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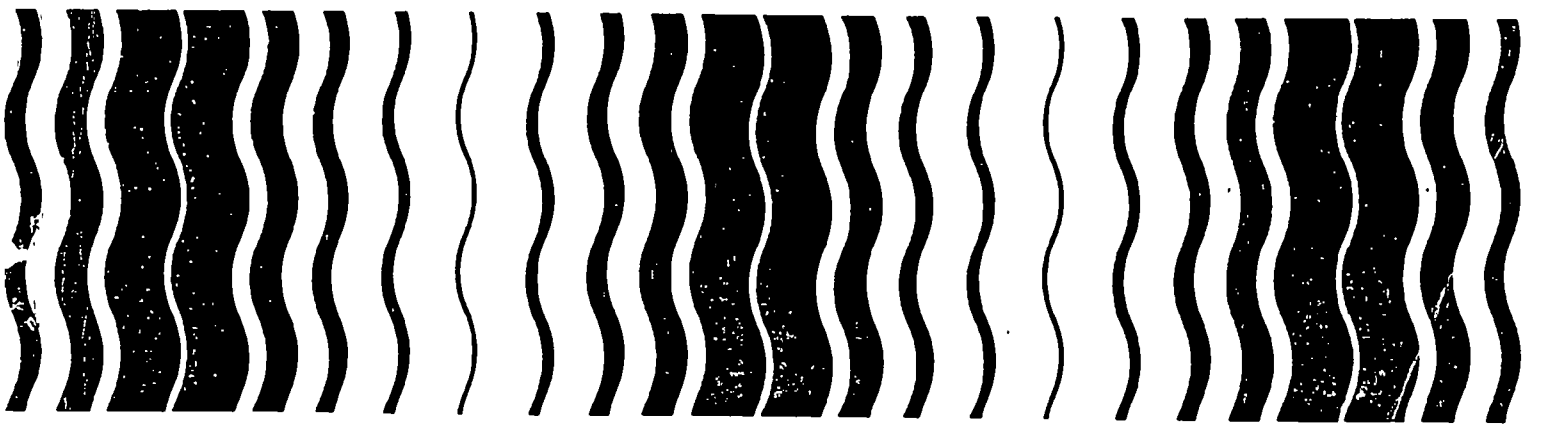
Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing Captan

as the Active Ingredient



GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

CAPTAN

AS THE ACTIVE INGREDIENT

EPA CASE NUMBER 0120

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460
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APPENDICES

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides generally will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may determine that, in order to remain in compliance with FIFRA, the registrant must provide additional data to support existing registrations, modify its product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in unreasonable adverse effects on the environment. The Registration Standard may lead to initiation of a Special Review if it appears that use of the product may cause unreasonable adverse effects on the environment. The Special Review can result in a decision by the Agency to require a change in the conditions of registration, suspension, or cancellation of the registration.

The scientific review, which is not contained in this Guidance Package but is available from the National Technical Information Service, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data regarding the hazards

that may result from the intended use of the pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who does not currently qualify but wishes to qualify for the formulator's exemption may change his his source of supply to a registered source, provided the the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide (captan), based on an evaluation of 19 registered manufacturing-use products (MUPs), and certain end-use products (EUPs) containing captan as the sole ingredient. Labeling requirements, tolerances, special local needs registrations authorized by section 24(c) of the FIFRA, as well as registrations under section 3 of FIFRA were considered in this analysis. The Agency sets forth the data requirements that must be met to register or reregister products covered by this Standard.

This Standard addresses registration requirements for current and future MUPs and labeling requirements for EUPs. Captan MUPs that differ appreciably from the ones described here may require amendments to this Standard. Also, use-patterns that differ from those described here may also require amendments to this Standard.

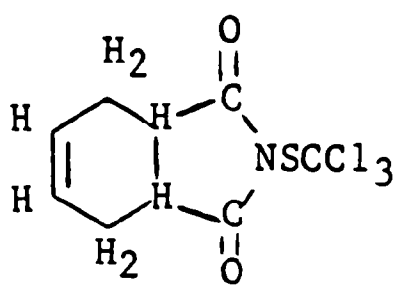
B. DESCRIPTION OF CHEMICAL

Captan is the acceptable common name for N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide and was officially recognized by the Interdepartmental Committee on Pest Control. Trade names for captan are Merpan, Orthocide, SR-406, and Vancide 89. It is in the pesticide classification known as fungicide and dicarboximides or chlorinated organosulfur compounds.

There are 19 technical and formulation intermediate products that may be used in the manufacturing of end-use pesticide. The Office of Pesticide Programs Internal Control Number (EPA Shaughnessy Number) for captan is 081301, and its CAS Number is 133-06-2.

Captan has the following identifying characteristics:

Empirical Formula: $C_9H_8Cl_3NO_2S$
Molecular Weight: 300.61
Structural Formula:



Color: Pure is white crystals; technical is white to buff colored amorphous powder.

Odor: Pure is odorless, the technical is pungent.

Melting Point: 158-164 °C

Vapor Pressure: Less than 10^{-6} mm Hg at 25 °C.

Solubility: Practically insoluble in water, soluble in acetone, ethanol, kerosene, xylene, chloroform, and benzene.

Stability: Regarded as stable. Decomposes slowly at the melting point. In solution captan decomposes rapidly depending on the pH and temperature, being slower at pH 4 and rapid at pH above 10 at constant temperature.

Captan is a broad spectrum fungicide which is registered with the EPA for use in the culture of both food and nonfood crops and as an industrial fungicide. It is registered for use as a foliar fungicide to be applied to a wide variety of fruit, vegetable, nut, and ornamental crops, for application to seeds and plant propagules, as a preplant application to soil and as a post-harvest application to many fruit and vegetable crops. Captan is also used for application to produce packing boxes, to soil and crops grown in greenhouses, to house plants, to home gardens, to dog and cat dusts and shampoos, and to hand soaps. It is incorporated into plastics, oil-base paints, wall paper pastes, textiles, paper, and cosmetics. It is registered either as single active ingredient formulations or in combination with other fungicides and with insecticides. It is approved by the U.S. Food and Drug Administration for use in cosmetics and shampoos for humans.

Biological Activity

Captan has been considered to be a nonsystemic broad spectrum fungicide, however, there is some information to support a conclusion that it and one or more of its metabolites are systemic in plants. The rate of movement in plants appears to be slower than other systemic fungicides. Its fungicidal activity persists on leaf surfaces for a shorter time than thiram or captafol. In a comparative study under similar conditions its activity persisted 2.2 weeks, while thiram and captafol persisted for 3.0 and 5.6 weeks, respectively (D. Neely, Phytopathology: Vol. 60:505-510).

There are 494 FIFRA Section 3 registered pesticide products that bear ingredient statements that include captan as one of the active ingredients. These products involve 118 registrants. There are 66 FIFRA Section 24(c) registered pesticide products that bear ingredient statements that include captan as one of the active ingredients. These products were registered by 24 States to permit uses that meet particular special local needs. There are also 76 intrastate registrations held by 29 registrants; these must be registered under Section 3 of FIFRA (50 FR 25889).

C. REGULATORY POSITION AND RATIONALE

The potential risks associated with the use of pesticide products containing captan to control fungi in agricultural and non-agricultural applications were detailed in the Captan Special Review Document of June, 1985. The preliminary notice of determination concluding the special review of pesticide products containing captan was published on June 21, 1985 (50 Federal Register 25884-25889). In that Notice, the Agency concluded that studies conducted on mice and rats have shown statistically significant increases in incidences of certain tumors. Furthermore, the agency found that the use of captan resulted in dietary and environmental exposure that may pose unreasonable risks to human health unless certain steps are taken. Accordingly, the Agency proposed to cancel or deny Federal registrations of products containing captan for use on food crops with the proviso that in the final decision that EPA would continue any use on food where data are submitted demonstrating that captan residues on food are sufficiently lower than EPA's estimates or that alternative application methods will sufficiently reduce dietary exposure to captan. EPA also proposed in its preliminary determination that protective clothing and/or equipment be worn for specific non-food agricultural and non-agricultural uses of captan and that revised labeling be required on products intended for non-food use.

The Agency has also identified certain data requirements for captan and its metabolites for residue chemistry and toxicology, and issued a section 3(c)(2)(B) Data Call-In Notice on April 29, 1985 requesting that data.

This registration standard for captan incorporates the regulatory changes proposed in the preliminary determinaton of the Special Review, with the understanding that some or all of the food uses may be retained in the final determination. Other regulatory determinations set forth in this Standard evolved from the data reviewed in the process of preparing this Standard. The data requirements that conform to the April 29, 1985, Section 3(c)(2)(B) Data Call-In Notice are not changed by this Standard. The dates for submission of the required data under the Data Call-In Notice remain the same as stated in that Notice. The toxicology data required by the Data Call-In Notice have been received by the Agency and have been found adequate. However

residue chemistry data for reduction of dietary exposure are still outstanding under the April 29, 1985 Notice. This requirement includes (1) Residue Reduction Data (section 171-4(c)) required on certain agricultural commodities to establish the extent to which residues from captan-treated crops may be reduced (see 3(a) below for details), and must be submitted 12 months from the date the registrants received the Notice, and (2) Crop Residue Data as described in 3(d) herein must be sumitted 24 months from the date the registrants received the Notice.

Based on a review and evaluation of all available data and other relevant information on captan the Agency has made the following determinations:

1. EPA has determined in a preliminary determination of the Special Review of captan that pesticide products containing captan for use on food crops do not meet the statutory standard for registration under FIFRA and that, based on available data, there are no modifications to the terms and conditions of registration which would bring these products into compliance with the statute. However, in the final Special Review decision, EPA will retain any use where data are submitted that demonstrate that actual residues are sufficiently lower than current tolerances or that modifications to application practices will sufficiently reduce dietary risk.

   Accordingly, EPA has proposed to cancel the registration of each pesticide product containing captan and labeled for use on any food crop, whether the product is registered under section 3 or 24(c) of FIFRA. However, if registrants or other parties submit data showing that food residues are sufficiently lower than EPA estimated or that alternative application methods will sufficiently lower dietary residues of captan, then EPA will consider continuing the registrations of captan for use on food. EPA also proposed to deny applications for Federal registration of captan products for use on food crops.

   EPA is requiring registrants to submit residue data to support tolerances for the combined residues of captan and its major metabolite, delta^4-tetrahydrophthalimide (THPI); and to determine actual residue levels before making a final decision on cancellation of registrations of products for this use. EPA also is requiring submission of residue data to establish tolerances for seed treatment, although it is not proposing to cancel registration for use for seed treatment.

EPA has also determined that the terms and conditions for registration of pesticide products containing captan for certain other uses must be amended in order to bring these products into compliance with the statutory standard.

Rationale: The principal concern about the risk posed by captan is that its use on agricultural crops poses a risk of cancer to humans through dietary exposure. EPA's concern is based primarily on the results of animal studies showing statistically significant increases in the incidences of gastrointestinal adenocarcinomas in male and female mice and kidney tumors in male rats. EPA is also concerned about the human health risks to persons applying captan to crops, mixing or loading formulations, working in fields or nurseries with crops treated with the pesticide, and mixing captan into end-use products such as mattresses, shower curtains, and paints. Based on the oncogenic potency demonstrated in animal studies and on estimates of human exposure to captan, EPA has assessed lifetime cancer risks from dietary and applicator exposure to end-use captan products.

EPA has calculated lifetime oncogenic risks for dietary, worker and end-product exposure, based on human exposure estimates and a potency factor derived from three studies. Two studies conducted by Chevron in 1981 and 1983 showed a statistically significant increase in adenocarcinomas in the gastrointestinal tracts of male and female mice. The results of a study conducted by Stauffer Chemical Company showed a statistically significant increase in kidney tumors in male rats. Analysis of the data from these three chronic feeding studies show a dose-related increase in tumors.

If a pesticide is determined to be an oncogenic agent, it is classified for regulatory purposes on the weight-of-the-evidence, which involves consideration of the quality and adequacy of the data and the kind of responses induced by a potential oncogen (49 Federal Register, 46296-46297). The evidence for determining captan's oncogenic classification consists of: 1) an increased incidence in uncommon adenomas and adenocarcinomas of the upper gastrointestinal (GI) tract in the Charles River CD-1 strain of mouse in the two previously mentioned

Chevron studies and one Stauffer study (1985), 2) an increased incidence of these GI tumors in a National Cancer Institute study using the B6C3F1 strain of mouse (1977), 3) Captan is also associated with a small dose-related increased incidence of kidney tumors in a second species, the Charles River CD rat, 4) Captan shows positive mutagenic activity in gene mutation and chromosomal aberration tests, in vitro, but not in vivo, 5) Other structurally related compounds also demonstrate oncogenic potential. Captafol (with the same ring structure) is associated with a small treatment-related increase in renal tumors in the Charles River CD rat. Folpet (with the same side chain) is associated with a treatment-related increased incidence of intestinal tumors in the Charles River CD-1 mouse.

On the basis of this information, the EPA has classified captan as a "probable human carcinogen," Group B2, under EPA's proposed guidelines (49 FR 46294).

Using the multistage model for a risk assessment of captan's oncogenic potential, the Agency has determined the Q_1^{*s} for 5 sets of dose-to-tumor relationships. The geometric mean of these Q_1^{*s} is 2.3×10^{-3} $(mg/kg/day)^{-1}$. The Q_1^* values represent the upper 95% bound on the slope of the dose response.

Accurate residue data upon which EPA could base a calculation of dietary risk estimates are not available. Therefore, EPA used the highest residue levels that are legally permissible, the tolerance levels, as a basis for its dietary risk estimates. Basing these estimates on the tolerance levels is reasonable because the Food and Drug Administration (FDA) monitors residue levels to ensure that the tolerances are not exceeded and may seize any foods with residues exceeding the tolerances. Thus, in the absence of actual residue data, EPA is confident that residues are no higher than the current tolerances. EPA is requiring residue data from the registrants and will include such data in calculating its final risk assessment before taking final regulatory action. At this time, however, EPA has calculated an upper bound estimate of total dietary risk of 10^{-3} to 10^{-4} and is proposing regulatory action on that basis. The quantitative designation "10^{-3}", i.e. 0.001, represents the upper 95 percent confidence limit on the probablity of developing cancer as extrapolated from animal data. The actual probability thus may be lower.

In addition, these risks are based on worst-case assumptions about dietary exposure (i.e., that food residues are at current maximum allowable levels and that 100 percent of the food crops are treated with captan). Data from market basket surveys suggest that the exposure, and hence the risk, may be substantially lower. Thus, the actual human risks are probably lower than those estimated by EPA, although definitive data are lacking to predict those lower risks.

Use of captan on seeds may result in residues of captan and/or its metabolites on the plants that grow from the seeds; however, EPA has no data for plant residues from seed treatment and no tolerances have been established. While EPA is assuming at this time that the residues would be insignificant due to the limited amount of pesticide that can be transferred from the seed coating to the whole plant, EPA is requesting such residue data from the registrants before making a final determination on the dietary risks to humans.

EPA has also quantified the oncogenic risk to agricultural applicators, mixer/loaders, and fieldworkers, as well as nonagricultural applicators and end users. Without protective measures, the upper 95% bound estimates of risk to agricultural applicators range from 10^{-5} to 10^{-7} for dermal and inhalation exposure, while estimates for mixer/loaders range from 10^{-5} to 10^{-7}. Using exposure data from studies on exposure from picking strawberries, EPA's upper 95% bound estimates of lifetime risk for fieldworkers range from 10^{-4} to 10^{-6}.

For non-agricultural uses of captan, EPA's assessment of oncogenic risk for use in plastics, adhesives, paints, and cosmetics ranges from negligible to significant. For persons engaged in the manufacture of plastics, paints, and cosmetics treated with captan, the potential risk from exposure to captan is negligible if gloves, protective clothing, and respirator (dust mask for cosmetic incorporation) are worn. For persons engaged in the manufacture of captan-treated adhesives, the upper 95% bound estimate of potential risk from captan incorporation is 10^{-5} if no protective clothing is worn. For end-users of products containing captan, the upper 95% bound estimates of risk range from 10^{-4} for human exposure to shampoos for animals to 10^{-9} for aerosol sprays if no gloves are worn.

In the preliminary Special Review determination, EPA considered restrictions other than concellation of registrations that would reduce the dietary risks posed by captan, as well as exposure to applicators, mixer/loaders, fieldworkers, and product end-users. Among the risk reduction measures short of cancellation that are available to EPA are changes in the directions for use on the pesticide's labeling and classification of the pesticide for "restricted use" pursuant to FIFRA section 3(d), EPA concluded that certain restrictions could be adequate to reduce exposure and risks to an acceptable level for applicators, mixer/loaders and fieldworkers, as well as for most non-agricultural end-users. Such restrictions include extending the preharvest interval and modifying application practices, or prohibiting post-harvest application. However, dietary exposure and residue data necessary to calculate any reduction in dietary risks are unavailable, so that EPA cannot consider these as viable options until such data are available. EPA has encouraged interested persons to submit data on alternative mechanisms for reducing dietary exposure to captan and any data that would be used to refine the risk assessment.

It has been demonstrated that captan falls within Toxicity Category IV (40 Code of Federal Regulations §162.10(h)(1)) based on oral toxicity, Toxicity Category III based on inhalation toxicity, Toxicity Category I based on eye irritation and is a dermal sensitizer. Captan has produced decreased pup litter weights in reproduction studies, however it does not appear to be a teratogen for either the rabbit or Golden Syrian hamster.

2. The Agency has concluded that captan is not a teratogen in hamsters.

   EPA requested additional information (Federal Register, Volume 50, p. 25886) to determine whether captan was teratogenic in hamsters. Adequate data has been submitted and the Agency has concluded that the reported effect of fused ribs in hamster was within normal background incidence for the species.

3. The Agency has required certain residue chemistry data on an expedited basis. This requirement was the subject of a special Section 3(c)(2)(B) data call-in notice dated April 29, 1985. This notice was sent to all registrants of products that bear labeling for either manufacturing or formulation use. The letter specified the following data requirements:

   As specified in the Pesticide Assessment Guidelines, Subdivision O, with sections indicated below, of the Pesticide Data Requirements, part 158.125:

   a. Residue Reduction Data

   Section 171-4(c). Residue data are required for the following agricultural commodities to establish the extent to which residues from captan-treated crops may be reduced. Depending on the commodity, data are needed on residue levels present after washing, peeling, and/or cooking (processing). These data are required under section 171.4(c)(2)(IV)(b) for better estimation of actual residues consumed.

   Samples may be fortified with captan at tolerance levels in the laboratory; field treated crop samples are not required, but may be used if desired. Residues of both captan and tetrahydrophthalimide (THPI) should be analyzed before and after processing. Commodities marked with an asterisk (*) should be fortified with captan and THPI separately or together, with THPI fortified at one-half the tolerance level of captan and analyzed before and after cooking. The purpose of this study is to determine whether captan and THPI residues are heat labile.

	Washing	Peeling	Processing/or Cooking
almonds	-	x (blanching)	x (roasting)
apples, pears, quince (choose 1)	x	x	x
*apricots, peaches (choose 1)	x	x	x
avocados	-	x	-
*beans, peas, (dry and succulent including soy, choose 2)	x (succulents)	x (shelling dry beans)	x
beets, turnips, rutabagas (roots, choose 2)	x	x	x
blackberries, dewberries, rasp berries (choose 1)	x	-	x
blueberries, cranberries (choose 1)	x	-	x
broccoli, cauliflower (choose 1)	x	-	x
cabbage	x	-	x
cantalopes, honeydews, muskmelon, watermelon (choose 2)	-	x	-
*carrots	x	x	x
celery	x	-	x
cherries, grapes, plums (prunes), mangoes, nectarines (choose 1 large, 1 small)	x	x (large)	x
corn	-	x (husking)	x
cucumbers, eggplant, summer squash (choose 1)	x	x	x
garlic, leek, onion, shallot (choose 1 dry, 1 green)	x (green)	x (dry)	x
*grapefruit, lemon, lime, orange, tangerine	-	-	x (juice)
greens (beet, collard, kale, mustard, turnip, spinach, choose 2)	x	-	x
lettuce	x	-	-
peppers (including pimientos, choose 2)	x	x	x
pineapple	-	x	x
*potatoes	x	x	x
pumpkins, squash (choose 1)	-	x	x
rhubarb	x	-	x
*strawberries	x	-	x
taro	x	x	x
tomatoes	x	x	x

b. Analytical Methodology

Section 171-4(b). In order to confirm the market basket data already submitted, validation data for the analytical methodology used by the registrants must be provided as required under Section 171-4(b).

c. Feeding Studies

Section 171-4(c). Poultry feeding studies are required because the data on eggs and tissues are lacking. Eggs and tissues should be analyzed for parent compound captan and its three metabolites tetrahydrophthalimide (THPI), 3-hydroxy THPI, and 5-hydroxy THPI as required under Section 171-4(c)(3)(d). The highest feeding level should be equivalent to 10 times the maximum level likely to be consumed by poultry.

d. Crop Residue Data

Section 171-4(c). Residue data for captan and tetrahydrophthalimide are needed for all registered crops. These data should be gathered in accordance with the Data Requirements of 40 CFR 158.125, with reference to the Pesticide Assessment Guidelines, Subdivision O, Section 171-4(c). Specifically, the data should reflect the maximum total number of applications (preplant, at-plant, preharvest, and post-harvest, as registered), the maximum registered application rate, minimum preharvest intervals, and be geographically representative of the growing areas for each crop. Residue levels must be reported separately for each stage of application for which a crop is registered--preplant, at-plant, preharvest, and postharvest. For example, if a crop is registered for at-plant and preplant use of captan, residue levels of captan and THPI in the harvested crop must be measured and reported separately. If a crop is registered for preplant, preharvest and postharvest use of captan, the residues must also be reported separately. Processing studies should be performed where applicable with reference to 171-4(c)(2)(iv)(a). A storage stability study should support harvest to analysis intervals and storage conditions (e.g., temperature).

e. Seed Treatments

Section 171-4(c). The seed treatments using captan were registered as nonfood uses. The Agency has since determined that, unless radiolabeled studies showing no uptake are provided, seed treatments are food uses, and normally require low-level (method sensitivity) tolerances. Because captan is used to treat seed from a number of commodities not having

established tolerances and since no tolerances have yet been proposed to cover the possible residues from seed treatments, EPA requires residues data for captan and THPI for representative crops to support low level tolerances covering seed treatments. Residue data for crops grown from treated seed must be submitted for corn, soybeans, rice or a small grain, potatoes, and two of the vegetables having seed treatments. Assuming that detectable residues are not found in these crops, the residue data from these six crops can be translated to other crops in support of additional tolerances for seed treatments. If detectable residues are found, then data for additional crops may be required, depending on the level observed.

Rationale: The Agency is concerned about captan's oncogenic potential and needs the data mentioned above to complete the Special Review. In addition, the data are inadequate to support registration of seed, seed-piece and other plant propagule uses as non-food and non-feed uses. Data requirements to support these uses are listed in Tables A and B.

4. The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to captan. When the required studies under §158.130 are submitted, a complete environmental exposure assessment can be made.

   An interim 4-day reentry interval has been imposed for the agricultural uses of captan until adequate data have been submitted as specified in Table A, Section 158.140, Subdivision K, Re-entry.

Rationale: Captan meets the chronic (oncogenic effects in mice and rats) and use-pattern (application to growing crops) criteria of 40 CFR 158.140 for submission of reentry exposure data. Fieldworker exposure data are available for strawberry harvesters but not for other crop harvesters; the data were summarized in the Captan Position Document 2/3. Table 22 of that document estimates risks of 10^{-4} to 10^{-6} (B_2) for picking and weeding strawberries under the assumption of a 35-year working lifetime. As this captan registration standard proposes not to reregister captan for food uses, the period of exposure for which an interim reentry interval will be in effect is likely to be about three years (the time necessary to complete a cancellation action). Therefore the estimated risk to fieldworkers is roughly an order of magnitude lower. The exposure data on which this risk assessment was based (Table 13 of the PD 2/3) were generated from seven field exposure studies, four of which were carried out while strawberries were being harvested three to four days after captan application (the other three studies involved longer periods after application). The Agency has accordingly decided to set an interim reentry interval of four days for captan to prevent workers from reentering treated fields without protective clothing. Reentry is permissible during this time provided that appropriate protective clothing is worn. Registrants are required to submit reentry data for captan in accordance with 40 CFR 158.140. When data are submitted, the Agency will reevaluate this restriction.

5. In order to evaluate Captan's potential to contaminate ground water the Agency is requiring the following studies:

158.130 Environmental Fate

161-1	Hydrolysis
161-2	Photodegradation in water
161-3	Photodegradation on soil
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
162-3	Anaerobic Aquatic Metabolism
163-1	Leaching and Adsorption/Desorption
164-1	Soil Dissipation

158.120 Product Chemistry

63.8	Solubility
63.11	Octanol/ water Partition Coefficient

Rationale: There are inadequate data to conclude that captan does not pose a ground water problem due to potential leaching of metabolites and/or degradates. The Agency is concerned about surface water and possible ground water contamination by captan and its degradates. Metabolites and degradates in soil have not been adeqately studied. Therefore, mobility studies and the fate of the metabolites and degratates are required. In order to characterize the potential for captan to enter ground water, the Agency needs the studies mentioned above.

6. Acute toxicity studies on estuarine and marine organisms and simulated or actual field testing with aquatic organisms are required under this Standard. Data from fish early life stage studies, aquatic invertebrate life cycle studies, aquatic organisms accumulation and simulated or actual field testing with aquatic organisms may be required pending results from environmental fate studies. Both the needed environmental fate data and the above mentioned data are to be submitted on an expedited basis. Protocols addressing the simulated or actual field studies must be submitted for approval by the Agency prior to conducting the studies.

   Rationale: The Agency is concerned about the fish toxicity and toxic effects to estuarine and marine organisms because captan is very highly toxic to fish. The available environmental fate data are insufficient to fully assess the potential for exposure of nontarget organisms to captan. When the required studies under 40 CFR §158.130 are submitted, a complete environmental exposure assessment can be made for accumulation in fish.

   There are insufficient data to characterize the acute and chronic toxic effects of captan on aquatic invertebrates. Toxicity data are needed for assessing the hazards to aquatic invertebrates. Use of captan as a seed treatment for rice and as a foliar application to citrus and cranberries may create an acute hazard for nontarget fish and aquatic invertebrates. Use on citrus may result in a hazard to two endangered bird species by reducing their food supply. Everglade Kites consume apple snails and Wood Storks consume fish. Both the apple snail and fish populations may be critically reduced by exposure to captan and its degradates. The ecological effects and exposure assessment data bases are insufficient to preclude exposure to such risks. Therefore, simulated and/or actual field studies to quantify such risks are required.

7. In order to meet statutory standards product labeling must be revised to include a requirement to use protective clothing. In addition, all end-use products intended for crop use, except seed uses and plant propagule treatments, must bear labeling restrictions for crop rotation and for reentering treated areas. (Refer to Section F, Required Labeling).

   Rationale: To reduce risk from captan's oncogenic potential and its toxicity to fish, and to maintain existing registrations, registrants must revise product labeling as specified in Section F of this Standard.

8. Manufacturing-use pesticide products containing captan as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard.

   Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to permit new captan registrations.

   Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or inadequate (see Section 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs and sets a timetable for generation of needed data. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration of captan products.

9. The Agency has reevaluated the use of detreated seed corn for feed use for cattle and hogs, since stating (Federal Register, Vol. 50, p 25888, June 21, 1985) that the practice of using detreated seed corn for feeding of cattle and hogs may be continued as long as the seed is washed to reduce captan below a 100 parts per million (ppm) tolerance level and the seed is used only for feeding of cattle and hogs up to 14 days prior to slaughter. The Agency expects to take action to revoke the tolerance regulations that permit the use of detreated seed corn within one year from the date this Standard is received by the American Seed Trade Association, who originially requested that these tolerances be established (EPA PP No. 3E1367 and EPA FAP No. 3E1367), if the following concerns are not resolved:

a. Residue chemistry data must be submitted for detreated corn seed that had been treated at the maximum labeled dosage of 3.21 oz. of active ingredient captan per 100 lbs. of corn seed, the data should be from such seed that had been in storage for 3, 6, 12 and 18 months. It is assumed that samples of such captan treated seed may be found in commerce. If there is a question as to the history of the samples used, then a study must be instituted and conducted to assure that the data are acceptable. In any regard, studies with samples from commerce must be submitted within the time frame stated above.

b. An acceptable method for informing corn seed treaters and corn seed distributors of acceptable methods for detreating captan treated corn seed must be proposed.

c. An acceptable handling procedure for captan treated seed corn (to be detreated) to assure that there are no other pesticides on the seed must be proposed.

Rationale: The regulations for residues of captan in detreated seed corn (21 CFR 561.65) and for residues of captan in fat, meat and meat byproducts of cattle and hogs (40 CFR 180.103) do not identify permitted methods for detreating the captan treated corn seed. The Federal Register Notice (46 FR 55091-55092) which established the regulation (21 CFR 561.65) mentions washing and roasting, thereby implying that these are acceptable methods. The Agency has inadequate data to support either washing or roasting when the maximum registered dosage of 3.21 oz of captan per 100 lbs of seed had been applied. The Agency now has data to show that captan metabolites occur in milk and meat. The tolerances for negligible residues of 0.05 ppm in fat and meat and meat byproducts of cattle and hogs was established (46 FR 55113-55114) without identifying the metabolites that occur in animal tissues. A review of the record shows that there were no acceptable residue data to support the roasting detreatment method at any dosage or period of storage. The data deficiencies for residues of captan in food is covered in Section G and Table A of this Standard.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

All products that contain captan as the sole active ingredient are subject to this standard and must bear required labeling and either comply with the acute toxicity limits, product composition, and use patterns requirements listed in Section E of this document, or submit data and a justification to amend the standard to encompass such products.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 87 percent captan and 5 percent related derivatives as the active ingredients. Each manufacturing-use product must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use captan products must be substantially similar to that in the currently registered technical product. Any manufacturing-use product not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing captan for acute toxicity category I, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing captan may be labeled for formulation only into end-use products for use as a fungicide for foliar applications to fruit, nut, vegetable, and ornamental crops, for application to seeds and plant propagules, as a preplant application to soil, as post-harvest application to fruit and vegetable crops, and for application to produce packing boxes, to soil and crops grown in greenhouses, to house plants, to home gardens, to dog and cat dusts and shampoos and to hand soaps. Captan may be labeled for incorporation into plastics, oil-

base paints, wall paper pastes, textiles, paper, and cosmetics. It may be registered either in single active ingredient formulations or in combination with other fungicides and with insecticides.

4. Labeling of New and Existing Stock of Registered Products

All captan product registrations must be amended to reflect the required labeling as specified under Section F (which follows) within six months after the date of this Standard. Existing stocks of all captan products in the channels of trade after one year must bear the required labeling as specified under Section F.

F. REQUIRED LABELING

All technical grade and manufacturing-use products (MUPs) and end-use products (EUPs) must bear appropriate labeling as specified below and in 40 CFR §162.10. Other portions of this guidance package contain specific information regarding labeling requirements. Required labeling must be submitted within 90 days from the date of receipt of this Standard.

1. Ingredient Statement

The labeling ingredient statement for MUPs and EUPs must identify the active ingredient as:

Active Ingredients	By Wt.
*Captan	%
Related Derivatives	%
Inert Ingredients.....	%
*N-Trichloromethylthio-4-cyclohexene-1,2-dicarboximide.	

2. Precautionary Statements:

All products, MUPs and EUPs, must bear the following labeling precautionary statements:

"DANGER
Causes irreversible eye damage. Harmful if swallowed or inhaled. May cause allergic skin reactions. Do not get in eyes. Wear goggles or face shield when handling. Avoid contact with skin and clothing. Remove and separately launder clothing before reuse."

3. Environmental Hazards Statements

Manufacturing-Use Product Statements

"The product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

End-Use Product Statements

a. All EUPs that allow foliar application must bear the hazard precaution (which does not apply to cranberry and taro uses on EUP labels):

"This pesticide is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

b. In addition to the above statement, all EUPs that bear claims for foliar applications to cranberries and taro must include the following environmental hazard precautions as part of the use directions for cranberries and taro:

"This pesticide is toxic to fish. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes."

c. All EUPs that allow seed treatment must bear the following environmental hazard precaution:

"This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes In the event that treated seeds are spilled and cannot be salvaged, completely cover them with soil."

d. Endangered Species Precautions

(Additional precautionary labeling may be required pending results from the information submitted in response to the required environmental chemistry and

ecological effects data. The total potential risk to endangered species cannot be evaluated on the basis of the limited data presently available to EPA.)

The following precautions must be added to EUPs that bear claims for outdoor uses when the product is distributed in the States of Alabama, New Mexico, Tennessee, Texas, and Virginia:

"It is a violation of Federal laws to use any pesticide in a manner that results either in the death of an endangered species or adverse modification of its habitat."

The use of this product may pose a hazard to certain Federally designated endangered species known to occur in specific areas within the following counties:

STATE Species (BULLETIN NO.)	COUNTY
ALABAMA	Lauderdale
Slackwater Darter	Limestone
(EPA/ES-85-05)	Madison
NEW MEXICO	Chaves
Pecos gambusia	Eddy
(EPA/ES-85-21)	
TENNESSEE	Lawrence
Slackwater Darter	Wayne
(EPA/ES-85-04)	
Freshwater Mussels	Hancock
(EPA/ES-85-07)	Claiborne
	Hawkins
	Sullivan
TEXAS	Reeves
Pecos gumbusia	Jeff Davis
(EPA/ES-85-20)	Pecos
Commanche Springs Pupfish	Reeves
(EPA/ES-85-22)	Jeff Davis
VIRGINIA	Smyth
Freshwater Mussels	Scott
(EPA/ES-85-06)	Lee
	Washington
	Grayson

Before using this product in the above counties you must obtain the EPA Bulletin specified to your area. This Bulletin identifies areas within these counties where the use of this pesticide is prohibited, unless specified otherwise in the Bulletin. The EPA Bulletin is available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the Regional Office of the U.S. Fish and Wildlife Service. THIS BULLETIN MUST BE REVIEWED PRIOR TO PESTICIDE USE. Call 1-800-000-0000, toll free, if you have any questions or cannot obtain the appropriate bulletin."

4. Use Precaution Statements

a. The following statements are to be added under the labeling section, "Direction for Use", as specified:

For All EUPs That Claim Agricultural Uses:

"Mixers, loaders and applicators, when mixing, loading and applying must wear mid-forearm to elbow length natural or synthetic rubber, vinyl or plastic gloves impermeable to captan, boots or overshoes, one piece overalls which has long sleeves and long pants, face shield or goggles, and a hat or other appropriate head covering."

"Fieldworkers and harvesters must wear natural or synthetic rubber, vinyl, or plastic gloves impermeable to captan residues. Leather or fabric gloves are not acceptable."

If the product is a liquid, the following statement must be added:

" A chemical resistant apron must be worn when mixing and loading this product."

If the product is a dust, granular or wettable powder the following statement must be added:

"A dust mask must be worn when mixing and loading this product."

For all products:

"Clothing worn while loading, mixing and applying this product must be laundered separately from other clothing before reuse. Clothing that may have been drenched or heavily contaminated must be disposed of in accordance with state and local regulations."

For All EUPs

The following precaution may be added:

"Applicator's protection may also be obtained by use of an enclosed tractor cab with a properly filtered air supply."

For All EUPs That Claim Homeowner Uses (Yards and Gardens, House Plants, Shampoos, etc.):

"Wear natural or synthetic rubber, vinyl, or plastic gloves impermeable to captan when using indoors or outdoors. When using outdoors wear long pants and long sleeved shirt and apply with the wind to your back. Wash nondisposable gloves thoroughly with soap and water before removing.

Clothing worn while handling this product must be laundered separately from other clothing before reusing."

b. All EUPs intended for crop use, except seed, seed piece, and plant propagule treatements must bear the following use restrictions:

i. Do not rotate a foliar treated crop with crops other than those with registered captan uses.

ii. Do not allow persons to enter treated areas within 4 days following application unless protective clothing is worn. Conspicuously post reentry information at site of application.

iii. Water from cranberry bogs and wetland taro fields (in which either cranberry plants or taro plants had been treated with captan) must not be used for irrigation of crops other than those with registered captan uses.

c. For EUPs that bear labeling for use in greenhouses the following statements must be added:

"Only the applicator is permitted to be in the greenhouse during application of captan to soil. Open vents to greenhouse during application and at least for 1 hour after application."

"Workers planting in captan treated soil in greenhouses must wear gloves impermeable to captan."

G. Tolerance Reassessment

1. Non-Seed Applications

The established tolerances for captan are presently expressed as the fungicide captan (N-trichloromethylthio-4-cyclohexane-1,2-dicarboximide) without specifying the metabolites. The following metabolites have been identified in plants:

delta^4-tetrahydrophthalimide (THPI,II),
delta^4-tetrahydrophthalamic acid (THPAM, III),
4,5-epoxyhexahydrophthalimide (THPI-epoxide, V),
3-hydroxy-delta^4-tetrahydrophthalimide (3-OH THPI, VI),
5-hydroxy-delta^3-tetrahydrophthalimide (5-OH THPI, VII),
and N-(trichloromethylthio)-4,5-epoxyhexahydrophthalimide (captan-epoxide, IV).

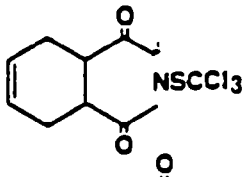
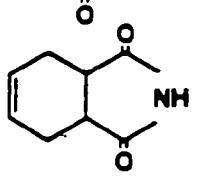
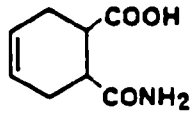
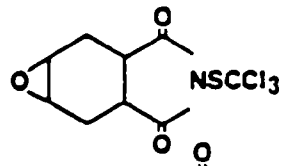
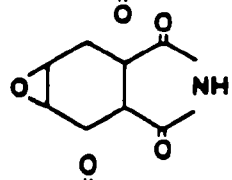
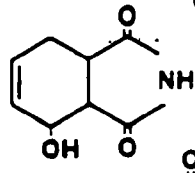
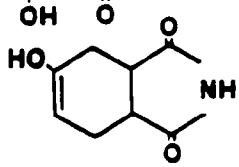
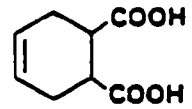
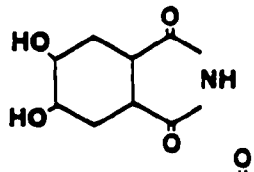
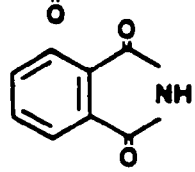
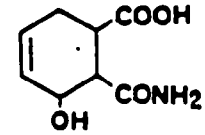
The major residues are the parent, THPI, and THPAM; the minor residues are THPI-epoxide, captan epoxide, and 3- and 5-OH THPI.

The following metabolites have been identified in tissues, organs, and milk of goats:

delta^4-tetrahydrophthalimide (THPI, II),
4,5-epoxyhexahydrophthalimide (THPI-epoxide, V),
3-hydroxydelta^4-tetrahydrophthalimide (3-OH THPI, VI),
5-hydroxydelta^3-tetrahydrophthalimide (5-OH THPI, VII),
and 4,5-dihydroxyhexahydrophthalimide (4,5-di-OH HHPI, IX),
delta^4-tetrahydrophthalamic acid
(THPAM, III) and phthalimide (PI, X) have been identified as minor metabolites in milk (III), tissues (X), and organs (X).

The following table identifies the structures of captan and its metabolites with identifying codes and abbreviations.

Captan and its metabolites*

CODE	STRUCTURE	CHEMICAL NAME	ABBREVIATION
I		N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide	Captan
II		Δ^4-Tetrahydrophthalimide	THPI
III		Δ^4-Tetrahydrophthalamic acid	THPAM
IV		N-(trichloromethylthio)-4,5-epoxyhexahydrophthalimide	Captan-epoxide
V		4,5-Epoxyhexahydrophthalimide	THPI-epoxide
VI		3-Hydroxy-Δ^4-tetrahydrophthalimide	3-OH THPI
VII		5-Hydroxy-Δ^3-tetrahydrophthalimide	5-OH THPI
VIII		Δ^4-Tetrahydrophthalic acid	THPAL
IX		4,5-Dihydroxyhexahydrophthalimide	4,5-diOH HHPI
X		Phthalimide	PI
XI		3-Hydroxy-Δ^4- tetrahydrophthalamic acid	3-OH THPAM

*As there have been no studies in which the trichloromethyl side chain has been radiolabelled, the fate of this side chain is not understood.

The following table lists the present tolerances in parts per million for residues of captan.

Raw Agricultural Commodity	Parts Per Million in Captan Residues U.S.	Canada	Mexico	Codex
ALMOND, HULLS	100.0I*	-	-	-
ALMONDS	2.0I	-	-	-
APPLES	25.0**	5.0	25.0	25.0
APRICOTS	50.0	5.0	-	20.0
AVOCADOS	25.0	-	-	-
BEANS, DRY	25.0I	-	25.0	-
BEANS, SUCCULENT	25.0I	-	25.0	10.0
BEETS, GREENS	100.0	-	-	-
BEETS, ROOTS	2.0	-	-	-
BLACKBERRIES	25.0	-	-	-
BLUEBERRIES (HUCKLEBERRIES)	25.0	5.0	-	20.0
BROCCOLI	2.0	-	2.0	-
BRUSSELS SPROUTS	2.0	-	-	-
CABBAGE	2.0	-	2.0	-
CANTALOUPS	25.0	-	25.0	-
CARROTS	2.0	-	2.0	-
CATTLE, FAT	0.05	-	-	-
CATTLE, MBYP	0.05	-	-	-
CATTLE, MEAT	0.05	-	-	-
CAULIFLOWER	2.0	-	2.0	-
CELERY	50.0	-	50.0	-
CHERRIES	100.0	5.0	-	50.0
COLLARDS	2.0	-	-	-
CORN, SWEET (K+CWHR)	2.0	-	2.0	-
COTTON, SEED	2.0	-	2.0	-
CRABAPPLES	25.0	5.0	25.0	25.0
CRANBERRIES	25.0	5.0	-	10.0
CUCUMBERS	25.0	-	25.0	10.0
DEWBERRIES	25.0	-	-	-
EGGPLANT	25.0	-	-	-
GARLIC	25.0	-	25.0	-
GRAPEFRUIT	25.0I	-	-	15.0
GRAPES	50.0	5.0	-	-
HOGS, FAT	0.05	-	-	-
HOGS, MBYP	0.05	-	-	-
HOGS, MEAT	0.05	-	-	-
HONEYDEW Melons	25.0	-	25.0	-
KALE	2.0	-	-	-

Continued

Raw Agricultural Commodity	Parts Per Million in Captan Residues U.S.	Canada	Mexico	Codex
LEEKS	50.0	-	-	-
LEMONS	25.0 I	-	-	15.0
LETTUCE	100.0	-	100.0	10.0
LIMES	25.0 I	-	-	15.0
MANGOES	50.0	-	50.0	-
MUSKMELONS	25.0	-	25.0	-
MUSTARD, GREENS	2.0	-	-	-
NECTARINES	50.0	-	-	-
ONIONS, DRY BULB	25.0	-	25.0	-
ONIONS, GREEN	50.0	-	50.0	-
ORANGES	25.0 I	-	-	15.0
PEACHES	50.0	5.0	40.0	15.0
PEARS	25.0	5.0	25.0	25.0
PEAS, DRY	2.0	-	2.0	-
PEAS, SUCCULENT	2.0	-	2.0	-
PEPPERS	25.0	-	-	10.0
PIMENTOS	25.0	-	-	10.0
PINEAPPLES	25.0 I	-	25.0	-
PLUMS (FRESH PRUNES)	100	5.0	-	15.0
POTATOES	25.0 I	-	2.0	20.0
PUMPKINS	25.0	-	-	-
QUINCES	25.0	-	-	-
RASPBERRIES	25.0	5.0	-	10.0
RHUBARB	25.0	-	-	15.0
RUTABAGAS, ROOTS	2.0	-	-	-
SHALLOTS	50.0	-	-	-
SOYBEANS, DRY	2.0	-	2.0	-
SOYBEANS, SUCCULENT	2.0	-	2.0	-
SPINACH	100.0	-	100.0	• 20.0
SQUASH, SUMMER	25.0	-	-	-
SQUASH, WINTER	25.0	-	-	-
STRAWBERRIES	25.0	5.0	25.0	20.0
TANGERINES	25.0 I	-	-	15.0
TARO (CORN)	0.25	-	-	-
TOMATOES	25.0	5.0	-	15.0
TURNIPS, GREENS	2.0	-	-	-
TURNIPS, ROOTS	2.0	-	-	-
WATERMELONS	25.0	-	25.0	-

*I Interim tolerance pending evaluation of captan under Rebuttable Presumption Against Registration (RPAR) review on transfer of residues to meat, milk, and eggs from feeding the raw agricultural commodity or their byproducts.

** Established tolerance under regulation, Section 180.103, 40 CFR.

The following table lists requests for captan tolerance actions presently before the Agency.

Raw Agricultural Commodity	Proposed EPA Pesticide Petition Number	Parts Per Million in Captan Residues U.S.	Canada	Mexico	Codex
Almond Nutmeats	3F2898	1.0	-	-	-
Dill	9E2251	2.0	-	-	-
Kiwi Fruit	0E2427	1.0 or 10.0	-	-	20.0
Parsley	9E2250	100.0	-	-	-
Taro Leaves	7E1982	0.25	-	-	-

A feed additive regulation (§561.65, Title 21, Code of Federal Regulations; Parts 500 to 599) permits residues of captan at 100.0 ppm remaining on corn seed from its intended use as a seed protectant after detreatment. Detreated corn seed can be used only as a feed for cattle and hogs up to 14 days prior to slaughter.
The Federal Register Notice of Intent to Cancel Registration of Pesticide Products Containing Captan; Availability of Position Document 2/3 (FR, Vol. 50, page 25888) stated: "the practice of using detreated corn seed for feeding to animals may be continued as long as the seed is washed to reduce captan to a 100 ppm tolerance level." This Notice did not address the use of unwashed corn seed that had been detreated by roasting. To permit detreating by roasting the Agency is requiring data on the chemical fate of captan pyrolysis products and other other pesticides that may be present on seed corn.

A food additive regulation (§193.40, Title 21, Code of Federal Regulations Parts 170 to 199) permits 50.0 ppm residues of captan in or on washed raisins when present as a result of fungicidal treatment by preharvest application to grapes and postharvest application during the drying process.

2. Seed Applications

No tolerances have been established for captan residues in or on any crop commodity for which captan is registered solely for seed or plant propagule application, because heretofore seed or plant propagule applications were considered as nonfood uses. The EPA registered seed and plant propagule uses that have been considered as nonfood uses include: alfalfa, asparagus (plant propagule), barley, beans, beans (lima), beets (sugar), beets (table), bluegrass, broccoli, brussels sprouts, cabbage, cantaloupe, carrots, cauliflower,

clover, collards, corn (field), corn (sweet), cotton, cowpeas, crucifers, cucumbers, eggplants, flax, grasses, kale, legumes (small seeded), lentils, lespedeza, millet, milo, muskmelon, mustard, oats, onions (pelleting), peanuts (shelled and unshelled), peas, peppers, pineapple (plant propagule), potato (plant propagule), pumpkins, radish, rice, rutabaga, rye, safflower, sesame, sorghum, soybeans, spinach, squash, sugar beets, sunflower, swiss chard, tomatoes, trefoil, turnip, watermelons, and wheat.

3. Plant Metabolism

Available plant metabolism data are not completely adequate for identifying the metabolites that may result from the maximum uses and necessary to support the established tolerances. Quantification and identification of captan and certain metabolites were performed only for apples (following foliar or postharvest treatment) and oranges (postharvest treatment). As captan and captafol have common metabolites in plants, metabolism of captafol in tomatoes and corn were compared and evaluated with the apple and oranges metabolism studies. The studies in these plants were adequate; however, certain additional studies identified in Table A, Generic Data Requirements for Captan, §158.125, Residue Chemistry, are required to clarify the nature of residues of captan in plants.

Future tolerances and existing tolerances may require inclusion of certain metabolites in the expression of tolerance, depending on the results from the required potato and lettuce metabolism studies. In a Special Data Call-In Notice on Captan dated April 29, 1985, the Agency requested residue data for captan and THPI for all registered crops.

4. Animal Metabolism

Available animal metabolism data are not adequate to support the tolerances in meat; and to establish tolerances in milk and poultry and eggs. Adequate data are available to identify and quantify metabolism of the ring portion of the captan molecule, but no data are available on the metabolism of the trichloromethylthio moiety (side chain). Certain additional studies identified in Table A, Generic Data Requirements for Captan, §158.125 Residue Chemistry, are required to clarify the nature of residues of captan in animals.

Future tolerances and existing tolerances in meat, fat, and meat byproducts may require inclusion of certain metabolites in the expression of the tolerance, depending on the results from the required animal feeding studies. In a special Data Call-In Notice on Captan dated April 29, 1985, the Agency requested feeding studies and analyses for captan *per se*, THPI, 3-OH THPI, and 5-OH THPI.

5. Analytical Methods for Residues

Adequate gas chromatography (GC) and colorimetric methods are available for identifying and quantifying residues of captan in animal and plant commodities, with the exception of colorimetric methods which specify surface stripping rather than grinding or homogenating plant samples. Surface stripping is acceptable for samples treated postharvest only and analyzed shortly after treatment. Field treated samples must be ground or homogenized as part of the extraction procedure.

For enforcement purposes, FDA's Pesticide Analytical Manual, Method I, Vol. II, Pesticide Regulation Section 180.103 is acceptable for plant commodities. No validated method is available for enforcement of tolerances for residues of captan in animal commodities. Validation of a GC method given in MRID 00025123 must be completed. Validation of GC methods for determining delta^4-tetrahydrophthalimide (THPI, II) in plants and THPI and 3-hydroxy-delta^4-tetrahydrophthalimide (3-OH THPI, VI) in milk, eggs, animal tissue, and 5-hydroxy-delta^3-tetrahydrophthalimide (5-OH THPI, VII) in milk must be validated by method tryout. The GC method given in MRID 00045179 which determines delta^4-tetrahydrophthalamic acid (THPAM, III) in animal tissues must also be validated.

As the nature of residues in both plants and animals have not been adequately described, additional metabolites of concern may have to be identified and quantified. Methods for analysis must be submitted and validated for such residues.

Data on analytical methods for identifying and quantifying residues in plants and animal tissue are specified in Table A, Generic Data Requirements for Captan, §158.125.

6. Storage Stability

No data are available on the storage stability of residues of captan in animal commodities or in or on plant commodities. As the nature of residues in plants and animals has not been adequately described, if additional metabolites of concern are found, data on the storage stability of such residues in storage will be required.

The storage stability data required under this Standard is described in Table A, Generic Data Requirements for Captan, §158.125.

7. Amended Tolerances Needed to Allow Continued Registration of Uses:

a. Food Uses Registered with Established Tolerances

Under a California Special Local Needs registration (SLN No. CA780027) asparagus may be seed treated or root dipped. Under a Washington Special Local Needs registration (SLN No. WA800035) kohlrabi may be seed treated or soil treated. No tolerances exist for captan residues in either of the commodities. Tolerances must be proposed in a request for an EPA Pesticide Petition to cover the residues of captan that may occur in these commodities. Alternatively, these registered uses must be withdrawn by the States.

There are registered uses of captan treatment of soil for greenhouse benches in which vegetables are grown. The use-patterns involving these use sites should specify for use only with vegetables having tolerances for residues of captan.

b. Use as a Seed Treatment

Heretofore, seed treatments and plant propagule treatments have been considered nonfood uses. Available plant metabolism data (refer to Nature of the Residue in Plants section) indicate that residues of captan may be taken up into mature plants from treated seed. Therefore, seed treatments are uses for which residue data and requests for EPA Pesticide Petitions for proposed tolerances must be submitted. The nature of residues in plants is not adequately understood. If the required plant metabolism data indicate additional metabolites of concern, additional residue data and tolerance proposals for the metabolites will be required.

c. Need for Processing Studies

Processing studies are required for the following commodities: potatoes, beans, soybeans, tomatoes, oranges, plums, sweet corn, and cottonseed.

d. Tolerance Reductions Under Review

An EPA Pesticide Petition (No. 3F2898) proposing reduction of tolerances for the residues of captan in the following raw agricultural commodities: almonds, apricots, beans (dry and succulent), beet greens, blackberries, blueberries, cantaloupe, celery, cherries, cranberries, cucumbers, dewberries, grapefruit, grapes, honeydew, lemons, lettuce, limes, muskmelon, nectarines, oranges, peaches, peppers, plums, pumpkins, raspberries, rhubarb, spinach, squash (summer and winter), strawberries, tangerines, tomatoes, watermelon, and washed raisins is pending with the Agency. The amendment also requests that the expression of residues include delta^4-tetrahydrophthalimide.

e. Amendment Required for Established Tolerances

The following amendment to Section 180.103 for residue tolerances for captan are required: (i) "beets (roots)" in the regulation should be changed to "garden beets," the appropriate definition for this commodity; (ii) "taro (corn)" in the regulation should be changed to "taro root," the appropriate definition for this commodity; (iii) tolerances for residues in or on garlic, leeks, and shallots should be cancelled, since there are no registered uses of captan on these crops; (iv) "soybeans, succulent" and "soybeans, dry" should be deleted from the regulation and "soybean seed" should be added, since "seed" is the appropriate definition for this raw agricultural commodity; (v) tolerance proposals accompanied by residue data or feeding and grazing restrictions must be proposed for bean and pea vines and hay, and soybean forage, hay, and straw; (vi) "muskmelon" and "honeydew melon" should be deleted from the regulation since "cantaloupes" covers these commodities; (vii) "tangelos" should be deleted from the regulation because "tangerines" covers this commodity; (viii) in 1969 (April 12, 1969), 34 FR 6442 revised the 100 ppm plum tolerance to 50 ppm but this change was never incorporated into the regulation. This revision should be made; (ix) on receipt of the data requested for grapes, appropriate food/feed additive tolerances must be proposed for residues in juice and raisin waste; (x) the tolerance for residues in or on crabapples should be deleted from the regulation as no registered use for captan on this commodity exists; and (xi) tolerance proposals and residue data or feeding and grazing restrictions are needed for pineapple and cottonseed forage.

f. Label Restrictions Required

Captan may be used as a component of paper and paper board that may come in contact with aqueous and fatty foods [21 CFR 176.170(c)]. Residue data to support this

regulation are required to support the EPA registered use-pattern. Alternatively, label amendments are required to restrict the use of captan-treated packing boxes for fruits and vegetables having tolerances for residues of captan.

The theoretical maximum residue contribution (TMRC) from established tolerances is 12 mg/day based on a 1.5 kg diet. The changes in the residue definition, the tolerance proposals, and the pending tolerances noted above will all affect a change in the TMRC level. The data requirements to support established tolerances as listed in 40 CFR 180.103 are given in Table A.

The Provisional Maximum Permissible Intake (PMPI) for a 60 kg person is 0.75 mg/day based on a Provisional Acceptable Daily Intake (PADI) of 0.0125 mg/kg. The present TMRC represents 1600 percent of the PMPI. The inclusion of the major metabolite (THPI) in the tolerance expression may result in an increase in the TMRC and a greater percentage of the PMPE utilized.

The PADI for captan is based on a reproductive toxicity study in rats. A no-observed-effect level (NOEL) was established at 12.5 mg/kg/day for decreased pup weights. A safety factor of 1000 is used to derive the PADI because there was only chronic data on one species. The PADI will be changed to an ADI when chronic data on a second species (nonrodent) are submitted and found adequate. The data from the most sensitive species and a safety factor of 100 will be used. The NOEL of 12.5 mg/kg/day was based on reproductive toxicity excluding the issue of oncogenicity for which a risk assessment has been made.

H. Use Pattern Statement

Captan may only be used to formulate products with established use-patterns including both single active and multiple active ingredient products. Acceptable use-patterns are listed in the USDA Compilation of Registered Uses of Fungicides, Part I, pp. C-10-00.01 to C-10-00.21 and/or EPA Index to Pesticide Chemicals for captan (issued: August 4, 1983).

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)] and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B-- Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,C,E,F,G,H,I	Yes	00054789	No
81-2 - Acute Dermal Toxicity	TGAI	A,B,C,E,F,G,H,I	No	00054789	Yes (9 months)
81-3 - Acute Inhalation Toxicity -Rat	TGAI MP 5	A,B,C,E,F,G,H,I	Yes	00086288	No
81-4 - Primary Eye Irritation -Rabbit	TGAI	A,B,C,E,F,G,H,I	Yes	00128621	No
81-5 - Primary Dermal Iritation	TGAI	A,B,C,E,F,G,H,I	No	00054791	Yes (9 months)
81-6 - Dermal Sensitization	TGAI	A,B,C,E,F,G,H,I	Yes	00054791	No
81-7 - Acute Delayed Neurotoxicity - Hen 4	TGAI	-	-	-	-
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,C,E,I	Partially 6 (Rodent)		Yes (Non-rodent, 18 months)
82-2 - 21-Day Dermal	TGAI	A,B,C,E,F,G,H,I	No	-	Yes (12 months)

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology (continued)					
82-3 - 90-Day Dermal	TGAI	A,B,C,E,F,G,H,I	-	-	No
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,C,E,F,G,H,I	No	-	Yes (15 months)
82-5 - 90-Day Neurotoxicity-Hen/Mammal 4	TGAI	-	-	-	-
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,C,E	Partially (rodent)	00130316, 00129157, 00129163 (rat)	Yes (non-rodent, 36 months)
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,C,E	Yes	00130316, 00129157, 00129163, (rat) 00068076 00126845 (mouse)	No
83-3 - Teratogenicity - 2 species	TGAI	A,C,E	Yes	00093883 (rabbit), 00086806, 00126348 00078623 (hamster)	No
83-4 - Reproduction, 2-generation	TGAI	A,C,E	Yes	00125293 (rat) 00120315 (rat)	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,C,E	Yes	00087805, 00131715, 00114210, 00131725	No
84-2 - Chromosomal Aberration	TGAI	A,C,E	Yes	00131727, 00114210, 00131725	No
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,C,E	Yes	00053608	No
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,C,E	No	00098787	Yes (24 months)
85-2 - Domestic Animal Safety 4	Choice	-	-	-	-
85-3 - Dermal Absorption	PAIRA	A,C,E	Yes	00117083	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

§158.135 Toxicology
(continued)

1/ Composition: TGAI = Technical grade active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than indicated in Table A.
4/ This test is not required.
5/ The Manufacturing-Use Product (MUP) has added inerts, but will satisfy the requirement.
6/ The chronic rodent study satisfies part of this requirement.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CAPTAN

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00054789	No
81-2 - Acute Dermal Toxicity	MP	No	00054789	Yes (9 months)
81-3 - Acute Inhalation Toxicity -Rat	MP	Yes	00086288	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00128621	No
81-5 - Primary Dermal Irritation	MP	No	00054791	Yes (9 months)
81-6 - Dermal Sensitization	MP	Yes	00054791	No

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than 9 months from the date of receipt of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D,E,F,H,I	Partially	00096974	Yes[4] (6 months)
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B,C	No	--------	Yes (9 months)
161-3 - On soil	TGAI or PAIRA	A,	No	--------	Yes (9 months)
161-4 - In Air	TGAI or PAIRA	A	No	--------	Yes[5] (9 months)
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E,F,H	Partially	00070414	Yes[6] (24 months)
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Partially	00098881	Yes[7] (24 months)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	No	--------	Yes (27 months)
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	--------	Yes (27 months)
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,E,F,H	Partially	00096972	Yes[8] (6 months)
163-2 - Volatility (Lab)	TEP	A,E	No	--------	Yes[9] (12 months)
163-3 - Volatility (Field)	TEP	A,E,F	No	--------	Yes[10] (15 months

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/]
158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	No	--------	Yes (27 months)
164-2 - Aquatic (Sediment)	TEP	C	No	--------	Yes (27 months)
Water	TEP	C	No	--------	
164-3 - Forestry	TEP	-	-	--------	No
164-4 - Combination and Tank Mixes		-	-	---------	No
164-5 - Soil, Long-term	TEP	A,C	No	---------	Yes (50 months)
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No	-- -------	Yes (39 months)
165-2 - Rotational Crops (Field)	TEP	A,C	No	---------	Yes (50 months)
165-3 - Irrigated Crops	TEP	C	No	----------	Yes (39 months)
165-4 - In Fish	TGAI or PAIRA	A,B,C	No	----------	Yes (12 months)
165-5 - In Aquatic Non-Target	TEP	-	-	----------	--

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.140 Environmental Fate (continued)					
Subdivision K (Reentry)					
132-1 Foliar dissipation	TEP	A,B,C	No	----------	Yes (27 months)
132-1 Soil dissipation	TEP	A,B,C	No	----------	Yes (27 months)
133-3 Dermal Exposure	TEP	A,B,C	No	----------	Yes (27 months)
133-4 Inhalation Exposure	TEP	A,B,C	No	----------	Yes (27 months)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA - Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than indicated below in this table.
4/ Data on the trichloromethanethiol (TCMT) side chain of captan was incomplete and nonquantitative in the partically acceptable study (00096974). Complete information on the fate and rates of formation and degradation of this moiety is necessary before guidelines will be fulfilled.
5/ Because captan is applied as an EC and is suspended in water, hydrolysis will occur. Because there is incomplete environmental fate and chemical data on captan and TCMT under these conditions additional studies are required.
6/ The partially acceptable study (00070414) used carbonyl ^{14}C captan which acceptably documented the fate of the ring portion of the captan molecule. The fate of the TCMT side chain was not addressed. The fate, rate of formation and degredation of this portion of the captan molecule must be addressed in order to fulfill guidelines requirements.
7/ The partially acceptable study (00098881) used carbonyl ^{14}C captan which acceptably documented the fate of the ring portion of the captan molecule. The fate of the TCMT side chain was addressed, however it appears that the extraction technique used could preclude proper analysis of the fate of the side chain. The study is not required if an acceptable anaerobic aquatic study is conducted.
8/ The partially acceptable study (00096972) gives information on the leaching and adsorption/desorption characteristics of the parent captan molecule in clay and clay loam soils only. The leaching and adsorption/desorption characteristics of the parent compound must be addressed in sandy soil. The major degradation products (THPI and TCMT) were not addressed in all major soil types.
9/ As there is incomplete data on vapor pressure of captan and TCMT, additional studies are required.
10/ The requirements for field volatility studies are reserved pending the results of laboratory volitility studies of captan and its TCMT degredate.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]
158.145 Wildlife and Aquatic Organisms					
Avian and Mammalian Testing					
71-1 Avian Oral LD_{50}	TGAI	A,B,C,E[4], F[4],G,H,I[4]	Yes	GS0120-045[8] GS9999-001[8] 00020560[9]	No
71-2 Avian Dietary LC_{50}					
a. waterfowl	TGAI	A,B,C,G,H	Yes	00022923[8]	No
b. upland game	TGAI	A,B,C,E[4],F[4], G,H,I[4]	Yes	GS0120-047[9] 0014686[9] 00022923[8]	No
71-3 Wild Mammal Toxicity	TGAI	A,B	No		No
71-4 Avian Reproduction					
a. waterfowl	TGAI	A,B,C	Yes	00092896[8]	No
b. upland game	TGAI	A,B	Yes	00098295[8] 00104083[9]	No
71-5 Simulated and Actual Field Testing for Mammals and Birds	TEP	A,B,C	No		No
Aquatic Organism Testing					
72-1 Freshwater Fish LC_{50}					
a. warmwater	TGAI	A,B,C, G,H	Yes	GS0120-042[8] GS0144-012[8] 00034713[9] 00057845[8]	No
	TEP (50%)	C	No		Yes (9 months)
b. coldwater	TGAI	A,B,C,E[4],F[4],G,H,I[4]	Yes	00057846[8]; GS0144-012	No
	TEP (50%)	C	No		Yes (9 months)
72-2 Acute LC_{50} - Freshwater Invertebrates	TGAI	A,B,C,E[4],F[4],F,G,H,I[4]	Yes	00070751[9]; GS0120-041[8] 00028759[9]	No
	TEP (50%)	C	No		Yes (9 months)

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement		Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3 2)(B)[3]
72-3	Acute Toxicity - Estuarine and Marine Organisms					
	a. fish	TGAI	A,C	No		Yes[5] (12 months)
	b. shrimp	TGAI	A,C	No		Yes[5] (12 months)
	c. oyster	TGAI	A,C	No		Yes[5] (12 months)
72-4	Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,C	No		No
72-5	Fish Life-cycle	TGAI	A,C	Yes	00057846[8]	No
72-6	Aquatic Organism Accumulation	TGAI PAI or Degradation Product	A,C	No		Yes[6] (1 year)
72-7	Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,C	No		Yes[7]

FOOTNOTES TO TABLE A - WILDLIFE AND AQUATIC ORGANISMS

1/ Composition: TGAI = Technical grade of active ingredient; PAI = pure active ingredient; TEP = typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food crop; B = Terrestrial, Nonfood crop; C = Aquatic, Food crop; D = Aquatic, Nonfood crop; E = Greenhouse, Food crop; F = Greenhouse, Nonfood crop; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than indicated below.

4/ To support the MUP when use includes "Indoor."

5/ Data are required because the rice seed and citrus use patterns encompass greater than 300,000 acres in coastal counties of the U.S., therefore creating potential to impact marine/estuarine organisms.

6/ Refer to the requirements for environmental fate chapter.

7/ Protocols addressing this requirement are to be submitted to the Agency within three (3) months. Protocols must receive written Agency approval prior to conducting such studies. The date when the data are to be submitted will be determined by the Agency based on the protocols and will be given in the review of the protocols.

8/ Study fulfills guideline requirements when considered alone.

9/ Study must be combined with other studies to fulfill guideline requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact LD_{50}	TGAI	A,B,G,H	Yes	00080871 05001991	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B,G,H	No	-	No[4]
141-4 - Honeybee subacute feeding study	[Reserved][5]				
141-5 - Field testing for pollinators	TEP	A,B,G,H	No	-	No[4]

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Nonfood; C=Aquatic, Food Crop: D=Aquatic, Nonfood; E=Greenhouse, Food Crop; F=Greenhouse, Nonfood; G=Forestry; H=Domestic Outdoor; I=Indoor. D=Aquatic, Nonfood; E=Greenhouse, Food Crop; F=Greenhouse, Nonfood; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.
4/ As data from the acute contact test indicate low toxicity, no further testing is required.
5/ Reserved pending development of test methodology.
6/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition	Use Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	[Reserved[6]]				
142-2 - Aquatic insect life-cycle study	[Reserved[6]]				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved[6]]				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	[Reserved[6]]				

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	See Footnote A	Yes[3]
- Livestock	PAIRA and plant metabolites	Partially	See Footnote B	Yes[4]
174-4 - Residue Analytical Method				
- Plant residues	Pure Analytical Standards and metabolites	Partially	See Footnote C	Yes[5]
- Animal residues Presently there are no established tolerances	Pure Analytical Standard and metabolites	Partially	See Footnote C	Yes[5]
171-4 - Storage Stability Data	PAI	No	-	Yes[6]

A. Bibliographic Citations: 00058941, 00083100, 00096978, 00098790, 00098831, GS0120-001, 00128355.

B. Bibliographic Citations: 00058940, 00098786, GS0120-003, GS0120-004, 00128355, 00096901, 00096908.

C. Bibliographic Citations: 00002927, 00002928, 00003025, 00025123, 00025125, 00035246, 00035248, 00042645, 00042646, 00045174, 00045175, 00045176, 00045179, 00045182, 00045183, 00045184, 00045188, 00045189, 00053324, 00054015, 00054016, 00070201, 00071790, 00083393, 00085525, 00085526, 00090988, 00090989, 00096910, 00096982, 00097622, 00098720, 00098726, 00098731, 00098747, 00098751, 00098784, 00098789, 00098804, 00098810, 00098811, 00098817, 00098818, 00117087, GS0120-008, 00098894, 00128355, GS0120-011, 00128355.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2]/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Root and Tuber Vegetable Group[a]				
Beets, Garden[1]	EP	No	-	Yes
Carrots[2]	EP	No	-	Yes
Potatoes[3]	EP	No	00098716 00098894	Yes
Taro[4]	EP	No	00054016	Yes
Turnip[5]	EP	No	-	Yes
Leaves of Root and Tuber Vegetable Group[b]				
Beet Green[1]	EP	No	-	Yes
Taro Leaves[2]	EP	No	-	Yes[7]
Turnip Greens[3]	EP	No	-	Yes
Bulb Vegetable Group[c]				
Garlic[1]	EP	No	-	Yes[8]
Leeks[2]	EP	No	-	Yes[8]
Onions[3]	EP	No	-	Yes
Shallots[4]	EP	No	-	Yes[8]
Leafy Vegetables (except brassica) Group[d]				
Celery[1]	EP	No	-	Yes
Lettuce[2]	EP	Partially	00070201	Yes
Rhubarb[3]	EP	No	-	Yes
Spinach[4]	EP	Partially	00070201	Yes
Brassica Leafy Vegetable Group[e]				
Broccoli[1]	EP	Partially	00070201	Yes
Brussels Sprouts[2]	EP	No	-	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Cabbage[3]	EP	No	-	Yes
Cauliflower[4]	EP	No	-	Yes
Collards[5]	EP	No	-	No
Kale[6]	EP	No	-	Yes
Mustard Greens[7]	EP	No	-	Yes
Legume Vegetables Group[f]				
Beans (Dry and succulent)[1]	EP	Partially	00046914 00070201 00098710	Yes
Peas (Dry and Succulent)[2]	EP	No	-	Yes
Soybeans[3]	EP	Partially	00071790 00096982	Yes
Foliage and Legume Vegetable Group[g]				
Bean Vines and Hay[1]	EP	No	-	Yes
Pea Vines and Hay[2]	EP	No	-	Yes
Soybean Forage, Hay and Straw[3]	EP	Partially	00098709	Yes
Fruiting Vegetables (except Cucurbits) Group[h]				
Eggplant[1]	EP	Partially	00098709	Yes
Peppers[2]	EP	Partially	-	Yes
Tomatoes[3]	EP	Partially	00070201 00085526 00098708	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Cucurbit Vegetable Group[i]				
Cucumber[1]	EP	Partially	00098709	Yes
Melons (excluding watermelon)[2]	EP	Partially	00098818	Yes
Pumkins[3]	EP	No	-	Yes
Watermelon[4]		Partially	00128355	Yes
Citrus Group[j]				
Grapefruit[1]	EP	Partially	00128355	Yes
Lemmons[2]	EP	Partially	00085526	Yes
Limes[3]	EP	No	-	No
Oranges[4]	EP	Partially	00058941 00085524 00098759 00128355	Yes
Tangerines[5]	EP	No	-	No
Pome Fruits Group[k]				
Apples[1]	EP	Partially	00085526 00098722 00098789 00106602 00128355 00128355 00098711 00128355	Yes
Crabapples[2]	EP	No	-	Yes[8]

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2]/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Pears[3]	EP	Partially	0070201 00055526 00098722 00106602 00128355	Yes
Quinces[4]	EP	No	-	No
Stone Fruits Group[1]				
Apricots[1]	EP	Partially	00128355	Yes
Cherries[2]	EP	Partially	00128355	Yes
Nectarines[3]	EP	Partially	00128355	Yes
Peaches[4]	EP	Partially	00128355	Yes
Plums (fresh prunes)[5]	EP	Partially	00128355	Yes
Small Fruits and Berries Group[m]				
Blackberries[1]	EP	No	-	No
Blueberries[2]	EP	Partially	00046914 00070201 00090988 00128355	Yes
Cranberries[3]	EP	Partially	00070201	Yes
Dewberries[4]	EP	No	-	No
Grapes[5]	EP	Partially	00046914 00070201 00090988 00098726 00128355 00128355	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Raspberries[6]	EP	Partially	0070201	Yes
Strawberries[7]	EP	Partially	00046914 00070201 00090988 00117088 00128355	Yes
Tree Nuts Group[n]				
Almonds[!]	EP	Partially	00070201 00090988 00098804 00098811 00128355 00128355	Yes
Cereal Grains Group[o]				
Corn[1]	EP	Partially	00045176 00070201 GS0120-039 00128355	Yes
Herbs and Spices Group[p]				
Dill[1]	EP	Partially	-	No[7]
Parsley[2]	EP	Partially	-	No[7]
Avocado[q]	EP	No	-	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Mangoes[r]	EP	No	-	Yes
Cottonseeds	EP	Partially	0002928 00070201 00090988	Yes
Kiwi[t]	EP	Partially	-	No
Pineapple[u]	EP	Partially	00085526 00098719	Yes
Seed Treatments[v]	EP	Partially	0003025	Yes
Food Packing Boxes[w]	EP	No	-	Yes
Meat, Milk, Poultry and Eggs[x]	EP	Partially	00025125 00035246 00035248 00045178 00096910 00098751 00098808 00098810 0010453	Yes

§158.125 Residue Chemistry (continued)

a. A crop group tolerance is not appropriate at the present time for the following reasons:

Additional residue data are required to support the existing tolerances for captan residues in or on potatoes and carrots.

Data are required for two additional group members (radishes and sugar beets).

The registered uses of captan formulations on group members with established tolerances are markedly dissimilar (foliar, preplant, postharvest, and seed treatment.

The following data are needed for support of existing tolerances on the following commodities:

1. Beets, Garden (Beet, Roots) - No data were submitted to support the established tolerance for residues of captan in or on garden beets. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of foliar and/or preplant use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, depending upon the registrant's wishes, data from one of the following three test protocols must be submitted:

i. If the registrant wishes to retain registered preplant and foliar uses data depicting captan residues of concern in or on beets harvested after a preplant soil application of a WP formulation of 6.56 lb ai/A, followed by multiple foliar applications at 7- to 10- day intervals of a FlC or WP formulation at 1.2 lb ai/100 gal are required. Beets must be harvested on the day of last foliar application. Foliar applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit tests using ground equipment only. Also, the registrant should propose a label amendment limiting the number of gal/A/application, and the number of applications/season or lb ai/A/season to those reflected in the above-required tests. Tests must be conducted in WI, NY, CA, and TX, which represent prominent canning beet production areas (Ware, G.W., and J.P. McCollum, 1980; Producing Vegetable Crops, Interstate Printers & Publishers, Inc., p. 422). State production percentages are not available.

ii. If the registrant wishes to cancel foliar uses, then only data reflecting preplant tests described above are required and an appropriate tolerance revision must be proposed.

iii. If the registrant wishes to cancel foliar and preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to section entitled Seed Treatments for details of data requirements) and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

2. Carrots - The requested test protocols recognize that the registrant(s) may seek cancellation of foliar use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

   i. If the registrant wishes to retain foliar uses, tests must include multiple foliar applications at 6- to 10-day intervals with either a WP or F1C formulation at 3 lb ai/A/application and samples of mature roots must be obtained on the day of final treatment. These data must depict captan residues of concern. Applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Also, the registrant should propose a label amendment limiting the maximum number of applications or lb ai/season rate to that reflected in the above-required tests. These tests must be conducted in CA (51%), TX (14%), and either MI (7%), MN (2%), or WI (7%), which represent major U.S. carrot production areas; production percentages cited in Agricultural Statistics, 1984, p. 153, appear in parentheses.

   ii. If the registrant wishes to cancel foliar use and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

3. Potatoes - The available data are insufficient to assess the interim tolerance for residues of captan in or on potatoes for the following reasons: (i) no data were submitted concerning foliar applications; (ii) no data were submitted concerning residues resulting from postharvest applications; (iii) insufficient data were submitted reflecting residues resulting from seed piece treatment; (iv) no data were submitted reflecting residues of concern in processed products of potatoes; and (v) geographic representation was inadequate. The following additional data are required:

   The following requested test protocols recognize that the registrant(s) may seek cancellation of foliar and or postharvest use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, depending upon the registrant's wishes, data from one or more of the following three test protocols must be submitted:

   i. If the registrant wishes to retain registered foliar and postharvest uses, tests must include multiple foliar applications at 5- to 7-day intervals with a WP formulation at 6 lb ai/A/application. Samples must be harvested on the day of final treatment and, on the same day, receive a postharvest, slurry dip application with the 50% WP at 1.25 ai/100 gal. These data must depict captan residues of concern. Foliar applications must be made using both ground and aerial equipment.

§158.125 Residue Chemistry (continued)

Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Also, the registrant should propose a label amendment limiting the maximum number of applications or lb ai/A/season rate to that reflected in the above-required tests. These tests must be conducted in ID (~25%), OR (~6%) and ME (~7%), which represent the major U.S. potato production areas; state production percentages appear parenthetically (Agricultural Statistics, 1984, p. 165)

ii. If the registrant wishes to cancel foliar and postharvest uses and retain seed piece treatment uses, data depicting captan residues of concern in or on potatoes must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

iii. If the registrant wishes to cancel postharvest uses and retain foliar use, then only data reflecting foliar tests described above are required and an appropriate tolerance reduction should be proposed.

Data reflecting the concentration of residues of concern in processed products of potato (granules, chips, and dried potatoes). Data must reflect potatoes with measurable, weathered residues. Should residues be found to concentrate upon processing, appropriate food/feed additive tolerances must be proposed.

4. Taro - The available data are insufficient to assess the established tolerance for residues of captan in or on taro root because no data depicting residues in or on whole taro root were presented. The following additional data are required:

Residue data pertaining to compounds of concern in or on taro root harvested after a single preplant soil treatment at 50 lb ai/A. These tests must be conducted in HI, the only State in which captan is registered for use on taro, and must reflect application to wetland taro only.

5. Turnip - No data were submitted to support the established tolerance for residues of captan in or on turnip root. The following data are required:

Data depicting captan residues of concern in or on turnips harvested after a single preplant soil application, followed by incorporation, with a WP formulation at 7 or 14 lb ai/A; the maximum permissible per acre rate is to be specified by the registrant. Tests must be conducted in GA, TX, and either OH or PA which represent the major turnip production areas designated in Vegetable Crops, 15th Ed., H.C. Thompson and W.C. Kelly, 1957, p. 338; individual State production percentages are not available.

§158.125 Residue Chemistry (continued)

The registrant must propose a label amendment specifying the maximum rate permitted for the 5% D formulation. Residue tests reflecting this use will not be required unless the maximum rate is in excess of that specified for the WP formulation.

If the registrant wishes to cancel preplant uses and retain seed treatment uses, then data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

b. Leaves of Root and Tuber Vegetable Group - A crop group tolerance is not appropriate at the present time for the following reasons:

Additional data are required to support the existing tolerance for captan residues in or on turnip greens.

Registered uses, and established tolerances are dissimilar for members of the leaves of root and tuber group.

Residue data must be submitted and a use proposed for captan formulations on one additional group member (sugar beets).

1. Beet Greens - No data have been submitted to support the established tolerance for residues of captan in or on beet greens. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of preplant and/or foliar use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, depending upon the registrant's wishes, data from one of the following three test protocols must be submitted:

i. If the registrant wishes to retain registered preplant and foliar uses, data depicting captan residues of concern in or on garden beet greens harvested after preplant soil application with a WP formulation at 6.56 lb ai/A followed by multiple foliar applications at 7- to 10-day intervals with a F1C or WP formulation at 1.2 lb ai/100 gal are required. Beet greens must be harvested on the day of the last foliar application. Foliar applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Also, the registrant should propose a label amendment limiting the number of gal/A/application and the number of applications/season or lb ai/A/season to that reflected in the above-required tests. Tests must be conducted in WI, NY, CA, and TX, which represent prominent canning beets production areas (Ware, G.W., and J.P. McCollum, 1980; Producing Vegetable Crops, Interstate Printers & Publishers, Inc., p. 422). State production percentages are not available.

§158.125 Residue Chemistry (continued)

ii. If the registrant wishes to cancel foliar uses and retain preplant uses, then only data reflecting preplant tests described above are required and an appropriate tolerance reduction should be proposed.

iii. If the registrant wishes to cancel foliar and preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

2. Taro Leaves - No tolerance for residues of captan in or on taro leaves has been established. A tolerance of 0.25 ppm is pending for residues of captan in or on taro leaves [PP#7E1982; amendment of November 30, 1983].

3. Turnip Greens - No data were submitted to support the established tolerance for residues of captan in or on turnip greens. The following data are required:

Data depicting captan residues of concern in or on turnip greens harvested after a single preplant soil application, followed by incorporation, with a WP formulation at 7 or 14 lb ai/A; the maximum permissible per acre rate is to be specified by the registrant. Tests must be conducted in GA, TX, and either OH or PA which represent the major turnip production areas designated in Vegetable Crops, 5th Ed., H.C. Thompson and W.C. Kelly, 1957, p. 338; individual State production percentages are not available.

The registrant must propose a label amendment specifying the maximum rate permitted for the 5% D formulation. Residue tests reflecting this use will not be required unless the maximum rate is in excess of that specified for the WP formulations.

If the registrant wishes to cancel preplant uses and retain seed treatment uses, then data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to section entitled Seed Treatments for details of data requirements) and an appropriate tolerance revision must be proposed.

c. Bulb Vegetable Group - A crop group tolerance is not appropriate at the present time for the following reasons:

Additional data are required for green onions and bulb onions, two representative commodities (see Onions section for details of data requirements).

Use directions must be proposed for an additional representative commodity (garlic, leeks, or shallots) and appropriate supporting data must be submitted.

§158.125 Residue Chemistry (continued)

1. Garlic - As captan is not federally registered for use on garlic, we recommend that the established tolerance be cancelled. Alternatively, the registrant may propose use directions and submit appropriate supporting residue data.

2. Leeks - As captan is not federally registered for use on leeks, we recommend that the established tolerance be cancelled. Alternatively, the registrant may propose use directions and submit appropriate supporting residue data.

3. Onions - No acceptable residue data were available to assess the adequacy of the established tolerance. Data obtained with analytical methods which prescribed colorimetric determination of surface extractable residues rather than macerations of whole samples were considered inadequate. The following data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of preplant, foliar and/or postharvest use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated 6/85); thus, depending upon the registrant's wishes, data from one of the following test protocols must be submitted:

   i. If the registrant wishes to retain registered preplant, foliar and postharvest uses, data must be submitted depicting captan residues of concern in or on green and dry bulb onions treated once preplant with the 5% D at 2 lb ai/A and several times foliarly with the 5% D and, in separate tests, with a WP formulation at 1.5 lb ai/A. Foliar applications should begin at the normal time of disease development and continue at 7-day intervals until the day of harvest. On the final day of foliar treatment, green and dry bulb onions must receive a postharvest treatment (dip or spray) at 1.28 lb ai/100 gal using a WP formulation. Foliar applications must be by ground and aerial equipment (in separate tests); alternatively, the registrant may propose deletion of aerial use and submit only tests using group equipment. Also, the registrant(s) must propose a maximum permissible number of applications or lb ai/A/season; the data reflected above must reflect the maximum seasonal rate proposed. Tests should be conducted in CA (29.6%), TX (14.2%), OR (13.6%), MI (5.9%), and NY (7.3%), which represent the major U.S. onion production areas (Agricultural Statistics, 1984, p. 162); State production percentages are given parenthetically.

   ii. If the registrant wishes to cancel postharvest use and retain preplant and foliar uses, then only data reflecting preplant and foliar tests described above are required and an appropriate tolerance reduction should be proposed.

   iii. If the registrant wishes to cancel foliar and postharvest uses and retain preplant use, then only data reflecting preplant tests described above are required and an appropriate tolerance reduction should be proposed.

§158.125 Residue Chemistry (continued)

iv. If the registrant wishes to cancel foliar, preplant, and postharvest uses and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to the section entitled Seed Treatments for details of data requirements) and an appropriate tolerance revision must be proposed.

4. Shallots - As captan is not federally registered for use on shallots, we recommend that the established tolerance be cancelled. Alternatively, the registrant may propose use directions and submit appropriate supporting residue data.

d. Leafy Vegetables (except brassica) Group - A crop group tolerance is not appropriate at the present time for the following reason:

Additional data are needed to support the established tolerances for residues in or on lettuce (head and leaf), celery and spinach.

1. Celery - No acceptable residue data were available to assess the adequacy of the established tolerance. Data obtained with analytical methodology which prescribed colorimetric determination of surface extractable residues rather than macerations of whole samples were considered inadequate. No acceptable data were submitted which reflected any use of captan formulations. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of foliar use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

i. If the registrant wishes to retain foliar uses, tests must reflect multiple foliar applications of a WP formulation (applied at 1 lb ai/100 gal of spray, using 200 gal/A), and (in separate tests) a D formulation applied at 2.25 lb ai/A. Applications should be repeated at 7-day intervals.

ii. If the registrant wishes to cancel foliar uses and retain plant bed uses then tests must reflect multiple plant-bed applications of a WP formulation (and, in separate tests, a D formulation) applied at 6.5 lb ai/A (for the WP, the use rate should be 1 lb ai/100 gal of spray, applied at 450 gal/A).

§158.125 Residue Chemistry (continued)

These tests should reflect a 0-day posttreatment interval. The registrant may propose cancellation of uses of D formulations, in lieu of conducting studies with D formulations. Tests should use ground and (in separate tests) aerial application methods. The registrant may propose label modifications to eliminate aerial application in lieu of conducting aerial studies. Studies should be conducted in CA (57.5%) and FL (21.2%), which collectively represent 78.7% of total 1983 U.S. celery production (Agricultural Statistics, 1984, p. 156). The registrant must propose a maximum seasonal use rate, and provide supporting data.

2. Lettuce - The available data are insufficient to support the existing tolerance of 100 ppm captan for residues of captan in or on lettuce, since application methods and sample composition were not identified, leaf lettuce data were not provided, and few head lettuce tests reflected a 0-day posttreatment interval. The following additional data are required:

Data depicting captan residues of concern in/on both head lettuce (with and without wrapper leaves) and leaf lettuce from tests reflecting multiple foliar application of the 50% WP at 1 lb ai/100 gal of spray (using 200 gal spray/A), repeated at 7-day intervals are required. The tests must reflect a 0-day posttreatment interval. Ground equipment must be used to apply the compound; the registrant may conduct additional tests reflecting aerial application, or may propose label modifications to eliminate this use. The registrant may conduct additional tests reflecting the use of a D formulation at 2.5 lb ai/A, repeated at 7-day intervals by ground and air (see above) equipment, or may propose label modifications eliminating such uses. The registrant must propose a maximum seasonal use rate and provide supporting data. These tests should be conducted in CA (69.4%) and AZ (18.7%), which together represent 83.5% of the 1983 U.S. lettuce-growing regions (Agricultural Statistics, 1984, p. 160).

3. Rhubarb - The available data (a single study) do not provide sufficient information to permit the evaluation of the established tolerance for captan residues. The following data are required:

Data depicting residues of captan residues of concern in/on rhubarb from studies reflecting multiple foliar applications of a WP formulation (at 1 lb a/100 gal spray) and a 0-day PHI. The registrant must propose a maximum seasonal use rate and a maximum single application rate (lb ai/1000 ft^2) and provide supporting data. Tests should be conducted in MI (16.3%), OR (20.4%), and WA (39.5%), which collectively represent 76.2% of total U.S. 1978 rhubarb acreage (1978 Census of Agriculture, Vol. I, p. 187).

4. Spinach - The available data are inadequate for evaluation of the established tolerance for captan residues in/on spinach, since no data reflected the use of preplant or at-plant treatments, only two samples reflected multiple foliar treatments, geographic representation was inadequate, and no data reflected a 0-day posttreatment interval. The following additional data are required:

§158.125 Residue Chemistry (continued)

The requested test protocols recognize that the registrant(s) may seek cancellation of foliar, preplant, and/or at-plant use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

i. If the registrant wishes to retain registered preplant, at-planting, and foliar uses; data depicting captan residues of concern in or on spinach harvested after a single preplant broadcast application of a D formulation at 6 lb ai/A, an at-plant application of a WP or D formulation at 3.5 lb ai/A and multiple foliar applications at 7-day intervals (by ground and, in separate tests, aerial equipment) of a WP formulation at 1 lb ai/100 gal (applied at 200 gal/A), an EC at 0.21 lb ai/100 gal, and a D at 4.0 lb ai/A (each in separate tests). The registrant must propose a maximum gal/A rate (for the EC formulation) and a maximum seasonal use rate and provide supporting data. These tests reflect a 0-day posttreatment interval. The registrant may propose cancellation of D formulation uses and aerial application on spinach in lieu of conducting the tests representing these uses. Studies should be conducted in CA (38.1%), AR (4.5%), MD (5.2%), NJ (3.8%), OK (4.8%), and TX (20.1%), which collectively represent 76.5% of total 1978 U.S. spinach acreage (1978 Census of Agriculture, Vol. I, p. 187).

ii. If the registrant wishes to cancel foliar uses and retain preplant and at-plant uses, then only data reflecting preplant and at-plant above are required and an appropriate tolerance reduction should be proposed.

iii. If the registrant wishes to cancel foliar and preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

e. Brassica Leafy Vegetable Group - A crop group tolerance is inappropriate at the present time for the following reasons:

Available data do not support the established tolerance for residues in or on broccoli, a representative commodity of this group.

Data must be submitted for cabbage and mustard greens, representative commodities of this group.

1. Broccoli - The available data are inadequate to support the established tolerance because no data reflecting the registered preplant use were submitted. The following data are required:

§158.125 Residue Chemistry (continued)

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated 6/85); thus, data reflecting only one of the following test regimens are required:

i. If the registrant wishes to retain preplant use, data must be submitted pertaining to captan residues of concern in or on broccoli following preplant treatment with a WP formulation at 7.5 or 14 lb ai/A (the maximum application rate must be clarified). Tests must be conducted in CA where ~90% of the domestic broccoli is produced (Agricultural Statistics, 1984, p. 15

ii. If the registrant wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

2. Brussels Sprouts - No data were submitted for brussels sprouts. However, since the registered use on broccoli is similar to that on brussels sprouts, the requested data for broccoli will be translated to brussels sprouts.

3. Cabbage - No data were submitted to support the established tolerance for residues in or on cabbage. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

i. If the registrant wishes to retain preplant use, data must be submitted pertaining to captan residues of concern in or on cabbage (with and without wrapper leaves) following preplant treatment with a WP formulation at 7.5 or 15 lb ai/A (the maximum application rate must be clarified). Tests must be conducted in NY (~21%), FL (~17%), TX (~16%), WI (~9% and CA (~6%), which represent the major cabbage producing regions of the country (Ware, G.W. and J.P. McCollum. 1980. Producing Vegetable Crops, 3rd ed., p. 259); State production percentage are given in parentheses.

ii. If the registrant wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

4. Cauliflower - No data were submitted for cauliflower. However, since the registered use on broccoli is similar to that on cauliflower, the requested data for broccoli will be translated to cauliflower.

5. Collards - No data were submitted for collards. However, since the registered use on mustard greens is similar to that on collards, the requested data for mustard greens will be translated to collards.

6. Kale - No data were submitted for kale. However, since the registered use on mustard greens is similar to that on kale, the requested data for mustard greens will be translated to kale.

7. Mustard Greens - No data were submitted to support the established tolerance for residues of captan in or on mustard greens. Therefore, the following data are required.

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus data reflecting only one of the following test regimens are required:

   i. If the registrant wishes to retain preplant use, data must be submitted pertaining to captan residues of concern in or on mustard greens following preplant treatment with a WP formulation at 7.5 or 14 lb ai/A (the maximum rate must be clarified). Tests must be conducted in TX, CA, and GA, the leading producers of mustard greens (Seelig, R.A. 1970. Mustard Greens. Fruit and Vegetable Facts and Pointers. United Fresh Fruit and Vegetable Association); State production percentages were not available.

   ii. If the registrant wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues on concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

f. Legume Vegetables Group - A crop group tolerance is not appropriate at the present time for the following reasons:

   Data requirements to support the established tolerances for residues in or on beans (succulent and dry) and peas (succulent and dry) must be satisfied.

   The registered uses of captan formulations on beans and soybeans (foliar and preplant) differs from that for peas (preplant or at-plant).

§158.125 Residue Chemistry (continued)

1. Beans (Dry and Succulent) - The available data are inadequate for evaluation of the established tolerances for captan residues in or on dry and succulent beans, since submitted data did not depict residues on dry or lima beans, did not depict residues resulting from pre- or at-plant treatments to succulent bean varieties, did not reflect more than two foliar treatments per season (two in only one study), and did not provide adequate geographic representation. The following additional data are required:

   The requested test protocols recognize that the registrant(s) may sek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

   1. If the registrant wishes to retain preplant, at-plant, and foliar uses, tests must include: (i) a preplant broadcast treatment with a WP formulation at 6 lb ai/A; (ii) an at-plant treatment using a D formulation at 6 lb ai/A; and (iii) in separate tests, multiple foliar applications (at 4-day intervals) of a WP and, in separate tests, an EC formulation at 1.2 lb ai/100 gal of spray and of a D formulation at 3 lb ai/A/application. A maximum gal/A rate must be proposed for WP, F1C and EC formulations and the data requested must reflect this rate. Samples must be obtained on the day of final treatment and data must depict captan residues of concern. Applications are to be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial application and submit only tests using ground equipment. The registrant must propose a label restriction which gives the maximum number of applications allowed per season for foliar applications; the date required above must reflect that number.

      Snap bean tests should be conducted in the states of WI (36%), OR (21%), NY (15%), and MI (7%), which collectively represent 79% of 1983 U.S. snap bean production. Dried bean tests should be conducted in MI (29%), CA (15%), NE (14%), CO (11%), and ND (11%), which represent ~80% of 1983 U.S. dried bean production (data from Agricultural Statistics, 1984, pp. 151 and 256). Lima bean tests should be conducted in CA (58%), WI (9%), and DE (7%), which represent 74% of the 1977 U.S. lima bean production (G.W. Ware and J.P. McCollum, 1980, Producing Vegetable Crops, Interstate Printers & Publishers, Inc., Danville, IL, 508 pp.).

   2. If the registrant wishes to cancel foliar uses and retain preplant and at-plant uses, then only data reflecting preplant and at-plant tests described above are required and an appropriate tolerance revision must be proposed.

   3. If the registrant wishes to cancel preplant, at-plant, and foliar treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

Residues must be determined in cannery residue processed from snap, lima, and dried beans bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food additive tolerances must be proposed.

2. Peas (Dry and Succulent) - The established tolerances for captan residues in or on dry and succulent peas cannot be evaluated, since no data depicting captan residues on or in peas were submitted. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

1. If the registrant wishes to retain preplant uses, tests reflecting captan residues of concern in or on peas (one succulent and one dried variety) following a preplant soil broadcast treatment with a WP formulation at 6 lb ai/A. These tests must be conducted in the states of WA (2%), WI (27%), NM (19%), and OR (~10%), which collectively represent ~77% of 1983 U.S. pea produc (Agricultural Statistics, 1984, p. 163).

2. If the registrant wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

3. Soybeans - The available data are sufficient to assess the adequacy of the established tolerance and label directions, including the SLN registrations held by AR, MS, and TX. We recommend that the entries of soybeans, succulent, and soybeans, dry, be deleted from the 40 CFR 180.103(a) because the raw agricultural commodity of soybeans is seed. Insufficient processed product data are available to determine whether food/feed additive tolerances are required; thus, the following additional data are required:

Data reflecting residues in meal, hulls, soapstock, and crude and refined oil processed from seed bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

[Note: If the registrant elects to cancel SLN registrations for foliar use of captan formulations on soybeans, then additional data reflecting at-plant use will be required.]

g. Foliage of Legume Vegetable Group - A crop group tolerance is not appropriate at the present time, for the following reason:

§158.125 Residue Chemistry (continued)

Residue data and tolerance proposals must be submitted for vines and hay of beans and peas and for forage, hay, and straw of soybeans; alternatively a label restriction prohibiting the use of these feed items may be proposed (refer to the following sections for details).

1. Bean Vines and Hay - No tolerances have been established or proposed and no data are available pertaining to residues of captan in or on bean vines or hay. Since bean vines and hay are raw agricultural commodities, tolerance proposals must be submitted; alternatively, the registrant must propose feeding/grazing restrictions on treated crops. If the registrant elects not to impose livestock feeding restrictions, the following data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

   i. If the registrant wishes to retain preplant, at-plant, and foliar uses, tests must include: (i) a preplant broadcast treatment with a WP at 6 lb ai/A; (ii) an at-plant application of a D formulation at 6 lb ai/A; and (iii) in separate tests, multiple foliar applications (at 4-day intervals) of a WP and an EC at 1.2 lb ai/100 gal and of a D formulation at 3 lb ai/A/application. The registrant must propose a maximum gal/A/application rate for EC and WP formulations and submit data reflecting that rate. Samples must be obtained on the day of final treatment and data must depict captan residues of concern. Applications are to be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial application and submit only tests using ground equipment. The registrant must propose a label restriction which gives the maximum number of applications allowed per season for foliar applications; the data required above must reflect that number. Snap bean tests should be conducted in the states of WS (86%), OR (21%), NY (15%), and MI (7%), which collectively represent 79% of 1983 U.S. snap bean production. Dried bean tests should be conducted in MI (29%), CA (15%), NE (14%), CO (11%), and ND (11%), which represent ~80% of 1983 U.S. dried bean production (data from Agricultural Statistics, 1984, pp. 151 and 256). Lima bean tests should be conducted in CA (58%), WS (9%), and DE (7%), which represent ~74% of 1977 U.S. lima bean production (G.W. Ware and J.P. McCollum, 1980, Producing Vegetable Crops, Interstate Printers & Publishers, Inc., Danville, IL, 608 pp.).

   ii. If the registrant wishes to cancel foliar uses and retain preplant and at-plant uses, then only data reflecting preplant and at-plant tests described above are required.

§158.125 Residue Chemistry (continued)

iii. If the registrant wishes to cancel preplant, at-plant, and foliar uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements).

2. Pea Vines and Hay - No tolerances have been established for captan residues of concern in or on the vines and hay of peas nor are such tolerances proposed.

The registrant must either propose feeding/grazing restrictions for treated pea vines and hay, or propose tolerances for captan residues of concern in or on pea vines and pea hay, and support them with the following data:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

3. Soybean Forage, Hay and Straw - The registrant must either propose tolerances for captan residues of concern in or on soybean forage, straw, and hay and provide the supporting data described below, or must propose feeding and grazing restrictions. The available data are inadequate for tolerance proposal, since no data reflecting at-plant application were submitted. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

i. If the registrant wishes to retain preplant uses, tests reflecting captan residues of concern in or on soybean forage, hay, and straw following a preplant soil broadcast treatment with the 5% D formulation at 6 lb ai/A. These tests should be conducted in the states of IL (16%), IN (7.7%), IA (17%), MN (9.2%), MO (6.3%), ND (9.1%), and OH (6.5%), which collectively represent ~71.8% of U.S. 1983 soybean production (Agricultural Statistics, 1984, p. 128). Alternatively, the registrant may propose a feeding and grazing restriction.

ii. If the registrant wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements).

h. Fruiting Vegetable (except Cucumbers) Group - A crop group tolerance is inappropriate at the present time for the following reason:

§158.125 Residue Chemistry (continued)

Additional data are required to support established tolerances for residues in or on representative commodities, peppers and tomatoes.

1. Eggplant - The available data are inadequate to support the established tolerance because the data reflected only 1-2 applications whereas an unlimited number of treatments may be made, and no data representing the 0-day posttreatment interval were submitted. However, additional data are not required because the data requested for peppers will be translated to assess the established tolerance for residues in or on eggplant.

2. Peppers - The available data are inadequate to support the established tolerance because (i) no data reflected a 0-day posttreatment interval; (ii) the data reflected a limited number of applications whereas no maximum number of applications per season is established; (iii) no recovery data were submitted an analytical procedures (surface extraction or sample maceration) were unclear; and (iv) geographic representation was poor. The following additional data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain use of captan formulations to permit tolerance reductions (Captan Special Review Position Document, 2/3, dated June 1985); thus, data are required from one of the following treatment regimens.

   i. If the registrant wishes to retain foliar uses, tests must include multiple foliar applications with a WP formulation at 3 lb ai/A. Treatments must begin at first fruit set and continue at 3-day intervals throughout the growing season. Foliar tests should reflect 0-day posttreatment interval. Applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Trials must be conducted in CA (31%), FL (35%), and TX (13%), since these States represent the major U.S. pepper production areas as designated in Agricultural Statistics, 1981, p. 180.

   ii. If the registrant wishes to cancel foliar uses and retain seed treatments, data depicting residues of concern in or on representative crops must be submitted (refer to section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

2. Tomatoes - The available data are insufficient to assess the adequacy of the established tolerance because data reflecting a 0-day posttreatment interval were meager and geographic representation was inadequate. Furthermore, no data were submitted concerning concentration of residues upon processing. The following additional data are required:

§158.125 Residue Chemistry (continued)

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

i. If the registrant wishes to retain foliar and preplant uses, tests must include a preplant application with a D formulation at 7.5 lb ai/A and multiple foliar applications with a WP and, in separate tests, a D formulation at 5 lb ai/A/application. Treatments must begin at first fruit set and continue at 5-day intervals; samples of mature fruits must be obtained on the day of final treatment. These data must depict captan residues of concern. Foliar applications must be made using both ground and aerial equipment and greenhouse tests must be represented. The registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment for field tests. Tests must be conducted in CA where ~85% of tomatoes grown for processing are produced and FL where ~50% of the U.S. fresh market tomatoes are produced (Agricultural Statistics, 1984, p. 173).

ii. If the registrant wishes to cancel foliar uses and retain preplant use, data from tests, as described above, reflecting preplant use only must be submitted and an appropriate tolerance revision proposed.

iii. If the registrant wishes to cancel foliar and preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative commodities must be submitted (refer to section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

Data depicting residues in or on wet and dry pomace, puree, catsup and juice processed from tomatoes bearing measurable weathered residues are required. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

i. Cucurbit Vegetable Group - A crop group tolerance is not appropriate at the present time for the following reasons:

Data are required for the representative crops, cantaloupes, cucumbers, and summer squash (see Conclusions sections for these crops for details of data requirements).

Registered uses of captan formulations on cantaloupe and cucumbers (preplant, foliar, and postharvest) are dissimilar from the registered uses on other group members (preplant and foliar only).

§158.125 Residue Chemistry (continued)

1. Cucumbers - The submitted data for cucumbers do not adequately support the established tolerance for residues of captan in or on cucumbers because: (i) the submitted foliar data are too meager; (ii) the procedural steps (surface extraction or sample maceration) used in residue analysis were not clarified; and (iii) no postharvest treatment data are available. The following data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

   i. If the registrant wishes to retain preplant, foliar, and postharvest uses, tests must include: (i) a single preplant broadcast soil treatment with a WP formulation at 6 lb ai/A, and (ii) in separate tests, multiple foliar applications at 5-day intervals with a D formulation at 5 lb ai/A, a WP formulation at 1.5 lb ai/100 gal or the maximum lb ai/A rate, and an EC at 1.2 lb ai/100 gal. A maximum lb ai/A/application rate must be proposed for WP, F1C, and EC formulations and the requested data must reflect that rate. Also, a maximum permissible number of applications/season or lb ai/season must be proposed and represented in the data. Samples must be obtained on the day of final foliar treatment and treated postharvest with a WP or a F1C formulation at 1.28 lb ai/100 gal. These data must depict captan residues of concern. Foliar applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Tests must be conducted in CA, FL, TX, and MI which account for 58% of U.S. fresh market and 38% of U.S. processing production (Agricultural Statistics, 1981, p. 171).

   ii. If the registrant elects to cancel postharvest uses and retain preplant and foliar uses, only data reflecting the above-described preplant and foliar treatments are required and an appropriate tolerance reduction must be proposed.

   iii. If the registrant elects to cancel postharvest and foliar uses and retain preplant uses, only data reflecting the above-described preplant treatments are required and an appropriate tolerance reduction must be proposed.

   iv. If the registrant wishes to cancel preplant, foliar and postharvest uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

2. Melons (excluding watermelons) - The available data are not adequate to support the established tolerance for residues of captan in or on cantaloupes, honeydew melons, or muskmelons, since data were submitted that reflect only postharvest treatment. While we consider the submitted postharvest data adequate to describe residues resulting from this type of treatment, they are not adequate to indicate what residues will result from foliar or preplant uses. The following data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

   1. If the registrant wishes to retain preplant, foliar, and postharvest uses tests must include: (i) a single preplant broadcast soil treatment with a WP formulation at 6 lb ai/A, and (ii) in separate tests, multiple foliar applications at 5-day intervals with a D formulation at 5 lb ai/A, a WP formulation at 1.5 lb ai/100 gal or the maximum lb ai/A rate and with an EC at 1.2 lb ai/100 gal. A maximum lb ai/A/application rate must be proposed for the WP, F1C, and EC formulations and the requested data must reflect that rate. Also, a maximum permissible number of applications/season or lb ai/season must be proposed and represented in the data. Samples must be obtained on the day of final foliar treatment and treated postharvest with a WP or a F1C formulation at 1.28 lb ai/100 gal. These data must depict captan residues of concern in or on cantaloupes. Foliar applications must be made using both aerial and ground equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Tests must be conducted in CA which accounts for ~67% of U.S. cantaloupe production (Agricultural Statistics, 1981, p. 165).

   2. If the registrant elects to cancel postharvest uses and retain preplant and foliar uses, only data reflecting preplant and foliar treatments are required and an appropriate tolerance reduction must be proposed.

   3. If the registrant elects to cancel postharvest and foliar uses and retain preplant use, only data reflecting the above-described preplant treatments are required and an appropriate tolerance reduction must be proposed.

   4. If the registrant wishes to cancel postharvest, foliar, and preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to data requirements) and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

We recommend that the established tolerances for muskmelons and honeydew melons be deleted, since they are redundant with that for cantaloupes, the appropriate commodity according to Table 2 of the EPA Residue Chemistry Guidelines.

3. Pumpkins - No data were submitted for pumpkins. Data requested for cantaloupes will be used to assess the established tolerance.

   No data were submitted for winter or summer squash. Data requested for cantaloupes and cucumbers will be used to assess the established tolerances for residues in or on winter and summer squash, respectively. [Note: translated data may not be used for establishment of a group tolerance.]

4. Watermelon - The submitted data are inadequate to support the established tolerance for the residues of captan in or on watermelons because they do not reflect a 0-day posttreatment interval or the maximum registered use rate. Data requested for cantaloupes will be used to assess the established tolerance for residues in or on watermelon.

J. Citrus Group - A crop group tolerance is not appropriate at the present time for the following reasons:

Additional data must be submitted to support the established tolerances for residues in or on oranges, grapefruit, and lemons (refer to individual crop group sections for details).

The registered uses of captan formulations on oranges and tangerines (tangeloes) differ from those for grapefruit, lemons, and limes.

1. Grapefruit - The available data are insufficient to assess the adequacy of the established interim tolerance for residues of captan in or on grapefruit for the following reasons: (i) no data were submitted reflecting residues in or whole fruit following postharvest application; (ii) insufficient data were submitted (one datum) reflecting preharvest application; and (iii) geographical representation was inadequate. The following additional data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

   i. If registrant(s) wishes to retain tree skirt and postharvest uses, tests must include tree skirt treatments with a WP and a D formulation (in separate tests) at 10 lb ai/A. Two applications at 10-week intervals must be made, the first before winter rains. Trees must be thoroughly wet to a height of 4 feet. Fruit must be harvested at maturity and treated postharvest by spray and

§158.125 Residue Chemistry (continued)

dip (in separate tests) with a WP or F1C formulation at 1.28 lb ai/100 gal. Data must be conducted in FL (65%), TX (18%), or CA (12%), which collectively represent 95% of the U.S. grapefruit production (Agricultural Statistics, 1984, p. 200).

ii. If a the registrant wishes to cancel postharvest uses and retain tree skirt uses, then only test reflecting postharvest treatment are required and an appropriate tolerance revision must be proposed.

The registrant must propose a label amendment to delete the citrus by-product feeding restriction; such a restriction is inappropriate because utilization of citrus by-products is not under grower control.

2. Lemons - The available data are inadequate for evaluation of the established tolerance for captan residues in or on lemons because the submitted data did not depict residues following tree skirt applications, and postharvest treatments did not reflect the maximum registered rate. The following additional data are required:

The requested test protocols recognize that the registant may seek cancellaiton of certain uses of captan formulations to permit tolerance reduction (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required.

i. If the registrant wishes to retain tree skirt and postharvest uses, tests must include tree skirt treatment with a WP and, in separate tests, a D formulation at 10 lbs ai/A. Two applications at 10-week intervals must be made, the first before winter rains. Trees must be thoroughly wet to a height of 4 feet. Fruit must be harvested at maturity and treated postharvest by spray and dip, in separate tests, with a WP or F1C formulation at 1.28 lb ai/100 gals. These data must depict captan residues of concern. Tests must be conducted in AZ and CA which provide 20% and 80% respectively, of the U.S. lemon crop (Agr. Statistics 1984, p. 200).

ii. If the Registrant wishes to cancel postharvest uses and retain tree skirt use, then only tests utilizing the above-mentioned tree skirt treatments must be performed and an appropriate tolerance revision must be proposed.

3. Limes - No data were submitted pertaining to captan residues in or on limes. However, no data are required because the registered uses on lemons are similar to those on limes; therefore, the requested data for lemons will be translated to limes.

§158.125 Residue Chemistry (continued)

4. Oranges - The available daa are inadequate for evaluation of the established tolerance for captan residues in or on oranges because the submitted data did not depict residues following tree skirt applications, foliar tests did not reflect multiple applications, and postharvest treatents did not reflect the maximum registered rate. Furthermore, the submitted processing studies were insufficient to determine whether residues concentrate in processed products. The following additional data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulatins to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following test regimens are required:

1. If the registrant wishes to retain tree skirt, foliar and postharvest uses, tests must include (i) tree skirt treatments with a WP and, in separate tests, a D formulation at 10 lb ai/A. Two applications at 10-week intervals must be made, the first before winter rains. Trees must be throughly wet to a height of 4 feet; (ii) multiple foliar applications with a WP formulation (with and without spray sticker) at 5 lb ai/A/application made between petal fall and the time fruit is ~1/2" in diameter; and (iii) postharvest treatment by spray and dip, in separate tests, with a WP or F1C formulation at 1.28 lb ai/100 gal. These data must depict captan residues of concern. Foliar application must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. The registrant must propose a label amendment which gives the maximum number of foliar applications allowed per season; the data required above must reflect that number. Tests must be conducted in CA and FL which provide ~34% and 62%, respectively, of the U.S. orange crop (Agricultural Statistics, 1984, p. 200).

2. If the registrant(s) wishes to cancel postharvest use, and retain foliar and tree skirt uses, then only tests utilizing the above-mentioned foliar and tree skirt treatments must be performed and an appropriate tolerance revision msut be proposed.

3. If the registrant(s) wishes to cancel postharvest and foliar uses and retain tree skirt treatments, tests must be performed utilizing the above-mentioned tree skirt tests only and an appropriate tolerance revision must be proposed.

Residues of concern must be determined in dried pulp, oil, molasses, and juice processed from oranges bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed. [Note: this processing study will apply to all citrus crops.]

§158.125 Residue Chemistry (continued)

The registrant must propose a label amendment to delete the citrus by-product feeding restrictions; such a restriction is inappropriate because utilization of citrus by-products is not under grower control.

5. Tangerines - No data were submitted pertaining to captan residues in or on tangerines. However, no data are required because the registered uses on oranges are similar to those on tangerines (tangeloes); therefore, the requested data for oranges will be translated to tangerines. We recommend that the 40 CFR 180.103 entry for tangeloes be deleted since tangerines is considered a general category for both tangerines and tangeloes (40 CFR 180.1).

k. Pome Fruits Group - A crop group tolerance is inappropriate at the present time for the following reason:

Additional data are required for apples and pears, the representative commodities of this group (refer to crop sections for details).

1. Apples - The data indicate that residues will not exceed the established tolerance following postharvest treatment alone in accordance with registered uses. However, the data are insufficient to assess the established tolerance for residues in or on apples because no data were submitted reflecting residues from foliar applications at the maximum rate followed by postharvest treatment at the maximum registered rate. Therefore, the following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985). Therefore, only one of the following protocols need be addressed:

If the registrant wishes to retain foliar and postharvest uses, tests must include multiple foliar applications with a WP and, in separate tests, a D formulation at 8 lb ai/A/application. Treatments using an EC at 2 lb ai/100 gal must also be represented. Treatments must begin at delayed dormant and continue at 5-day intervals through first cover, then at 7-day intervals thereafter until harvest. Samples of mature fruits must be obtained on the day of final treatment and treated postharvest with a spray or dip in a WP or F1C formulation at 1.28 lb ai/100 gal. These data must depict captan residues of concern. Applications must be made using both ground and aerial equipment. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit only tests using ground equipment. Tests must be conducted in WA (35%), NY (13%), MI (10%), CA (6%), PA (6%), and VA (6%), (Agricultural Statistics, 1984, p. 187).

§158.125 Residue Chemistry (continued)

If the registrant(s) elect to cancel postharvest uses, data are required for foliar treatments, as described above, only; an appropriate tolerance revision should be proposed.

The available processing data indicate that concentration of residues does not occur in juice, dry pomace, or wet pomace.

2. Crabapples - Since captan is not federally registered for use on crabapples, we recommend that the 40 CFR 180.103(a) be amended by deleting the tolerance for crabapples. Alternatiely, the registrant may propose use directions and submit appropriate supporting residue data.

3. Pears - The data indicate that residues will not exceed the established tolerance following postharvest treatment in accordance with registered uses. However, the data are insufficient regarding foliar applications, or combinations of foliar and postharvest treatments for the following reasons: (i) no data were submitted reflecting residues from foliar applications at the maximum rate; (ii) no data were submitted reflecting residues from foliar applications at the maximum rate followed by postharvest treatment at the maximum registered rate. The data requested for apples will be translated to assess the established tolerances covering residues in or on pears. [It should be noted, however, that translated data may not be used to support a crop group tolerance.]

4. Quinces - No data were submitted in support of the established tolerance for quinces. However, since the registered foliar use on quince is similar to that on apples, the requested data for apples will be translated to quince.

1. Stone Fruits Group - A crop group tolerance is not appropriate at the present time for the following reasons:

The use directions are quite diverse for the commodities with registered uses in this crop group.

Data requirements to support the established tolerances for residues in or on cherries and peaches must be satisfied.

1. Apricots - The available data do not adequately support the established tolerance for the following reasons: (i) none of the submitted tests depicted residues following multiple applications as allowed under the current use directions; (ii) no aerial application data were submitted; and (iii) no tests were submitted depicting residues resulting from the registered postharvest use. Therefore, the following data are required:

§158.125 Residue Chemistry (continued)

The requested test protocols recognize that the registrant(s) may seek cancellation of some uses such as postharvest dip or spray treatments to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985). If the registrant(s) wish to retain delayed dormant, foliar, and pos harvest uses, tests must include: multiple foliar applications with, in separate tests, a D and a WP formulation at 5 lb ai/A and 1.5 lb ai/100 gal, respectively. Applications of all formulations must be made in separate tests using both aerial and ground equipment. Treatments must begin in red bud periods and continue through cover stages; the registrant must propose a maximum seasonal use rate and provide supporting data. Fruits must be obtained on the day of final treatment and immediately subjected to postharvest treatment with a WP or F1C formulation applied in a dip and as a spray (in separate tests) at 1.28 lb ai/100 gal. Data must reflect captan residues of concern. Tests must be conducted in CA where 96% of all domestic apricots are produced (Agricultural Statistic, 1984, p. 193, 1983 preliminary data). Alternatively the registrant(s) may elect to cancel certain uses. If postharvest uses are cancelled, then only foliar tests as described above are required. The registrant may propose deletion of aerial use and conduct tests with ground equipment only. An appropriate tolerance revision should be proposed if postharvest use is cancelled.

2. Cherries - The available data are insufficient to assess the adequacy of the established tolerance because (i) only one test represented residues following an application rate approaching or above the maximum single use rate; (ii) none of the tests depict residues following applications with D or EC formulations, (iii) no aerial application data were submitted; and (iv) no tests were submitted depicting residues resulting from the registered postharvest use. The following data are required:

The requested test protocols recognize that the registrant may seek cancellation of some uses such as postharvest dip or spray treatments to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985). If the registrant wishes to retain delayed dormant/foliar and postharvest uses, tests must include multiple foliar applications with, in separate tests, a D formulation at 10 lb ai/A/application and an EC and WP or F1C at 2 lb ai/100 gal. All tests must reflect use of ground and aerial equipment. Treatments must begin in pink bud periods and continue through cover stages; the registrant must begin in pink bud periods; the registrant must propose a maximum seasonal use rate and provide supporting data. Samples of mature fruit must be obtained on the day of final treatment and immediately subjected to postharvest treatment with a WP or F1C formulation applied, in separate tests, in a dip and as a spray at 1.28 lb ai/100 gal. Data must reflect captan residues of concern. Tests with sour cherries must be conducted in MI (60%) and NY (15%) and tests with sweet cherries must be conducted in MI (10%), NY (2%), OR (25%), and WA (50%) States which represent the major cherry growing regions in the U.S. (Agricultural Statistics, 1984, p. 196, 1983 preliminary data). Alternatively, the registrant(s) may elect to cancel or propose amendments to certain registered uses. If postharvest uses are cancelled, then only foliar tests as described above are required the registrant may propose deletion of aerial use and ocnduct tests with ground equipment only. If postharvest use is cancelled, an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

3. Nectarines - The available data are inadequate to support the established tolerance for the following reasons: (i) none of the tests depict residues following applications with D or EC formulations; (ii) no aerial application data were submitted; and (iii) no tests were submitted depicting residues resulting from the registered postharvest use. The use direction for nectarines are similar to those for peaches. Therefore, no data will be required depicting residues of concern in or on nectarines since, upon submission of the requested data for peaches, the data will be translated to nectarines.

4. Peaches - The available data are inadequate to support the established tolerance for the following reasons: (i) no tests depict residues following applications of the D formulations, (ii) residue data following aerial applications are not available, and (iii) no tests were submitted depicting residues following the registered postharvest use. The following data are required:

   The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses such as postharvest dip or spray treatments to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985). If the registrant wishes to retain delayed dormant/foliar and postharvest uses tests msut include multiple foliar applications with, in separate tests, a D formulation at 6 lb ai/A/application and an EC formulation at 2 lb ai/100 gal; all tests must reflect use of ground and aerial equipment. Treatments must begin in pink bud periods and continue through cover stages; the registrant must propose a maximum seasonal use rate and provide supporting data. Samples of mature fruit must be obtained on the day of final treatment and immediately subject to postharvest treatment with a WP or F1C formulation applied, in separate tests, in a dip and as a spray at 1.28 lb ai/100 gal. Data must reflect captan residues of concern. Tests must be conducted in CA (59%), GA (5%) or SC (~5%), and PA (5%) or NJ (5%), States which represent the major U.S. peach growing regions (Agricultural Statistics, 1984, p. 215, 1983 preliminary data). Alternatively, the registrant(s) may elect to cancel or propose amendments to certain registered uses. If postharvest uses are cancelled, then only foliar tests as described above are required and the registrant may propose deletion of aerial use and conduct tests with ground equipment only. If the postharvest use is cancelled, then an appropriate tolerance revision must be proposed.

5. Plums (fresh prunes) - The available data provide adequate support for the established tolerance; however, since no processing studies concerning residues on dried prunes are available, the following additional data are required:

   Residue data for prunes dried from plums bearing measurable, weathered residues. Should residues concentrate upon processing, an appropriate food additive tolerance must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

§158.125 Residue Chemistry (continued)

m. Small Fruits and Berries Group - A crop group tolerance is not appropriate at the present time, for the following reason:

Additional data are required for raspberries, blueberries, cranberries, grapes, and strawberries.

1. Blackberries - The existing tolerance cannot be evaluated, since no data depicting captan residues in/on blackberries have been submitted. Requested data for raspberries will be translated to blackberries (refer to the Raspberries section); therefore, no additional data are required for blackberries.

2. Blueberries - The available data do not provide adequate support for the established tolerance for captan residues in or on blueberries, since the reported data are meager, the majority of the data are incomplete and/or do not reflect a 0-day posttreatment interval, no data reflect aerial application, and captan residues found in one study reflecting a 0-day posttreatment interval exceeded the established tolerance level. The following additional data are required:

   Data depicting captan residues of concern in or on blueberries, from tests reflecting multiple foliar applications by air and (in separate tests) by ground equipment of a WP formulation at 2.5 lb ai/A. Applications must begin at midbloom and continue at 7-day intervals until berries are mature. Samples must be collected on the day of the final treatment. (Alternatively, if the registrant elects to propose cancellation of the aerial use, aerial data data need not be submitted.) These tests should be conducted in MI (41.2%), NJ (26.1%), and ME (18.1%), which collectively represent ~85.4% of 1983 U.S. blueberry production (Agricultural Statistics, 1984, p. 214).

3. Cranberries - The available data do not provide adequate support for the established tolerance for captan residues in or on cranberries, since data reflecting multiple applications are meager, no data reflect more than two treatments, no data reflect aerial application, no data reflect the use of multiple treatments with a 0-day posttreatment interval, and geographic representation is inadequate. The following additional data are required:

   Data depicting captan residues of concern in or on cranberries, from studies reflecting delayed dormant and multiple foliar applications of the 50% WP by ground equipment and (in separate tests) by air at 3.5 lb ai/A. Samples must be collected on the day of the final treatment. Alternatively, the registrant may elect to propose cancellation of aerial application, in which case aerial data need not be submitted. These studies should be conducted in the States of MA (48.3%) and WI (37.4%), which collectively represent ~86% of 1983 U.S. cranberry production (Agricultural Statistics, 1984, p. 208).

§158.125 Residue Chemistry (continued)

The registrant must propose a label restriction which gives the maximum number of applications allowed per season for foliar application; the data required above must reflect that number.

4. Dewberries - The existing tolerance cannot be evaluated, since no data depicting captan residues in/on dewberries have been submitted. Requested data for raspberries will be translated to dewberries (refer to the Raspberries section); therefore, no additional data are required for dewberries.

5. Grapes - The available data do not provide adequate support for the established tolerance for captan in or on grapes, since the amount of data reflecting full-season treatment patterns, maximum registered use rates, or 0-day posttreatment intervals is inadequate, and no data reflect aerial treatment. Also, data depicting residues in washed raisins do not reflect full-season treatments or aerial applications. The following additional data are required:

   Data depicting captan residues of concern in or on grapes and washed raisins from tests reflecting the following treatment program:

   1. Multiple foliar applications of a WP and an EC (in separate tests) at 1.96 at lb ai/250 gal spray A (before bloom, immediately after bloom, and at 7-day intervals thereafter), and (in separate tests) of a D formulation at 5 lb ai/A. Formulations must be applied by ground and (in separate tests) by air. Samples (grapes) must be collected immediately after the last application. Representative samples should be analyzed.

   2. Two postharvest applications of a WP, at 1.5 lb ai/A by air, and (in separate tests) of 1 lb ai/A by ground equipment to fruit from above tests on drying trays in the field. After treatment, raisins should be processed normally and analyzed for residues.

      Tests should be conducted in CA (89.3%) and NY (3.5%), States which collectively represent ~93% of the 1982 U.S. grape-growing regions (Agricultural Statistics, 1983, p. 210).

      The registrant must specify whether the "pomace" data submitted in PP#3F2898 were for wet or dry pomace. If the data were for wet pomace, data depicting residues in dried pomace processed from grapes bearing measurable weathered residues are required and an appropriate feed additive tolerance proposal, if needed.

      The available data indicate that captan residues concentrate in juice and raisin waste by factors up to 2x and 8x, respectively. On receipt of the data requested above, appropriate food/feed additive tolerances for these processed commodities must be proposed.

§158.125 Residue Chemistry (continued)

6. Raspberries - The available data do not adequately support the established tolerance for captan residues in or on raspberries, since the data are meager, and do not reflect multiple (more than two) applications, sampling on the day of harvest, the use of WP or F1C formulations or the maximum lb ai/100 gal rate. If 1.96 lb ai/100 gal are applied at 250 gal/A (maximum expected gal/A for raspberries), then the maximum expected rate is ~5 lb ai/A. Therefore, the following additional data are required:

   Data depicting captan residues of concern in or on raspberries, from tests reflecting the following full-season treatment program using a D formulation at 3 lb ai/A and a WP at 5 lb ai/250 gal/A (each in separate tests) applied by ground equipment and (in separate tests) by air; delayed dormant application; foliar application at bloom, two weeks postbloom, 3-5 days prehaverst, midharvest, and 8-10 days postmidharvest. Samples must be collected on the day of the last treatment. Alternatively, if the registrant elects to propose cancellation of aerial uses, aerial data need not be submitted. These tests should be conducted in the states of WA (51.5%) and OR (48.5%), which collectively represent ~100% of 1983 U.S. raspberry production (Agricultural Statistics, 1984, p. 214).

   The above requested data will also be used to evaluate the established tolerances for residues in or on blackberries and dewberries.

7. Strawberries - The available data do not provide adequate support for the established tolerance for captan residues in or on strawberries, since few studies reflected the use of maximum registered lb ai/100 gal (1.96) use rates for WP formulations, and none reflected maximum use rates for Ds or ECs. Furthermore, residue levels were found to approach tolerance levels in several studies reflecting the use of rates as low as 0.31x the maximum use rate, and postreatment intervals greater than 0 days. The following data are required:

   Data depicting captan residues of concern in or on strawberries, from tests reflecting the following full-season treatment program (samples must be collected immediately after the last treatment).

   i. Delayed dormant application by air or (in separate tests) by ground equipment of a WP and EC formulation at 5 lb ai/250 gal/A and (in separate tests), a D formulation at 5 lb ai/A.

   ii. Multiple foliar applications using the formulations and use rates listed under (i.) above. (Alternatively, if the registrant elects to propose cancellation of aerial uses, aerial data need not be submitted.) These tests should be conducted in the States of CA (70%) and OR (8.9%), which collectively represent 79% of 1983 U.S. strawberry-growing regions (Agricultural Statistics, 1984, p. 227).

§158.125 Residue Chemistry (continued)

The registrant must propose a label restriction which gives the maximum number of foliar applications allowed per season; the data required above must reflect that number.

n. Tree Nuts Group - A crop group tolerance is inappropriate at the present time for the following reasons:

No data have been submitted for pecan or English walnut, representative commodities of this group.

Additional data are required for almonds, a representative commodity of this group.

1. Almonds - The available data are insufficient to assess the adequacy of the established tolerances because data reflecting the maximum application rate were not submitted. The following data are required:

Data reflecting residues of concern in or on almond nutmeats and almond hulls resulting from multiple applications with either a WP or a F1C formulation at 16 lb ai/A/application. Treatments must take place at delayed dormant, popcorn, bloom, and petal fall, and at regular intervals thereafter up to 12 days prior to harvest. Applications must be made using both ground and aerial equipment, in separate tests. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit tests using ground equipment only. Tests must be conducted in CA, where virtually all domestic almonds are produced (Agricultural Statistics, 1984, p. 237).

We recommend that the registrant propose a label amendment deleting the feeding restriction on almond hulls treated later than 5 weeks after petal fall, as this commodity is not under grower control.

o. Cereal Grains Group - A crop group tolerance is inappropriate at the present time for the following reasons:

No data or registered use (other than seed treatment) exist for rice, sorghum, and wheat, representative commodities of this group.

Additional data are required for corn, a representative commodity of this group.

1. Corn - The available data are insufficient to assess the adequacy of the established tolerance for residues in or on sweet corn because data reflecting soil or foliar applications were not submitted. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of soil and/or foliar use of captan formulations to permit tolerance reductions (Captan Special Review Position

§158.125 Residue Chemistry (continued)

Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

i. If the registrant wishes to retain foliar and preplant uses, a maximum gal/A or lb ai/A rate must be proposed for the foliar use and the 50% WP must be applied accordingly using aerial and ground equipment (in separate tests) 10 days prior to harvest. All tests must include preplant soil treatment of the 50% WP or 5% D formulations at 6 lb ai/A. Alternatively, the registrant may propose a label amendment to omit aerial applications and submit foliar tests using ground equipment only. Samples must be analyzed for all captan residues of concern. Tests must be conducted in NY (11%), OH (8%), CA (7%), and FL (28%) which represent the major fresh market production regions and WI (25%) and WA (15%) which represent the major production regions for processing (Agricultural Statistics, 1984, p. 158).

ii. If the registrant wishes to cancel foliar use and retain preplant soil treatment use, mature sweet corn from geographic regions specified above must be harvested from tests in which the 50% WP or 5% D formulation was applied as a preplant soil treatment at 6 lb ai/A. An appropriate tolerance reduction should be proposed.

iii. If the registrant wishes to cancel preplant and foliar uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

Also, no data were submitted concerning concentration of residues in the processed product of sweet corn, cannery waste. The following data are required:

Residues of concern in cannery waste processed from sweet corn bearing measurable weathered residues. If concentrations of any residues of concern is found to occur, a suitable feed additive tolerance must be proposed.

The data are insufficient to assess the established tolerance for residues in or on detreated seed corn because no data were submitted depicting residues resulting from detreated seed that originally had been treated at the maximum allowable rate. The following data are required:

§158.125 Residue Chemistry (continued)

Residues of concern in or on corn seed treated (in a slurry) with a WP, D, or FlC formulation at 3.76 oz ai/100 lbs seed, and detreated by an acceptable process. Data must depict residues of concern both before and after detreating. If different methods of detreating are to be permitted, data must be presented depicting residues resulting from each method. Data must depict the influence of varying parameters of the detreating process, such as rate of seed treatment, volume of water required, temperature employed, etc. These data are to be used to establish the acceptable conditions for detreating by each process. A mechanism should be implemented to prevent the feeding of detreated seed which contain residues of pesticides in addition to those of captan.

p. Herbs and Spices Group - A crop group tolerance is inappropriate at the present time for the following reasons:

Tolerance proposals for dill and parsley are currently under review and no data have been submitted or tolerances established or proposed for other crop group members.

1. Dill - No conclusions may be made at the present time since the petition for use on dill is currently pending.

2. Parsley - No conclusion may be made at the present time since the petition for use on parsley is currently pending.

3. Avocado - No data were submitted to support the established tolerance for residues of captan in or on avocados. The following additional data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of foliar use of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

i. If the registrant wishes to retain foliar use, data reflecting captan residues of concern must be provided from avocados harvested on the same day as the last of multiple foliar applications, using a WP at 1 lb/100 gal/application (the registrant must propose a maximum seasonal use rate and submit data accordingly). Separate tests must be conducted utilizing aerial and ground (high and low volume) equipment. Alternatively, the registrant may propose deletion of the aerial use from label directions and submit only tests using ground equipment. The foliar tests must be conducted in CA and FL, which respectively represent ~89 and ~11% of the U.S. avocado production regions (Agricultural Statistics, 1984, p. 194).

§158.125 Residue Chemistry (continued)

ii. Should the registrant elect to cancel foliar application of captan to avocado, and retain seed treatment use, further data reflecting seed treatment may be required (refer to section entitled Seed Treatment for details of data requirements].

r. Mangoes - No data were submitted to support the established tolerance for residues of captan in or on mangoes. The following additional data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

If the registrant wishes to retain foliar and postharvest uses, tests must include multiple foliar applications with a WP formulation at 10 lb ai/A per application. Mangoes must be harvested on the day of last application and immediately treated postharvest with a WP or FlC formulation at 1.28 lb ai/100 gal in separate dip and spray tests. These data must depict captan residues of concern. Foliar application must be made using (in separate tests) appropriate aerial and ground (high and low volume) equipment. Alternatively, the registrant(s) may propose a label amendment to omit aerial application, and submit only tests using ground equipment. The registrant must proposed maximum seasonal application rate for foliar treatments and submit data accordingly. Tests must be conducted in FL which accounts for ~92% of the U.S. production area of mangoes (Census of Agriculture 1983, p. 193).

s. Cottonseed - The available data are insufficient to assess the established tolerance for residues of captan in or on cottonseed for the following reasons: (i) residue data did not reflect maximum permissible application for at-plant treatment; (ii) analysis for residues was not performed on whole cottonseed; (iii) geographical representation was poor; and (iv) insufficient data were submitted reflecting concentrations of residues in processed products of cottonseed. Furthermore, since forage is a raw agricultural commodity of cotton, either residue data must be submitted and a tolerance proposed, or a feeding restriction must be proposed. The following data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

1. If registrant(s) wish to retain at-plant (preplant) use of captan on cotton, tests must be performed utilizing a D formulation at 6 lb ai/A. Residue data must depict captan residues of concern in or on cottonseed and cotton forage. A tolerance for captan residues of conern in or on cotton forage must be proposed; alternatively, the registrant may propose feeding and grazing restrictions. Tests must be conducted in MS (15%), TX (23%), and CA (26%), since these states represent the major U.S. cotton growing regions (Agricultural Statistics, 1984, p. 63).

§158.125 Residue Chemistry (continued)

ii. If the registrant(s) wishes to cancel preplant uses and retain seed treatment uses, data depicting captan residues of concern in or on representative crops grown from treated seed must be submitted (refer to the section entitled Seed Treatment for details of data requirements) and an appropriate tolerance revision must be proposed.

Data depicting residues of concern in cottonseed processed products including meal, hulls, soapstock, crude oil, refined oil processed from cottonseed bearing measurable, weathered residues. Should concentration of residues be found to occur upon processing, then appropriate food/feed additives must be proposed.

t. Kiwi - No conclusions may be made at the present time since the petition for kiwi fruit is currently pending.

u. Pineapple - The available data are insufficient to assess the adequacy of the established tolerance because no data reflecting captan residues in or on whole fruit were presented and no date reflected postharvest treatments. Furthermore, no data were available concerning residues in or on pineapple forage or in pineapple processed products (bran and juice). Since pineapple forage is a raw agricultural product of pineapple, a tolerance proposal and supporting data must be submitted; alternatively, the registrant may propose a feeding restriction. The following additional data are required:

The requested test protocols recognize that the registrant(s) may seek cancellation of certain uses of captan formulations to permit tolerance reductions (Captan Special Review Position Document 2/3, dated June 1985); thus, data reflecting only one of the following treatment regimens are required:

i. If the registrant wishes to retain preplant, foliar and postharvest uses, data must be submitted depicting captan residues of concern in or on pineapple treated once preplant (as pineapple slips) and serveral times foliarly (ground equipment only) with the 50% WP. Preplant dip treatment is to be at 5 lb ai/100 gal and foliar treatments are to be at 2 lb ai/100 gal. The registrant must propose a maximum number of foliar treatments and submit data accordingly. Pineapples must be harvested on the day of last foliar application and subsequently given a postharvest application of 5 lb ai/100 gal, as a wash, and in separate tests, a dip. Foliar tests must be conducted in HI, which accounts for ~99% of the U.S. pineapple production area of the U.S. (Census of Agriculture, 1978, p. 204).

ii. If the registrant(s) wishes to cancel postharvest use, and retain preplant and foliar use, tests must be performed utilizing above-mentioned preplant and foliar treatments and an appropriate tolerance revision must be proposed.

§158.125 Residue Chemistry (continued)

iii. If the registrant(s) wishes to cancel foliar and postharvest use and retain preplant use, then tests must be performed utilizing above-mentioned preplant tests and an appropriate tolerance revision must be proposed.

Registrant must provide residue data for the RAC pineapple forage from the above tests, and propose a tolerance or propose appropriate feeding restrictions.

Residue data must be provided for bran and pineapple juice processed from pineapple bearing measurable, weathered residues. If residues are found to concentrate upon processing, then appropriate food/feed additive tolerances must be proposed.

v. Seed Treatments - Since ^{14}C-residues are taken up into pods, stems and leaves of soybean grown from seed treated with [^{14}C]captan (refer to Nature of the Residue in Plants; MRID 00083100), seed treatment must be considered a food use. Thus, all raw agricultural commodities of crops having seed treatment as a registered use of captan must have tolerances for residues of captan. The available data are adequate for cotton seed and corn seed only; following seed treatment at maximum rates, no measurable residues were found in or on these commodities. The data for soybeans, oats, and wheat are not adequate because rates well below the maximum permissible rates were used. The following data are required:

Representative commodities from the nongrass animal feeds; cereal grains; forage, fodder, and straw of cereal grains; and grass forage, fodder, and hay crop groups are given in 40 CFR 180.34 and the individual crops, flax, lentils, okra, peanuts, radishes, rape, sunflower, sugar beets, safflower, sesame, and Swiss chard must be seed-treated with captan according to the label directions of the product having the maximum permissible use rate. In many cases, the maximum rate is present on a multiple active ingredient formulation label. Samples of all raw agricultural commodities from each crop must be collected at the shortest interval after planting in which they could be used for food or feed purposes. Analyses should be made for all residues of concern. Tolerances reflecting maximum expected residue levels or, if no measurable residues are detected, at the limit of detection must be proposed.

The Special Report procedures for captan may result in cancellation of many uses on crops having tolerances for residues of captan. However, we expect that seed-treatment uses may not be cancelled (Captan Special Review Position Document 2/3, June 1985). If all uses, with the exception of seed treatment, are cancelled for any of the crops for which tolerances exist (see list under Use Directions and Limitations), seed treatment data collected according to the procedures outlined above will be required for those crops, or representative crops in each crop group. In such cases, appropriate tolerance revisions (reductions) must be proposed at the time of the data submission.

§158.125 Residue Chemistry (continued)

w. Food Packing Boxes - No data are available to support the food additive regulation for captan as a surface treatment on paper and paperboard for use in contact with food. Also, no data are available regarding the use of captan to surface-treat food packing boxes. Therefore, the following data are required:

The registrant is referred to 21 CFR 176.170(c) and (d) for data requirements regarding the use of captan as a surface treatment of paper and paperboard. All of the test procedures in Table 2 (section c) for food types I, II, and VIB must be completed using methods described in section d following surface treatment of paper and paperboard with captan at 0.225% retention, based on weight of the sheet, using the 75% WP formulation. No end test is required for food type VIII (dry solids with the surface containing no free fat or oil). However, 21 CFR 176.180(a) states that the "substances" (i.e., captan) must be "used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging."

All labels (50-80% WP) permitting treatment of food "packing boxes" must be amended with a restriction permitting use on boxes used to pack fruits and vegetables having esablished tolerances for residues of captan only. Furthermore, if these tolerances (or proposed tolerance revisions) are set to cover seed treatment or preplant use only, data are required to verify that residues resulting from treatment of packing boxes will not result in tolerance-exceeding values.

x. Meat, Milk, Poultry and Eggs - The maximum expected dietary intake of captan residues by beef cattle is 139 ppm up to 14 days prior to slaughter and 128 ppm for the 14 days prior to slaughter if the diet consisted of 20% bean cannery residue, 10% wet grape pomace, 30% cull potatoes, and 40% detreated corn seed up to 14 days prior to slaughter and 20% bean cannery residue, 10% wet grape pomace, 30% cull potatoes, 25% almond hulls, and 15% dry beans for the 14 days prior to slaughter. The maximum expected intake by dairy cattle is 139 ppm based on the diet described above that included detreated corn grain. For hogs, the maximum expected intake up to 14 days prior to slaughter is 124 ppm based on a diet consisting of 10% bean cannery residue, 10% wet grape pomace, 50% cull potatoes and 30% detreated corn seed and 99 ppm for the 14 days prior to slaughter based on a diet consisting of 10% bean cannery residue, 10% wet grape pomace, 50% cull potatoes, 20% dry beans, and 10% dry soybeans. The maximum expected intake by turkeys and broilers is 19 ppm based on a diet consisting of 3% wet grape pomace, 5% dry grape pomace, 5% dehydrated apple pomace, 7% cull potatoes, 10% dry beans, 20% soybeans, 30% soybean meal, 10% dry peas, and 10% cottonseed meal. For laying hens, the maximum expected intake is 34 ppm based on a diet of 3% wet grape pomace, 5% dry grape pomace, 5% pineapple bran, 20% cull potatoes, 15% dry beans, 50% dry soybeans, and 2% soybean meal.

§158.125 Residue Chemistry (continued)

[The contributions to the diet by wet grape pomace, cull potatoes, and bean cannery residue were corrected for dry matter percentages of 37%, 23%, and 9.4%, respectively. Thus, tolerances for residues in or on these commodities were multiplied by 2.7, 4.3, and 10.6, respectively, prior to determining their contribution of residues to the animal's diet. It should be noted, however, that data gaps exist for several feed commodities (refer to "Magnitude of the Residue in Plants"); thus, these "maximum expected intake" levels are subject to change.]

Presently, the nature of the residue in plants and animals is not adequately understood. On receipt of the data requested in the sections entitled "Nature of the Residue in Plants," "Nature of the Residue in Animals," and "Magnitude of the Residue in Plants," the adequacy of the residue data for animal products will be assessed and the adequacy of established tolerances for residues in animal products determined. Also, at that time pertinent sample storage and storage stability information for animal commodities will be required since such information is either inadequate or lacking at the present time.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

§158.125 Residue Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ Data* must be submitted no later than 24 months from the date of receipt of this Standard.

3/ Data reflecting the distribution and metabolism of carbonyl-labeled (^{14}C) captan in lettuce following foliar treatments, and in potato tubers following foliar and postharvest treatments. Application rates must be sufficiently high to permit complete ^{14}C-residues identification. Data reflecting the metabolism of ^{14}C-labeled trichloromethyl this moiety of the captan molecule in potato tubersand lettuce. Note: Samples from the metabolism studies requested above must also be analyzed using enforcement methods to ascertain method validity.

4/ Metabolism studies utilizing poultry. Animals must be dosed for three days with carbonyl-labeled (^{14}C) captan at a concentration in the total diet which will result in sufficient residues in the tissues and eggs for characterization. Animals must be sacrificed within 24 hours of the final dose (eggs must be collected twice daily). ^{14}C-Residues must be characterized in muscle, fat, kidney, liver, and eggs. Data reflecting the metabolism of ^{14}C-labeled trichloro methyl this moiety (side chain) of captan molecule in ruminants and chickens. Note: Samples from the metabolism studies requested above must also be analzed using enforcement methods to ascertain method validity.

5/ Method trials must be conducted to evaluate the GC methods given in MRID 00025123 for determination of captan residues in animal tissues, eggs, and mild. For enforcement purposes, Method I in PAM, Vol. II, Pesticide Reg. Sec. 180.130 is acceptable for plant commodities.

The nature of residues in plant and animals has not been adequately described. If additional metabolites of concern are detected in plants and/or animals products, the conclusions stated above may be changed.

* Required data, excluding the data required under the April 29, 1985, Section 3 (c)(2)(B), "Special Data Call-In-Notice on Captan and Its Metabolites for Residue Chemistry and Toxicology" notice. The schedule for submitting those data is not changed by this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN

§158.125 Residue Chemistry (continued)

6/ The storage stability of captan residues in or on animal and plant tissues is not adequately understood. The following additional data are required:

The storage intervals and conditions of storage of samples used to support all established tolerances for residues must be submitted. These data must be accompanied by data deputing the percent decline in residues at the times and under the conditions specified. On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

All residue data requested in this standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified.

7/ No conclusion can be made because a petition for residues in or on this raw agricultural commodity is pending with the EPA.

8/ There was federally registed use for this commodity. The tolerance must deleted or the use the crop must be registered.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 32691-1; CALHIO CHEMICALS, INC.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	Registration jacket	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	Registration jacket	No
63-3 - Physical State	TGAI	Yes	Registration jacket	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	TGAI	N/A[e]		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	Registration jacket	Yes

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Not required because the technical is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 32691-1; CALHIO CHEMICALS, INC.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI	Yes	Registration jacket	No
63-9 - Vapor Pressure	PAI	Yes	00098845	No
63-10 - Dissociation Constant	PAI	N/A[d]		No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	Partially	Registration jacket	Yes
63-13 - Stability	TGAI	Partially	Registration jacket	Yes
Other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Not required because the active ingredient is not an acid or base.

TABLE D

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a]; (EPA REG. NO. 239-2351; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?[e]	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862; Registration jacket	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained form desk references.
[e] Data requirements pertain to the basic formulation and the alternate formulation (refer to Confidential Appendix B).

TABLE E

GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 239-1246; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00098893	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	00098862	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00098893	No
63-3 - Physical State	TGAI	Yes	00098893	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	TGAI	N/A[e]		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	Registration jacket	Yes

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Not required because the technical is a solid at room temperature.

TABLE E
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 239-1246; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI	No		Yes
63-9 - Vapor Pressure	PAI	Yes		No
63-10 - Dissociation Constant	PAI	N/A[d]		No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Partially	00098893	Yes
Other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Not required because the active ingredient is not an acid or base.

TABLE F

GENERIC DATA REQUIREMENTS FOR CAPTAN 45% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2367; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 45% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE G

GENERIC DATA REQUIREMENTS FOR CAPTAN 80% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2058; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 80% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE H

GENERIC DATA REQUIREMENTS FOR CAPTAN 80% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2411; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 80% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Data requirements pertain to the basic formulation and the alternate formulations (refer to Confidential Appendix B).

TABLE I

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-829; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE J

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2137; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 - months from the date of this Standard.
[d] Information obtained from desk references.

TABLE K

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2388; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Data requirements pertain to the basic formulation and the alternate formulation (refer to Confidential Appendix B).

TABLE L

GENERIC DATA REQUIREMENTS FOR CAPTAN 92% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 239-2396; CHEVRON CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098862	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 92% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE M

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 19713-107; DREXEL CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE N

GENERIC DATA REQUIREMENTS FOR CAPTAN 1% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 4816-325; FAIRFIELD AMERICAN CORPORATION).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 1% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE O

GENERIC DATA REQUIREMENTS FOR CAPTAN 2.5% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 4816-411; FAIRFIELD AMERICAN CORP.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 2.5% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE P
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 7501-24; GUSTAFSON, INC.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	No		Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	No		Yes
63-3 - Physical State	TGAI	No		Yes
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	TGAI	N/A[e]		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Not required because the technical is a solid at room temperature.

TABLE P
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 7501-24; GUSTAFSON, INC.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI	No		Yes
63-9 - Vapor Pressure	PAI	Yes		No
63-10 - Dissociation Constant	PAI	N/A[d]		No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	No		Yes
Other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Not required because the active ingredient is not an acid or base.

TABLE Q
GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 45115-11; IDA, INC.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE R

GENERIC DATA REQUIREMENTS FOR CAPTAN 0.5% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 1021-610; MCLAUGHLIN GORMLEY KING CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	No		Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 0.5% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE S
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (UNREGISTERED; MAKHTESHIM CHEMICAL WORKS, LTD.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00098845	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration jacket for EPA Reg. No. 11678-1	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00098746	No
63-3 - Physical State	TGAI	Yes	00098746	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	Yes	00098746	No
63-6 - Boiling Point	TGAI	N/A[e]		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00098845	No

[a] The 92% technical is not a registered manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[E] Not required because the technical is a solid at room temperature.

TABLE S
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (UNREGISTERED; MAKHTESHIM CHEMICAL WORKS, LTD.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI	Partially	00098746	Yes
63-9 - Vapor Pressure	PAI	Yes	00098845	No
63-10 - Dissociation Constant	PAI	N/A[d]		No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	No		Yes
Other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		

[a] The 92% technical is not a registered manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Not required because the active ingredient is not an acid or base.

TABLE T

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a]; EPA REG. NO. 11678-1; MAKHTESHIM CHEMICAL WORKS LTD.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	N		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE U

GENERIC DATA REQUIREMENTS FOR CAPTAN 74% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-2; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 74% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE V

GENERIC DATA REQUIREMENTS FOR CAPTAN 81% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-15; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 81% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE W

GENERIC DATA REQUIREMENTS FOR CAPTAN 76% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-8; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 76% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE X

GENERIC DATA REQUIREMENTS FOR CAPTAN 76% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-14; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 76% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE Y

GENERIC DATA REQUIREMENTS FOR CAPTAN 83% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-12; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 83% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE Z

GENERIC DATA REQUIREMENTS FOR CAPTAN 86% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 11678-9; MAKHTESHIM CHEMICAL WORKS, LTD).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00098746; 00098741; Registration jacket for EPA Reg. No. 11678-12	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 86% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE AA
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 476-2099; STAUFFER CHEMICAL CO.)

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
62-2 - Certification of Ingredient Limits	TGAI	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	TGAI	Partially	00044657; 00098798; Registration jacket	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	Registration jacket	No
63-3 - Physical State	TGAI	Yes	Registration jacket	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	No		Yes
63-6 - Boiling Point	TGAI	N/A[e]		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	Registration jacket	Yes

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.
[e] Not required because the technical is a solid at room temperature.

TABLE AA
GENERIC DATA REQUIREMENTS FOR CAPTAN 92% TECHNICAL[a]; (EPA REG. NO. 476-2099; STAUFFER CHEMICAL CO.).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI	Yes	Registration jacket	No
63-9 - Vapor Pressure	PAI	Yes		No
63-10 - Dissociation Constant	PAI	N/A[d]		No
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Partially	Registration jacket	Yes
Other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		

[a] The 92% technical serves as a manufacturing-use product.
[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Not required because the active ingredient is not an acid or base.

TABLE BB

GENERIC DATA REQUIREMENTS FOR CAPTAN 90% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 476-2100; STAUFFER CHEMICAL CO.).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00044657; 00098798; Registration jacket for EPA Reg. No. 476-2099	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 90% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be submitted no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

TABLE CC

GENERIC DATA REQUIREMENTS FOR CAPTAN 80% FORMULATION INTERMEDIATE[a] (EPA REG. NO. 476-2119; STAUFFER CHEMICAL CO.).

Data Requirement	Composition[b]	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Disclosure of Ingredients	MP	Yes	--[d]	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Ingredient Limits	MP	Partially	Registration jacket	Yes
62-3 - Analytical Methods to Verify Certified Limits	MP	Partially	00044657; 00098798; Registration jacket for EPA Reg. No. 476-2099	Yes
Other Requirements:				
64-1 - Submittal of Samples	N/A	N/A		No

[a] The 80% formulation intermediate serves as a manufacturing-use product.
[b] Composition: MP = Manufacturing-use product.
[c] Data must be sampled no later than 6 months from the date of this Standard.
[d] Information obtained from desk references.

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to all products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4, IV-5, and IV-6 to determine the storage and disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing (name of pesticide) as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data (See Tables B).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be

met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing (name of pesticide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1), if applicable (if Table C lists required product-specific data).

c. Two copies of any required product-specific data, if applicable (if Table C lists required product-specific data).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing (name of pesticide) either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

Applications and other required information should be submitted to the following address:

Product Manager
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703)

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. 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, will be 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 attempted also 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 at any time 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 a 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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OMB Approval 2070-0057 (expires 5/31/86)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data.

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

(Expires 5/31/86)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner

☐ 1 I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements.

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

§162.10 LABELING REQUIREMENTS

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during

the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11
Vinyl chloride
Xylene