). The acute probabilistic dietary risk for captan is below the Agency's level of concern. Dietary exposure for females 13 - 50 years at the 99.9th percentile is 36% of the aPAD.

To assess chronic dietary exposure, a DEEM™ chronic exposure analysis was performed using anticipated residues and percent of crop treated information to estimate the anticipated residue contribution (ARC) for the general U.S. population and 22 subgroups. For the chronic (non-cancer) assessment, exposure was compared to the chronic population adjusted dose (cPAD). The chronic non-cancer dietary risk from exposure to captan does not exceed the Agency's level of concern, with all population subgroups having exposure values <2% of the cPAD. To the extent that this analysis uses anticipated residues, percent-crop-treated information and not published (recommended) tolerances, it is not a "worst-case" picture of the chronic dietary exposure to captan.

The dietary cancer risk does not exceed the Agency's level of concern. The upper bound dietary cancer risk for the U.S. population was estimated to be 1.3×10^{-7} from all food uses of captan supported for reregistration. The upper bound cancer risk from captan is below the level that the Agency generally considers a concern for excess lifetime cancer risk.

Summary of Dietary Risks

Risk Type	Population		Exposure (mg/kg/day)	% PAD or cancer risk
Chronic	Anticipated Residue Contribution	U.S. Population	0.000664	0.5% of cPAD
		Infants	0.001629	1.3% of cPAD
Cancer[1]	U.S. Population		0.00005	1.3×10^{-7}
Acute	Females 13-50 (99.9th percentile)		0.036	36% aPAD

[1] Based on the Q_1^* of 2.4×10^{-3} $(mg/kg/day)^{-1}$.

The acute dietary risk assessment for captan used the latest percent crop treated, revised anticipated residues, average residues from field trial data and/or monitoring data, and residue reduction/concentration upon processing. The acute probabilistic dietary risk for captan is below the Agency's level of concern (% Population Adjusted Dose <100%) for the Females 13 - 50 subgroups at the 99.9th percentile of exposure.

c. Dietary Exposure from Drinking Water

To assess the risk posed to human health from consumption of water containing captan residues, the Agency conducted three separate risk assessments to account for acute, chronic (non-cancer) and chronic (cancer) exposure. Each of these assessments used identical estimates for the expected concentration of captan in drinking water from both surface and groundwater sources. Based on these assessments, the Agency has determined that the consumption of drinking water containing residues of captan is not a concern.

Groundwater

The Agency has modeled groundwater resources using SCI-GROW. SCI-GROW is based on the fate properties of the pesticide, the application rate, and the existing body of data from small-scale ground water monitoring studies. Since the model assumes that the pesticide is applied at its maximum rate in areas where the ground-water is particularly vulnerable to contamination, the estimated maximum concentration derived using SCI-GROW should be considered a high-end to bounding the estimate of acute exposure.

The SCI-GROW model (ver. 2.0) predicts that groundwater concentrations of captan and THPI residues are not likely to exceed 3.4 µg/L. The SCI-GROW estimate was based on the maximum captan application rate of 32 lbs ai/A per year (8 applications of 4 lbs ai/A, 8 applications of 2.26 lb ai/A for THPI), aerobic soil metabolism half life of 1.3 days (an average half life of 10.7 days for THPI), and a K_{oc} value of 200 mL/g (2.2 mL/g for THPI).

Surface Water

Due to the range of field dissipation half-lives (2.5 to 24 days), substantial amounts of captan could be available for runoff to surface waters for a few days to several weeks post-application. Most captan runoff is expected to occur via dissolution in runoff water as opposed to adsorption to eroding soil. Based on its environmental fate properties, captan should not persist in surface waters under most hydrological or chemical conditions.

The major captan degradate of toxicological concern, THPI, exhibits low soil/water partitioning (K_d values < 1), indicating that most runoff will occur via dissolution in runoff water as opposed to adsorption to eroding soil. THPI degrades at rates comparable to those of captan (relatively rapidly) under aerobic conditions.

The State of Illinois (Moyer and Cross 1990) sampled 30 surface water sites for pesticides at various times from October 1985 through October 1988. Captan was included in the analyses because of its substantial use in Illinois. Total (dissolved and adsorbed to suspended sediment) captan was not detected above a detection limit of 0.05 ug/L in any of 580 samples collected from the 30 sites sampled.

The Agency also used computer modeling (PRZM-EXAMS) to estimate captan residues at a single surface water site over multiple years. Based on the model predictions and the environmental fate characteristics of THPI, the Agency predicts that THPI will reach drinking water from the current use pattern. Each site represents reasonably high exposure and was simulated over 36 years. The Agency recommends that 668 ppb be considered as a conservative estimate for acute surface drinking water levels of THPI. The average chronic level for 365 days (1 year) is 10.8 ppb.

The Tier 2 estimated environmental concentration (EEC) for captan is 4 ppb for peaches 90-days after application. Since THPI is not considered a carcinogen, surface and ground water EECs (4 ppb and 0.02 ppb, respectively) for captan *per se* will be compared to the cancer DWLOC for captan.

DWLOCs for Acute Exposure

Acute DWLOCs were calculated based on acute dietary (food) exposure and standard body weights and water consumption figures. These standard values are: 70kg/2L/day (adult male), 60 kg/2L/day (adult female), and 10 kg/L/day (child). To calculate the DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation:

$$DWLOC_{acute}\ (\mu g/L) = \frac{[\text{acute water exposure (mg/kg/day) x body weight(kg)}]}{[\text{consumption (L/day) x } 10^{-3}\ \text{mg}/\mu g]}$$

where acute water exposure (mg/kg/day) = [aPAD - acute food (mg/kg/day)].

These calculations resulted in the following values:

Acute Exposure and DWLOC

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	$DWLOC_{acute}$ (μg/L)	PRZM EXAMS (μg/L)	SCI-GROW (μg/L)
Females 13-50	0.1	0.036	0.064	1920	668	3.40

The acute DWLOC of 1920 μg/L is a far greater value than the conservative numbers that were calculated for the acute drinking water exposure through modeling (668 μg/L for surface water and 3.40 μg/L for ground water). Therefore, acute drinking water exposure added to the acute dietary exposure does not result in a risk concern.

Chronic (non-cancer) Drinking Water Levels of Comparison (DWLOCs)

Chronic DWLOCs were calculated using the same inputs and similar equations as in the acute DWLOCs. These calculations resulted in the following values:

Chronic (non-cancer) Exposure and DWLOC

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	$DWLOC_{chronic}$ (μg/L)	PRZM-EXAMS (μg/L)	SCI-GROW (μg/L)
US Population	0.13	0.00	0.13	4550	10.8	3.40
Infants <1 yr	0.13	0.00	0.13	1300	10.8	3.40

Since these results (4550 and 1300 μg/L) are much greater for both populations than the ground water and surface water (10.8 ppb and 3.4 ppb, respectively) model numbers, chronic drinking water with chronic dietary exposure is not of concern.

DWLOCs for Chronic (Cancer) Exposure

To calculate the chronic (cancer) DWLOC, the cancer dietary food exposure was subtracted from the upper bound dietary cancer value using the equation

$$DWLOC_{cancer}\ (\mu g/L) = \frac{[1 \times 10^{-6} - \text{food risk}_{cancer}]}{2.4 \times 10^{-3}\ (mg/kg/day)^{-1}} \times 70kg/2L/day \times 10^{3}\ \mu g/mg,$$

where cancer water exposure (mg/kg/day) = [negligible risk for cancer = 1×10^{-6} - upper bound cancer value (mg/kg/day) as $Q_1^* = 2.4 \times 10^{-3}\ (mg/kg/day)^{-1}$.

$$\frac{[1 \times 10^{-6} - 1.3 \times 10^{-7}]}{2.4 \times 10^{-3}\ (mg/kg/day)^{-1}} \times 70kg/2L/day \times 10^{3}\ \mu g/mg = 13 = DWLOC_{cancer}\ (\mu g/L)$$

Using conservative dietary exposure values and a conservative equation (male consumption is greatest among the three, hence the greatest exposure is expected) a resulting 13 ppb drinking level of comparison is greater than all the model drinking number values generated for chronic scenarios for both ground and surface water (0.02 ppb and 4.0 ppb respectively.). Drinking water with dietary consumption is not a concern for purposes of this risk assessment.

d. Occupational Handlers Risk and Exposure

Occupational exposure to captan residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities. Postapplication occupational dermal exposure is expected during harvesting and scouting activities.

Based on the toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational handler. In addition, the Agency has conducted a postapplication dermal exposure assessment for occupational uses.

(1) Scenarios/Assumptions in Occupational Assessment

The Agency has identified 14 exposure scenarios to represent occupational handler exposure during mixing, loading, and applying captan to agricultural crops and non-agricultural use sites. These occupational scenarios reflect a broad range of application equipment, application methods, and use sites. The scenarios were classified as short-term (1-7 days) and intermediate-term (1 week to several months) based primarily on the frequency of exposure. A long-term exposure duration is not expected.

The Agency's first step in performing a handler exposure assessment is to complete a baseline exposure assessment. The baseline scenario generally represents a handler wearing long pants, a long-sleeved shirt, shoes, socks and no chemical-resistant gloves. If the level of concern is met or exceeded, then increasing levels of risk mitigation, such as PPE (personal protective equipment) and engineering controls, are used to recalculate the MOEs until exposure is sufficiently reduced to achieve an appropriate margin of exposure.

Exposure for all captan use scenarios (except for potato seed piece treatment and potato planting) was developed using the Pesticide Handlers Exposure Database (PHED) Version 1.1. The PHED was developed by Health Canada, The American Crop Protection Association, and EPA. PHED was initially released for public use in 1992. PHED is a generic/surrogate exposure database containing a large number of measured values of dermal and inhalation exposure for pesticide workers (e.g., mixers, loaders, and applicators) involved in handling and applying pesticides. The database currently contains data for over 2000 monitored exposure events. Use of surrogate or generic data is appropriate since it is generally believed that the physical

parameters of the handling and application process (e.g., the type of formulation used, the method of application, and the type of clothing worn), not the chemical properties of the pesticide, control the amount of dermal and inhalation exposure. Thus, PHED typically allows exposure and risk assessments to be conducted with a much larger number of observations than are normally available from a single exposure study.

The dermal unit exposures from PHED are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, shoes, socks and chemical-resistant gloves, unless noted. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. The inhalation exposure values are reported as geometric means (lognormal distributions), unless otherwise noted. For mixer/loaders of wettable powder formulations, an 80% protection factor was included to account for use of dust/mist respirators.

Seed and Seed-piece Treatment

The Agency is addressing two occupational exposure scenarios associated with the seed and seed-piece treatment use:

1. Bulk Seed Treatment: To address occupational exposures while operating commercial or smaller on-farm bulk seed treatment equipment, the Agency has considered a special study conducted in 1980 to assess the potential exposure of workers during seed potato treatment. In that study, the investigators monitored handlers pouring captan into seed hoppers of potato seed-piece dusting machines, handlers cutting and sorting the treated potato seed-pieces, operators of potato seed-piece planters, and observers involved in the planting operations.

2. Seed Treatment, Planter Box: There are no activity-specific data to address the use of captan as a planter-box seed treatment, at planting time. To address this scenario, the mixer/loader data for wettable powder formulations available in the Agency's Pesticide Handlers Exposure Database (PHED V1.1) were used. The Agency determined that soybeans were the crop most likely to require planter-box seed treatment, as most other crop seeds are normally pretreated. The activity consists of adding a small quantity of captan to soybean seed after it has been loaded into the soybean planter seed hoppers. Captan is either mixed into the top few inches of seed to help disperse the captan dust or left alone to be mixed by normal shaking of the hopper as it moves through the field. The assumptions used for this scenario include the treatment of enough soybean seed to plant 100 acres/day (six-row planter with 30 inch rows planted at 4 mph), and a treatment rate of 0.066 lb ai/bushel at 1.13 bushels planted per acre. Individuals are estimated to use captan 5 days per year as planter box treatment.

Spray Treatments

Captan is applied via sprayer to almonds, apples, apricots, blueberries, cherries, grapes, plums, strawberries, caneberries, nectarines, peaches, and ornamentals. Captan is applied via airblast, groundboom, aerial and chemigation.

Surrogate exposure data to address handler exposure for these applications are available in the Agency's PHED V1.1. Handlers are assumed to use captan 7 days per season for strawberries and 3 days per season for the remaining fruit crops.

Almonds and strawberries were considered the crops most likely to be treated by aircraft because strawberries are grown in rows and almonds occasionally need emergency treatments during periods of extensive rain when ground equipment cannot be used. Although the registrant has indicated that treating 350 acres of strawberries by aircraft is unrealistic, the assessment for strawberry fields is representative of mixing/loading for all aircraft applications. The Agency has determined that, though such strawberry acreage is rare, it is possible to treat 350 acres in a day. In addition, almonds are routinely treated in 350 acre increments. Furthermore, the 1994 USDA Agricultural Chemical Usage data do not refute the 350 acre estimate. Strawberries are also likely to be treated by groundboom equipment and orchard and trellis crops are assumed to be treated by airblast equipment. Surrogate data are available to distinguish handler exposure for individuals treating dwarf fruit trees and trellis crops, such as grapes, from those individuals treating traditionally cultivated orchards.

The risk assessment for groundboom applications to strawberries is assumed to be a reasonable worst-case surrogate for applications to field-grown ornamentals. An exposure assessment for greenhouse ornamentals will be conducted only for the hand-held equipment scenarios, such as high pressure and backpack sprayers.

For the high pressure exposure scenario in greenhouses, the Agency assumes one hour per day for mixing/loading and applying the pesticide 26 days per year. Although it is unlikely that a backpack sprayer could deliver 100 gallons per hour, the Agency assumes one pound ai handled per day for 26 days per year.

Greenhouse soil treatments are similar to the greenhouse foliar treatments. The only exception is when the application is directed to the soil around the plants rather than the foliage. Therefore, the exposure and risk assessment for applications to greenhouse ornamentals using hand-held equipment is a reasonable worse-case surrogate for greenhouse soil treatments.

Application to Golf Courses

There are surrogate data available to address application of captan to golf courses. For this use, the Agency has assumed the use of groundboom equipment, and that a typical golf course consists of 40 acres of fairways. The golf course is assumed to be treated 10 times a year.

In-Plant Additives for Paints, Plastics, Rubber, and Adhesives

Data are available in PHED V1.1 to address worker exposure to captan used as a preservative/fungicide in paints, vinyl, plastics, rubber, and adhesives. Mixer/loader data available in PHED were used to address workers adding captan during the manufacturing of these industrial products, since these uses appear to be similar to those of an agricultural mixer/loader. Captan is weighed then added to the various products which are typically made in batches (e.g., paint). Although plastic and vinyl are relatively inert, captan is used to control molds attacking plasticizers (such as ethylene glycol), which are added to enhance the properties of plastics such as toughness and flexibility.

According to information available at the time of the PD 2/3, captan's use as an additive to industrial products was very limited. It was anticipated that an even lower market share could be expected in the future. Exposure scenarios addressing the addition of captan into specialty paints having pesticidal claims and into adhesives to promote longer shelf-life were selected as representative scenarios for the industrial uses.

For captan formulated into paint products, a rate of 12 lbs ai/100 gallons paint was used, with a total of 36 lbs ai/day added. The use of captan in these products is reportedly limited; thus, EPA estimates that workers will be exposed 10 days per year.

Commercial painter exposures while applying paints containing captan were also estimated. The commercial exposure assessments were conducted using PHED V1.1. EPA estimates that commercial painters are exposed 15 days per year for 70 years. The painter assessment is used as a reasonable worse-case surrogate for other secondary handler exposures to products such as adhesives.

Post-Harvest Fruit Dip Applications for Apples, Cherries, and Pears

There are no activity-specific data to address the use of captan as a postharvest dip treatment for apples, cherries, and pears to control spoilage during storage and transit. The main activity is the mixing/loading of captan into the dip/drench tank. Most of the application is mechanized and involves relatively low exposure potential. These activities include overseeing the apples being conveyed in and out of the dip/drench area, and operating forklifts to convey field boxes or bulk bins of fruit for dipping or storage. Dipping the fruit by hand involves relatively high exposure potential. Although EPA has no data to assess the exposures and risks from hand dipping, these data are being called in with this RED. The only data available in PHED V1.1 to address this scenario are those for the mixer/loader handling a wettable powder. This activity is assumed to result in the highest exposure. In the PD 2/3, it was determined that a mixer/loader would prepare four batches per day for a period of 6 weeks (in West Virginia) to 32 weeks (in Washington state). The dip tank sizes are assumed to range from 1000 to 3000 gallons, which amounts to 30-160 days exposed per year.

(2) Occupational Handlers Risk Conclusions

A single non-cancer endpoint effect was identified for both dermal and inhalation exposures. For certain handler activities, dermal exposure was assumed to occur once daily and subsequent absorption was assumed to result from a single exposure event where residues remain on the skin for 8 hours and are absorbed at 0.4% per hour. For other handler activities, dermal absorption at 0.4% per hour was assumed to result from continuous exposure for 8 hours during a single day. MOEs below 100 for combined dermal and inhalation exposure represent a risk concern for the Agency.

Most short- and intermediate-term risks to handlers using captan are above 100. MOEs that are above 100 range from 240 to 43,000. Of the risk estimates for the 14 scenarios, only three were below 100: mixing/loading wettable powders for aerial applications and chemigation, use by professional lawn care operators, and handlers loading wettable powders for seed-piece treatment.

For mixing/loading to support aerial applications and chemigation, the Agency has determined that inhalation exposure is a large component of the combined dermal and inhalation exposure estimate. These risks can be mitigated with the use of water-soluble packaging, in which case the MOE of 41 becomes 1000. Alternatively, application rates could be reduced to 1.2 lbs ai/A or less.

To estimate cancer risk, inhalation exposure was combined with dermal exposure to provide an equivalent oral dose for comparison against the Q_1^* 2.4×10^{-3} $(mg/kg/day)^{-1}$. No handler risk exceeded 5.9×10^{-6}. Most handler scenarios have cancer risks in the 10^{-7} and 10^{-8} range, which do not exceed the Agency's level of concern for occupational handlers.

(3) Occupational Incidents

Captan is in Toxicity Category I for primary eye irritation and is a moderate skin sensitizer. According to the information provided in incident reports reviewed by the California Pesticide Illness Surveillance Program between 1982 and 1990, there were 14 eye/skin incidents reported for reentry workers, 14 eye/skin incidents reported for mixer/loader/applicators, and 10 eye/skin incidents reported for other activities such as dipping flowers, preparing root and bulb dips, moving recently treated seed with forklifts, and exposure to spray drift.

There are many uncertainties associated with eye/skin incidence reporting and the Agency's ability to mitigate these adverse effects. Some of the uncertainties include:

The majority of incident reports are associated with pesticide applications that are applied as tank mixes. These tank mixes often involve other active ingredients which may also be irritants or sensitizers;

Symptoms such as conjunctivitis and irritation can be caused by soil, sweat, and foreign objects such as plant material irrespective of any pesticide used;

Eye incidents are typically under-reported for reasons such as fear of employer reprisal, migrant workers not wanting to attract attention to themselves, and the cost of medical treatment; and

Few states require incident reporting. Captan is used more frequently in areas outside California (one of the few states requiring physicians to report pesticide incidents) where conditions, such as high humidity, favor the plant diseases controlled by captan.

e. Occupational Post-Application Exposure and Risk

The Agency has determined that there is potential exposure to persons entering treated sites following application of captan-containing products for the purposes of harvesting low growing fruits, harvesting tree fruits, scouting, weeding, hoeing, and other non-harvesting activities, pruning and thinning fruit crops. Post-application exposure is particularly likely following foliar applications to ornamentals (field and greenhouse), golf-course and sod farm turfgrass. Post-application exposure is likely to be less significant in industrial and manufacturing settings. Postapplication scenarios were classified as intermediate-term (7 days to several months) based primarily on the frequency of exposure.

Current labels include a restricted-entry interval (REI) of 4 days, however, the use on strawberries has an REI of 24 hours. The current labels allow early entry for an unlimited length of time during the last 48 hours of the REI, provided early-entry PPE is worn.

(1) Assumptions for Occupational Post-Application

The following assumptions and factors were used to complete the postapplication exposure and risk assessment:

Average work day interval represents an 8 hour workday.

Average body weight of an adult postapplication worker is 60 kg (non-cancer risk concerns) or 70 kg (cancer risk concerns).

Dislodgeable foliar residues (DFRs) represent combined captan and THPI residues; the combined values were used for exposure assessment for short-and intermediate-term risk; THPI was not included in the exposure for cancer risk.

(2) Occupational Postapplication Risk Conclusions

To estimate non-cancer risks, MOEs for various REIs were derived by a comparison of dermal exposure estimates against a NOAEL of 10 mg/kg/day for intermediate exposure.

To estimate cancer risk for harvesters, the Agency assumed 80 days (national use) and 120 days (California) for the number of days exposed per year, and 35 years of exposure over a 70 year lifetime. The Q_1^* of 2.4×10^{-3} $(mg/kg/day)^{-1}$ was used to calculate risk. The assessment shows risks ranging from 1.8×10^{-5} to 7.7×10^{-6}. The assumption of 80 to 120 days of exposure to 24-hour post application residues is conservative. The risks presented are considered a worst-case scenario because they do not address percent crop treated or typical rates. Actual risks are expected to be much lower.

The REIs that will be established are: 12- hours for seed treatment uses; 24-hours for strawberries, almonds, apples, apricots, cherries, nectarines, plums/fresh prunes, and peaches; 3-days (72-hours) for blueberries, raspberries, blackberries, and grapes; 4-days (96-hours) for ornamentals, and 24-hours for soil treatments.

f. Residential Exposure and Risk

Residential exposure to captan residues via dermal and inhalation routes can occur during handling, mixing, loading, and applying activities. Postapplication residential dermal exposure is expected during gardening or other recreational activities. Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and for occupational and residential postapplication dermal and inadvertent oral ingestion exposure to adults and/or children.

Potential captan residential use sites may include lawns, ornamentals, fruit trees, and strawberries. According to the National Home and Garden Pesticide Use Survey Final Report, Volume 1 (March, 1992), the major use of captan in the home garden is on edible food crops (about 65%), followed by roses and other ornamentals (about 26%), and lawns (about 8%). It is available to the home gardener as dust (D), wettable powder (WP) and emulsifiable concentration (EC) formulations containing captan at 6 - 50% active ingredient. Captan is also incorporated into paints and adhesives as an industrial preservative.

Equipment for residential uses include low-pressure handwand, hose-end sprayer, backpack sprayer, and shaker can. In addition, powders or dusts may be mixed dry with vegetable seeds in a bag or jar prior to planting, or mixed with water to form a solution for dipping root cuttings, bulbs, and corms to prevent seed rot or damping off.

(1) Residential Handler Risk

Captan may be applied at 7- to 14-day intervals throughout the growing season; however, the duration of exposure is expected to be short-term (1-7 days) for residential handlers because it is unlikely that home gardens would require continuous daily applications for a period of time greater than one week. Short-term risks to residential handlers do not exceed the Agency's level of concern. MOEs range from 240 to over 100,000.

Cancer risk estimates to residential handlers do not exceed the Agency's level of concern. The results of the cancer risk assessment indicate that risks for all residential handler scenarios are in the 10^{-7} and 10^{-8} range.

(2) Residential Post-application Risk

Although captan may be absorbed through the skin or respiratory tract, postapplication inhalation exposure is expected to be minimal for all residential scenarios, including applying captan-treated paint. Only dermal exposure is expected for postapplication harvesting activities. Based on the half-life of captan residues on leaf surfaces (10 to 43 days), the duration of postapplication dermal exposure is expected to be either short-term (1-7 days) or intermediate-term (1 week to several months).

The Agency is concerned about toddlers exposed to captan through residential uses on lawns. The MOE for toddlers' hand-to-mouth contact from residues on low-growing plants is approximately 11. The MOE for toddlers' hand-to-mouth contact from residues on turf is 2. To mitigate this use, the technical registrants have agreed to voluntarily cancel the use of captan on all turf, except at sod farms and golf courses. To ensure toddlers are not exposed to residues of captan on treated sod, the Agency is establishing a 48-hour harvesting prohibition interval.

Based on the currently registered maximum application rate to turf, MOEs are 20 and 25 for adults and toddlers, respectively. However, when the application rates to turf are reduced, these risks are effectively mitigated and MOEs for both groups are above 100. MOEs for dermal exposure in treated gardens ranged from 2,000 to 45,500.

Dermal postapplication exposures and risk to youths and adults playing golf at golf courses did not exceed the Agency's level of concern. The Agency determined that the MOEs are 110,000 and 180,000 for youth and adult golfers, respectively. This assessment assumed 4 hours of play for 18 holes of golf.

Cancer risk estimates from postapplication exposure do not exceed the Agency's level of concern. The results of the cancer risk assessment indicate that risks for all assessed residential postapplication scenarios are in the 10^{-7} and 10^{-8} range.

g. Aggregate Risk

In examining aggregate risk, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure can include pesticide residues in drinking water, exposure from pesticides uses in and around the home, and exposure in non-residential settings, such as, parks, schools, etc.

Acute Aggregate Risk

An acute aggregate assessment estimates risk from one day's exposure to food and water. Acute exposure (food only) to captan was 36% of the aPAD for females 13-50 years of age (the only population of concern for acute exposure), which does not exceed the Agency's level of concern. Since drinking water monitoring data for captan were not available, drinking water levels of comparison (DWLOCs) were calculated and compared to estimated environmental concentrations (EECs) that were generated by the PRZM-EXAMS and SCI-GROW models. The EECs for surface and ground water were less than the acute DWLOCs, indicating that acute aggregate exposure to captan does not exceed the Agency's level of concern.

Short-Term Aggregate Risk

Aggregate short-term risk assessments provide estimates resulting from residential exposures of 1-7 days duration, plus food and water exposures. Typically, high-end residential exposure estimates are added to estimates of food and water exposure for comparison to an appropriate NOAEL from a toxicity study. For captan, the developmental and maternal toxicity endpoint of 10 mg/kg/day from a developmental toxicity study is used for short-term assessments. Three major aggregate short-term exposure scenarios were considered reflecting the turf, ornamentals/fruit trees, and paint additives uses of captan. Exposures to golfers was not included in the aggregate assessment because the risks posed by this scenario is expected to be negligible.

Use of captan on turf results in postapplication exposures to children which exceed the Agency's level of concern, based on hand-to-mouth exposure. Because any additional exposure via food or drinking water would only cause risk estimates to further exceed the level of concern, the Agency concludes that aggregate short-term exposures resulting from use of captan on turf exceeds the level of concern. These uses are being voluntarily canceled to mitigate this risk.

Residential exposure from use of captan on fruit trees/ornamentals or from painting does not exceed the Agency's level of concern when aggregated with food and drinking water exposure. Aggregate exposure scenarios include application residential scenarios. The painting scenario is calculated for adults only and assumes that children do not paint.

Aggregate Short-Term Risks for Captan

	Mixer/Loader/Applicator		Food		Total		
Scenario	Exposure (mg/kg/day)	MOE*	Exposure (mg/kg/day)	MOE	Exposure (mg/kg/day)	MOE	DWLOC (ppb)
Ornamental/ Fruit Tree	0.029	345	0.0007	14,300	0.03	330	2,100
Airless Paint Sprayer	0.025	400	0.0007	14300	0.026	390	2,220

*Exposures compared to NOAEL of 10 mg/kg/day from Developmental Toxicity Study in Rabbits.

$$DWLOC_{short\ term} = \frac{\text{Allowable short-term water exposure (mg/kg/day) x body weight (kg)}}{\text{water consumption (L/day) x } 10^{-3} \text{ (mg/}\mu\text{g)}}$$

where Allowable short-term water exposure =NOAEL/UF - chronic food exposure - residential exposure

As an example, exposure to adults who are mixing/loading/applying to ornamentals:

Allowable short-term water exposure = (10/100) - 0.001 - 0.029 = 0.07 mg/kg/day

$$\frac{0.07 \text{ mg/kg/day} * 60 \text{ kg}}{0.001 \text{ (mg/µg) } 2 \text{ L/day}} = 2{,}100 \text{ ppb } DWLOC_{ST} \text{ adult females}$$

Chronic (Non-cancer) Aggregate Risk

A chronic aggregate assessment estimates risk from long term exposure to food and water and also includes residential exposure if any long term scenarios are identified. No chronic non-cancer exposure scenarios are expected from residential uses of captan.

DWLOCs for chronic dietary exposure were discussed earlier in this document. The calculations indicate that DWLOCs greatly exceed estimated environmental concentrations and therefore there is no concern for chronic aggregate food and water exposure.

Chronic (Cancer) Aggregate Risk

Aggregate cancer assessments estimate risk from lifetime exposures to food and water plus residential exposure. Multiple residential exposure scenarios may be included in aggregate cancer assessments if they have a reasonable probability of occurrence over a lifetime. As in the previous aggregate assessments, exposures to golfers was not included because the risks are expected to be negligible. Risks of 10^{-6} or less are considered to be of negligible risk concern for the general population.

The following table illustrates aggregate cancer risks associated with some residential exposure scenarios. It should be noted that use on turf is not included in the table because noncancer risks were not acceptable by themselves for turf uses of captan.

Aggregate Cancer Risks for Captan

Residential Exposure Activity	Residential Cancer Risk	Food Cancer Risk	Aggregate Food and Residential	$DWLOC_{cancer}$ ppb
Primary handler - Mixing/loading/applying wettable powders to fruit trees	$6.5x10^{-7}$	1.3×10^{-7}	7.8×10^{-7}	3.2
Secondary handler - Painting with a brush	8.5×10^{-8}	1.3×10^{-7}	2.2×10^{-7}	11
Postapplication - Ornamentals	4.2×10^{-8}	1.3×10^{-7}	1.7×10^{-7}	12

$$DWLOC_{cancer} = \frac{\text{Allowable water risk x body weight (kg)}}{Q_1^* \text{ (mg/kg/day)}^{-1} \text{ x water consumption (L/day)} \times 10^{-3} \text{ mg/}\mu\text{g}}$$

Allowable water risk = 10^{-6} - Food risk - Residential risk

Example: Painting with a brush

Allowable water risk = $10^{-6} - 1.3x10^{-7} - 8.5x10^{-8} = 7.8 \times 10^{-7}$

$$\frac{7.8 \times 10^{-7} * 70 \text{ kg}}{2.4 \times 10^{-3} \text{ (mg/kg/day)}^{-1} * 0.001 \text{ mg/}\mu\text{g} * 2 \text{ L/day}} = 11 \text{ ppb } DWLOC_{short\ term}$$

Water models predict environmental concentrations of captan in ground and surface water of 0.02 ppb and 4.0 ppb respectively. A $DWLOC_{cancer}$ greater than 4.0 ppb is obtained for any residential scenario (or combination of plausible scenarios) with a risk estimate of less than $2.3x10^{-7}$. Although mixing/loading/applying wettable powders to fruit trees is associated with a cancer risk of 6.5×10^{-7}, this risk level still only yields an aggregate risk of 1.05×10^{-6}. Therefore, no residential aggregate scenario is of a concern to the Agency for cancer.

Captan and folpet share a common metabolite, thiophosgene, which is believed to be responsible for the carcinogenic effects of these compounds. Thiophosgene is a highly reactive, short-lived species. Studies indicate that thiophosgene causes local irritation of the site with which it comes in contact, and is believed to cause tumors through the irritation of the duodenum. Because they are so short-lived, thiophosgene residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the rate of formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst case estimate. For captan, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 1.3×10^{-7}. For folpet, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 9.8×10^{-8}. If these two risks are added together the total risk is 2.3×10^{-7} The aggregate cancer Drinking Water Level of Comparison ($DWLOC_{cancer}$) based on this total cancer risk estimate is 11 ppb, using the captan Q_1^* of 2.4×10^{-3}. The estimated environmental concentration (EECs) for folpet are 1 ppb (sw) and less than 1 ppb (gw). The EECs for captan are 4 ppb (sw) and less than 1 ppb (gw). The largest EEC of 4 ppb is less than the DWLOC, the Agency's level of concern. This aggregate assessment is for dietary exposure

only. The tumor of concern occurs in the GI tract (duodenum/jejunum-ileum) as a result of oral dosing. The relevance of dermal exposure to a GI tract tumor is unknown at this time. Thus, the Agency concludes that an aggregate cancer risk estimate considering dietary (food and water) exposure only for captan and folpet based on their common metabolite thiophosgene is appropriate.

e. Cumulative Effects

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question, such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

At this time, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments; however, there are pesticides for which the common mechanism issues can be resolved. An example of this would be pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

FQPA requires the Agency to consider the cumulative exposure to pesticides operating by a common mechanism of toxicity. Policy to permit the estimation of cumulative exposure is currently under development but is not yet complete. At such time as policy defining how to conduct a cumulative assessment has been finalized, the risk assessments of captan (and folpet) will be revisited to determine whether a common mechanism is operative with any other pesticide and, if so, whether a cumulative risk assessment is warranted.

C. Environmental Assessment

1. Ecological Toxicity Data

In addition to estimating risk to human health, the Agency also assesses risks to terrestrial species and aquatic organisms, including avian species, mammals, and fish. The exposure and risk estimates that follow represent major agricultural use sites and reflect both the range of terrestrial and of aquatic non-target exposure scenarios expected with the use of captan on terrestrial plants.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of captan to avian species, the Agency required an avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail).

The results reported in the following tables indicate that captan is practically non-toxic to the Northern bobwhite quail and mallard, on both an acute and subacute dietary basis.

Avian Acute Oral Toxicity Findings

Species	% a.i.	LD_{50} mg/kg	Citation	Toxicity Category	Satisfies Guideline
Northern bobwhite	Tech	> 2,150	GS0120-045	practically nontoxic	Yes
Mallard Duck	Tech	> 2000	GS9999-001	practically nontoxic	Yes

Avian Subacute Dietary Toxicity Findings

Species	% a.i.	LC_{50} ppm	Citation (MRID)	Toxicity Category	Satisfies Guideline
Northern Bobwhite	Tech	> 2,400	00022923	slightly toxic or practically non-toxic	Yes
Mallard	Tech	> 5000	00022923	practically non-toxic	Yes
Mallard	90%	>5200	43869803	practically non- toxic	Yes
Northern Bobwhite	90%	>5200	43869802	practically non- toxic	Yes
Northern Bobwhite	Tech	> 4640	00104686	slightly toxic or practically non-toxic	No

The studies are acceptable and fulfill guideline requirements. (MRIDs 43869802, 43869803, GS0120045, GS9999001, 00022923, 00104686).

(2) Birds, Chronic

Since captan has repeated exposure through multiple applications, avian reproduction studies are required. The avian reproduction studies for captan indicate that exposure up to 1000 ppm in the diet does not affect reproduction. Multiple foliar applications of captan result in peak maximum predicted residues slightly above 1000 ppm, however, when the exposure and risk are further refined to consider concentrations and methods of application, the resulting predicted residues are below this concentration. Therefore, no further data are needed and the guideline requirement is fulfilled. This issue is further discussed in the Exposure and Risk to Nontarget Terrestrial Animals section. (MRIDs 00098295, 00098296).

(3) Mammals, Acute and Chronic

Mammal testing was not required by the Agency's Ecological Effects Division since captan is not acutely toxic. Mammalian data are reported in the following table.

Mammalian Toxicity Findings

Species	Test Type	NOEL ppm	LOEL ppm	Citation (MRID)
Rat	Acute oral	LD_{50} 9g/kg		00054789
Rabbit	Developmental	330	990	41826901
Hamster	Developmental	2000	4000 incr. resorption	00086803
Rat	One generation	>500	>500	00120315
Rat	Three generation	250	500 reduced pup wt	00125293

The acute oral LD_{50} was used to determine toxicity. The mammalian data indicate that captan is practically non-toxic to the rat on an acute oral basis (MRID 00054789).

(4) Insects

A honey bee acute contact LD_{50} study is required when the proposed use will result in honey bee exposure. Studies on the honeybee using technical captan indicate that the LD_{50} is greater than 10μg a.i./bee, and that there is 9.8% mortality at 215 μg a.i./bee. There is sufficient information to characterize captan as relatively nontoxic to honeybees. The guideline requirement is fulfilled (MRID 00113613, 05001991).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the acute toxicity of captan to freshwater fish, the Agency required two freshwater fish toxicity studies. Both a coldwater species (preferably the rainbow trout), and a warmwater species (preferably the bluegill sunfish) should be used.

Freshwater Fish Acute Toxicity Findings

Species	% a.i.	96-hr LC_{50} ppb ai	Citation (MRID)	Toxicity Category	Satisfies Guideline
Bluegill sunfish	90	310	GS0120042	highly toxic	Yes
Bluegill sunfish	88.4	72	00057846	very highly toxic	Yes
Fathead minnow	88.4	65	00057846	very highly toxic	Yes
Brook trout	88.4	34	00057846	very highly toxic	Yes
Coho salmon	90	137	40098001	highly toxic	Yes
Harlequin fish	89	300	05020144	highly toxic	No
Brown trout	90	26.2	40098001	very highly toxic	Yes

The results of the 96-hour acute toxicity studies indicate that captan is highly to very highly toxic to fish. The guideline requirements are fulfilled for testing with technical material (MRID GS0120042, 00057846, 40098001, 05020144).

The Agency waived the acute formulated product testing with a 50% wettable powder (WP) formulation since the confidential statement of composition for the captan 50 WP and 80 WP end use products showed that the major and minor inerts are not likely to enhance the toxicity of captan.

Degradate testing was required because captan is short-lived (hydrolyzes at pH 7 in about 6 hrs) and the major degradate(s) are believed to be stable and exist at concentrations greater than 10%. The following data were submitted on the major degradates of captan, THPI and THPAm.

Freshwater Fish Acute Toxicity Findings

Species	% a.i.	96-hr LC_{50} (ppb)	Citation (MRID)	Toxicity Category	Satisfies Guideline
Rainbow trout	96% THPI	>120,000	43869806	practically non toxic	Yes
Rainbow trout	95% THPAm	> 126,000	44738801	practically non toxic	Yes

There is sufficient information to characterize THPI and THPAm as practically non-toxic to fresh water fish. Considering these results, bluegill studies will not be required. The guideline requirement using THPI and THPAm are fulfilled (MRIDs 43869806, MRID 44738801).

A fish full life cycle on parent captan has been submitted, therefore the fish early life stage study will not be required. The results from this study indicate that fathead minnow growth and survival is affected between 16.5 and 39.5 ppb. The NOEL is 16.5 ppb, and the LOEL is 39.5 ppb. The guideline requirement for the fish full life cycle testing is fulfilled (MRID 00057846).

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. The results from a test using first instar *Dapnia magna* are shown in the following table:

Freshwater Invertebrate Toxicity Findings

Species	% a.i.	48-hr. EC_{50} (ppm)	Citation (MRID)	Toxicity Category	Satisfies Guideline
Daphnia magna	Tech	>7.1	00070751	moderately toxic or less	No
Daphnia magna	93%	>3.25	43869807	moderately toxic or less	No
Daphnia magna	90%	8.4	GS0120041	moderately toxic	Yes
Daphnia magna	Tech	1.3 (26 hr.)	00002875	moderately toxic	No

There is sufficient information to characterize captan as moderately toxic to *Daphnia magna*. The guideline requirement is fulfilled (MRID 00070751, GS0120041, 00002875, 43869807).

Since degradate testing is required, data were submitted on 96% THPI (%a.i.) using *Daphnia magna*. Results indicated that the 48-hr LC_{50} is greater than 113 ppm a.i. There is sufficient information to characterize the captan degradate THPI as practically non-toxic to *Daphnia magna*. (MRID 43869808). The guideline requirement is fulfilled. The results of the rainbow trout study with THPAm demonstrate that the 96-hour LC_{50} was greater than 126 ppm, and the NOEC was 126 ppm. From these results, the Agency determined that THPAm is practically non-toxic to the rainbow trout (MRID 44738801), and there will be no requirement to test *Daphnia magna* with THPAm.

Aquatic invertebrate life-cycle testing was required because captan is applied repeatedly by air blast or aerial equipment and may contaminate waterways via drift and runoff. Results from a submitted study using parent captan indicate reproductive effects in *Daphnia magna* occur at nominal concentrations between 0.56 and 1.0 ppm. This study was conducted as a static renewal;

neither the concentrations of parent captan nor THPI were measured in the test solutions. The reduced length and decreased number of young seen at 1.0 ppm are attributed to captan since THPI appears to be 100x less toxic acutely than parental captan. Although continuous exposure to parental captan would yield a lower NOEL, static renewal is more representative of aquatic organism exposure to captan under field conditions. Subsequent applications of captan would mimic the repeated dosing of the static renewal study. In light of these factors and the greater sensitivity of fish, the value added of repeating this study is low. The Agency is not requiring additional data at this time. (MRID 44148801)

(3) Estuarine and Marine Animals, Acute

The foliar use of captan on turf, lawns, and golf courses could result in exposure to estuaries and marine environments, and therefore acute toxicity testing with estuarine and marine organisms was required.

The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters, using technical captan. The registrant has recently submitted two 96-hour acute toxicity studies, one using sheepshead minnow and another using saltwater mysid. (MRIDs 44806504, 44806503), and these studies are in review. A 96-hour shell deposition study is still required, as an earlier study (MRID 00127865) was conducted using the dungeness crab, which is not a preferred test species. This study showed captan to be moderately toxic to dungeness crab. The Agency is not requiring testing using formulated products at this time, pending submission and evaluation of technical testing.

c. Toxicity to Plants

(1) Terrestrial

Tier 1 terrestrial plant testing (seedling emergence and vegetative vigor) would normally be required for captan due to phytotoxicity label statements (the captan 50WP label indicates that necrotic spotting of immature leaves of some orchard crops may occur under certain conditions). However, based on captan's use as a seed treatment, and since captan is non-systemic, the Agency is not requiring a Tier II emergence study. In addition, the vegetative vigor study would not likely demonstrate the occurrence of spotting on the usual non-woody species. Therefore, the vegetative vigor study is also waived.

(2) Aquatic

Aquatic plant testing is required for captan since it has outdoor non-residential terrestrial uses and it may move off-site during application by drift. Testing on the following five species was required due to effects seen in tests with several algal species using captan: *Selenastrum*

capricornutum, *Lemna gibba*, *Skeletonema costatum, Anabaena flosaquae*, and a freshwater diatom. Tier 2 toxicity data on technical captan are listed below:

Nontarget Aquatic Plant Toxicity Findings

Species	% a.i.	EC50 ppm	Citation (MRID)	Satisfies Guideline
Selenastrum capricornutum	90	1.77	43869809	Yes
Skeletonema costatum	99.8	0.18	44806502	Yes
Pavlova lutheri	99	0.55	40228401	No
Isochrysis galbana	99	0.21	40228401	No
Scenedesmus subspicatus	92.7	0.32	252586	No
Anabaena flosaque	99.8	1.2	44806501	Yes
Lemna gibba	99.8	12.7 (7-day)	44806503	Yes

The results indicate that several algae species experienced a 50% inhibition in growth at less than 1 ppm (MRID 40228401). Species other than those tested previously are required. The registrant has submitted studies with three other aquatic species: *Lemna gibba, Anabaena flosaquae*, and *Skeletonemema costatum*. (MRIDs 44806501, 44806502, 44806503). The Agency has sufficient information to use for the risk assessment, and additional data is not required at this time.

Though not required by the Agency, the registrant submitted a study with THPI on the alga *Selenastrum capricornutum*. The results indicate that aquatic concentrations of THPI up to 180 ppm are not toxic to *Selenastrum capricornutum*. (MRID 43869810).

2. Environmental Fate

a. Environmental Fate Assessment

Captan degrades rapidly in the environment with a half-life of less than one day. Hydrolysis and aerobic soil metabolism appear to be the major routes of captan dissipation in the environment. In water and soil, the sulfur-nitrogen bond cleaves, separating the trichloro-methylthio (TCMT) and tetrahydrophthalimide (THPI) moieties of the molecule. The TCMT moiety degrades moderately rapidly to rapidly by aerobic soil metabolism to CO_2, thiophosgene, and inorganic sulfur and chlorine. Thiophosgene dissipation is expected to be dependent on volatilization (est. vapor pressure=29.7 mm Hg and estimated Henry's Law constant=0.00586 atm-m_3 $mole^{-1}$). However, thiophosgene was not detected as a volatile component in any of the submitted laboratory studies. THPI also degrades moderately rapidly to rapidly by aerobic soil metabolism to a series of ring-containing products (including THPAm) and ultimately to CO_2.

Captan photodegradation on soil also occurs, but is secondary to hydrolysis and aerobic soil metabolism. Evidence indicates that residues of THPI may be present in soil several months following captan application. THPI is potentially mobile and may leach in the soil profile. Freundlich K_d values for THPI ranged from 0.01 to 0.17 mL/g in six soils. THPI may move with surface runoff.

b. Environmental Fate and Transport

Parent captan degrades relatively rapidly. However, there is a potential for the degradate THPI to reach ground and surface water due to application rates and multiple applications of captan.

c. Degradation

Hydrolysis: ^{14}C-trichloromethyl captan hydrolyzed in sterile aqueous buffer solutions at pH 5, 7, and 9, with half-lives of 18.8 hr, 4.9 hr, and 8.3 min, respectively. Two unidentified degradates, both of which degraded rapidly to $^{14}CO_2$, were detected in the study (MRID 41176301).

Two other hydrolysis studies were also reviewed. One study (MRID 00096974) provided information on the hydrolysis of ^{14}C-carbonyl captan, and described the fate of the ring portion of the molecule in sterile aqueous solutions at a pH range of 2-9. Another study (MRID 40208101) provided acceptable information on the hydrolysis of ^{14}C-trichloromethyl captan at pH 9. Taken together, these three studies fulfill the data requirement. (MRIDs 00096974, 40208101, 41176301).

Photodegradation In Water: Because hydrolysis, not photolysis, was responsible for captan degradation in an aqueous photolysis study reviewed previously, the Agency concluded that the photodegradation in water data requirement for captan would be fulfilled upon submission of acceptable hydrolysis data for pH 5. The Agency concluded that captan is stable to photolysis in aqueous solution at pH 5. No additional data on the photodegradation of captan in water are required at this time (MRIDs 40208102 and 41176301).

Photodegradation on Soil: In studies where ^{14}C-captan labeled in the cyclohexene and trichloromethyl positions was applied to moist sandy loam soil and irradiated with natural sunlight, captan degraded with half-lives of 5 and 15 days, respectively. The half-lives for dark controls were 10 and 21 days, respectively. After 5 days of irradiation of ^{14}C-cyclohexene captan, 21.3% of the applied radioactivity was present as tetrahydrophthalamide (THPI) and 9.4% was present as cyclohex-4-ene-2-cyano-1-carboxylic acid (THCY). No other single degradate contained more than 3.2% of the applied radioactivity. For ^{14}C-trichloromethyl captan, the only reported degradate was $^{14}CO_2$, which comprised 41.7% of the applied radioactivity after 16 days of irradiation.

The soil photolysis data submitted are acceptable and fulfill the data requirement. No additional data for captan photodegradation on soil are required at this time (MRID 40658009, 40658010).

Aerobic Soil Metabolism: Carbonyl-labeled captan, incubated aerobically in a sandy loam, degraded very rapidly with 99% degradation by day 7. Ninety-five percent of the applied ^{14}C was present as $^{14}CO_2$ after 322 days. THPI and THPAm were the major degradates identified. The maximum reported THPI concentration occurred at day 7, when 66% of the applied radioactivity was present in this degradate. Other soil metabolites of captan in quantities exceeding 0.01 ppm were tetrahydrophthalic acid (THPAI), 5,6 dihydroxyhexahydrophthalamide (diol), and THPI-epoxide.

In an aerobic soil metabolism study using trichloromethyl (TCM)-labeled active ingredient, captan degraded with a half-life of less than 1 day in a sandy loam. After 1 day, 46% of the applied radioactivity was detected as $^{14}CO_2$, 19.4% was undegraded captan, and 16.7% was unextractable ^{14}C residues. No non-volatile metabolites were detected. In a study submitted in support of captafol, a compound similar to captan in structure and degradation products, THPI degraded with a half-life of approximately 4 days. Other degradation products were not identified (MRIDs 00070414 and 40658007).

Two studies were submitted to determine the degradation rates of THPI in soil. For THPI, the data provided supplemental information that shows 10 ppm THPI degraded with half-lives (using best fit equations) of 5.4, 5.8 and 19.5 days, respectively, in aerobically incubated Hyde Farm sandy loam, Speyer 2.2 loamy sand, and Speyer 2.1 sand soils. The Agency calculated half-lives that were similar (using linear regression of the natural logarithms - (ln) of concentration): 5.8, 6.9 and 20 days, respectively, for Hyde Farm sandy loam, Speyer 2.2 loamy sand, and Speyer 2.1 sand soils. THPI accounted for less than 0.1 ppm at Day 26 (Hyde Farm sandy loam), Day 33 (Speyer 2.2 loamy sand), and at Day 50 (Speyer 2.1 sand soil). The study did not identify any degradates of THPI. (MRID 43868902).

Anaerobic Soil Metabolism: After 1 day of aerobic incubation followed by 29 days of anaerobic incubation, only 4.0% of the radioactivity applied to a sandy loam soil was undegraded trichloromethyl-labeled [^{14}C] captan, 85.6% had evolved as $^{14}CO_2$, 0.8% was uncharacterized, and 16.6% was unextractable. About 80% of the parent captan had degraded during the 1-day aerobic period. In addition to THPI, THPAm, and THPAI, a cyano-acid metabolite of captan, THCY, was identified. Up to 20% of the applied radioactivity was detected as THCY. THCY and THPAm were stable in anaerobic conditions (MRID 40658008).

In another anaerobic soil metabolism study, carbonyl-labeled [^{14}]C captan was completely degraded after one week of anaerobic soil conditions. Qualitative reporting of results indicated that four metabolites, including THPI and THPAm, were detected with very little $^{14}CO_2$ evolved, implying that the degradates formed were stable to further anaerobic degradation (MRID 00098881).

Aerobic Aquatic Metabolism: This study determined the fate of captan and degradates in water-sediment systems with two contrasting types of sediment. The Old Basing water system, a method for extracting test sediment, included clay loam at a pH of 8.0 with 12.5 % organic carbon, and the Virginia water system included a loamy sand at a pH of 6.2 with 3.1 % organic carbon. The application rate was chosen to simulate accidental spraying into a water body during normal agricultural practices.

The study provides acceptable information that shows captan degrades in the aerobic aquatic environment with a half-life of less than 24 hours in soil and water. This study fulfills the guideline requirement. Maximum concentrations of degradates detected, as a percentage of parent captan applied, were: 81.2% THPI at Day 0, 27% THPAm at Day 7, 10.8% THPAI at Day 14, and 9.4% THPI epoxide at Day 1. (MRIDs 00096974, 40114502).

The Agency calculated the half-life of THPI in the Old Basing system to be 7 days. THPI concentrations in the Virginia water system decreased from 51.1% of applied at Day 30 to less than 0.1 % by Day 60.

The Agency concluded that once captan reaches surface water and hydrolyses (within 24 hours), the degradates (THPI, THPAm, THPAI, and THPI epoxide) probably will not persist in surface water longer than 60 days (MRID 43868905).

d. Mobility

Leaching, Adsorption/Desorption: Soil thin layer chromotography (TLC) data indicate that captan is slightly mobile to relatively immobile in various soils. These data, combined with the hydrolysis, soil metabolism, and terrestrial field data (see below) indicate that captan is labile, and demonstrate that the parent compound is not likely to leach significantly in soil.

Two of captan's degradates, THPI and THPAm, appear to have the potential to be mobile in the soil and to reach surface water via runoff and/or erosion during periods of precipitation and/or irrigation. (MRID 43868911). As further confirmatory data, laboratory data submitted for captafol, a pesticide with a chemical structure similar to captan, also indicate that the degradates THPI and THPAm are mobile. (MRID 40658011).

Laboratory Volatility: Volatility does not appear to be an important route of dissipation for parent captan. Over a 9-day period, approximately 0.003% of ring-labeled captan volatilized from a sand soil treated at a rate of 1 lb a.i./A. Approximately 3.9% of the applied radioactivity volatilized from TCM-labeled captan. None of the labeled volatiles were parent captan (MRID 00160301).

e. Accumulation

Bioaccumulation in Aquatic Organisms: Two studies, one each for cyclohexene-labeled and TCM-labeled captan, were reviewed and indicate that residues do not accumulate substantially in bluegill sunfish. When exposed to a nominal concentration of 5 µg/L of ring-labeled ^{14}C-captan for 28 days, bluegill sunfish had ^{14}C bioaccumulation factors of 102X, 126X, and 113X for edible, non-edible, and whole fish tissue, respectively. After a 14-day depuration period, ^{14}C-residues in edible tissue, non-edible tissue, and whole fish declined by 94%, 96%, and 95%, respectively. Degradates in exposure water and fish metabolites were not identified. Accumulated residues were largely eliminated during the depuration period. The data requirement is satisfied and the Agency is not requiring additional fish accumulation data for captan at this time. (MRID 40756601, 40756602, 40225601, 00160301).

f. Field Dissipation

Terrestrial Field Dissipation: Six studies were submitted, all of which provide supplemental information.

Parent captan degraded with half-lives of 2.5 to 24 days and was relatively immobile to slightly mobile at six sites. The maximum depth at which captan was detected was 6-12 inches. The degradate THPI was detected at all sites and declined to less than detectable (0.01 ppm) levels between 14 and 184 days after the final captan treatment. THPI was relatively immobile to slightly mobile in the study soils. Its maximum depth of detection was 6-12 inches.

The field studies provide relatively consistent estimates of the parent compound's half-life and the rates of formation and decline of THPI. It is unlikely that any further studies of this type will change the overall assessment of the dissipation, degradation, mobility, or accumulation of captan residues in the environment. Therefore, the Agency is not requiring additional terrestrial field dissipation data at this time (MRID 40823901, 40893601, 40893602, 40893603, 40932201, 40932202).

g. Spray Drift

No captan-specific studies were reviewed. Droplet size spectrum and drift field evaluation studies (guidlines 201-1 and 202-1) were required since the captan products may be applied by aircraft and orchard airblast and due to the concern for potential risk to nontarget aquatic organisms. However, to satisfy these requirements, the registrant, in conjunction with other registrants, formed the Spray Drift Task Force (SDTF). The SDTF has completed and submitted to the Agency its series of studies which are intended to characterize spray droplet drift potential. Factors which appear to affect drift potential and considered in the studies of similiarly applied pesticides include application methods, application equipment, meteorological conditions, crop geometry, and droplet characteristics.

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling as specified in Section V . The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, the following spray drift related language is required on product labels that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method: "Do not allow this product to drift."

h. Water Resources

(1) Ground Water

Modeling

SCI-GROW (Screening Concentrations in Groundwater) is a model for estimating concentrations of pesticides in groundwater and is based on the fate properties of the pesticide, the application rate, and the existing body of data from small-scale groundwater monitoring studies. The model assumes that the pesticide is applied at its maximum rate in areas where the groundwater is particularly vulnerable to contamination. Usually a considerable portion of any use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimates. The model is based on permeable (sandy) soils that are vulnerable to leaching and that overlie shallow (10 to 30 feet deep) groundwater. The estimated maximum concentration derived using SCI-GROW should be considered an upper-bound estimate of acute exposure. If the risk associated with this estimate is exceeded either at the acute or chronic endpoints, refinement of the exposure estimate will be necessary to better characterize actual exposures.

The screening estimate was made based on a maximum application rate of 32 lbs ai/A per year for captan and calculated maximum application rate of 21.36 lb ai/A for THPI. The THPI application rate was derived by multiplying the maximum annual rate of 32 lb ai/A of captan by 0.66, which is the maximum amount of THPI detected in the aerobic soil metabolism study as a percentage of applied captan. The Agency used the aerobic soil metabolism half-life of 1.3 days for captan (an average half-life of 10.7 days for THPI) and a K_{oc} value for captan of 200 mL/g (2.2 mL/g for THPI). The SCI-GROW screening model (ver. 2.0) predicts captan residues of 0.02 μg/L in groundwater and cumulative captan residue (captan and THPI) of 3.4 μg/L.

Monitoring

The information from the Pesticides in Ground Water Database (PGWD) provides only a limited picture of captan's leaching potential. The PGWD provides the largest compilation of captan ground water data, detailing results of analyses performed no later than 1990. There are few data that suggest that captan will leach to ground water as a result of normal agricultural use. The California summary in the PGWD does not detail whether the samples taken were from known captan use areas, or were part of large-scale survey studies.

Captan was not detected in the National Pesticide Survey. The greatest number of samples were taken in California between 1984 and 1989. Four samples had detections of captan out of 1158 analyzed with a range of concentrations from 0.1 to 0.5 ppb.

The PGWD reports that no captan was detected in 670 samples taken from 7 other states between 1983 and 1990. However, the study summaries indicated that the majority were not specifically designed to sample captan use areas. Survey studies in Illinois, Indiana, Texas and Virginia were designed to characterize regional ground-water or drinking-water quality. Specific use of captan was not investigated in Maine, Rhode Island and Oregon.

As discussed earlier, the environmental fate data for captan suggests that it would not pose a risk for leaching to ground water. At a pH level of 7.0, captan degrades to THPI by hydrolysis with a half-life of 5 to 6 hours. At a pH of 9.0, the half-life is only 3.6 to 8 minutes. Therefore, degradation of captan to THPI would begin with mixing of the fungicide with water for application.

Captan applied to foliage will not be immediately available for infiltration into the soil. Studies from the mid-1980's addressed the dissipation of captan from foliage, and derived a range of half-lives of 3 to 13 days. A further study done on strawberries in California led to a foliar dislodgeable residue half-life estimate of 9 days. Previous Agency calculations used a foliar half-life of 10 days. Any captan that reaches the soil surface after application would be subject to an aerobic soil metabolism half-life of less than a day. Therefore, parent captan is unlikely to pose a risk of ground water contamination. A concentration of 0.5 ppb is recommended for highly conservative exposure estimates.

THPI: There are no data on captan degradate THPI, either in the PGWD or in the National Pesticide Survey. However, fate data for THPI suggest that this degradate would be unlikely to leach to ground water under most agricultural scenarios. Although laboratory studies show THPI to be quite mobile, the aerobic soil metabolism half-lives for THPI calculated for three soils were 6, 7 and 19.5 days. The soils for which the 6 and 19.5 day half-lives calculated were from the same sandy soil types (85 and 90% sand, respectively), but the 19.5 day half-life pertains to the soil with an organic matter content of 0.7%, as opposed to 3.7% for the other. Therefore, soils that are quite sandy and have very low organic matter contents seem to provide the only scenario in which THPI might leach to ground water. Data suggest that even under this scenario, the amount of THPI that might be available for leaching is limited.

Captan is applied foliarly, and has a reported foliar dissipation rate of 9 or 10 days (Willis and McDowell, 1987). It also degrades almost completely by hydrolysis in less than a day. Therefore, unless significant amounts of captan are inadvertently applied to the soil by drift, or a significant rainstorm washes all applied captan from foliage soon after application, all THPI formed will not be uniformly made available for leaching by a single effective application to the soil. It is not clear from our data what percentage of parent captan is converted to THPI by hydrolysis. However, THPI formed through aerobic soil degradation of captan accounted for a maximum 66% of the parent compound in laboratory studies.

Furthermore, a very small portion of crops (orchard fruit trees) to which captan is applied will be grown on sandy soils with very low organic matter. In addition, most crops on the captan label have fewer than half of their total acreage treated with captan. The one exception to both statements is strawberries, which are grown predominantly on such soils, and which are almost universally treated with captan. The potential for leaching is reduced for strawberries by the use of plastic sheeting mulch and subsoil drip irrigation. In Florida, one of the major states where strawberries are grown, the very shallow depth to ground water makes it very likely that THPI concentrations could be found in ground water.

(2) Surface Water

Due to the range of field dissipation half-lives (2.5 to 24 days), substantial amounts of captan could be available for runoff to surface water for a few days to several weeks post-application. The relatively low soil/water partitioning of captan for 4 soils indicates that most captan runoff will be via dissolution in runoff water as opposed to adsorption to eroding soil.

Captan is susceptible to rapid abiotic hydrolysis and to fairly rapid microbiological degradation under both aerobic and anaerobic conditions. Consequently, it is not expected to persist in surface waters under most hydrological or chemical conditions. Its relatively low soil/water partitioning indicates that most of the captan in surface waters will be dissolved in the water column as opposed to adsorbed to suspended and bottom sediment. As discussed earlier, the bioaccumulation potential for captan is relatively low.

The State of Illinois (Moyer and Cross 1990) sampled 30 surface water sites for pesticides at various times from October 1985 through October 1988. Substantial use in Illinois was a criterion for pesticides being included in the analyses. Total (dissolved and adsorbed to suspended sediment) captan was not detected above a detection limit of 0.05 ug/L in any of 580 samples collected from the 30 sites sampled.

The major degradates, THPI and THPAm, exhibit low soil/water partitioning indicating that most of their runoff will be via dissolution in runoff water as opposed to adsorption to eroding soil. Both degrade at rates comparable to those of captan (relatively rapidly) under aerobic conditions.

Based on fate characteristics and model predictions, the Agency believes THPI could reach surface drinking water sources. Surface water concentrations were modeled with PRZM2 and EXAMS using the Georgia peach scenario that produced the highest 90-day aquatic pesticide level for captan. Chemical-specific inputs, standard model parameters and the PRZM2 input file are available. The results of the PRZM2-EXAMS simulation of THPI concentrations resulting from maximum label use-rate of captan on peaches are shown below.

Average THPI Concentration (ppb)

Frequency (years)	Peak	96-Hour	21-Day	60-Day	90-Day	Yearly
1/10	668	385	123	50.9	34.1	10.8

The Agency recommends that 668 ppb be considered as a highly conservative estimate for acute surface drinking water levels of THPI. Average chronic levels for 90 and 365 days are 34.1 and 10.8 ppb, respectively.

Tier 2 surface water modeling used the following data for input into the PRZM-EXAMS modeling. The following shows the scenarios used:

Parameter	Value
Soil K_{oc}	200 L/g
Aerobic soil half-life	1.25 days
Anaerobic soil half-life	1.85 days
Photolysis half-life (pH 7)	0.42 days
Hydrolysis (pH 5, 7 and 9)	0.8, 0.25, 0.006 days
Water Solubility	3.3 mg/L
Vapor Pressure	8.0 E-8 Torr
Henry's Law Constant	9.59 E-10 Atm. M^3Mol^{-1}

PRZM-EXAMS Modeling Input Scenarios

Crop	Location	Weather (MLRA)	Soil	Soil Taxonomy
Almonds	Los Angeles, CA	C-20	Rincon Silty clay loam	Mollic Haploxeralf
Apple	Columbia, NY	R-144B	Lehigh Silt loam	Aquic Hapludalf
Peaches	Spartanburg, SC	P-136	Cecil Sandy loam	Typic Hapludult
Prunes	Los Angeles, CA	C-20	Rincon Silty clay loam	Mollic Haploxeralf
Cherries	San Joaquin, CA	C-17	Chino Silt loam	Aquic Haploxeroll
Blueberries	Van Burn, MI	L-97	Rimer Loamy sand	Arenic Hapludalf

3. Ecological Exposure and Risk Characterization

a. Risk Quotient (RQ) and the Level of Concern (LOC)

The Levels of Concern are criteria to indicate potential risk to nontarget organisms. The criteria indicate whether a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. To determine whether an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. Acute effect levels are as follows:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

Chronic effect levels are as follows:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and *either*
-The NOEL for chronic aquatic studies, *or*
-The Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, the Agency presumes a risk of concern to that particular category. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

IF...	THEN the Agency presumes...
Mammals and Birds	
The acute RQ > LOC of 0.5,	High acute risk
The acute RQ >LOC of 0.2,	Risk that may be mitigated through restricted use
The acute RQ > LOC of 0.1,	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered species
Fish and Aquatic Invertebrates	
The acute RQ > LOC of 0.5	High acute risk
The acute RQ > LOC of 0.1	Risk that may be mitigated through restricted use
The acute RQ >LOC of 0.05	Acute effects may occur in Endangered species
The chronic RQ > LOC of 1	Chronic risk *and* Chronic effects may occur in Endangered species
Plants	
The RQ > LOC of 1	High risk
The RQ > LOC of 1	Endangered plants may be affected

No separate criteria exist for restricted use or chronic effects for plants.

b. Exposure and Risk to Nontarget Terrestrial Animals

(1) Birds

Residues found on dietary food items following captan application are compared to LC_{50} values to predict hazard. The maximum concentrations of residues of captan which may be expected to occur on selected avian or mammalian dietary food items following both single and multiple foliar application rates are provided in the tables below. Residues per lb ai applied for the four food types are developed from Hoerger and Kenaga (1972) and Kenaga (1973), with modifications suggested by Fletcher et. al. (1994); the "broadleaf plants" category includes forage and is considered applicable to small insects while the "fruits" category includes seeds and is considered applicable to large insects.

There are no definitive risk quotients for avian acute risk since definitive LC_{50}s are not available (3 deaths occurred at 5200 ppm in the bobwhite quail study --MRID 43869802, but no mortality was reported at 4640 ppm in MRID 00104686). The following terrestrial exposure table for a single application shows that no acute avian LOCs are exceeded for any use pattern.

Terrestrial EECs - Single Application*

Use Site	Applic. rate	Food item	max EEC (ppm)
Almonds	4.5	short grass	1,260
		long grass	578
		broadleaf plants/ insects	709
		seeds	79
Apples Peaches Nectarines Turf	4	short grass	960
		long grass	440
		broadleaf plants/ insects	540
		seeds	60
Pears Plums/fresh prunes Strawberries	3	short grass	720
		long grass	330
		broadleaf plants/ insects	405
		fruits/seeds	45
Apricots Blueberries	2.5	short grass	600
		long grass	275
		broadleaf plants/ insects	338
		fruits/seeds	38
Cherries Grapes	2	short grass	480
		long grass	220
		broadleaf plants/ insects	270
		fruits/seeds	30

Maximum residues from a single application are below the no-mortality levels for all species tested and are thus unlikely to result in avian mortality from dietary exposure.

For multiple applications, a terrestrial exposure model called FATE is used to estimate residues based on accumulation from repeat applications at a given interval and degradation rate due to estimated foliar dissipation. Since actual foliar half-life data are not available, the dissipation half-life (9 days) was estimated, based partly on dislodgeable residue information available to the Agency. Where maximum residue values are used, captan concentrations are expressed as EEC maximum (max) and average maximum (avg. max.). When mean values are used captan concentrations are expressed as EEC average mean.

Terrestrial EECs -- Multiple Applications*

Use Site	App. rate (lbs ai/A)	No. of apps.	Applic. interval (days)	Food item	EEC (ppm) max.	EEC (ppm) avg. max.	EEC (ppm) max. mean	EEC (ppm) avg. mean
Almonds	4.5	5	5	short grass	3,368	2168	1192	767
				long grass	1,545			
				broadleaf plants/insects	1,895	1220	630	406
				seeds	211			
Turf	4	8	7	short grass	2,272	1572		N/A
				long grass				N/A
				broadleaf plants/insects	1278	859		N/A
				seeds	142	95		N/A
Apples	4	7	7	short grass	2,250	1485	797	526
				long grass	1,161			
				broadleaf plants/insects	1266	835	422	278
				seeds	159			
Peaches Nectarines	4	8	3	short grass	3,921	2589	1388	917
				long grass	1,797	1187	588	388
				broadleaf plants/insects	2205	1456	735	486
				seeds	245			
Pears Plums/fresh prunes	3	9	7	short grass	1714	1170	607	415
				long grass	786			
				broadleaf plants/insects	964	658	321	220
				fruits/seeds	107			
Strawberries	3	7	7	short grass	1688	1113	598	394
				long grass				
				broadleaf plants/insects	949	626	316	208
				fruits/seeds	105	70		
Apricots Blueberries	2.5	14	7	short grass	1439	1038	510	368
				long grass	660			
				broadleaf plants	811	585	271	196
				fruits/seeds	91			

Use Site	App. rate (lbs ai/A)	No. of apps.	Applic. interval (days)	Food item	EEC (ppm) max.	EEC (ppm) avg. max.	EEC (ppm) max. mean	EEC (ppm) avg. mean
Cherries Grapes	2	7	3	short grass	1,865	1219	660	432
				long grass	855			
				broadleaf plants/insects	1,049	686	350	229
				fruits/ seeds	117			

Each of the above crop groupings has a similar use pattern. The number of applications (based on maximum seasonal rates) and application intervals for underlined crops are considered representative. Foliar half-life used is 9 days.

For the sites evaluated, estimated maximum residues resulting from multiple applications at the maximum rates and minimum intervals are below the no-mortality level in all avian LC_{50} tests. Thus, it appears unlikely that these dietary residues would result in avian mortality.

Avian reproduction testing was conducted at up to 1000 ppm, with no effects reported. An evaluation of all foliar uses at the maximum label rates; multiple applications and minimum intervals would potentially result in maximum residues greater than 1000 ppm on most avian food items. However, without data for higher concentrations, the Agency cannot determine if higher residues could cause adverse reproductive effects. A refinement of the exposure assumptions for orchards suggests lower residues and therefore less likelihood for chronic risk. The refined exposure assessment is based on the following assumptions:

1) Maximum residues were outliers resulting from a direct application. Note that in the case of short grass the maximum (240 ppm) vs. the mean value (85 ppm) differ by 3X.

2) To be consistent with the assumption in aquatic exposure models for aerial or mist blowers, only a portion (<100%) of the application rate is assumed to hit or be retained in the target area at the time of or shortly after application.

3) The duration of a bird's exposure to the specific dose level should be considered.

Assuming a direct application of 100% of the applied rate reaches the orchard floor to contaminate short grass (as contrasted with a bare floor, long grass or even an intermediate substrate such as broadleaf vegetation) these average residues for short grass in almond orchards could range from 767 to 2168 ppm (based on mean and maximum values respectively). Given the previously mentioned assumptions for orchard uses, chronic risks to both birds and small ground-dwelling mammals will be based on average mean values unless stated otherwise. Since none of the average mean values exceed the NOEL of 1000 ppm, there does not appear to a chronic risk to birds from captan's use in orchards.

Captan's use on crops such as strawberries and turf results in a direct application to avian food items; consequently the average maximum value was compared to the NOEL for a preliminary chronic risk assessment resulting in risk quotients are between 1 and 2.2. Repeating the avian reproduction study would reduce the uncertainty, but the value added would be low. In the case of turf, residues could be reduced as result of increased biomass as the grass grows and the subsequent cutting and potential removal of clippings (especially on the intensively cared-for turf-- greens, tees and lawns). Strawberries grown commercially (where direct application of captan use is likely to occur) will have little if any competing vegetation -- especially if the strawberries are grown using plastic mulches. Since captan residues are below 1000 ppm for insects, fruit and the strawberry plants, no chronic risk is anticipated.

(2) Mammals

Small mammal exposure is addressed using the acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} uses the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

Small Mammal Food Consumption in PPMs (Based on an LD_{50} = 9 gm/kg)

Small Mammal	Body Weight (gm)	% Weight Eaten/Day	Food/Day (gm)	Est. LC_{50}/Day (ppm)
Meadow Vole	46 gms	61 %	28.1 gms	14733 ppm
Adult Field Mouse	13 gms	16 %	2.1 gms	55714 ppm
Least Shrew	5 gms	110 %	5.5 gms	8181 ppm

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the residues listed above to calculate a risk quotient (EEC/LC_{50}). The estimated LC50 in these calculations can be considered as the concentration of toxicant in a day's diet, lethal to 50% of a test population.

Single applications of captan to almonds, apples, peaches, nectarines, turf, plums/fresh prunes, strawberries, apricots, blueberries, cherries and grapes with single application rates ranging from 2 - 4.5 lbs a.i/A result in risk quotients (RQ) less than 0.1. The exposure estimates used for terrestrial risk assessment are based on the work of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). All of the single application residues leave a predicted residue below the level of concern for all acute risk categories of mammals, including endangered species.

Acute and chronic risk quotients for multiple applications were also evaluated. The quotients serve as a screen for depicting the potential acute and chronic risk to small mammals. The chronic risk quotients are expressed based on the range of NOELs of 250 and 2000 ppm

extracted from mammalian reproduction and developmental studies. The following table indicates that the acute restricted and endangered species LOCs are exceeded for almonds and peaches, and that the acute endangered species LOC is exceeded for all other sites. Chronic risk to small mammals is predicted to occur for all foliar uses when residues are based on maximum estimated exposure values.

Quotients -- Multiple Applications, Maximum EEC*

Use Site	App. rate	# Apps.	App. interval (days)	Small mammal	Acute RQ	Chronic RQ
Turf	4	8	7	meadow vole	0.15	1.14-9.1
				field mouse	<0.1	0.07-0.6
				least shrew	0.16	0.64-5.1
Almonds	4.5	5	5	meadow vole	0.23	1.7-13.5
				field mouse	<0.1	0.11-0.84
				least shrew	0.23	0.95-7.6
Apples	4	7	7	meadow vole	0.17	1.3-10.1
				field mouse	<0.1	0.1-0.64
				least shrew	0.17	0.71-5.7
Peaches Nectarines	4	8	3	meadow vole	0.27	2.0-15.7
				field mouse	<0.1	0.12-9.8
				least shrew	0.27	1.1-8.8
Pears Plums/fresh prunes	3	9	7	meadow vole	0.12	0.9-6.9
				field mouse	<0.1	0.05-0.43
				least shrew	0.12	0.5-3.9
Strawberries	3	7	7	meadow vole	0.11	0.8-6.8
				field mouse	<0.1	0.5-3.8
				least shrew	0.11	0.1-0.6
Apricots Blueberries	2.5	14	7	meadow vole	0.1	0.7-5.8
				field mouse	<0.1	0.1-0.36
				least shrew	0.1	0.4-3.2
Cherries Grapes	2	7	3	meadow vole	0.13	0.9-7.5
				field mouse	<0.1	0.1-0.47
				least shrew	0.13	0.5-4.2

Each of the above crop groupings has a similar use pattern. The number of applications (based on maximum seasonal rates) and application intervals for underlined crops are considered representative. Foliar half-life used is 9 days. The current standardized models are as follows: -meadow vole consuming short grass; -adult field mouse consuming seeds; -least shrew consuming forage and small insects

Multiple application risk quotients have been calculated based on the following assumptions:

1. The turf use is a direct application to food of the following: short grass for the herbivore (the meadow vole) and the insects for the insectivore (the shrew) and the seeds of the granivore (field mouse). Acute risk will be based on maximum Fletcher residues and chronic risk will be compared to the average maximum Fletcher residue values.

2. Strawberry use is direct application to food of ground foraging insectivores, fruit eaters and herbivores (see above). Acute and chronic risk is based on the same principle as turf.

3. Most other crops are orchard crops with indirect application to non-target plant material. Cover on orchard floors could vary from bare ground to short grass, long grass or broadleaf plants. The understory would not be sprayed directly, but contaminated by some spray at the time of application and by material dripping from tree canopy. The understory could be food for the vole. The broadleaf plants value (between the short grass and long grass) is used for the herbivorous meadow vole. The field mouse and the shrew would ingest seeds and insects on the floor that have not been sprayed directly.

Mammal Risk Quotients*

Use Site	App. rate	# Apps.	App. interval (days)	Small mammal	Acute RQ	Chronic RQ
Turf	4	8	7	meadow vole	0.17**	0.8-6.3***
				field mouse	<0.1	<0.3
				least shrew	0.17**	0.4-3.4***
Almonds	4.5	5	5	meadow vole	<0.1	<0.3-1.6
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-1.6
Apples	4	7	7	meadow vole	<0.1	<0.3-1.1
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-1.1
Peaches Nectarines	4	8	3	meadow vole	<0.1	<0.3-1.9
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-1.9
Pears Plums/fresh prunes	3	9	7	meadow vole	<0.1	<0.3-0.9
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-0.9
Strawberries	3	7	7	meadow vole	0.11**	0.5-4.4***
				field mouse	<0.1	<0.3
				least shrew	0.11**	0.3-2.5***
Apricots Blueberries	2.5	14	7	meadow vole	<0.1	<0.3-0.8
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-0.8

Use Site	App. rate	# Apps.	App. interval (days)	Small mammal	Acute RQ	Chronic RQ
Cherries Grapes	2	7	3	meadow vole	<0.1	<0.3-0.9
				field mouse	<0.1	<0.3
				least shrew	<0.1	<0.3-0.9

Note: number of applications (based on maximum seasonal rates) and application intervals for underlined crops are representative of crop groupings. Estimated foliar "half-life" used is 9 days. The current standardized models are as follows: -meadow vole consuming short grass; -adult field mouse consuming seeds; -least shrew consuming forage and small insects. Broadleaf plants value is used to calculate meadow vole risk quotients in orchard crops.

* Multiple Applications: Mean maximum EEC for acute risk (except as noted); Average Mean EEC for chronic risk(except as noted)

** Maximum Fletcher residue value

*** Average maximum Fletcher residue value

With multiple applications, the acute endangered species LOC is exceeded for turf use, as is the chronic risk for herbivores and insectivores. The magnitude of this risk may be small if this use is for spot treatment on sod farms, golf greens, or even home lawns. Strawberries potentially exceed endangered species concern for small insectivores and herbivores. No other sites exceed any of the acute LOCs. The multiple applications of uses of captan for almonds, apples and peaches exceed the chronic LOC for herbivores by slightly over 1.0. The actual risk could be lower as the residues (even though they were the average mean value over the application period) were based on the understory being directly sprayed. The indirect spray values are likely less than those predicted for a direct spray. Consequently, the chronic risk would be further reduced. The acute and chronic risk from captan's use on strawberries is uncertain depending upon the use of maximum (some risk) or mean Fletcher residue values (minimal risk).

(3) Terrestrial Insects

Ecological toxicity data on honey bees indicate that captan does not appear to pose a risk to insects. No further risk assessment will be conducted.

(4) Nontarget Aquatic Animals

Expected Aquatic Concentrations: The Agency uses the GENeric Expected Environmental Concentration program (GENEEC) to calculate screening level EECs in water based on drift and runoff from a 10 hectare field to a 1 hectare x 2 meter deep water body. These EEC's take into account degradation in the field prior to a rain event as well as degradation and partitioning in the pond. Since the Agency does not have a refined exposure scenario for turf, the GENEEC program was used. GENEEC was also used to estimate the exposure from typical use rates for the following sites: almonds, apples, peaches, prunes, and cherries.

A refined EEC is included for those use sites that the Agency modeled using the Pesticide Root Zone Model (PRZM2) to simulate pesticide movement off site via drift and field runoff, and the Exposure Analysis Modeling System (EXAMS II) to simulate pesticide fate and transport in an aquatic environment (one hectare x 2 meter deep).

Estimated Environmental Concentrations (EECs) for Captan*

Crop	Application Method	Application Rate in lbs a.i./A (No. of applics.)	Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	60-day EEC (ppb)	90-day EEC (ppb)
Turf	foliar	4.0 (8)	43.4	11.6	2.2	0.8**	
Almonds	spray blast	4.5 (5)	91.7	19.8	5.5	3.3	2.6
Apples	spray blast	4.0 (8)	49.6	10.6	3.3	2.9	2.0
Peaches	spray blast	4.0 (8)	104.8	19.5	6.9	6.0	4.0
Prunes	spray blast	3.0 (9)	57.9	13.1	3.8	3.5	2.6
Cherries	spray blast	2.0 (7)	6.9	2.0	1.1	0.97	0.65
Blueberries	spray blast	2.5 (14)	36.8	6.7	1.7	1.6	1.5

*EECs for all sites, except turf, from Agency review using PRZM2 (version 2.3) and EXAMS II. Turf EECs from GENEEC model .
**average 56-day EEC

(5) Freshwater Fish

The acute and chronic risk quotients are reported below:

Risk Quotients (RQ) for Freshwater Fish

Crop/appl. rate (lb ai/A)/ # of appls.	Acute RQ	Chronic RQ
Turf (4.0)/ 8	1.6	0.03
Almonds (4.5)/ 5	3.5	0.10
Apples (4.0)/ 8	1.9	0.08
Peaches (4.0)/ 8	4.0	0.16
Prunes (3.0)/ 9	2.2	0.10
Cherries (2.0)/ 7	0.3	0.03
Blueberries (2.5)/ 14	1.4	0.05

Acute RQ = initial EEC/LC50 (LC50 for brown trout, most sensitive species, = 26.2 ppb); Chronic RQ = 90-day EEC*/geometric mean of fish full life-cycle NOEL and LOEL (= 25.5 ppb, fathead minnow)
*56-day EEC for turf (GENEEC model)

Foliar turf applications and air blast applications to fruit and nut crops (except cherries) are expected to exceed high acute risk, restricted use, and endangered species LOCs for fish. Use on cherries exceeds only the restricted use and endangered species LOCs. These RQ's are based on the lowest fish LC_{50}. The three lake trout studies illustrate that, regardless of the test conditions: (flow through vs static) or duration (24 vs 96 hour) the LC_{50} values are very similar (53 - 75 ppb for 24 hr LC_{50} and 49 - 53 for 96 hr LC_{50}). Although using an LC50 of 50 ppb would reduce the risk quotient by approximately one half, the acute high risk, restricted use and and endangered species LOC remain exceeded except for cherries where only the endangered species LOC is exceeded.

Chronic risk to fish is not expected based on the MATC (geometric mean of the NOEL and LOEL) derived from fathead minnow fish full life when compared to the EEC averaged over 90 days. A lower MATC can be estimated for the most sensitive fish, brown trout, by dividing an application factor of 5.3 into 26.2 ppb (the brown trout 96 hour LC_{50}). The middle value was selected simply to strike a balance between the other values. Utilizing the application of 5.3 results in a MATC of 4.8 ppb for the brown trout. Since this value is not exceeded by the highest 90 day EEC (3.0 ppb) there does not appear to be a chronic risk to fish.

(6) Freshwater Invertebrates

The acute and chronic risk quotients are reported below:

Risk Quotients (RQ) for Freshwater Invertebrates

Crop/application rate (lb ai/A)	Acute RQ	Chronic RQ
Turf (4.0)	0.03	<0 02
Almonds (4.5)	0.08	<0 02
Apples (4.0)	0.04	<0.02
Peaches (4.0)	0.08	<0.02
Prunes (3.0)	0.04	<0.02
Cherries (2.0)	0.01	<0.02
Blueberries (2.5)	0.03	<0.02

lowest LC50 for *D. magna* = 1300 ppb; acute RQ = initial EEC/LC50; chronic NOEL < 560 ppb.

The endangered species acute LOC is exceeded for the following modeled sites: turf, almonds, and peaches. There does not appear to be a chronic risk to aquatic invertebrates for any use. It is not likely that the daphnia chronic NOEL would be lower than the highest 21 day EEC, much less the next highest 21 day EEC of 6.9 ppb for peaches.

(7) Estuarine and Marine Animals

In order to assess the risk to estuarine organisms from the turf use the Agency requires a 96-hour LC_{50} study for an estuarine fish, shrimp, and a 48-hour embryo larvae study OR a 96-hour shell deposition study with oysters. The registrant recently submitted a 96-hour LC_{50} study with the sheepshead minnow and a static toxicity study with the saltwater mysid, and must submit a 96-hour shell deposition study.

c. Ecological Risk Due to Seed Treatments

Foliar treatments of captan would generally be expected to pose a greater risk to aquatic life because of repeat applications, runoff, and drift. Also, foliar treatments are not soil-

incorporated whereas seed treatments would be to varying degrees. The Agency does not currently have the capacity to estimate runoff resulting from seed treatments.

In general, seed treatments have the potential to pose risks to birds since seeds could be attractive as a food item. In the case of captan, however, the chemical is generally in the practically nontoxic category for birds, implying low risk. The highest exposure, and thus risk, would appear to be with grass seed. That use is at the highest labeled application rate (9 oz. ai/100 lbs of seed). Captan is broadcast, as opposed to being placed in furrows, and is applied to lightly cover the seeds, allowing for germination. This rate translates into approximately 5625 ppm on the seeds. If a bird's diet were composed entirely of treated seeds, the residues would be slightly higher than the highest test level in most dietary studies, where no mortality was seen. Since a bird's diet does not consist entirely of seeds, there is expected to be no risk.

d. Endangered Species

The Agency has concerns about the exposure of threatened and endangered animal and fish species to captan. With multiple applications, the acute endangered species LOC has been exceeded on turf. Additionally, LOCs are exceeded for endangered species of freshwater fish for all foliar, turf and spray blast applications including almonds, apples, peaches, prunes, cherries and blueberries. LOCs are exceeded for endangered species of freshwater invertebrates for turf, almonds and peaches.

The Agency is developing a crop-based program - the Endangered Species Protection Program to identify all pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

e. Risk Characterization Summary

The ecological risk analysis indicates that captan is relatively a short-lived fungicide in terrestrial environments. Persistence of the parent in ground or surface water is not expected. Direct and indirect evidence indicates that residues of THPI and THPAm may persist in the soil for several months following captan application. Neither of the major degradates is likely to leach to ground water except in cases where soils are quite sandy and of low organic matter content.

No acute or chronic toxicity to birds was recorded at any of the concentrations tested (maximum levels of 5000 ppm and 1000 ppm, respectively). The potential for chronic risk to

avian species is uncertain because test animals were not dosed at levels sufficient to cause an effect. Although risk quotients were therefore not established for avian species, mulitple applications of captan at the minimum application interval would potentially result in maximum residues greater than the 1000 ppm NOEL for most avian food items.

A refinement of the exposure assumptions for orchards suggests lower residues and therefore less likelihood for chronic risk. The refined exposure assessment is based on the following:

1) Maximum residues were outliers resulting from a direct application. Note that in the case of short grass the maximum (240 ppm) vs. the mean value (85 ppm) differ by 3X.

2) Direct application to avian food items will only occur in the cases of turf, strawberries and insects and fruits in the orchard canopy.

3) To be consistent with the assumption in aquatic exposure models for aerial or mist blowers, only a portion (<100%) of the application rate is assumed to hit or be retained in the target area at the time of or shortly after application.

4) The duration of a bird's exposure to the specific dose level should be considered.

Assuming a direct application of 100% of the applied rate reaches the orchard floor to contaminate short grass (as contrasted with a bare floor, long grass or even an intermediate substrate such as broadleaf vegetation) these average residues for short grass in almond orchards could range from 767 to 2168 ppm (based on mean and maximum values respectively). Only the higher value exceeds the NOEL by 2. Given the previously mentioned assumptions for orchard uses, chronic risks to birds will be based on average mean values unless stated otherwise. Since none of the average mean values exceed the NOEL of 1000 ppm there does not appear to a chronic risk to birds from captan's use in orchards.

Captan's use on strawberries and turf results in a direct application to avian food items; consequently the average maximum value was compared to the NOEL for a preliminary chronic risk assessment. The NOEL (>1000 ppm) is exceeded in some instances; the risk quotients are between 1 and 2.2. Repeating the avian reproduction study would reduce the uncertainty, but the value added would be low. In the case of turf, residues could be reduced as result of increased biomass as the grass grows and the subsequent cutting and potential removal of clippings (especially on the intensively cared-for turf-- greens, tees and lawns). Strawberries grown commercially (where direct application of captan use is likely to occur) will have little if any competing vegetation -- especially if the strawberries are grown using plastic mulches. Since captan residues are below 1000 ppm for insects, fruit and the strawberry plants, no chronic risk is anticipated.

Acute risk to mammals is not expected from the use of captan according to label directions. However, there is chronic risk to mammals predicted for all foliar uses at the

maximum predicted EECs. Captan was considered non-toxic to the required insect test species, the honeybee.

Captan is acutely toxic to fish and predicted EEC's exceed levels of concern for acute risk to freshwater fish for most crops simulated. Chronic risk to fish is not anticipated at any of the single or multiple use rates. The EECs used for these assessments are based on the maximum application rates and minimum application intervals allowed on the captan label.

Typical rates are usually less than the maximum label rates. The following tables show that although the resulting EECs are less than those for maximum application rates, acute levels of concern for freshwater fish are still exceeded when captan is applied at typical rates.

Estimated Environmental Concentrations (EECs) for Captan*

Crop	Application Method	Typical Appl. No. of applics. x (rate)	Initial EEC (ppb)	21-day EEC (ppb)	56-day EEC (ppb)
Turf	foliar	----------	-----	----	----------
Almonds	spray blast	1 x (2.7)	27.5	1.4	0.5
Almonds	spray blast	2 x (2.7)	28.1	1.4	0.5
Apples	spray blast	3 x (2.3)	23.9	1.2	0.4
Peaches	spray blast	3 x 1.6	16.6	0.9	0.3
Prunes	spray blast	1 x (2.7)	27.5	1.4	0.5
Cherries	spray blast	2 x (2.3)**	23.9	1.2	0.4
Blueberries	spray blast	---------	-----	---	---

*Maritz report of 1991 (EPA)
**Higher than maximum label rate

Risk Quotients (RQ) for Freshwater Fish

Total seasonal application rate (lb ai/A)	Acute RQ
Turf ----	----
Almonds (3.1)	1.0 *
Apples (8.0)	0.8 *
Peaches (4.3)	0.6 *
Prunes (3.7)	1.0 *
Cherries (5.0)	0.8 *
Blueberries -----	---

Acute RQ = initial EEC/LC50 (LC50 for brown trout, most sensitive species, = 26.2 ppb)
* exceeds high acute, restricted use and endangered species LOC's

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing an active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of data to support reregistration of products containing captan. The Agency has completed its review of these data. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of captan and lists those studies that the Agency found acceptable.

These data were also sufficient to allow the Agency to determine that captan, labeled and used as specified in this Reregistration Eligibility Decision, can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that products registered for these specific uses containing captan as the sole active ingredient are eligible for reregistration, provided actions are taken as specified in this document. Actions needed to reregister particular products are addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the review and evaluation of the data required for reregistration, the current guidelines for conducting acceptable studies to generate these data, and published scientific literature. Although the Agency has found most uses of captan are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing captan, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient captan, the Agency has sufficient information on the health effects of captan and on its potential for causing adverse effects in fish, wildlife, and the environment. The Agency has determined that captan products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, the Agency concludes that products containing captan are eligible for reregistration, subject to the terms and conditions of this RED, except for those with uses on turf and aerially-applied wettable powder formulations. Products applied to turf at sod farms or golf courses are eligible for reregistration; uses at all other turf sites are being voluntarily cancelled. Wettable powder formulations that are applied aerially are eligible for reregistration, provided either: 1) the products are packaged in water soluble packaging; or 2) the application rates are reduced to a level that is no higher than 1.2 lb ai/A.

2. Eligible and Ineligible Uses

The Agency has determined that some uses of captan are eligible for reregistration under the conditions specified in this Reregistration Eligibility Decision. The uses of captan on turf, other than sod farms and golf courses, and the aerial use of the wettable powder formulations require changes before they may be eligible for reregistration.

B. Regulatory Position

To lessen the risks posed by captan, EPA is requiring the following mitigation measures for captan-containing products:

Voluntary cancellation of all turf uses, other than those at sod farms or golf courses, to lessen the hand-to-mouth ingestion risk to toddlers.

Various combinations of chemical-resistant gloves, chemical resistant aprons/coveralls, eye protection, water soluble packaging for wettable powders, and dust/mist respirators to lessen the risks to workers

Labeling changes to lessen risks to nontarget aquatic organisms. Specific label language is provided in Section V of this document.

The following is a summary of the Agency's regulatory position and rationale for managing risks associated with the use of captan. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances for captan, with the amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water. Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way.

EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be available at present.

At this time, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments; however, there are pesticides for which the common mechanism issues can be resolved. For example, pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

Captan and folpet share a common metabolite, thiophosgene, which is believed to be responsible for the carcinogenic effects of these compounds. Thiophosgene is a highly reactive, short-lived species. Studies indicate that thiophosgene causes local irritation of the site with which it comes in contact, and is believed to cause tumors through the irritation of the duodenum. Because they are so short-lived, thiophosgene residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet

since the rate of formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimated cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst case estimate. For captan, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 1.3×10^{-7}. For folpet, the dietary cancer risk estimate for the US population from exposure to residues in/on food is 9.8×10^{-8}. If these two risks are added together the total risk is 2.3×10^{-7} The aggregate cancer Drinking Water Level of Comparison ($DWLOC_{cancer}$) based on this total cancer risk estimate is 11 ppb, using the captan Q_1^* of 2.4×10^{-3}. The estimated environmental concentration (EECs) for folpet are 1 ppb (sw) and less than 1 ppb (gw). The EECs for captan are 4 ppb (sw) and less than 1 ppb (gw). The largest EEC of 4 ppb is less than the DWLOC, the Agency's level of concern. This aggregate assessment is for dietary exposure only. The tumor of concern occurs in the GI tract (duodenum/jejunum-ileum) as a result of oral dosing. The relevance of dermal exposure to a GI tract tumor is unknown at this time. Thus, the Agency concludes that an aggregate cancer risk estimate considering dietary (food and water) exposure only for captan and folpet based on their common metabolite thiophosgene is appropriate.

In assessing acute aggregate dietary risk, EPA used a NOAEL of 10 mg/kg/day from a developmental study in rabbits. Because the NOAEL is from a developmental study the sub-population of females 13 - 50 years, is the subgroup of interest. The acute dietary risk assessment was a highly refined, and therefore reasonably realistic, probabilistic (Monte Carlo) assessment that used anticipated residues and percent crop treated data. EPA estimates that residues of captan in diets of females 13 - 50 years accounts for 36% of the acute PAD. This leaves 64% of the acute PAD for aggregate risk. The DWLOC corresponding to 64% of the acute PAD is approximately 1900 ppb. Because the predicted ground water concentration is only 3.40 ppb and the predicted peak surface water concentration is 668 ppb, aggregate acute exposure and risk are not of concern.

The chronic (non-cancer) aggregate assessment was performed using percent crop treated data, and anticipated residues which considered USDA and FDA pesticide monitoring data and reduction/concentration factors. The drinking water assessment used modeling, as above, to predict ground and surface water concentrations of captan. Chronic dietary exposure to the US population accounts for less than 1% of the chronic PAD. This leaves 99% of the chronic PAD for aggregate risk. For the general population, the DWLOC corresponding to 99% of the chronic PAD is approximately 4500 ppb, which is far greater than the predicted groundwater concentration of 3.4 ppb and the predicted surface water concentration of 10.8 ppb. Therefore, the Agency concludes that the aggregate chronic exposure and risk are not of concern.

b. Determination of Safety for Infants and Children

The Agency has determined that the established tolerances for captan, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty of no harm for

infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of captan residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from captan residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. Based on the current data requirements, captan has a complete database for developmental and reproductive toxicity. Reliable studies cited earlier in this document demonstrated no increased sensitivity of rats, rabbits or hamsters to *in utero* and or post-natal exposure to captan. The Agency has determined that the Safety Factor can be removed (reduced to 1X) based on the developmental and reproductive toxicity studies available for captan, as described previously in Section III(B)2(a) of this document. Therefore, the Agency has concluded that a total uncertainty factor of 100 (10X for interspecies extrapolation, i.e. using animal data for humans, 10X for intraspecies variability, i.e. differences in how humans react to a pesticide, and 1X for the FQPA safety factor for protection of infants and children) is adequate to protect infants and children.

EPA estimates that the residues of captan in the diets of infants and children, specifically the sub-population infants less than 1-year, account for approximately 1.5% of the chronic PAD. As discussed earlier, at this level of contribution from food the drinking water dietary contribution is far below the predicted concentration. Therefore, aggregate chronic exposure and risk to infants and children are not of concern.

The Agency has not yet made a final decision concerning the possible common mechanism of toxicity and the potential for cumulative effects of captan and other compounds. Also, the Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, captan will be revisited to assess cumulative effects, if warranted. Therefore, for the purposes of the tolerance reassessments in this RED document, EPA has considered the risks of captan only.

During the early stages of the FQPA implementation process, the Agency recognizes that some decisions will be made as if FQPA were fully in place. These early case-by case decisions are not intended to set broad precedent regarding the application of FQPA to other Agency regulatory determinations nor are these meant to constrain the Agency as it proceeds with further policy development and future rulemaking. Therefore, the Agency may, at a later date, reconsider actions or decisions as described in this RED.

c. Endocrine Disruptor Effects

FQPA requires EPA to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." EPA has been working with interested stakeholders, including other government agencies, public interest

groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disruptor Screening Program was published in the Federal Register of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds to implement this program, further testing of captan and end-use products for endocrine effects may be required.

2. Tolerance Reassessment

Tolerances for plant and animal commodities currently listed in 40 CFR §180.103(a) are for residues of captan *per se*. This tolerance definition is to be retained for plant commodities; however, the tolerance expression for residues in livestock commodities should be "the combined residues of captan and its metabolite THPI...". Section 180.103 should be subdivided as follows: (a1) General - for plant commodities, (a2) General - for animal commodities, (b) Section 18 Emergency Exemptions - reserved, (c) Regional Registrations - reserved, and (d) Indirect or Inadvertent Residues - reserved.

A Federal Register Notice was published on February 5, 1998, proposing to revoke the following tolerances: avocados, garlic, leeks, shallots, taro, and pimentos. The final revocation notice was published in the Federal Register on October 26, 1998, and became effective on January 25, 1999. Captan is not applied directly on pears, as a foliar spray, but may be applied as a post-harvest application. All applications of captan to caneberries (raspberries and blackberries) are 24(c) registrations, that is, Special Local Needs (SLNs) in Oregon, Washington, Ohio, Pennsylvania, and South Carolina. The reassessed tolerances are presented below.

Tolerance Reassessment Summary for Captan

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.103 (a1)			
Almonds	2	0.25	Formerly interim tolerance in 40 CFR §180.103 (b); re-establish permanent; data indicate tolerance can be lower
Almond hulls	100	75	Formerly interim tolerance in 40 CFR §180.103 (b); re-establish permanent; data indicate tolerance can be lower
Apples	25	25	
Apricots	50	10	Available data indicate tolerance can be lowered
Beans, dry	25	Reassign	Formerly interim tolerance under 40 CFR §180.103 (b); Crop Group Tolerance to be established for legume vegetables

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Beans, succulent	25	Reassign	Formerly interim tolerance under 40 CFR §180.103 (b); Crop Group Tolerance to be established for legume vegetables
Beet, greens	100	Reassign	Crop Group Tolerance to be established for leaves of root and tuber vegetables
Beet (roots)	2	Reassign	Crop Group Tolerance to be established for root and tuber vegetables
Blackberries	25	Reassign	Crop Subgroup Tolerance to be established for caneberries
Blueberries (huckleberries)	25	20	The available data indicate the tolerance can be lowered; tolerance of 20 is also compatible with CODEX
Brassica (cole) Leafy Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan.
Broccoli	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Brussels sprouts	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Bulb Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Cabbage	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Caneberries	None	25	Crop Subgroup Tolerance
Cantaloupes	25	Reassign	Crop Group Tolerance to be established for cucurbit vegetables
Carrots	2	Reassign	Crop Group Tolerance to be established for root and tuber vegetables
Cauliflower	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Celery	50	Reassign	Crop Group Tolerance to be established for leafy vegetables (except Brassica)
Cereal Grains (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Cereal Grain (Forage, Fodder, and Straw) (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Cherries	100	50	Available data indicate tolerance can be lowered

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Collards	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Corn, sweet (K+ CWHR)	2	Reassign	Crop Group Tolerance to be established for cereal grains
Cottonseed (seed treatment only)	2	0.05	*Cotton, seed.* Non-detectable residues of captan
Cucurbit Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Cucumbers	25	Reassign	Crop Group Tolerance to be established for cucurbit vegetables
Dewberries	25	Reassign	Crop Subgroup Tolerance to be established for caneberries
Dill, seed (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Eggplants	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Flax, seed (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Flax, straw (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Foliage of Legume Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Fruiting Vegetables (except cucurbits) (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Grapes	50	25	Available data indicate tolerance can be lowered
Grasses (Forage and Hay)	None	0.05	Represents non-detectable residues of captan
Honeydew melons	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Kale	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Leafy Vegetables (except *Brassica*) (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Leaves of Root and Tuber Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Legume Vegetables (succulent or dried) (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Lettuce	100	Reassign	To establish crop group tolerance for leafy vegetables (except Brassica)
Mangoes	50	Revoke	No registered products for this use
Muskmelons	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Mustard greens	2	Reassign	Crop Group Tolerance to be established for Brassica (cole) leafy vegetables
Nectarines	50	25	Available data indicate tolerance can be lowered
Non-Grass Animal Feeds (Forage, Fodder, Straw, and Hay) (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan
Onions, dry bulb	25	Reassign	Crop Group Tolerance to be established for bulb vegetables
Onions, green	50	Reassign	Crop Group Tolerance to be established for bulb vegetables
Okra (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Peaches	50	15	Available data indicate tolerance can be lowered; tolerance of 15 also compatible with CODEX
Peanuts (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Peanut hay (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Pears (post-harvest only)	25	25	Represents non-detectable residues of captan.
Peas, dry	2	Reassign	Crop Group Tol. to be established for legume vegetables
Peas, succulent	2	Reassign	Crop Group Tol. to be established for legume vegetables
Plums (fresh prunes)	100	10	Available data indicate tolerance can be lowered
Peppers	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Potatoes	25	Reassign	Formerly interim tolerance established under 40 CFR §180.103 (b); Crop Group Tolerance to be established for root and tuber vegetables
Pumpkins	25	Reassign	To establish crop group tolerance for cucurbit vegetables
Rape, seed (Seed treatment only)	None	0.05	Represents non-detectable residues of captan

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Rape, forage (Seed treatment only)	None	0.05	Represents non-detectable residues of captan
Raspberries	25	Reassign	Crop Subgroup Tol. to be established for caneberries
Root and Tuber Vegetables (Seed treatment only)	None	0.05	Crop Group Tolerance; represents non-detectable residues of captan.
Rutabagas (roots)	2	Reassign	Crop Group Tol. to be est. for root and tuber vegetables
Safflower seed (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Sesame seed (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Soybeans, dry	2	Reassign	Crop Group Tol. to be est. for legume vegetables
Soybeans, succulent	2	Reassign	Crop Group Tol. to be est. for legume vegetables
Spinach	100	Reassign	Crop Group Tolerance to be established for leafy vegetables (except Brassica)
Squash, summer	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Squash, winter	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Strawberries	25	20	Available data indicate tolerance can be lowered; tolerance of 20 is also compatible with CODEX
Sunflower, seeds (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Sunflower, forage (Seed treatment only)	None	0.05	Represents non-detectable residues of captan.
Tomatoes	25	Reassign	Crop Group Tolerance to be established for fruiting vegetable (except cucurbit)
Turnip, greens	2	Reassign	Crop Group Tolerance to be established for leaves of root and tuber vegetables
Turnips, roots	2	Reassign	Crop Group Tol. to be est. for root and tuber vegetables
Watermelons	25	Reassign	Crop Group Tolerance to be established for fruiting vegetables (except cucurbit)
Tolerances required under 40 CFR §180.103 (a2)			
Cattle, fat	0.05	0.15	Tolerance increase to include THPI in expression
Cattle, mbyp	0.05	0.30	Tolerance increase to include THPI in expression

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Cattle, meat	0.05	0.20	Tolerance increase to include THPI in expression
Goats, fat	None	0.15	
Goats, mbyp	None	0.30	
Goats, meat	None	0.20	
Hogs, fat	0.05	0.15	Tolerance increase to include THPI in expression
Hogs, mbyp	0.05	0.30	Tolerance increase to include THPI in expression
Hogs, meat	0.05	0.20	Tolerance increase to include THPI in expression
Horses, fat	None	0.15	
Horses, mbyp	None	0.30	
Horses, meat	None	0.20	
Milk	None	0.10	
Sheep, fat	None	0.15	
Sheep, mbyp	None	0.30	
Sheep, meat	None	0.20	

Codex Harmonization

Several maximum residue limits (MRLs) for captan have been established by Codex in various commodities. Codex MRLs are defined in terms of captan *per se.* Currently, the captan residues regulated by Codex and the U.S. are all plant commodities and are therefore equivalent.

Codex MRLs and Applicable U.S. tolerances.

Commodity	MRL (mg/kg)[1]	US Tolerance (ppm)	Recommendation
Apple	25	25	
Blueberries	20	25	US tolerance to be decreased to 20 ppm
Citrus fruits	15[2]	N/A	
Dried grapes	5[2]	N/A	US tolerance to be revoked.
Peach	15	50	US tolerance to be decreased to 15 ppm.
Pear	25	25	

Commodity	MRL (mg/kg)[1]	US Tolerance (ppm)	Recommendation
Strawberry	20	25	US tolerance to be decreased to 20 ppm
Tomato	15	0.05	US tolerance to be revoked; to establish crop group tolerance for Fruiting Vegetables (except cucurbits); seed treatment only

[1]All captan MRLs are final (CXL).

[2]JMPR 1990 had proposed to withdraw the CXL in view of no expected uses.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs:

- Compatibility between U.S. tolerances and Codex MRLs exists for apples and pears.
- No questions of compatibility exist with respect to commodities where: (1) no Codex MRLs have been established but U.S. tolerances exist; or (2) Codex MRLs have been established but U.S. tolerances do not exist.

a. Human Health Risk Mitigation

(1) Acute Dietary Mitigation

Acute dietary exposure is below the Agency's level of concern for the population of concern (females 13-50 years of age). The 99.9th percentile of acute exposure through food to females 13-50 years occupies 36% of the acute PAD. No additional mitigation is required.

(2) Chronic (non-cancer) Dietary Mitigation

The chronic dietary risk from captan is below the Agency's level of concern. The most exposed group is infants less than 1-year old. The exposure to this group occupies less than 1.3% of the chronic PAD. No additional mitigation is required.

(3) Chronic (cancer) Dietary Mitigation

The dietary cancer risk for captan is below the Agency's level of concern. The upper bound dietary cancer risk was calculated to be 1.3 x 10^{-7} for all registered uses of captan, including refinements such as processing factors and percent crop treated data. No additional mitigation is required.

(4) Worker Mitigation

Agricultural uses of captan must have MOEs (Margins of Exposure) greater than or equal to 100 when considering short-term and intermediate-term scenarios, for both dermal and

inhalation exposures. Additionally, since captan has been classified as a carcinogen, the occupational cancer risk considers both dermal and inhalation exposures. As a general rule, occupational cancer risks should be in the range of 10^{-4} to 10^{-6} or lower. For captan, carcinogenic risks vary from 1.3×10^{-5} to 1.7×10^{-9}. Thus, no additional mitigation to address occupational carcinogenic risks is required.

For Mixer/Loaders

Wettable powder (aerial application): The total margin of exposure (MOE) for workers mixing/loading a wettable powder formulation for aerial application is 41 even with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require water soluble pouches, and chemical-resistant gloves to mitigate the risks when mixing/loading wettable powders for aerial applications. With this mitigation the MOE becomes 1000. A chemical-resistant apron is not required since the high inhalation exposure is the primary factor in requiring the use of water soluble pouches.

Wettable powder (chemigation application): The aerial application scenario will be used as the surrogate for chemigation. The Agency will require the use of an engineering control (water soluble pouches), and chemical-resistant gloves to mitigate the risks when mixing/loading wettable powders for chemigation.

Wettable powder (airblast application): The total MOEs for workers mixing/loading a wettable powder formulation for airblast application of captan range from 270 to 530 with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator when mixing/loading wettable powders for airblast applications.

Wettable Powder (groundboom application): The total MOE for workers mixing/loading a wettable powder formulation for groundboom application of captan is 710 with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator when mixing/loading wettable powders for groundboom applications.

Wettable Powder (greenhouse - high pressure spray): The total MOE for workers mixing/loading a wettable powder formulation for a high pressure spray in a greenhouse is approximately 43,000 with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator when using a high pressure spray.

Wettable Powder (golf course - ground equipment): The total MOE for workers mixing/loading a wettable powder formulation for applying by ground equipment on a golf course is 240 with the use of chemical-resistant gloves and dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator for applying by ground equipment on a golf course.

Wettable Powder (adding to paints or adhesives - industrial use): The total MOEs for workers mixing/loading a wettable powder formulation for adding to paints and adhesives in a manufacturing operation range from 1,400 to 5,400 with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator for adding captan to paints and adhesives.

Wettable Powder (seed treatment): The total MOEs for workers mixing/loading a wettable powder formulation for a seed treatment such as use in a hopper box range from 78 with the use of chemical-resistant gloves to 12,000 with the use of chemical-resistant gloves and a dust/mist respirator. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator for handlers who are treating seeds.

Wettable Powder or Dust (soil and greenhouse bench treatment): The previous scenario wettable powder (seed treatment) will be used as the surrogate for the use of a dust formulation for soil and greenhouse bench treatments. The Agency will require the use of chemical-resistant gloves and a dust/mist respirator for handlers working a captan end-use product into the soil and for handlers seeding and transplanting into the treated soil immediately at the time of application.

Wettable Powder (fruit dips): The total MOE for workers mixing/loading a wettable powder formulation for preparing a solution for dipping apples, pears, or cherries is 1,200 with the use of chemical-resistant gloves and a dust/mist respirator. Thus the Agency will require the use of chemical-resistant gloves and a dust/mist respirator when mixing/loading a solution for use as a dip.

Liquids/Flowable (aerial): The total MOE for workers mixing/loading a liquid formulation for an aerial application of captan is 350 with the use of chemical-resistant gloves. Thus the Agency will require the use of chemical-resistant gloves when mixing/loading liquid/flowables for aerial application.

Liquids/Flowable (airblast): The total MOEs for workers mixing/loading a liquid/flowable formulation for an airblast application of captan ranges 2,300 to 4,600 with the use of chemical-resistant gloves. Thus the Agency will require the use of chemical-resistant gloves when mixing/loading liquid/flowables for airblast application.

Liquids/Flowable (groundboom): The total MOE for workers mixing/loading a liquid/flowable formulation for an aerial application of captan is 6,200 with the use of chemical-resistant gloves. Thus the Agency will require the use of chemical-resistant gloves when mixing/loading liquid/flowables for groundboom application.

Handling of Treated Seed

Use of Treated Seed: Handlers may need to move/place treated seed when drying or bagging, or loading treated bags of seed into planting equipment. Additionally, captan can also be

used on seed potatoes, which can then require cutting and sorting. The Agency will require that handlers using open bags of treated seed wear a dust/mist respirator, chemical-resistant gloves and eye-protection. Captan end-use products that can be used to treat seed potatoes will require the use of a dust/mist respirator, chemical-resistant gloves and eye-protection when cutting and sorting treated seed potatoes.

For Applicators

Aerial: At baseline, the total MOE for workers applying captan using aerial equipment is 2,500. No additional mitigation is required.

Airblast: At baseline, the total MOEs for workers applying captan using airblast equipment vary from 240 to 1,100. No additional mitigation is required.

Groundboom: At baseline, the total MOE for workers applying captan using groundboom equipment is 11,000. No additional mitigation is required.

Planting of Treated Seeds (including potato seed pieces): At baseline, using captan specific data the total MOE for the observer riding on the rear of the planter was 2083. No additional mitigation is required.

Golf courses (ground equipment): At baseline, the total MOE for workers applying captan to golf courses using ground equipment is 3,600. No additional mitigation is required.

Paints (brush): At baseline, the total MOE for commercial painters applying captan containing paint using brushes is 690. No additional mitigation is required.

Paints (sprayer): The total MOE for commercial painters applying captan containing paint using a sprayer with the use of a dust/mist respirator is 72. The Agency will require the use of a dust/mist respirator and waterproof gloves when applying captan-containing paint with a sprayer, which results in an MOE of 160.

Paints (roller): Although no data were available to assess the exposure from this scenario, the Agency does not expect the risk to be significantly higher than that of the paint brush scenario. No additional mitigation is required. However, the Agency will require submission of data to assess this scenario.

High Pressure Spray: The total MOE for workers applying captan using high pressure spray equipment is 5,300 with the use of chemical-resistant gloves. The Agency will require the use of chemical-resistant gloves.

Post-Harvest Fruit Dip: There are no activity specific data to address the use of a solution of captan as a dip for apples, cherries, and pears. Once the solution has been mixed, most of the application is mechanized (such as operating fork lifts) and the potential for exposure

is considered to be low. Due to the absence of data, the Agency will restrict post-harvest dipping activities to mechanized activities only - no hand dipping. Workers who are assisting in the mechanized activity must wear chemical-resistant gloves and chemical-resistant apron.

Mixer/Loader/Applicator

Wettable Powder (low pressure handwand): The total MOE for workers mixing/loading/applying a wettable powder formulation of captan using a low pressure handwand is 9,000 with the use of chemical-resistant gloves. The Agency will require the use of chemical-resistant gloves.

Liquid/Flowable (low pressure handwand): The total MOE for workers mixing/loading/applying a liquid/flowable formulation of captan using a low pressure handwand is 270,000 with the use of chemical-resistant gloves. The Agency will require the use of chemical-resistant gloves.

Backpack/Knapsack: The total MOEs for workers mixing/loading/applying a captan solution using a back/knapsack vary from 1,400 to 5,500 with the use of chemical-resistant gloves. The Agency will require the use of chemical-resistant gloves.

Root Dip Treatment: No data are available to assess this scenario. The Agency will require the submission of exposure data to assess this scenario. Until these data are submitted, reviewed by the Agency, and used to re-evalaute this scenario, the Agency will require the use of a chemical-resistant apron and chemical-resistant gloves, which is assumed will provide adequate protection.

Flagger

Flagger: At baseline, the total MOE for flaggers is 840. No additional mitigation is required.

Post-application Exposure

Since captan is toxicity category I for eye irritation, under the Worker Protection Standard interim REI policy a 48-hour reentry interval (REI) is required for harvesters. However, the captan registrant has submitted chemical specific data on strawberries, grapes and peaches that can be used to establish REIs. These three crops were used as surrogates for all other crops to which captan can be foliar-applied.

Captan can be used as a seed treatment for a variety of crops and as a foliar spray to almonds, apples, apricots, blueberries, caneberries (raspberries and blackberries), cherries, grapes, nectarines, peaches, strawberries, and ornamentals.

Seed Treatments: The Agency is establishing a 12-hour REI for seed treatment uses. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no contact with the soil/media subsurface.

Strawberries, Almonds, Apples, Apricots, Cherries, Nectarines, Plums/fresh Prunes, and Peaches: Based on the risks that were calculated from the submitted strawberry and peach data, the Agency is establishing a 24-hour REI for strawberries, almonds, apples, apricots, cherries, nectarines, and peaches.

Blueberries, caneberries, and grapes: The risks that were calculated from the submitted grape data were MOEs of 60 on Day 2 and 170 on Day 5. Since the target MOE of 100 would be achieved between Day 2 and Day 5, the Agency is establishing a 3-day (72-hour) REI for blueberries, caneberries, and grapes.

Ornamentals: The risks that were calculated from the submitted strawberry data, as well as data from other sources, considered that ornamental workers could work with captan-treated plants from three to six hours per day. Working three hours the MOE was 400 on Day 1. Working six hours the MOE was 100 on Day 5. Due to the uncertainties in the number of hours that workers would be in contact with captan-treated soils and plants, the Agency is establishing a 4-day REI for ornamentals, which is the REI that is on the current labels. The current labels allow early entry for an unlimited length of time during the last 48 hours of the REI, provided early-entry PPE is worn. For ornamental uses only, this will be maintained.

Soil Treatments: Based on the interim WPS REI policy, the Agency is establishing a 48-hour REI for soil and greenhouse bench treatments. Once the treatment, and immediately following seeding and transplanting activities are complete, the surface of the soil cannot be disturbed for 48 hours.

Sod Farms: Based on the interim WPS REI policy, the Agency is establishing a 48-hour REI for sod farms. The Agency is also establishing an additional harvesting prohibition interval of 48 hours.

Early-Entry PPE: The following early entry PPE is required: long-sleeved shirt, long pants, coveralls, shoes and socks, chemical-resistant gloves, and protective eyewear. Double notification is not required. Protective eyewear is required because captan is classified as toxicity category I for eye irritation potential.

Eye-Protection: In addition to the entry restrictions discussed above, the Agency is establishing additional post-application requirements due to eye irritation concerns. Under the Worker Protection Standard a 48-hour REI would be established for captan. However, by the end of the 48-hour interval, the residues from captan would not necessarily have dissipated to a level where eye irritation is no longer a concern. The information available to the Agency indicates re-entry incidents can occur 5 to 8 days after application. Due to the uncertainties in

determining a set time interval when eye irritation from residues are no longer a concern, the Agency sought an alternative to an REI as the only means of adequately mitigating eye irritation concerns. To mitigate eye irritation concerns from post-application exposures, the Agency is requiring that, for at least seven days following the application of captan:

-- At least one container designed specifically for flushing eyes is available in operating condition at the WPS-required decontamination site for workers entering the area treated with captan, and

-- Workers are informed orally, in a manner they can understand:

  -- that residues in the treated area may be highly irritating to their eyes,

  -- that they should take precautions, such as refraining from rubbing their eyes, and to keep the residues out of their eyes,

  -- that if they do get residues in their eyes, they should immediately flush their eyes with the eyeflush container that is located at the decontamination site, and

  -- how to operate the eyeflush container.

The following table summarizes the personal protective equipment (PPE) that are required for each use scenario of captan. These PPE are required either to mitigate a risk that was identified during the reregistration process, or because the risk assessment supporting reregistration assumed that these PPE were being used by pesticide handlers or applicators.

Summary of Required Worker Personal Protective Equipment

Exposure Scenario	Baseline PPE Required	Additional PPE Required	Engineering Controls
Mixing/Loading WP for aerial or chemigation	yes	Chemical-resistant gloves	water soluble pouch
Mixing/Loading WP for airblast, groundboom, high pressure sprayer, golf courses	yes	Chemical-resistant gloves, dust/mist respirator	n/a
Adding WP to paint at manufacturer	yes	Chemical-resistant gloves, dust/mist respirator	n/a
Mixing /Loading WP for seed treatment	yes	Chemical-resistant gloves, dust/mist respirator	n/a
Mixing/Loading post-harvest fruit dips	yes	Chemical-resistant gloves, dust/mist respirator	n/a
Mixing/Loading wettable powder or dust for soil and greenhouse bench treatment	yes	Chemical-resistant gloves, dust/mist respirator	n/a
Mixing/Loading liq./flowables for aerial, airblast or groundboom	yes	Chemical-resistant gloves	n/a
Handling treated seeds	yes	Chemical-resistant gloves, dust/mist respirator, eye protection	n/a
Aerial, airblast, groundboom application	yes	no	n/a
Planting of treated seed	yes	no	n/a
Application to golf courses (ground equip.)	yes	no	n/a
Applying ready-to-use paint with brush or roller	yes	no	n/a
Applying ready-to-use paint w/ sprayer	yes	Water-proof gloves, Dust/mist respirator	n/a
Applying High Pressure Spray	yes	Chemical-resistant gloves	n/a
Operation of fruit dip process	yes	Chemical-resistant gloves, Chemical-resistant apron	restricted to mechanical operations only
Mixing/Loading WP or liquid flowables then applying w/ low pressure handwand	yes	Chemical-resistant gloves	n/a
Mixing/Loading then applying w/ backpack/knapsack	yes	Chemical-resistant gloves	n/a
Mixing/Loading then applying as root-dip	yes	Chemical-resistant gloves, Chemical-resistant apron	n/a
Flagger	yes	no	n/a

(5) Residential Mitigation

Handler

Residents (homeowners) may purchase captan formulated as a wettable powder, dust or liquid or in a ready-to-use paint. Thus, residential exposure can occur when applying paints containing captan with a brush, a sprayer, or a roller. Other exposures can occur when homeowners mix and then use a captan-containing solution to treat their fruit trees and ornamentals. Data were not available to assess applying paint with a paint roller, mixing/loading/applying a solution of captan as a dip treatment, or loading/applying a dust formulation with a shaker can or in a bag. The Agency is requiring the submission of exposure data to assess these scenarios (see Section V). The MOEs for all other scenarios are greater than 100, therefore, no additional mitigation is required.

Post-Application

Dermal postapplication exposures and risk to youths and adults playing golf at golf courses did not exceed the Agency's level of concern. The Agency determined that the MOEs are over 100,000 for youth and adult golfers, respectively. Therefore, no mitigation is necessary.

Around the home both adults and children can be exposed to residues of captan that remain after application is complete. Based on the available data both dermal and inhalation post-application exposure from captan-containing paints is expected to be negligible. All MOEs for both adults and children were greater than 100; no additional mitigation is required.

(6) Drinking Water Mitigation

The Agency's upper bound estimates of acute, chronic, and carcinogenic drinking water exposure are below the appropriate Drinking Water Level of Comparison (DWLOC). Therefore, the risk from drinking water is below the Agency's level of concern. No additional mitigation is required.

(7) Aggregate Mitigation

As discussed earlier, aggregate acute or chronic (non-cancer) food and drinking water exposures are not expected to exceed 100% of the acute or chronic PAD, respectively. No additional mitigation is required.

Generally, an aggregate carcinogenic assessment considers dietary (food and water) and residential (handler and post-application) exposures. The Agency considers residential post-application exposure to captan from its use in paints to be negligible because dermal and inhalation exposures are likely to be minimal. Therefore, the Agency has considered only residential handler exposure together with dietary and drinking water exposure in its aggregate risk assessment. The aggregate cancer risk, including drinking water and residential handler

exposure, as previously explained, is less than the Agency's level of concern. No additional mitigation is required.

A short-term aggregate risk assessment considers consumption of food and water and short-term residential exposures. Residential exposure from use of captan on fruit trees and ornamentals does not exceed the Agency's level of concern when aggregated with food and drinking water exposures. Exposure to adults from painting aggregated with exposures from food and drinking water also does not exceed the Agency's level of concern.

However, the use of captan results in post-application hand-to-mouth exposures to children which do exceed the Agency's level of concern. Since these post-application exposures alone exceed the Agency's level of concern, an aggregate assessment which would only further exceed the level of concern was not performed.

(8) Ecological Risk Mitigation

Mammalian and Avian Mitigation

There is a chronic risk to small herbivorous mammals following multiple applications at application rates greater than 4 lb ai/acre. Only reducing the label application rates can reduce these risks. However, the Agency does not expect chronic risk to occur since application rates are generally less than label maximums and the only uses with rates greater than 4 lb ai/A are almonds (at 4.5 lb ai/acre) and turf at sod farms and golf courses (to be reduced to 4.3 lb ai/acre).

Aquatic Species Mitigation

Captan is acutely toxic to fish and exceeds acute high risk for fish for all application rates, except cherries. Chronic risk to fish is not anticipated at any of the single or multiple use rates. The Agency will require protective measures for foliar applications similar to those for aerial applications to minimize exposure due to drift and run-off to aquatic sites near the crop treatment area. Additional data are needed for a complete risk assessment to further assess risks to estuarine and marine organisms.

3. Occupational (both Worker Protection Standard and non-WPS) Labeling Rationale

During the reregistration process, EPA considers all relevant generic and product-specific information to decide what protections and risk mitigation are needed for all products. Products may be used in various occupational settings, which may or may not be covered by the Worker Protection Standard (WPS).

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses covered by the WPS. Uses

covered by the WPS include all commercial and research uses on farms, forests, nurseries, and in greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). The WPS covers not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in. The WPS labeling requirements pertaining to personal protective equipment (PPE), restricted-entry intervals (REI), and notification are interim. These requirements are to be reviewed and revised, as appropriate, during reregistration and other Agency review processes.

There are many products that contain captan. Some products containing captan are intended primarily for occupational use and some are intended primarily for homeowner use. Most of the occupational uses are covered under the WPS.

Personal Protective Equipment for Handlers (Mixers, Loaders, Applicators, etc.)

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

For each end-use product, PPE requirements for pesticide handlers will be determined by comparing the PPE requirements based on the toxicity of the active ingredient, as listed in the earlier table, with the PPE required based on the acute toxicity of the end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) would apply to the end-use product. As discussed in the risk mitigation section above, the additional PPE is needed due to captan's classification as toxicology category I for eye irritation.

Post-Application/Entry Restrictions

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REIs) for all uses covered by the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

The WPS prohibits routine entry to perform hand labor tasks during the REI and requires PPE to be worn for other early-entry tasks that require contact with treated surfaces. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

For captan, the Agency has determined that no regulatory action is needed as the result of acute or other adverse effects of the active ingredient. The early-entry PPE requirements will be established on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the end-use products.

4. Other Labeling Requirements

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing captan. For the specific labeling statements, refer to Section V of this document.

a. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED.

In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register. EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has completed and distributed over 300 county bulletins.

b. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to apply the data and the AgDRIFT computer model to its risk assessments. After

the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risk associated with aerial as well as other application types where appropriate.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements, responses and labeling changes necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of captan for the eligible uses has been reviewed and determined to be substantially complete. Specific product chemistry data is required for each of the technical grade active ingredients and the formulation intermediates. These requirements will be specified by registration number in the Data Call In. Additionally, the following guideline data requirements must be provided to support the continuing registration:

72-3(b)	Acute Estuarine/Marine Toxicity - Mollusk
81-1	Acute Oral Toxicity (rat)
81-2	Acute Dermal Toxicity (rat/rabbit)
81-3	Acute Inhalation Toxicity (rat)
875.2400	Dermal Exposure[1]
875.2500	Inhalation Exposure[1]

These data are considered to be confirmatory and are not expected to change the conclusions of this RED.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the labeling contained in the table at the end of this section.

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1 Required for root dip treatments - Conduct studies concurrently in indoor and outdoor sites. The studies must be sufficient to account for both the occupational (peach pre-plant) and the residential scenarios.

Required for application of paint by roller - See note above.

Required for residential application of dusts by shaker can and in a bag. Studies must be conducted concurrently for outdoor sites.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Label changes are necessary to implement mitigation measures outlined in Section IV above. These changes include updated PPE restrictions, and ecological restrictions. Specific language to implement these changes is specified in the following table.

3. Required Labeling Changes Summary Table

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into a fungicide for the following use(s): Seed treatment: alfalfa, clover, barley, beans (snap, cowpeas, lentils, soybeans), beets (table and sugar), bluegrasses, broccoli, Brussels sprouts, cabbage, cauliflower, carrots, cucumber, collards, corn (field and sweet), cotton, eggplant, flax, grasses, kale, lespedeza, lettuce, melons (cantaloupe, honeydew, watermelon, and muskmelons), mustard greens, oats, okra, onion, peanuts, peas, peppers, potatoes, radish, rape, rutabaga, rye, safflower, sesame, sorghum (milo and hulled), spinach, squash, pumpkin, sunflower, Swiss chard, tomato, trefoil, turnips, wheat Foliar treatment: almonds, apples, apricots, blueberries, cherries, grapes, nectarines, peaches, plums/fresh prunes, strawberries, caneberries (raspberries, blackberries, dewberries) Post-harvest dip: apples, cherries, pears Pre-plant root dip: peaches Non-Food/Ornamentals: azaleas, begonias, camellias, carnations, chrysanthemums, conifers, dichondra, gladiolus, turf (sod farm and golf course), flowering plants, roses Soil: seedbeds and greenhouse bench treatments Indoor/industrial: paints, plastics, adhesives, coatings	Directions for Use
One of these statements may be added to allow reformulation of the product for specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Environmental Hazards Statements required by the RED and Agency label policies	"This chemical is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
Handler PPE requirements for wettable powders formulated in water soluble packages	Personal Protective Equipment (PPE) "Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart." All mixers, loaders, applicators, flaggers, and other handlers (including handlers participating in transplanting as part of root dip treatments) must wear: - long-sleeved shirt and long pants, - shoes plus socks. - chemical resistant gloves (except for flaggers, pilots, and applicators driving motorized equipment) - chemical resistant apron when participating in dip treatments.	Precautionary Statements: Hazards to Humans and Domestic Animals
Handler PPE requirements for wettable powders *(not in water soluble packages)*.	Personal Protective Equipment (PPE) "Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers (including handlers participating in seeding and transplanting as part of root-dip or greenhouse-soil treatments and persons handling/cutting/sorting treated potato seed pieces) must wear : - long-sleeved shirt and long pants, - shoes plus socks. - chemical resistant gloves (except applicators driving motorized equipment),	Precautionary Statements: Hazards to Humans and Domestic Animals

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	- chemical resistant apron when participating in dip treatments. In addition, a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N^2, R, P, or HE filter must be worn by all handlers *except* (1) applicators driving motorized equipment and (2) mixers/loader/applicators participating in backpack, low-pressure handwand/handgun, and dip treatments."	
Handler PPE requirements for liquid/flowables	Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." All mixers, loaders, applicators, flaggers, and other handlers (including handlers participating in transplanting as part of root dip treatments) must wear: - long-sleeved shirt and long pants, - shoes plus socks. - chemical resistant gloves (except for flaggers, pilots, and applicators driving motorized equipment,) - chemical resistant apron when participating in dip treatments.	
Handler PPE requirements for dusts	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts chemical resistant materials). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." All mixers, loaders, applicators and other handlers(including handlers participating in seeding and transplanting as part of greenhouse-soil treatments) must wear: - long-sleeved shirt and long pants - chemical resistant gloves - shoes plus socks - dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH approved respirator with any N^2, R, P, or HE filter	Precautionary Statements: Hazards to Humans and Domestic Animals

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals after PPE requirements
Engineering controls for products formulated in water-soluble packets.	"Engineering Controls" "IMPORTANT: Water-soluble packets when used correctly qualify as a closed loading system under the WPS. Mixers and loaders using water-soluble packets (1) must wear the PPE specified above for mixers and loaders and (2) must be provided a NIOSH-approved dust/mist respirator (type specified below), and (3) must have the respirator immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown. The respirator must be either a dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N^2, R, P, or HE filter."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box)
Environmental Hazards for products used in seed treatments only	"Environmental Hazards" "This chemical is toxic to fish. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements under Environmental Hazards
Environmental Hazards for products used for outdoor terrestrial uses	"Environmental Hazards" "This chemical is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate."	Precautionary Statements under Environmental Hazards

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Restricted-Entry Interval for WPS products as required by Supplement Three of PR Notice 93-7	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of :" "12 hours for planter box-type or hopper-box seed treatment uses. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no contact with the soil/media subsurface." "24 hours for strawberries, almonds, apples, apricots, cherries, nectarines, plums/fresh prunes, and peaches" "48 hours for soil treatments and root dips: For soil and greenhouse bench treatments and root dips, once the treatment and any seeding or transplanting tasks done as part of the treatment are complete, the 48-hour REI begins. Exception, once the seeds or transplants are planted in the soil, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no contact with the soil subsurface." "48 hours for sod farms" "72 hours for blueberries, raspberries, blackberries, dewberries, and grapes" " 96 hours for ornamentals. Exception: For the last 48 hours of the REI, workers may enter the treated area to perform hand labor or other tasks involving contact with anything that has been treated, such as plants, soil or water, without time limit, if they wear the early-entry PPE listed below.	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	Early Entry PPE "PPE required for early entry to treated areas that is permitted under the Worder Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: - coveralls, - protective eyewear, - chemical-resistant gloves made of any water-proof material, - shoes plus socks."	Directions for Use, Agricultural Use Requirements Box
Additional Post-Application Requirements	**Eye-Protection:** To mitigate eye irritation concerns from post-application exposures, the Agency is requiring that, for at least seven days following the application of captan: 1. at least one container designed specifically for flushing eyes is available in operating condition at	Directions for Use, Agricultural Use Requirements Box

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	the WPS-required decontamination site for workers entering the area treated with captan, and 2. workers are informed orally, in a manner they can understand: -- that residues in the treated area may be highly irritating to their eyes, -- that they should take precautions, such as refraining from rubbing their eyes, to keep the residues out of their eyes, -- that if they do get residues in their eyes, they should immediately flush their eyes with the eyeflush container that is located at the decontamination site, and -- how to operate the eyeflush container.	
Double Notification Requirements	**Double Notification:** Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
Application Restrictions for products applied as liquid sprays (regardless of application equipment)	"Do not allow this product to drift." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use
Foliar Drift language for products applied by foliar spray application	"Foliar Spray Drift Management" "Avoiding spray drift from foliar applications is the responsibility of the applicator. Similar to aerial spray drift, the interaction of many equipment-and-weather-related factors determine the potential for spray drift from foliar applications. To protect water resources, the applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use
Spray Drift language for products applied aerially	"Aerial Spray Drift Management" "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."	Directions for Use

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Drift Language for products applied aerially	"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to applications using dry formulations. 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. Where states have more stringent regulations, they should be observed. The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information."	Directions for Use
Drift Language for products applied aerially	"Aerial Drift Reduction Advisory" "This section is advisory in nature and does not supersede the mandatory label requirements." **"INFORMATION ON DROPLET SIZE "** "The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions)."	Directions for Use

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Drift Language for products applied aerially	**"CONTROLLING DROPLET SIZE"** "Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets. Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.	Directions for Use
Drift Language for products applied aerially	Number of nozzles - Use the minimum number of nozzles that provide uniform coverage. Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential. Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."	
Drift Language for products applied aerially	**"BOOM LENGTH"** "For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."	Directions for Use
Drift Language for products applied aerially	**"APPLICATION HEIGHT"** "Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."	Directions for Use

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Drift Language for products applied aerially	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)"	Directions for Use
Drift Language for products applied aerially	**"WIND"** "Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."	Directions for Use
Drift Language for products applied aerially	**"TEMPERATURE AND HUMIDITY "** "When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."	Directions for Use
Drift Language for products applied aerially	**"TEMPERATURE INVERSIONS "** "Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	Directions for Use

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Drift Language for products applied aerially	**"SENSITIVE AREAS"** "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use
Application Restrictions for wettable powders not in water-soluble packaging	"Do not apply this product with aerial or chemigation equipment"	Directions for Use
Application Restrictions for wettable powders in water-soluble packaging	"Do not apply this product to seeds or seed pieces."	Directions for Use
Other Use/Application Restrictions	**For foliar applications:** "The maximum application rate for almonds is 4.5 lb ai/acre, with a maximum seasonal application rate of 20 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 30 days. Note the Restricted Entry Interval is 24 hours. Almond hulls may be fed to livestock." "The maximum application rate for apples is 4 lb ai/acre, with a maximum seasonal application rate of 32 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours" "The maximum application rate for apricots is 2.5 lb ai/acre, with a maximum seasonal application rate of 12.5 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours" "The maximum application rate for blueberries is 2.5 lb ai/acre, with a maximum seasonal application rate of 35 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 72 hours" "The maximum application rate for cherries is 2 lb ai/acre, with a maximum seasonal application rate of 14 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours"	Directions for Use under General Precautions and Restrictions and/or Applications Instructions

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	"The maximum application rate for grapes is 2 lb ai/acre, with a maximum seasonal application rate of 12 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 72 hours." "The maximum application rate for nectarines is 4 lb ai/acre, with a maximum seasonal application rate of 24 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours." "The maximum application rate for peaches is 4 lb ai/acre, with a maximum seasonal application rate of 32 lbai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours." "The maximum application rate for plums/fresh prunes is 3 lb ai/acre, with a maximum seasonal application rate of 27 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours." "The maximum application rate for strawberries is 3 lb ai/acre, with a maximum seasonal application rate of 24 lb ai/acre per crop cycle*. Preharvest interval (PHI) = 0 days. Note the Restricted Entry Interval is 24 hours." "The maximum application rate for raspberries and blackberries is 2 lb ai/acre, with a maximum seasonal application rate of 10 lb ai/acre per season. Note the Restricted Entry Interval is 24 hours. Preharvest interval (PHI) = 3 days" * Crop cycle is defined as prebloom through postharvest.	
Other Use/Application Restrictions (continued)	**For post-harvest fruit dips:** "For apples, pears, and cherries use 1.25 lb ai/100 gallons of water." "For use in mechanical fruit-dip operations only. Hand dipping of fruit is prohibited." **For applications to turf (sod farms):** "The maximum application rate for turf (sod farms) is 4.3 lb ai/acre, with a maximum seasonal application rate of 8.6 lb ai/acre per season. Note the Restricted Entry Interval is 48 hours. Harvesting Prohibition Interval = 48 hours"	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Other Use/Application Restrictions (continued)	**For seed treatments:** alfalfa, clover, lespedeza, or trefoil seeds "For slurry seed treatments use 4 ounce ai/100 lb seed." "For dust seed treatments use 6 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." barley seeds "For slurry seed treatments use 1.5 ounce ai/100 lb seed." "For dust seed treatments use 1.5 ounce ai/100 lb seed." "For planter box seed treatments use 0.8 ounce ai/100 lb seed." bean seeds "For slurry seed treatments use 1.3 ounce ai/100 lb seed." "For dust seed treatments use 1.9 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." beets (table) seeds "For slurry seed treatments use 6 ounce ai/100 lb seed." "For dust seed treatments use 9 ounce ai/100 lb seed." bluegrass seeds "For slurry seed treatments use 4.1 ounce ai/100 lb seed." "For dust seed treatments use 6 ounce ai/100 lb seed." broccoli, Brussel sprouts, cabbage, and cauliflower seeds "For slurry seed treatments use 1.1 ounce ai/100 lb seed." "For dust seed treatments use 1.1 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." carrot seeds "For slurry seed treatments use 4.4 ounce ai/100 lb seed." "For dust seed treatments use 6.75 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	cantaloupe, cucumber, or tomato seeds "For slurry seed treatments use 1.6 ounce ai/100 lb seed." "For dust seed treatments use 2.25 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed." collards or kale seeds "For slurry seed treatments use 0.5 ounce ai/100 lb seed." corn (field) seeds "For slurry seed treatments use 1.1 ounce ai/100 lb seed." "For dust seed treatments use 1.1 ounce ai/100 lb seed." corn (sweet) seeds "For slurry seed treatments use 2ounce ai/100 lb seed." "For dust seed treatments use 2 ounce ai/100 lb seed." "For planter box seed treatments use 1 ounce ai/100 lb seed." cottonseeds (acid delinted) "For slurry seed treatments use 2.5 ounce ai/100 lb seed." "For dust seed treatments use 1.5 ounce ai/100 lb seed." cottonseeds (machine delinted) "For slurry seed treatments use 2.25 ounce ai/100 lb seed." "For dust seed treatments use 2.25 ounce ai/100 lb seed." cottonseeds (fuzzy) "For slurry seed treatments use 3.5 ounce ai/100 lb seed." "For dust seed treatments use 2.25 ounce ai/100 lb seed." cottonseeds (reginned) "For slurry seed treatments use 3.5 ounce ai/100 lb seed." cottonseeds (unspecified) "For planter box seed treatments use 1 ounce ai/100 lb seed."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	cowpeas "For slurry seed treatments use 1.5 ounce ai/100 lb seed." "For dust seed treatments use 2.25 ounce ai/100 lb seed." eggplant seeds "For slurry seed treatments use 2.7 ounce ai/100 lb seed." "For dust seed treatments use 4.5 ounce ai/100 lb seed."	
Other Use/Application Restrictions (continued)	flax seeds "For slurry seed treatments use 2 ounce ai/100 lb seed." "For dust seed treatments use 2.6 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." grass seed "For slurry seed treatments use 4.1ounce ai/100 lb seed." "For dust seed treatments use 9 ounce ai/100 lb seed." mustard or rape seeds "For slurry seed treatments use 0.8ounce ai/100 lb seed." oat seeds "For slurry seed treatments use 2ounce ai/100 lb seed." "For dust seed treatments use 2 ounce ai/100 lb seed." "For planter box seed treatments use 0.8 ounce ai/100 lb seed." okra seeds "For planter box seed treatments use 0.5 ounce ai/100 lb seed." onion seeds "For pelleting, use 0.8 pound ai/ lb seed." "For seeder box seed treatments use 0.75 pound ai/3 lb seed." peanut seeds "For slurry seed treatments use 3 ounce ai/100 lb seed."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	"For dust seed treatments use 3 ounce ai/100 lb seed." pea seeds "For slurry seed treatments use 1.3 ounce ai/100 lb seed." "For dust seed treatments use 1.9 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed." pepper seeds "For slurry seed treatments use 1.5 ounce ai/100 lb seed." For dust seed treatments use 2.25 ounce ai/100 lb seed." potato seed pieces "For dust seed piece treatments use 1.2 ounce ai/100 lb seed." radish seeds "For slurry seed treatments use 1.1 ounce ai/100 lb seed." "For dust seed treatments use 1.1 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." rutabaga seeds "For slurry seed treatments use 2.3 ounce ai/100 lb seed." "For dust seed treatments use 3.4 ounce ai/100 lb seed." rye seeds "For slurry seed treatments use 1.5 ounce ai/100 lb seed." "For dust seed treatments use 1.5 ounce ai/100 lb seed." "For planter box seed treatments use 0.25 ounce ai/100 lb seed." safflower seeds "For planter box seed treatments use 1 ounce ai/100 lb seed." sesame seeds "For slurry seed treatments use 0.8 ounce ai/100 lb seed."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	sorghum seeds (milo) "For slurry seed treatments use 3 ounce ai/100 lb seed." sorghum seeds (hulled) "For slurry seed treatments use 3 ounce ai/100 lb seed." "For dust seed treatments use 3 ounce ai/100 lb seed."	
Other Use/Application Restrictions (continued)	soybean seeds "For slurry seed treatments use 1.3 ounce ai/100 lb seed." "For dust seed treatments use 1.9 ounce ai/100 lb seed." "For planter box seed treatments use 1.75 ounce ai/100 lb seed." spinach seeds "For slurry seed treatments use 3.3 ounce ai/100 lb seed." "For dust seed treatments use 4.5 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed." squash, pumpkin, muskmelon, or watermelon seeds "For slurry seed treatments use 1 ounce ai/100 lb seed." "For dust seed treatments use 1.5 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed." sugar beet seeds (eastern US) "For slurry seed treatments use 6 ounce ai/100 lb seed." sugar beet seeds (western US) "For slurry seed treatments use 3 ounce ai/100 lb seed." sugar beet seeds (unspecified) "For slurry seed treatments use 6 ounce ai/100 lb seed." "For dust seed treatments use 9 ounce ai/100 lb seed." "For planter box seed treatments use 2 ounce ai/100 lb seed." sunflower seeds	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
	"For slurry seed treatments use 2 ounce ai/100 lb seed." "For planter box seed treatments use 0.5 ounce ai/100 lb seed." Swiss chard seeds "For slurry seed treatments use 6 ounce ai/100 lb seed." "For dust seed treatments use 9 ounce ai/100 lb seed." Turnip seeds "For slurry seed treatments use 1.5 ounce ai/100 lb seed." "For dust seed treatments use 2.25 ounce ai/100 lb seed." Wheat seeds "For slurry seed treatments use 1 ounce ai/100 lb seed." "For dust seed treatments use 2 ounce ai/100 lb seed." "For planter box seed treatments use 0.8 ounce ai/100 lb seed."	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Products Intended for Occupational Use (Non-WPS only)		
Handler PPE Requirements for wettable powders *(presume no aerial or chemigation applications)*	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers (including handlers participating in transplanting as part of root-dip treatments and persons handling/cutting/sorting treated potato seed pieces) must wear : - long-sleeved shirt and long pants, - shoes plus socks. - chemical resistant gloves (except applicators driving motorized equipment), - chemical resistant apron when participating in dip treatments. In addition, a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH-approved respirator with any N^2, R, P, or HE filter must be worn by all handlers *except* (1) applicators driving motorized equipment and (2) mixers/loader/applicators participating in backpack, low-pressure handwand/handgun, and dip treatments."	
Handler PPE Requirements for liquid/flowables *(presume no aerial or chemigation applications)*.	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts correct chemical resistant materials). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." All mixers, loaders, applicators, and other handlers (including handlers participating in transplanting as part of root dip treatments) must wear: - long-sleeved shirt and long pants, - shoes plus socks. - chemical resistant gloves (except for applicators driving motorized equipment) - chemical resistant apron when participating in dip treatments.	

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Handler PPE Requirements for dusts	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts chemical resistant materials). If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." All mixers, loaders, applicators and other handlers (including handlers participating in seeding and transplanting as part of greenhouse-soil treatments) must wear: - long-sleeved shirt and long pants - chemical resistant gloves - shoes plus socks - dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C *or* a NIOSH approved respirator with any N^2, R, P, or HE filter	
Handler PPE Requirements for wettable powders added to paints or adhesives at the manufacturing process	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (registrant inserts correct gloves). If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G, or H] on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: - Long-sleeved shirt and long pants, - chemical resistant gloves, - shoes plus socks, - dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C, or a NIOSH approved respirator with any N^2, R, P, or HE filter."	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately after PPE Requirements

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Engineering Controls for dusts and wettable powders added to paints or adhesives in the manufacturing process	"Engineering Controls" "When handlers use closed systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people *AND* the system is functioning properly and is used and maintained in accordance with the manufacturer's written operating instructions, the handlers need not wear the dust/mist respirator. However, the respirator must be immediately available for use in an emergency."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately after PPE and User Safety Requirements)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box)
Environmental Hazards	"Environmental Hazards" "This chemical is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate."	
Entry Restrictions for liquid/flowables and wettable powders (not required for wettable powders added to paints or adhesives)	"Post-Application/Entry Restrictions: -- For applications to ornamentals at non-commercial sites and golf-course turfgrass, do not enter or allow others to enter until sprays have dried." -- For applications to seeds: All persons handling unbagged treated seed must be wearing the personal protective equipment required on this labeling for handlers. -- For post-application fruit dips: Do not contact or allow others to contact the treated fruit until sprays have dried."	Directions For Use under General Precautions and Restrictions

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Early Entry Restrictions for dust formulations	"Post-Application Restrictions: - For applications to seeds: All persons handling unbagged treated seed must be wearing the personal protective equipment required on this labeling for handlers.	Directions For Use under General Precautions and Restrictions
Application Restrictions for products used in commercial seed treatment	"Seed that has been treated with this product that is then packaged and offered for sale or distribution must contain the following labeling: This bag contains seed treated with captan. To avoid possible adverse health effects, when opening this bag to load the treated seed, wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, NIOSH-approved dust-mist respirator (dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C, or a NIOSH approved respirator with any N[2], R, P, or HE filter) and eye protection." "Labels attached to treated bags of seed must state:'Treated Seed - Do Not Use for Food, Feed, or Oil Purposes'."	Directions for Use
Application Restrictions for all dusts and wettable powders used to treat potato seed pieces	"When handling/cutting/sorting treated potato seed pieces, wear long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, NIOSH-approved dust-mist respirator (dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C, or a NIOSH approved respirator with any N[2], R, P, or HE filter) and eye protection."	Directions for Use
Application Restrictions (not required for wettable powder added to paints or adhesives)	"The maximum application rate for turf (golf course) is 4.3 lb ai/acre with a maximum seasonal application rate of 8.6 lb ai/acre.". "Do not apply to home lawns, parks, schools, and other recreational areas."	Directions for Use
Restrictions for products applied as liquid sprays (any type of equipment) - not for wettable powders added to paints or adhesives	"Do not allow this product to drift." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Directions for Use

Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Application Restrictions for wettable powders added to paints or adhesives	"This product cannot be added to paint or adhesive products unless the paint or adhesive product label contains the following statements:" "When using this product, wear long-sleeved shirt and long pants. When applying this product by sprayer, water-proof gloves and a NIOSH-approved dust mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N2, R, P, or HE filter must also be used."	Directions for Use
Other Use/Application Restrictions	For seed treatment rates: see Occupational Use (WPS and non-WPS) section For application rates also see Products Intended Primarily for Residential/Consumer/Homeowner section	Directions for Use
Products Intended Primarily for Residential/Consumer/ Homeowner Use		
Environmental Hazards	"Environmental Hazards" "This chemical is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements after User Safety Recommendations under "Environmental Hazards"
Early Entry Restrictions for liquid formulations	"ENTRY RESTRICTIONS: Do not allow people or pets to enter the treated area until sprays have dried"	Directions For Use in General Precautions and Restrictions
Early Entry Restrictions for dry formulations	"ENTRY RESTRICTIONS: Do not allow people or pets to enter the treated area until dusts have settled."	Directions For Use in General Precautions and Restrictions
Application Restrictions for products applied as liquid sprays (any equipment)	"Do not allow this product to drift." "Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	

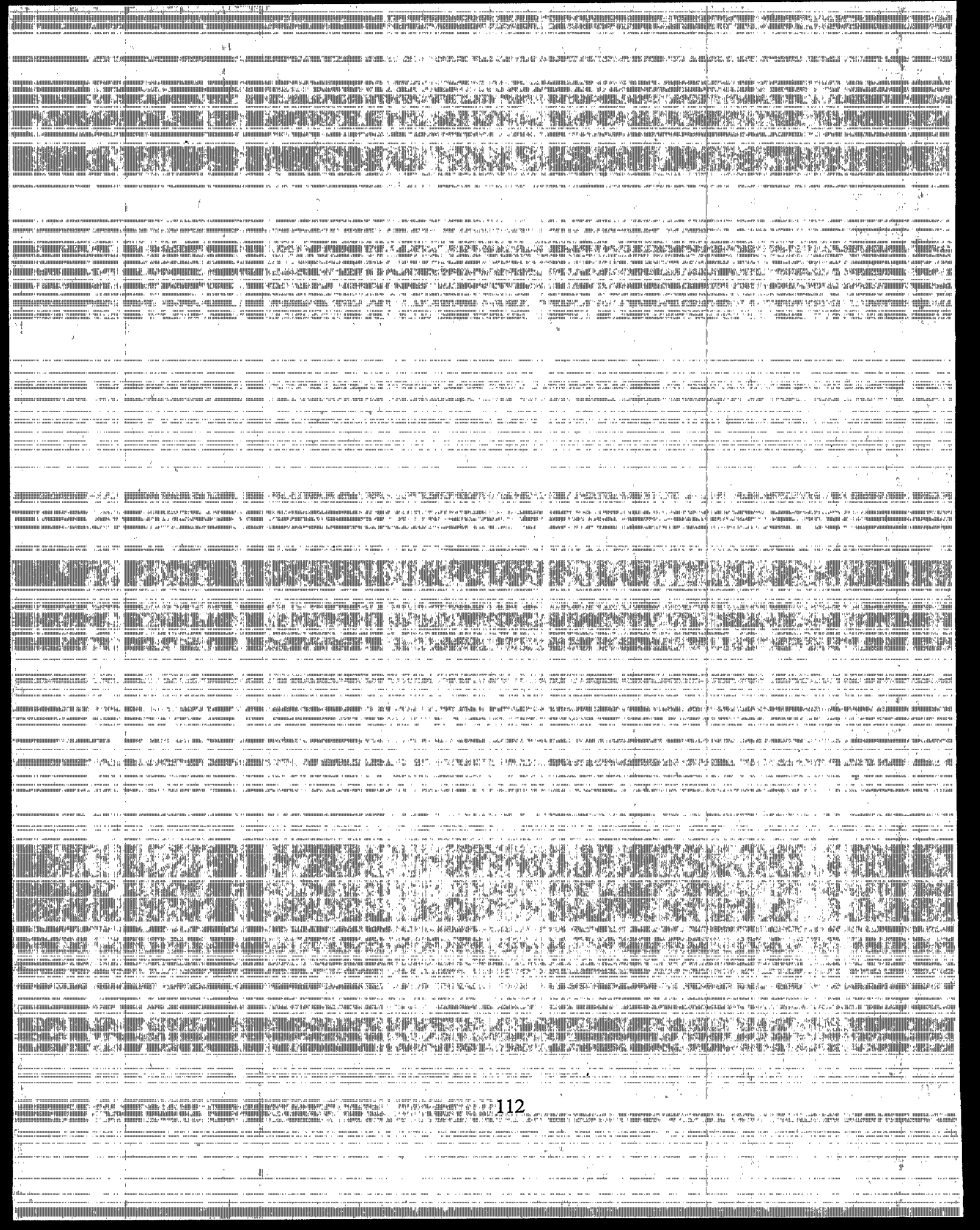
Summary of Required Labeling Changes for Captan		
Description	**Required Labeling**	**Placement on Label**
Other Use/Application Restrictions	"Do not apply to lawns."	
Maximum Application Rates	**For use on ornamentals as a root dip:** Azalea, carnation, chrysanthemum: 0.3 ounce ai/gallon **For use on gladiolus corms:** 0.3 ounce ai/gallon **For use on tuberous begonia:** 1.2 ounce ai/gallon **For use on azalea, carnation, chrysanthemum, and roses:** 0.2 ounce ai/gallon **For use as a seed treatment:** beans, cabbage, corn, melons, peas, squash: 0.02 ounce ai/pound seeds beets, Swiss chard: 0.08 ounce ai/pound seeds spinach: 0.04 ounce ai/pound seeds **For post-harvest use on apple and peach trees and grapes:** 0.02 ounce ai/gallon	

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell captan products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES



APPENDIX A - Table of Use Patterns Subject to Reregistration

Appendix is over 80 pages long and is not being included in the RED. Copies of Appendix A are available upon request as per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case number 0120 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to captan in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 605-6000.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
Gustafson, Inc. 7501-24 Using formulators exemption (repack)			
Tomen Agro, Inc. 66330-31, 66330-32, 66330-33, and 66330-34			
61-1	Chemical Identity	All	CSF
61-2A	Start. Mat. & Mnfg. Process	All	40021301
61-2B	Formation of Impurities	All	40021301
62-1	Preliminary Analysis	All	40021301
62-2	Certification of limits	All	CSF
62-3	Analytical Method	All	40021201
63-2	Color	N/A	N/A
63-3	Physical State	N/A	N/A
63-4	Odor	All	40021202
63-5	Melting Point	All	40021202, 40231801
63-6	Boiling Point	N/A	N/A
63-7	Density	All	40021202, 40231801
63-8	Solubility	All	40021202, 40231801

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
63-9	Vapor Pressure	N/A	N/A
63-10	Dissociation Constant	N/A	N/A
63-11	Octanol/Water Partition	All	40021201
63-12	pH	All	40021202, 40231801
63-13	Stability	All	40021202, 40231801
63-14	Oxidizing/Reducing/Action	All	DATA GAP FOR MUP
63-15	Flammability	N/A	N/A
63-16	Explodability	All	DATA GAP FOR MUP ONLY
63-17	Storage Stability	All	DATA GAP FOR MUP ONLY
63-18	Viscosity	N/A	N/A
63-19	Miscibility	N/A	N/A
63-20	Corrosion Characteristics	All	DATA GAP FOR MUP ONLY
Makhteshim-Agan of North America 11678-1			
61-1	Chemical Identity	All	CSF
61-2A	Start, Mat, & Mnfg. Process	All	40121701, 40231301
61-2B	Formation of Impurities	All	40121701
62-1	Preliminary Analysis	All	40021201
62-2	Certification of limits	All	CSF
62-3	Analytical Method	All	40021201
63-2	Color	N/A	N/A
63-3	Physical State	N/A	N/A
63-4	Odor	N/A	N/A
63-5	Melting Point	All	40231201
63-6	Boiling Point	N/A	N/A
63-7	Density	All	40231201

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
63-8	Solubility	All	40231201
63-9	Vapor Pressure	N/A	N/A
63-10	Dissociation Constant	N/A	N/A
63-11	Octanol/Water Partition	All	40021202
63-12	pH	All	40231201
63-13	Stability	All	40231201
63-14	Oxidizing/Reducing Action	All	DATA GAP
63-15	Flammability	N/A	N/A
63-16	Explodability	All	DATA GAP FOR MUP ONLY
63-17	Storage Stability	All	DATA GAP FOR MUP ONLY
63-18	Viscosity	N/A	N/A
63-19	Miscibility	N/A	N/A
63-20	Corrosion Characteristics	All	DATA GAP FOR MUP ONLY

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19713-258

REFS lists this as a formulation intermediate, will be addressed in Product DCI

ECOLOGICAL EFFECTS

71-1A	Acute Avian Oral - Quail/Duck	ABCHIKLM	GS0120045, GS9999001, 00020560 00151236
71-2A	Avian Dietary - Quail	ABCHIKLM	00022923, 00104686, 43869802
71-2B	Avian Dietary - Duck	ABCHIKLM	00022923, 43869803

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
71-4A	Avian Reproduction - Quail	ABCK	00098295
71-4B	Avian Reproduction - Duck	ABCK	00098296, 00104083
72-1A	Fish Toxicity Bluegill	ABCHIKLM	GS0120042, 05020144, 00057846
72-1B	Fish Toxicity Bluegill (TEP)	ABCK	WAIVED
72-1C	Fish Toxicity Rainbow Trout	ABCHIKLM	00057846
72-1D	Fish Toxicity Rainbow Trout (TEP)	ABCK	WAIVED
	Fish Toxicty Rainbow Trout (THPI)	ABCK	43869806
	Fish Toxicity Rainbow Trout (THPAm)		44738801
72-2A	Invertebrate Toxicity	ABCHIKLM	00070751, GS0120041, 00002875, 43869807
72-3A	Estuarine/Marine Toxicity - Fish	ABCK	44806504
72-3B	Estuarine/Marine Toxicity - Mollusk	ABCK	DATA GAP
72-3C	Estuarine/Marine Toxicity - Shrimp	ABCK	44806503
72-4A	Early Life Stage Fish	ABCK	00057846
72-4B	Life Cycle Invertebrate	ABCK	44148801
72-5	Life Cycle Fish	ABCK	00057846
122-1A	Seed Germination/Seedling Emergence	ABCK	WAIVED
122-1B	Vegetative Vigor	ABCK	WAIVED

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
123-2	Aquatic Plant Growth	ABCK	44806501, 44806502, 44806503
141-1	Honey Bee Acute Contact	ABCK	05001991
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ACHIL	00054789, DATA GAP
81-2	Acute Dermal Toxicity - Rabbit/Rat	ACHIL	40021401, DATA GAP
81-3	Acute Inhalation Toxicity - Rat	ACHIL	00148070, 00086288, DATA GAP
81-4	Primary Eye Irritation - Rabbit	ACHIL	00128621
81-5	Primary Dermal Irritation - Rabbit	ACHIL	40021401
81-6	Dermal Sensitization - Guinea Pig	ACHIL	00054791
81-8	Acute Neurotoxicity - rat		44041501
82-1A	90-Day Feeding - Rodent	AH	00120316, 00129163, 00129164, 00129157
82-1B	90-Day Feeding - Non-rodent	AH	40893604
82-2	21-Day Dermal - Rabbit/Rat	ACHIL	40273201
82-4	90-Day Inhalation - Rat	ACHIL	41234402
82-7	Subchronic Neurotoxicity - rat		44041502
83-1A	Chronic Feeding Toxicity - Rodent	AH	00120316, 00129163, 00129164, 00129157
83-1B	Chronic Feeding Toxicity - Non-Rodent	AH	40893604
83-2A	Oncogenicity - Rat	AH	00120316, 00129163, 00129164, 00153207, 00129157

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
83-2B	**Oncogenicity - Mouse**	AH	1977 NCI STUDY, 00068076, 00126845
83-3A	**Developmental Toxicity - Hamster**	AH	00078623, 00086803
83-3B	**Developmental Toxicity - Rabbit**	AH	00093883, 41826901
83-4	**2-Generation Reproduction - Rat**	AH	00120315, 00125293
84-2A	**Gene Mutation (Ames Test)**	ACHIL	00087805, 00131715, 00114210
84-2B	**Structural Chromosomal Aberration**	ACHIL	00131725, 00131727
84-4	**Other Genotoxic Effects**	ACHIL	00058608, 00098897
85-1	**General Metabolism**	AH	41505401, 41505402, 41505403, 41505404
85-2	**Dermal Penetration**	ACHIL	00117083
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	AC	40823902, 40966502, 40988601, 40988602, 40988603, 40988604, 43012903, DATA GAP
132-1B	**Soil Residue Dissipation**	AC	40988601, 40988602, 40988603, 40988604, 40966502
133-3	**Dermal Passive Dosimetry Exposure**	AC	40988601, 40985601, 40966501, 40966502, DATA GAP
133-4	**Inhalation Passive Dosimetry Exposure**	AC	40988601, 40985601, 40966501, 40966502
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	ABCDEFH I	00096974, 40208101, 41176301
161-2	**Photodegradation - Water**	ABC	40208102, 41176301
161-3	**Photodegradation - Soil**	A	40658009, 40658010

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
162-1	Aerobic Soil Metabolism	ABEFH	00070414, 40658007
162-2	Anaerobic Soil Metabolism	A	00098881, 40658008
163-1	Leaching/Adsorption/Desorption	ABCEFH	40658011
163-2	Volatility - Lab	AE	40231001
164-1	Terrestrial Field Dissipation	ABH	40823901, 40893601, 40893602, 40893603,
165-4	Accumulation in Fish		40756601, 40756602, 40225601, 40225602, 00160301
201-1	Droplet Size Spectrum		Satisfied by Spray Drift Task Force
202-1	Drift Field Evaluation		Satisfied by Spray Drift Task Force
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	ABCH	00058941, 00083100, 00096978, 00098790, 00098831, 00128355, GS120-001, 40658005, 40658006, 41746001, 42109601
171-4B	Nature of Residue - Livestock	ABCH	00058940, 00096901, 00096908, 00098786, 00128355, 00162723, GS120-004, 40658002, 40658003, 40658004, 42568801, 42756401, 43266701, 43266702

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C/D	**Residue Analytical Method - Plants and Animals**	ABCH	00002927, 00002928, 00003025, 00025123, 00025125, 00025129, 00035246, 00035248, 00042645, 00042646, 00045174, 00045175, 00045176, 00045179, 00045182, 00045183, 00045184, 00045188, 00045189, 00053324, 00054015, 00054016, 00070201, 00071790, 00083393, 00085525, 00085526, 00090988, 00090989, 00096910, 00098726, 00098731, 00098747, 00098751, 00098784, 00098789, 00098804, 00098810, 00098811, 00098817, 00098818, 00098894, 00117087, 00128355, GS120-008, GS120-011, 41393001, 41386501, 41406901, 43548601
171-4E	**Storage Stability**	ABCH	40752301, 41039101, 41557601, 42803901, 43875603
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	ABCH	00025125, 00035246, 00035248, 00045178, 00096910, 00098751, 00098808, 00098810, 00104753, 40010501, 42296002
171-4K	**Crop Field Trials**		
	Root and Tuber Group	ABCH	
	Beet roots		40189806, 41149104, 41306101, 41306102, 41468401
	Carrots		40189806, 41149104, 41306101, 41306102, 41468401
	Potatoes		00098716, 00098894, 00054016, 40189806, 41149104, 41306101, 41306102, 41468401

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT	USE PATTERN	CITATION(S)
Rutabagas		40189806, 41149104, 41306101, 41306102, 41468401
Taro		40189806, 41149104, 41306101, 41306102, 41468401
Turnip roots		40189806, 41149104, 41306101, 41306102, 41468401
Leaves of root and tuber group	ABCH	
Beet greens		40189821, 41149102, 41306101, 41306102, 41468401
Turnip greens		40189821, 41149102, 41306101, 41306102, 41468401
Bulb Vegetables	ABCH	
Garlic		40189806, 41149104, 41306101, 41306102, 41468401
Leeks		40189806, 41149104, 41306101, 41306102, 41468401
Onions, dry bulb		40189806, 41149104, 41306101, 41306102, 41468401
Onions, green		40189806, 41149104, 41306101, 41306102, 41468401
Shallots		40189806, 41149104, 41306101, 41306102, 41468401
Leafy vegetables group	ABCH	
Celery		00070201, 00159599, 40189821, 41149102, 41306101, 41306102, 41468401

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT	USE PATTERN	CITATION(S)
Lettuce		00070201, 00159605, 40189821, 41149102, 41306101, 41306102, 41468401
Spinach		00070201, 00159606, 40189821, 41149102, 41149103, 41306101, 41306102, 41468401
Brassica Leafy Vegetables Group	ABCH	
Broccoli		40189821, 41149102, 41306101, 41306102, 41468401
Brussels sprouts		40189821, 41149102, 41306101, 41306102, 41468401
Cabbage		40189821, 41149102, 41306101, 41306102, 41468401
Cauliflower		40189821, 41149102, 41306101, 41306102, 41468401
Collards		40189821, 41149102, 41306101, 41306102, 41468401
Kale		40189821, 41149102, 41306101, 41306102, 41468401
Mustard greens		40189821, 41149102, 41306101, 41306102, 41468401
Legume Vegetables Group	ABCH	
Beans, dry		00046914, 00070201, 00098710, 40189820, 41149101, 41306101, 41306102, 41468401
Beans, succulent		00046914, 00070201, 00098710, 40189820, 41149101, 41306101, 41306102, 41468401
Peas, dry		40189820, 41149101, 41306101, 41306102, 41468401

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT	USE PATTERN	CITATION(S)
Peas, succulent		40189820, 41149101, 41306101, 41306102, 41468401
Soybeans, dry		00003025, 00071790, 00096982, 40189820, 41149101, 41306101, 41306102, 41468401
Soybeans, succulent		00071790, 00096982, 00098709, 40189820, 41149101, 41306101, 41306102, 41468401
Fruiting vegetables group	ABCH	
Eggplant		00098709, 40189820, 41149101, 41306101, 41306102, 41468401
Peppers		40189820, 41149101, 41306101, 41306102, 41468401
Pimentos		40189820, 41149101, 41306101, 41306102, 41468401
Tomatoes		00070201, 00085526, 00098708, 40189820, 40189823, 40189824, 41149101, 41306101, 41306102, 41468401
Curcurbit vegetable group	ABCH	
Cantaloupe		00098818, 40189820, 41149101, 41306101, 41306102, 41468401
Cucumbers		00098709, 40189820, 41149101, 41306101, 41306102, 41468401
Honeydew melons		00098818, 40189820, 41149101, 41306101, 41306102, 41468401
Muskmelons		00098818, 40189820, 41149101, 41306101, 41306102, 41468401
Pumpkins		40189820, 41149101, 41306101, 41306102, 41468401
Squash, summer		00098818, 40189820, 41149101, 41306101, 41306102, 41468401

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT	USE PATTERN	CITATION(S)
Squash, winter		00098818, 40189820, 41149101, 41306101, 41306102, 41468401
Watermelons		00128355, 40189820, 41149101, 41306101, 41306102, 41468401
Pome fruits Group	ABCH	
Apples		00085526, 00098711, 00098722, 00098789, 00106602, 00128355, 00159597, 40189803, 40745403, 42252201, 42252202
Pears		00070201, 00085526, 00098722, 00106602, 00128355, 40189815
Stone fruits Group	ABCH	
Apricots		00128355, 40189805
Cherries		00128355, 40189808
Nectarines		00128355, 40189813
Peaches		00128355, 40189814, 40745406, 40745407
Plums (fresh prunes)		00128355, 40189816
Small fruits and berries group	ABCH	
Blackberries		42712801
Blueberries		00046914, 00070201, 00090988, 00128355, 41039101
Dewberries		42712801
Grapes		00046914, 00070201, 00090988, 00098726, 00128355, 00159601, 00162037, 40189811, 40189812, 40745405, 42254202
Raspberries		00070201, 42712801, 4422201

Data Supporting Guideline Requirements for the Reregistration of Captan

REQUIREMENT		USE PATTERN	CITATION(S)
	Strawberries		00046914, 00070201, 00090988, 00117088, 00128355, 00159607, 40189822, 40745408
	Tree nuts group	ABCH	
	Almonds		00070201, 00090988, 00098804, 00098811, 00128355, 00159596, 00162037, 40189802, 40745402
	Almond hulls		00070201, 00090988, 00098804, 00098811, 00128355, 00159596, 00162037, 40189802, 40745402
	Cereal grains group	ABCH	
	Corn, sweet		00003025, 00045176, 00070201, 00128355, GS120-039, 40189809, 41149103, 41306101, 41306102, 41468401
	Miscellaneous commodities	ABCH	
	Cottonseed		00002928, 00003025, 00070201, 00128355, GS120-039, 40189820, 41149101, 41306101, 41306102, 41468401
171-4L	Processed Food	ABCH	
	Apples		00098789, 00159597, 42296003, 40189804, 42563102
	Grapes		00128355, 00159601, 00162037, 40189812, 42296004, 42563101
	Plums/Prunes		40189817
171-5	Reduction of Residues		00159595, 00159596, 00159597, 00159599, 00159601, 00159605
165-1	Rotational Crops (Confined)	ABCH	41404001, 42378401

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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00002927	Devine, J.M.; Horton, W.E. (1972) Determination of Captan N-Trichloromethylmercapto-4-cyclohexene-1,2,-dicarboximidein Cottonseed: Report No. 120. (Unpublished study received on unknown date under 0F0939; prepared by State Univ. College--Oswego, Lake Ontario Environmental Laboratory, submitted by Uniroyal Chemical, Bethany, Conn.; CDL:094582-A)
00002928	Uniroyal Chemical (1972) Residues in PPM: Vitavax. (Unpublished study received on unknown date under 0F0939; CDL:094582-B)
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00020560	Schafer, E.W. (1972) The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21(?) :315-330. (Also In unpublished submission received Apr 25, 1978 under 476-2180; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-C)
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00025123	Chevron Chemical Company (1979) Determination of Captafol, Captan, THPI, and 3-OH THPI in Tissues and Eggs and Determination of Captan, THPI, 3-OH THPI, and 5-OH THPI in Milk and Cream. Undated method nos. RM-6-G-2, RM-1G-1 and RRC-75-32. (Unpublished study received Jan 2, 1980 under 239-2211; prepared in cooperation with Stauffer Chemical Co.; CDL:099190-F)

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MRID	CITATION
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00026453	Pack, D.E. (1979) The Anaerobic Soil Metabolism of Carbonyl-14C Captafol. (Unpublished study received Jan 2, 1980 under 239-2211; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 099189-A)
00035246	Haumschild, D.; Wingender, R.J. (1972) Report to American Seed Trade Association, Inc.: Tissue Residue Study for Captan and Tetrahydrophthalimide in Crossbred Steers Fed Technical Captan: IBT No. J1255. Includes methods entitled: Determination of Captan and Determination of Tetrahydrophthalimide (THPI). (Unpublished study received Jun 27, 1977 under 3E1367; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:096174-A)
00035248	Taylor, R.E.; Brunhouse, E. (1972) Captan Study for American Seed Trade Association. Includes method RM-1E dated May 26, 1972. (Unpublished study including letter dated Feb 1, 1973 from J.C. Calandra to Ron Harris, received Jun 27, 1977 under 3E1367; prepared by Harris Laboratories, Inc., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:096174-D)
00042645	Rappaport, S.H.; Katague, D.B. (1978) Determination of Captan Residues in Crops by Gas Chromatography. Method RRC-76-30R dated Mar 27, 1978. (Unpublished study received Sep 25, 1980 under 0E2427; prepared by Stauffer Chemical Co., submitted by New Zealand, Ministry of Agriculture and Fisheries, Wellington, New Zealand; CDL:099651-C)
00042646	New Zealand, Ministry of Agriculture and Fisheries (19??) Method for the Determination of Captan Residues in Kiwifruit. (Unpublished study; CDL:099651-D)

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MRID	CITATION
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00045179	Patchett, G.G. (1973) Determination of Tetrahydrophthalamic acid Residues in Cattle and Hog Tissues. Method no. WRC 73-38 dated May 17, 1973. (Unpublished study received on unknown date under 3E1367; prepared by Stauffer Chemical Co., submitted by American Seed Trade Association, Inc., Kalamazoo, Mich.; CDL:096507-F)
00045182	American Seed Trade Association, Incorporated (19??) Determination of Captan Residues on Treated Seed Corn. Undated method. (Unpublished study received Mar 9, 1967 under 3E1367; CDL:096507-J)
00045183	American Seed Trade Association, Incorporated (19??) Method for Determination of Captan Residue on Corn. (Unpublished study received Mar 9, 1967 under 3E1367; CDL:096507-K)
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MRID	CITATION
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00046914	Hensill, G.S. (1957) Phaltan Research Report 1957. (Unpublished study received Oct 28, 1957 under unknown admin. no.; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:119324-A)
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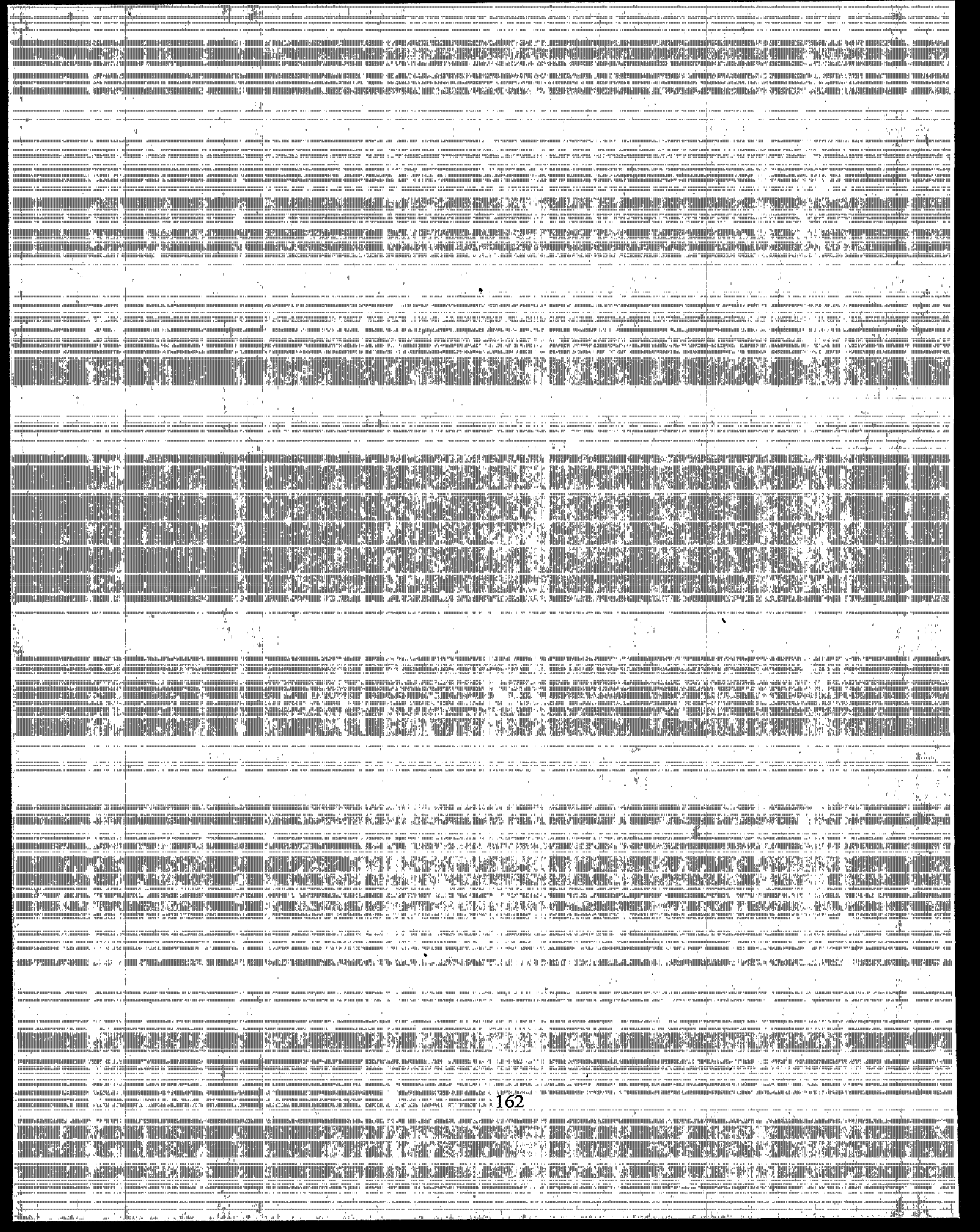


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient(s). Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. how you will comply with the requirements set forth in this Notice and its Attachments 1 through 4; or,

2. why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or,

3. why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I	-	Why You Are Receiving This Notice
Section II	-	Data Required By This Notice
Section III	-	Compliance With Requirements Of This Notice
Section IV	-	Consequences Of Failure To Comply With This Notice
Section V	-	Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI	-	Inquiries And Responses To This Notice

The Attachments to this Notice are:

Attachment 1	-	Data Call-In Chemical Status Sheet
Attachment 2	-	Data Call-In Response Form (Insert A)
Attachment 3	-	Requirements Status And Registrant's Response Form (Insert B)
Attachment 4	-	List Of All Registrants Sent This Data Call-In Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

SECTION II. DATA REQUIRED BY THIS NOTICE

A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form (Insert A) must be submitted as part of every response to this Notice. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert A). If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Insert B), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Requirements Status and Registrant's Response Form (Insert B). You must also complete a Data Call-In Response Form (Insert A) by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support and Emergency Response Branch, Registration Division, (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,

b. every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

c. you must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form (Insert A), and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form (Insert A). If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form (Insert B). Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form (Insert B) and option 6b and 7 on the Data Call-In Response Form(Insert A).

If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

5. Request for Data Waivers. Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form (Insert B). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),

4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),

5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),

6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those

studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form (Insert B) and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form (Insert B) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data --

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development --

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in

the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study --

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(7) " *raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(7), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration

Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study --

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies --

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PR Notice 98-5) EPA Form 8570-34 .

D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver -- Option 8 on the Requirements Status and Registrant's Response Form (Insert B). Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption

will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.

c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.

e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above),

indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).

h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):

(1) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver.

2. Request for Waiver of Data --Option 9 on the Requirements Status and Registrant's Response Form (Insert B). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form (Insert B) indicating the option chosen.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

A. NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B); or,

   b. fulfill the commitment to develop and submit the data as required by this Notice; or,

c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Federal Insecticide, Fungicide, and Rodenticide Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must

also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person listed in Attachment 1, the Data Call-In Chemical Status Sheet.

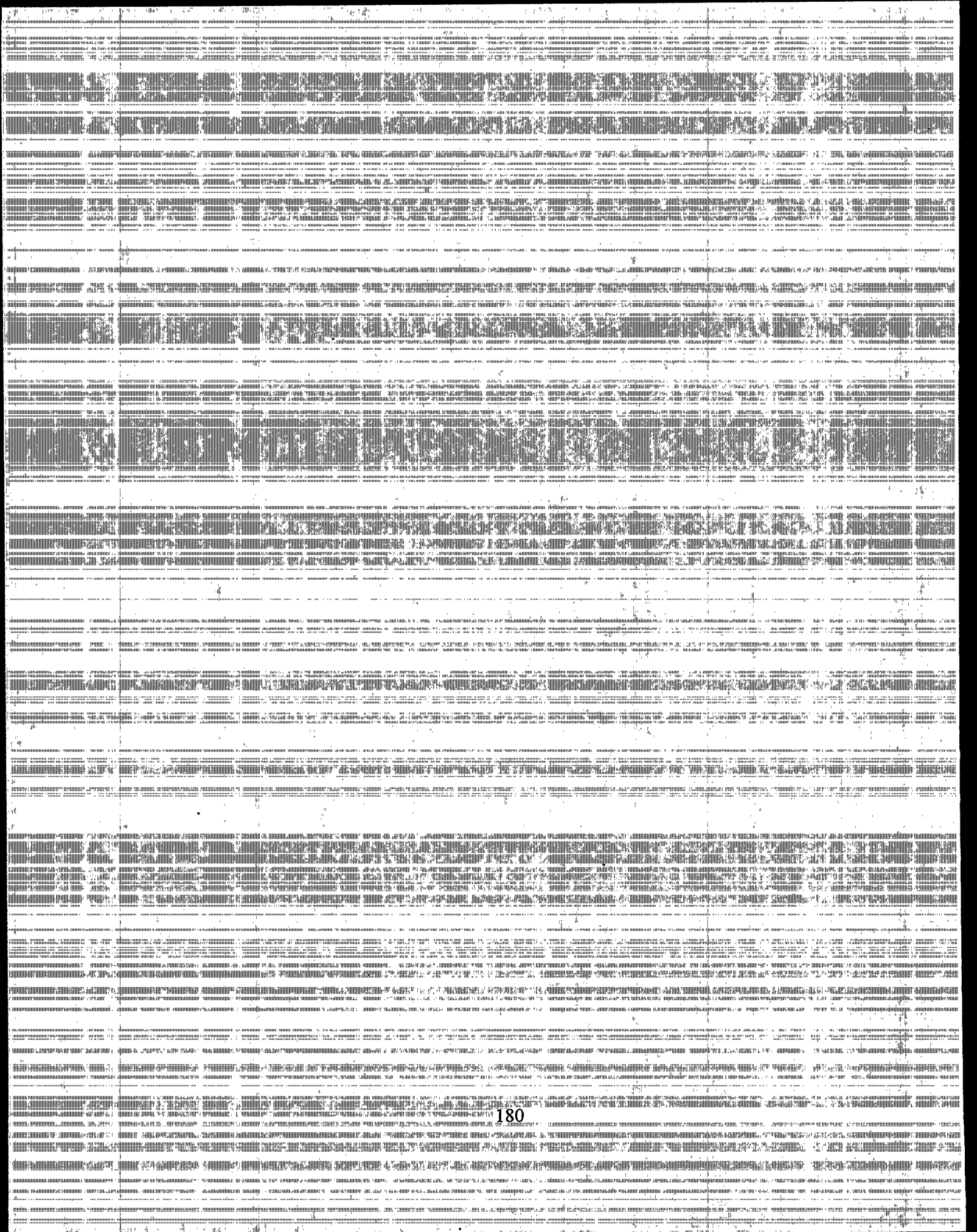
All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) and any other documents required by this Notice, and should be submitted to the contact person identified in Attachment 1. If the voluntary

cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division



CAPTAN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing captan.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of captan. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Captan Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for captan are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on captan are needed. These data are needed to fully complete the reregistration of all eligible captan products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Kylie Rothwell at (703) 308–8055.

All responses to this Notice for the generic data requirements should be submitted to:

Kylie Rothwell, Chemical Review Manager
Special Review and Registration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: Captan

SPECIFIC INSTRUCTIONS FOR THE GENERIC DATA CALL-IN RESPONSE FORM (INSERT A)

This Form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form Items 5 through 7 must be completed by the registrant as appropriate Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U S Environmental Protection Agency, 401 M St , S W , Washington, D C 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D C 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number and address.

Item 2. This item identifies the ease number, ease name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this data call-in but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. Cheek this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. You do not need to complete any item on the Requirements Status and Registrant's Response Form for any product that is voluntarily canceled.

Item 6a. Check this item if this data call-in is for generic data as indicated in Item 3 and if you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and-any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. Check this Item if the data call-in is a generic data call-in as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this data call-in. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7a. Check this item if this call-in if a data call-in as indicated in Item 3 for a manufacturing use product (MUP), and if your product is a manufacturing use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrants' Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 7b. Check this item if this call-in is a data call-in for an end use product (EUP) as indicated in Item 3 and if your product is an end use product for which you agree to supply product-specific data. Attach the Requirements Status and Registrant's Response Form (Insert A) that indicates how you will satisfy those requirements.

Item 8. This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.

Item 9. Enter the date of signature.

Item 10. Enter the name of the person EPA should contact with questions regarding your response.

Item 11. Enter the phone number of your company contact.

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0120 Captan Chemical # and Name 081301 Captan	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN					

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANTS RESPONSE FORM (INSERT B)

Generic Data

This form is designed to be used for registrants to respond to call-in- for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of generic data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggesting for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS

Item 1. This item identifies your company name, number, and address.

Item 2. This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. This item identifies the date and type of data call-in.

Item 4. This item identifies the guideline reference numbers of studies required to support the product(s) being reregistered. These guidelines, in addition to requirements specified in the Data Call-In Notice, govern the conduct of the required studies.

Item 5. This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form (Insert B).

Item 6. This item identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:

A.	Terrestrial food
B.	Terrestrial feed
C.	Terrestrial non-food
D.	Aquatic food
E.	Aquatic non-food outdoor
F.	Aquatic non-food industrial
G.	Aquatic non-food residential
H.	Greenhouse food
I.	Greenhouse non-food crop
J.	Forestry
K.	Residential
L.	Indoor food
M.	Indoor non-food
N.	Indoor medical
O.	Indoor residential

Item 7. This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows.

EP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP_*	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites

TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI	Technical Grade Active Ingredient
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
MET	Metabolites
IMP	Impurities
DEGR	Degradates

***See: guideline comment**

Item 8. This item identifies the time frame allowed for submission of the study or protocol identified in item 2. The time frame runs from the date **of your** receipt of the Data Call-In Notice.

Item 9. Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

1. (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocol and progress reports required in item 5 above.

2. (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

3. (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am submitting a copy of the form "Certification of Offer to Cost Share in the Development of Data" that describes this offer/agreement. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to making an offer to share in the cost of developing data as outlined in the Data Call-In Notice.

4. (Submitting Existing Data) I am submitting an existing study that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

5. (Upgrading a Study) I am submitting or citing data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I

have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

6. (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. I am providing the Agency's classification of the study.

7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

9. (Request for Waiver of Data) I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching an identification of the basis for this waiver and a detailed justification to support this waiver request. The justification includes, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Item 10. This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. Enter the date of signature.

Item 12. Enter the name of the person EPA should contact with questions regarding your response.

Item 13. Enter the phone number of your company contact.

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0120 Captan
Chemical # and Name 081301
Captan

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
72-3(b)	Estu/mari tox. mollusk					ACK	TGAI	12 mos.	
81-1	Acute oral tox. rat		Y			ACHIK	TGAI	24 mos.	
81-2	Acute dermal tox. rabbit/rat		Y			ACHIK	TGAI	24 mos.	
81-3	Acute inhal. tox rat		Y			ACHIK	TGAI	24 mos.	
133-3 *	Dermal passive dosimetry expo		Y			ACHIK		24 mos.	
133-4 *	Inhal. passive dosimetry expo		Y			ACHIK		24 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

* COMMENTS FOR GUIDELINE REQUIREMENTS

Case # and Name
0120 Captan
Chemical # and Name
081301 Captan

GUIDELINE	COMMENT
133-3	Studies are to be conducted according to guideline 875.2400. Required for root dip treatments and application of paint by roller. Studies must be conducted concurrently in both indoor and outdoor sites. Studies must be sufficient to account for both the occupational (peach pre-plant for root dip) and residential scenarios. Also required for residential application of dusts by shaker can and bag. Studies are to be conducted concurrently for outdoor sites.
133-4	Studies are to be conducted according to guideline 875.2500. Required for root dip treatments and application of paint by roller. Studies must be conducted concurrently in both indoor and outdoor sites. Studies must be sufficient to account for both the occupational (peach pre-plant for root dip) and residential scenarios. Also required for residential application of dusts by shaker can and bag. Studies are to be conducted concurrently for outdoor sites.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Insert B, Requirements Status and Registrant's Response Form (Insert B), within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-605-6000).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form (Insert A), and the Requirements Status and Registrant's Response Form (Insert B). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form (Insert B) must be submitted for each product listed on the Data Call-In Response Form (Insert A) unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form(Insert A). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form (Insert A) and Requirements Status and Registrant's Response Form (Insert B), initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. **Voluntary Cancellation** - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form (Insert A), indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form (Insert B). If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. **Satisfying the Product Specific Data Requirements of this Notice** There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. **Request for Product Specific Data Waivers.** Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form (Insert A) that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form (Insert A) related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form(Insert A). These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form (Insert A) are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will

not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must

fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, **all of the following three criteria must be clearly met**:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3

Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each

of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-34, Certification with Respect to Citations of Data (in PR Notice 98-5).

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice,

pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form(Insert A) and a Requirements Status and Registrant's Response Form(Insert B);

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell,

distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLEUNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI.INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form (Insert A) and a completed Requirements Status and Registrant's Response Form (Insert B) for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form (Insert A) need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

CAPTAN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing captan.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of captan. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Captan Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for captan are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on captan are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible captan products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Karen Jones at (703) 308-8047.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Captan**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes.**" If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**"

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**" If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0120 Captan	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNN-NNNNN		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9 . **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to**

Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was

conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

7. I request a waiver for this study because it is inappropriate for my product **(Waiver Request).** I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4).**

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0120 Captan

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
830.1550	Product identity & composition (1)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1600	Descriptn materials used to produce the product (1,2)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
830.1620	Description of production process (1,2,52)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1650	Description of formulation process (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1670	Discussion of formation of impurities (1,3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
830.1700	Preliminary analysis (1,4,52)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
830.1750	Certified limits (1,5)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.1800	Enforcement analytical method (1,53)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6302	Color (51)					ABCDEFGHIJKLMNO	MP	8 mos.	
830.6303	Physical state (51)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
830.6304	Odor (51)					ABCDEFGHIJKLMNO	MP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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OMB No. 2070-0107
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SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0120 Captan

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
		(6)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
830.7000	pH	(9)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.7100	Viscosity	(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
		(7)					ABCDEFGHIJKLMNO	TGAI	8 mos.	
830.7300	Density						ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
830.6314	Oxidation/reduction: chemical incompatability	(10)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6315	Flammability	(11)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6316	Explodability	(12)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6317	Storage stability	(18)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
		(13)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6319	Miscibility	(50)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6320	Corrosion characteristics						ABCDEFGHIJKLMNO	MP/EP	8 mos.	
830.6321	Dielectric breakdown voltage	(15)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
870.1100	Acute oral toxicity	(1,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1200	Acute dermal toxicity	(1,2,37)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.1300	Acute inhalation toxicity	(3)					ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	
870.2400	Acute eye irritation	(2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	
870.2500	Acute dermal irritation	(1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0120 Captan EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
870.2600	Skin sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0120 Captan

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product;TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).

2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.

3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.

5 Certified limits are not required for inert ingredients in products proposed for experimental use.

6 Required if technical chemical is solid at room temperature.

7 Required if technical chemical is liquid at room temperature.

9 Required if test substances are dispersible with water.

10 Required if product contains an oxidizing or reducing agent.

11 Required if product contains combustible liquids.

12 Required if product is potentially explosive.

13 Required if product is a liquid.

15 Required if end-use product is liquid and is to be used around electrical equipment.

18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

50 Required if product is an emulsifiable liquid and is to be diluted with water.

51 Required for MP. Refer to PR Notice 92-5.

52 Required for all non-integrated products.

53 Required for all non-integrated products and on a case-by-case basis for integrated products.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0120 Captan

Footnotes (cont.):

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

EPA'S BATCHING OF CAPTAN PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredient Captan the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

All of these products contain the active ingredient captan (cis-N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide). Several labels report containing related derivatives as well. Some batches also contain other

active ingredients. Batches 1 through 7B have only captan as an active ingredient and are listed first. Batch 2 may cite Batch 1. Batch 7B may cite the products in Batch 7A. The following batches, 8 through 16, have more than one active ingredient. Those products that cannot be batched are in the last table.

A dermal sensitization study is not required. Captan is known to cause dermal sensitization in humans, therefore, all products will automatically be labeled as such, unless an acceptable dermal sensitization test on the product is negative.

Furthermore, due to the known severe eye irritation potential of captan, waivers will be accepted for primary eye irritation under the condition that the guideline will be classified as category I. In addition, batches indicated with the double asterisk (**) need to address the eye irritation guideline individually by submitting data or requesting a waiver.

The first table batches several technicals.

BATCH NO.	EPA REG. NO.	% of Captan and Related Derivatives on Label	Formulation Type
1	1965-11	90	Solid
	7501-24	92	Solid
	11678-1	88	Solid
	19713-258	88	Solid
	19713-500	88	Solid
	66330-31	90	Solid
	66330-32	90	Solid
	66330-33	90	Solid
	66330-34	86.94	Solid
	72304-3	88	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
2	7501-92	73.3	Solid
	19713-385	80.1	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
	34704-430	80	Solid
	34704-431	80	Solid
	51036-168	80.1	Solid
	66330-1	75	Solid
	66330-3	80.1	Solid
	66330-13	75	Solid
	66330-25	75	Solid
	66330-28	80.1	Solid
	66330-29	79.6	Solid
	66330-30	75	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
3	16-151	50	Solid
	239-729	50	Solid
	270-289	50	Solid
	769-540	50	Solid
	2935-470	50	Solid
	19713-235	50	Solid
	19713-261	50	Solid
	19713-268	50	Solid
	34704-676	50	Solid
	42056-3	50	Solid
	51036-166	48.9	Solid
	66222-1	50	Solid
	66330-21	50	Solid

	66330-26	48.9	Solid
	66330-27	50	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
4**	2935-484	38.52	Liquid
	7501-26	38.25	Liquid
	19713-156	38.5	Liquid
	19713-161	38.5	Liquid
	51036-167	39.6	Liquid
	51035-171	39.6	Liquid
	51036-181	38.2	Liquid
	66330-23	39.6	Liquid
	7501-27	38.25	Liquid
	66330-24	37.66	Liquid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
5	7501-8	29.35	Liquid
	34704-649	30	Liquid
	34704-659	30	Liquid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
6	400-225	24.4	Solid
	7501-116	25.5	Solid

	9779-98	25.0	Solid
	19713-197	25	Solid
	34704-567	25	Solid
	66330-12	25.1	Solid
	66330-20	25	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
7A**	829-215	7.5	Solid
	5481-250	7.5	Solid
	10107-97	7.5	Solid
	34704-22	7.5	Solid
	34704-149	7.5	Solid
	34704-654	7.5	Solid
	62575-6	10.1	Solid
	66330-10	9.9	Solid
	66330-11	7.4	Solid
	66330-15	10	Solid
	66330-16	7.5	Solid
	66330-18	10	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
7B**	34704-668	5.0	Solid
	66330-14	5.0	Solid
	66330-17	5.0	Solid

The following batches contain products which have more than one active ingredient. The first batches include two active ingredients which have already been batched: metalaxyl and sulfur. The batching for those will remain as has already been published, and products not included in the original batching will be assigned below if batchable and put in the unbatched table at the end of this document if not.

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
8	4-355	Captan - 6.03 Malathion - 6.00 Methoxychlor - 10.00 Sulfur - 25.00	Solid
	572-62	Captan - 6.0 Malathion - 6.00 Methoxychlor - 10.00 Sulfur - 25.00	Solid
	829-236	Captan - 6.0 Malathion - 6.0 Methoxychlor - 9.0 Sulfur - 25.0	Solid

Below are batches that include products with captan and other active ingredients not previously batched.

BATCH NO.	EPA REG. NO.	% Active Ingredients	Formulation Type
9	68119-14	Captan - 32.76 Lindane - 16.60	Solid
	42056-14	Captan - 33.5 Lindane - 16.60	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
10	7501-38	Captan - 12.24 Lindane - 25.00	Solid
	34704-653	Captan - 12.5 Lindane - 25.00	Solid
	66330-19	Captan - 12.5 Lindane - 25.0	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
11	7501-36	Captan - 19.6 Carboxin - 20.0	Solid
	66330-22	Captan - 20.0 Carboxin - 20.0	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
12	5905-252	Captan - 70.0 Methoxychlor - 3.0	Solid
	34704-652	Captan - 75.4 Methoxychlor - 3.00	Solid
	66330-4	Captan - 73.9 Methoxychlor - 5.0	Solid
	66330-6	Captan - 75 Methoxychlor - 3	Solid
	66330-7	Captan - 72.5 Methoxychlor - 5.0	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
13	68119-10	Captan - 37.5 Diazinon - 25.0	Solid
	42056-18	Captan - 37.5 Diazinon - 25.00	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
14	4-122	Captan - 12.0 Carbaryl - 0.30 Malathion - 6.00 Methoxychlor - 12.00	Liquid

	5887-162	Captan - 12.0 Carbaryl - 0.30 Malathion - 6.00 Methoxychlor - 12.00	Liquid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
15	68119-11	Captan - 15.0 Diazinon - 15.0 Lindane - 25.0	Solid
	42056-11	Captan - 15.0 Diazinon - 15.00 Lindane - 25.00	Solid

BATCH NO.	EPA REG. NO.	% of Active Ingredients	Formulation Type
16	7501-111	Captan - 18.4 Etridiazol Terrazole - 2.5 Maneb - 18.75 PCNB - 10.0	Solid
	7501-153	Captan - 18.4 Etridiazol - 2.5 Maneb - 18.75 PCNB - 10.0	Solid

The following products would not fit in a batch. Therefore testing must be performed on these independently unless indicated by an asterisk. See acceptable batching for products with asterisk following table.

EPA REG. NO.	% of Active Ingredients	Formulation Type
4-59	Captan - 6.0 Carbaryl - 0.5 Malathion - 3.0 Methoxychlor - 6.0	Solid
70-179*	Captan - 10.0 Diazinon - 30.0	Solid
70-190	Captan - 7.0 Malathion - 5.00 Methoxychlor - 10.00	Solid

EPA REG. NO.	% of Active Ingredients	Formulation Type
239-568	Captan - 15.0 Malathion - 7.5 Methoxychlor - 15.0	Solid
400-93	Captan - 36.7 Carboxin - 37.5	Solid
400-136*	Captan - 12.3 Carboxin - 12.5	Liquid
572-185*	Captan - 7.0 Malathion - 4.0 Methoxychlor - 5.0	Solid
769-645	Captan - 20.0 PCNB - 14.00 Thiram - 19.00	Solid
769-901	Captan - 15.0 Malathion - 7.50 Methoxychlor - 19.75	Solid
802-235	5.1	Solid
2935-522	Captan - 30.0 Maneb - 30%	Solid
7401-355	Captan 6.4 Malathion - 8.07 Methoxychlor - 9.60	Liquid
7401-438	Captan - 10.0 Malathion - 7.50	Liquid
7501-9	29.35	Solid
7501-43*	Captan - 24.4 Carboxin - 12.5	Liquid
7501-77	29.35	Liquid
7501-129	Captan - 29.0 Thiabendazole - 0.55	Liquid
7501-130	Captan - 29.0 Thiabendazole - 0.55	Liquid
7501-131	Captan - 20.25 PCNB - 8.4 Thiabendazole - 1.0	Liquid

EPA REG. NO.	% of Active Ingredients	Formulation Type
7501-139	Captan - 45.0 Carboxin - 10.0 PCNB - 15.0	Solid
7501-150	Captan - 12.78 Baytan - 6.25	Solid
10107-94	Captan - 7.5 Streptomycin sulfate - 0.01	Solid
10163-194	Captan - 30.0 2,6-Dichloro-4-nitroaniline - 30.0	Solid
19713-126*	18.86	Liquid
19713- 145*	Captan - 25.0 Diazinon - 25.00	Solid
19713-260*	75	Solid
19713-362	80.0	Solid
19713-405*	78.3	
29664-2	37.3	Liquid
33955-408	Captan - 12.0 Malathion - 6.00 Methoxychlor - 12.00	Solid
34704-30	5.0	Solid
34704-342	10.0	Solide
34704-427	50.0	Solid
34704-650	Captan - 30.0 Methoxychlor - 2.00	Liquid
34704-651*	70.0	Solid
34704-655*	30.0	Liquid
34704-681	15.0	Solid
34704-760	Captan -10.0 Malathion - 10.00 Methoxychlor - 10.00	Liquid
42056-1	18.86	Liquid

EPA REG. NO.	% of Active Ingredients	Formulation Type
66330-2*	65.0	Solid
66330-5	62.9	Solid
66330-8	Captan - 65.0 Methoxychlor - 10.0	Solid
66330-9	62.9	Liquid
66330-16	7.5	Solid
68119-6	Captan - 25.0 Thiabendazole - 0.68	Solid
68119-7	Captan - 30.0 Thiabendazole - 0.53	Liquid
68119-12	Captan - 15% Lindane - 25% Diazinon - 15.52% Metalaxyl - 1.0%	Solid

*the following batching schemes are acceptable:
70-179 may cite batch 13
400-136 may cite batch 11
572-185 may cite 34704-760
7501-43 may cite batch 11
19713-126 may cite 42056-1
19713-145 may cite batch 13
19713-260 may cite batch 2
19713-405 may cite batch 2
34704-651 may cite batch 2
34704-655 may cite batch 4A

List of All Registrants Sent This Data Call-In Notice

Case # and Name

0120 Captan

Chemical # and Name

081301 Trichloromethylthio-4-cyclohexene-1,2-dicarboximid

Company Number	Company Name	Additional Name	Address	City & State	Zip
007501	GUSTAFSON, INC.		BOX 660065	DALLAS TX	75266
010182	ZENECA AG PRODUCTS		BOX 15458	WILMINGTON DE	19850
011678	MAKHTESHIM CHEMICAL WORKS_LTD	C/O MAKHTESHIM-AGAN OF N. AMERICA	551 FIFTH AVE SUITE 1100	NEW YORK NY	10176
019713	DREXEL CHEMICAL CO		BOX 13327	MEMPHIS TN	38113

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk. DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
      Biopesticides and Pollution Prevention Division (BPPD) Contacts
      Antimicrobials Division Organizational Structure/Contact List
   c. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   d. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   e. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   f. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

   National Technical Information Service (NTIS)

5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.