United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-98-024
December 1998

Reregistration Eligibility Decision (RED)

1,3-Dichloropropene

United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA-738-F-98-014
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EPA

R.E.D. FACTS

1,3-Dichloropropene

Pesticide Reregistration

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

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers and uses these data to evaluate the human health and environmental effects of each pesticide, including aggregate exposures from all sources of pesticide residues, whether infants and children have heightened susceptibility to pesticide residues, and whether there are cumulative effects of pesticides and other compounds with a common mechanism of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters those pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0328, 1,3-Dichloropropene (1,3-D or trade name Telone).

Use Profile

1,3-D is a pre-plant soil fumigant used to control nematodes and is registered for use on soils to be planted to all crops. Combining chloropicrin with 1,3-D increases herbicidal and fungicidal properties. The registrant, Dow AgroSciences, is also developing a formulation to be applied in drip irrigation systems as a pre-plant soil fumigant. 1,3-D use is restricted to certified applicators and is applied using specialized tractor-drawn rigs which inject 1,3-D 12" to 18" beneath the soil surface. Soil sealing after application is required, and is accomplished by compacting the top layer of soil, applying a water seal, or using tarps. The 1,3-D labels require handlers to wear respirators (except for a limited exception for applicators in enclosed cabs). The labels also

stipulate a 300 foot no-treatment buffer from occupied buildings to reduce risks to residents who live near treated fields and will require as of August 1, 1999 a 100 foot no-treatment buffer from drinking water wells. The registrant suggests a waiting period (a week for every 10 lbs. 1,3-D applied) before planting any crops due to phytotoxicity.

The Agency expects 1,3-D use to increase as it replaces certain methyl bromide soil fumigant uses. Methyl bromide is being phased out under the Clean Air Act and the Montreal Protocol because it has been identified as an ozone depletor. Methyl bromide is a soil fumigant used primarily on ornamentals and higher-value fruit and vegetable crops (e.g.,strawberries, tomatoes). Currently, the highest methyl bromide soil fumigation use occurs in Florida and California.

Regulatory History

1,3-D was first registered as a pesticide in the U.S. in 1954. EPA issued a Registration Standard for 1,3-D in October 1986, as well as an October 8, 1986 Federal Register notice announcing a Special Review of 1,3-D based on cancer concerns for workers. An October 1986 Data Call-In (DCI) required additional residue chemistry, inhalation exposure, and environmental fate data.

1,3-D labels were modified in 1992 and again in 1996 to include measures to minimize exposures to workers and for residents who live near treated fields. The Worker Protection Standard (WPS) requirements for 1,3-D were included in those label changes. On September 30, 1998, Dow AgroSciences requested additional modifications (see the section titled "Product Labeling Changes Required"), which will take effect August 1, 1999.

Currently, there are ten 1,3-D products registered to three companies. There are also three Special Local Needs (or FIFRA section 24(c) registrations for products containing 1,3-D.

Human Health Assessment

Toxicity

In studies using laboratory animals, 1,3-D generally has been shown to be of moderate acute toxicity by the oral and dermal routes and has been placed in Toxicity Category II (the second highest of four categories) for these effects.

1,3-D is not considered to be a developmental toxicant, though it does have some mutagenic properties. EPA has classified 1,3-D as a B_2, possible human, carcinogen by both the inhalation and oral routes of exposure. This classification is based on adrenal, liver, forestomach, thyroid, mammary and lung tumors in both rats and mice by both routes of exposure.

Dietary Exposure

Studies developed for reregistration show no residues in crops grown in 1,3-D-treated soils. The Agency has classified 1,3-D as a non-food use

pesticide and thus no tolerances or exemptions from the requirement of a tolerance are required. Because there are no tolerances, no tolerance reassessment was included in this reregistration action, nor are there conflicts with the CODEX international maximum residue levels.

Other studies conducted for reregistration show that 1,3-D can make its way to ground water under use allowed by 1,3-D labels, where it may pose risks for residents who obtain their drinking water from wells in the vicinity of treated fields. Thus the dietary assessment is based on exposures to 1,3-D in ground water.

The dietary assessment also includes exposures to two degradates of toxicological concern: 3-chloroallyl alcohol and 3-chloroacrylic acid. EPA does not have data for a full assessment of the toxicity of these degradates and thus assumed toxicological and carcinogenic equivalency to the parent.

Occupational and Residential Exposure

1,3-D is injected into the soil as a liquid which then quickly volatilizes through the soil profile, some of which moves up into the atmosphere. Based on current use patterns, handlers (loaders and applicators) may be exposed to 1,3-D during and after normal use. Since 1992, the 1,3-D labels have been modified to include engineering controls (closed loading, equipment to shut off 1,3-D flow at row turns, and soil sealing), personal protective equipment (respirators and chemical-resistant protective clothing) and other controls (5-day REI).

Residents who live near treated fields may also be exposed to volatilized 1,3-D which enters the atmosphere during the two week period following application. Some of the label measures mentioned above were also designed to minimize 1,3-D levels that volatilize after application, and thus serve to also reduce residential exposures as well. In addition, lowered application rates and a 300 foot no-treatment buffer on 1,3-D labels reduce residential exposures.

Residents who live near treated fields can also be exposed through drinking water. A prospective ground water study conducted in Florida has shown 1,3-D and degradate levels of concern in ground water, due mainly to permeable soils and shallow water tables. A ground water study conducted in Wisconsin showed even higher concentrations of 1,3-D where soils are permeable and water tables shallow, suggesting cold areas are even more vulnerable to ground water contamination since 1,3-D degradation is slower under colder conditions.

Human Risk Assessment

1,3-D generally is of moderate acute toxicity. For chronic non-cancer effects, anticipated residues (from drinking water) for the overall U.S. population represents less than one percent of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year

lifetime. Based on results from the Florida study, the most highly exposed subgroup of non-nursing infants less than one year old has an anticipated residue contribution which represents less than one percent of the RfD. This fraction of the allowable RfD below 100 is considered to be an acceptable dietary exposure risk.

The Agency also assessed the risk resulting from chronic 1,3-D exposures to occupational handlers. The NOEL for inhalation exposure is 0.091 mg/L (from the 2-year chronic rat study). EPA assessed risks to handlers using Margins of Exposure (MOE's). The MOE is a ratio of the NOEL to the estimated daily exposure. EPA generally is not concerned with MOE's greater than or equal to 100. The MOE's for 1,3-D, which were in the 560 to 1960 range, are acceptable.

EPA classifies 1,3-D as a Group B_2, probable human, carcinogen by both the inhalation and oral routes of exposure. In January of 1998, Dow AgroSciences submitted new information to support regulating 1,3-D as a non-linear carcinogen (i.e. that below a certain level of exposure, there is no cancer risk). EPA is scheduling a review of this information for 1999, however, will not reassess 1,3-D cancer risks until all EPA policies on regulating non-linear carcinogens are in place.

Dietary Risk - Because exposure through foods grown on treated soils is not expected, dietary risk is assumed to be solely from drinking 1,3-D residues in ground water. The Agency assessed the results from prospective ground water monitoring studies, which were conducted in Florida and Wisconsin and thought to represent vulnerable sites for ground water contamination. EPA based the 1,3-D risk assessment on levels found in on-site wells, although all 1,3-D labels as of August 1, 1999 will require a 100' no-treatment setback from drinking water wells.

From the Wisconsin site, levels (1,3-D plus degradates) found in on-site wells were associated with risk estimates at 10^{-3}. For the general population, EPA generally is not concerned with lifetime cancer risks at or below 1×10^{-6}. Based on risks in the 10^{-3} range, 1,3-D labels are being modified to prohibit use in areas similar to the Wisconsin site.

From the Florida site, which was used to estimate risks for the general population, cancer risk estimates (1,3-D plus degradates) from wells located within the field were approximately 4×10^{-6}. The prospective studies were not designed to assess risks from wells located away from treated fields and thus EPA cannot quantify risks with the 100' setback, though the levels found 100 feet off-site were about 15 times lower than those found in on-site wells. Therefore, the risk estimates for exposure to 1,3-D through drinking water are considered to overestimate risk.

Worker Risk - Inhalation -- For workers, cancer risk estimates are in the 10^{-5} to 10^{-6} range, taking into account certain personal protective equipment and engineering controls. Under EPA's Worker Risk Policy, the Agency considers risks of 10^{-6} or lower not to be of concern and carefully examines

risks in the range of 10^{-4} to 10^{-6} to seek ways of reducing risks prior to reregistration. The 1,3-D labels have been modified to include label measures, such as soil sealing, lowered rates, soil moisture and deeper injection, which are expected to reduce worker risks, although the mitigation value could not be quantified. EPA considers worker risk to have been adequately mitigated.

Residential Risk - Inhalation -- For residents who live at the 300 foot buffer, risk estimates are 6×10^{-6}, however, this estimate does not include the full value of mitigation measures listed above and is conservative in the assumption that a person would spend 16 hours a day at 300 feet from the treated field during the two-week period following fumigation when 1,3-D volatilization occurs for 30 years.

Uncertainties in the Risk Assessment - In addition to the uncertainties discussed above, there were numerous uncertainties in the studies used to assess exposures. The largest source of uncertainty was trying to conduct monitoring studies for a highly volatile chemical. Under normal use conditions, there are a variety of uncontrollable environmental factors that ultimately affect an individual's exposure. The limited number of monitoring sites also contributed to the uncertainty related to EPA's risk estimates. Nonetheless, EPA believes that these studies provide the best information for conducting the 1,3-D risk assessment.

Aggregate Risk for the General Population -- EPA has determined that it is appropriate to aggregate risks from the inhalation and dietary routes of exposure. For residents who live 300 feet from a treated field, the aggregated lifetime cancer risk estimates are 1×10^{-5}. This estimate, however, is associated with numerous uncertainties. Taking into account the unquantifiable mitigation measures and more realistic assumptions on exposure, EPA believes risks will be adequately mitigated under approved labeling presented in the RED.

Environmental Assessment

The Agency has adequate data to assess the toxicity of 1,3-D to non-target organisms and on 1,3-D's environmental fate. The registrant is also developing confirmatory data on the degradates, as well as data on estuarine and marine environments since 1,3-D use is expected to expand in Florida with the methyl bromide phase-out.

Environmental Fate

The data submitted for reregistration show that 1,3-D is mobile and persistent (particularly in colder areas). High quality data show that 1,3-D can contaminate ground water under normal use conditions. EPA believes the potential for ground water contamination is highest where soils are permeable and water tables are shallow. Where these characteristics occur in colder areas, 1,3-D not only enters ground water, but persists under colder conditions. While EPA does not expect significant levels of 1,3-D in surface water, one

study suggests that airborne levels of 1,3-D can be transported to adjacent surface water resources. The registrant is conducting a run-off study and other monitoring as confirmatory data.

Ecological Effects

1,3-D is highly toxic to invertebrate species, moderately toxic to birds and mammals and moderately toxic to fish. These toxicity patterns are also expected for estuarine and marine organisms; the registrant is generating additional studies since 1,3-D use is expected to expand to estuarine and marine environments.

Ecological Effects Risk Assessment

Assessment of submitted studies demonstrates that 1,3-D can contaminate ground water under normal use conditions. EPA also reviewed other sources of ground water sampling and found few detects, even in counties where high rates of 1,3-D are applied every year. Thus, EPA believes that 1,3-D use poses the potential for localized ground water contamination, rather than widespread aquifer contamination. The registrant is amending 1,3-D labels to prohibit use under the most vulnerable conditions (permeable soils, shallow ground water, and cold temperatures).

The two degradates of toxicological concern, 3-chloroacrylic acid and 3-chloroallyl alcohol, were also detected in ground water studies. For the current assessment, EPA assumed equivalent ecotoxicological parameters; the registrant is conducting confirmatory data for the environmental fate and ecotoxicity of the degradates.

Risk Mitigation

Since 1992, 1,3-D labels have been modified twice to include measures to mitigate risks to workers and residents who live near treated fields. On September 30, 1998, Dow AgroSciences again requested label modifications, which are scheduled to appear on all 1,3-D labels no later than August 1, 1999. The measures added since 1992, together with the new modifications, are summarized below:

- Measures to mitigate worker risks - Lowered maximum rates (lowered by 30% to 65% depending on the crop); Deletion of selected use sites; Closed loading requirements; Technology to minimize 1,3-D spillage during application, Improved product stewardship materials, Coveralls over short-sleeved shirt and short pants; Chemical-resistant gloves and footwear; Chemical-resistant apron (for direct handlers), A respirator requirement for all 1,3-D handlers (except those in certain closed cabs); Restricted entry increased to 5 days; Soil moisture and soil sealing requirements; Modified application techniques.
- Measures to mitigate residential inhalation risks - 300' no-treatment buffer; Lowered application rates (by 30% to 65% depending on the crop); Loading

requirements; Technology to minimize 1,3-D spillage during application; Soil moisture and soil sealing requirements; Modified application techniques.

- Measures to mitigate residential drinking water risks - Ground water advisory; Prohibition of use in certain northern tier states (N.D., S.D., WI, MN, N.Y., ME, N.H., VT, MA, UT, MT) with shallow ground water and vulnerable soils (effective 8/1/99); 100' buffer between drinking water wells and treated fields (effective 8/1/99); Prohibition of use in areas overlying karst geology (effective 8/1/99).

Additional Data Required

The following additional generic studies for 1,3-D are being conducted for EPA to confirm its regulatory assessments and conclusions. Because Dow AgroSciences has already agreed to conduct these studies, there is no generic DCI associated with this RED. For 1,3-D, Dow AgroSciences is conducting the following studies: Freshwater fish early life stage; Freshwater aquatic invertebrate life cycle; Estuarine/marine fish LC 50; Estuarine/marine invertebrate LC50; Estuarine/marine invertebrate LC50; Tier I and Tier II aquatic plant; Seed germination and seedling emergence; Vegetative vigor; Tier I and Tier II terrestrial plants; Aerobic aquatic metabolism. For the degradates (3-chloroacrylic acid and 3-chloroallyl alcohol), Dow AgroSciences is conducting the following studies:

Acute oral-rat; Acute dermal toxicity (rabbit/rat); Primary eye irritation (rabbit); Primary dermal irritation; dermal sensitization;a battery of mutagenicity data; developmental toxicology; subchronic 90-day feeding study; aquatic aerobic metabolism; adsorption/desorption; hydrolysis; vapor pressure; Henry's Law Constant; acute fish toxicity; acute aquatic invertebrate toxicity; Tier I and Tier II aquatic plant studies.

Dow AgroSciences is also conducting a tap water monitoring program to assess whether levels of 1,3-D and/or its degradates of concern appear in drinking water in areas with high 1,3-D use. The monitoring program is designed so that risk reduction measures are initiated if 1,3-D and/or its degradates are detected above the Office of Water's Health Advisory of 0.2 ppb.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

Per the September 30, 1998 agreement with Dow AgroSciences, EPA has contacted all end-use registrants of products containing 1,3-D to inform them of the required label changes, which are to take effect August 1, 1999. The new labels are to contain the additional label measures as follows:

Prohibitions in certain northern tier states (N.D., S.D., WI, MN, N.Y., ME, N.H., VT, MA, UT, MT) with vulnerable soils, prohibition of use in areas

overlying karst geology and 100 foot no-treatment set-backs from drinking water wells.

Regulatory Conclusion

The use of 1,3-D, in accordance with pending label changes, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

1,3-D products will be reregistered once the required confirmatory data, required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. 1,3-D products which also contain chloropicrin will not be reregistered until the active ingredient chloropicrin is determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for 1,3-D during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone (703)305-5805.

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

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone (513)489-8190, fax (513)489-8695.

Following the comment period, the 1,3-D RED document will also be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone (703) 605-6000 or (800) 553-6847.

For more information about EPA's pesticide reregistration program, the 1,3-D RED, or reregistration of individual products containing 1,3-D please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone (703)308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.

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

DEC 22 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case [0328] which includes the active ingredient 1,3-Dichloropropene (or trade name Telone). The enclosed Reregistration Eligibility Decision (RED), which was approved on September 30, 1998, contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It also includes requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

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

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

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

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Karen Jones (703) 308-8047. Address any questions on required generic data to the Special Review and Reregistration Division representative, Lisa Nisenson (703) 308-8031.

Sincerely,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Enclosures

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

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

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

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

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

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

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

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

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

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

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

By U.S. Mail:

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

By express:

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

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

REREGISTRATION ELIGIBILITY DECISION

1,3-DICHLOROPROPENE (1,3-D)

LIST A

CASE 0328

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
ADD	Average Daily Dose
AADD	Annual Average Daily Dose
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP (or EUP)	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection

LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
µg/L	Micrograms per liter
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NAWQA	National Water Quality Assessment - USGS Water sampling Program
NTP	National Toxicology Program
N/A	Not Applicable
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PD	Position Document related to a Special Review
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Section 24 © of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Overview

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision for the pesticide 1,3-dichloropropene (1,3-D, or trade name Telone). This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered products. 1,3-D is a soil fumigant used to control nematodes and certain soil diseases. 1,3-D is registered for use on soils to be planted with all food and feed crops. 1,3-D is classified as a non-food use pesticide when used as a pre-plant soil fumigant and thus there are no tolerances or exemptions from the requirement of a tolerance (for pineapples, 1,3-D is applied at-plant, however there are no residues in food since fruit are not borne until the third year of growth). 1,3-D is a restricted use pesticide and as such can only be applied by certified applicators. There are no homeowner uses of 1,3-D.

1,3-D products are sold in bulk or mini-bulk (1000 gallon) containers and require no mixing prior to loading. All 1,3-D product labels require closed loading systems for transfers between the bulk containers and the specialized application rig, which is tractor-drawn. Most 1,3-D use involves injecting the fumigant into soil at depths from 12-18" deep, followed by soil sealing such as compaction, a water seal or tarp. The soil seal is used to minimize the amount of 1,3-D which volatilizes into the atmosphere after application. There are also four state registrations (known as SLN's) for 1,3-D application through drip irrigation, which is also applied pre-plant.

1,3-D was placed in EPA's Special Review process in 1986 based on cancer concerns for workers. The potential for ground water contamination and residues in crops grown in treated soils were also cited as concerns to be investigated. In 1991, the Special Review of 1,3-D incorporated risks to residents who live in the vicinity of treated fields for inhalation exposures. Since 1991, the registrant of 1,3-D, Dow AgroSciences, has modified 1,3-D registrations to address worker and residential concerns as detailed below.

The Agency has concluded that 1,3-D, when labeled and used as specified in this Reregistration Eligibility Decision (RED) document, will not cause unreasonable risks to human health or the environment and that all labeled uses are eligible for reregistration. The Agency is requiring data on two degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid, to confirm the Agency's assumption that the acid and alcohol are of equal or less toxicity than 1,3-D.

Recent Label Modifications for Risk Mitigation

In 1992 and in 1996, Dow AgroSciences, requested label changes to reduce levels of 1,3-D which volatilize into the atmosphere during fumigant transfers, application and the post-fumigation time period. Measures added to 1,3-D labels were shut-off valves to prevent 1,3-D from spilling at row turns, closed loading, soil sealing, a 300-foot no-treatment buffer from occupied structures, improved product stewardship, a phase-out of drum delivery, and reduced

application rates. These measures reduced the largest sources of 1,3-D exposures, specifically, the pooling of 1,3-D at row turns when the application "knives" were lifted out of the ground and spills during loading. These measures reduced exposures not only for workers, but for anyone in the vicinity of treated fields.

On September 30, 1998, Dow AgroSciences requested modification of the terms and conditions of 1,3-D registrations to include use prohibition in certain northern tier states (ND, SD, MN, NY, ME, NH, VT, MA, UT, MT, WI) based on ground water concerns, a 100-foot no-treatment buffer around drinking water wells, prohibition of use in areas overlying karst geologies and additional monitoring to confirm that use of 1,3-D does not pose unreasonable risks when used according to product labels. These measures reduce risks for anyone who drinks water from wells in the vicinity of treated fields.

Risk Concerns - Human Health

1,3-D is classified as a B_2 carcinogen by both the oral and inhalation routes of exposure. The 1,3-D risk assessment presents aggregated risks for both routes of exposure. Because EPA does not have toxicity data on the alcohol and acid degradates, EPA assumed carcinogenic and toxicological equivalence to the parent, thus oral exposure and risk estimates are comprised of 1,3-D plus the degradates (unless specifically noted).

Due to 1,3-D's carcinogenicity, environmental fate and use patterns, EPA has concerns that use could result in exposure to residues in air and/or water. EPA's cancer risk estimates for workers who follow label restrictions are in the 10^{-5} to 10^{-6} range. For residents who live near treated fields, lifetime cancer inhalation risk estimates are in the 10^{-5} to 10^{-8} range taking into account a 300 foot no-treatment buffer, but not taking into account other measures (e.g., lowering application rates by 30-65%, soil sealing measures) which were not amenable to quantification under the highly variable field study conditions.

For reregistration, EPA required a prospective ground water study in Wisconsin, which was believed to be highly vulnerable to ground water contamination from 1,3-D use. The registrant also submitted to the agency the results of a prospective ground water study conducted in Florida. Based on the results of these studies and other sampling programs, EPA believes that exposures from well water near treated fields vary depending on factors such as depth to ground water, temperature, soil permeability, and distance from the treated field. Lifetime cancer risk estimates from the Florida study are 4×10^{-6} (on-site wells which do not account for the 100 foot buffer). In Wisconsin, lifetime cancer risks for all age groups, and chronic non-cancer risks for infants and children, were unacceptably high. Cancer risks associated with levels from on-site wells were in the 10^{-3} range. As noted above, the September 30, 1998 modification includes a use prohibition for northern tier states with characteristics similar to the Wisconsin site and will be added to 1,3-D labels as of August 1, 1999.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. In the Florida study, time weighted average

(TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 357 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures; results in both studies indicate that exposures were considerably lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. Should residues of 1,3-D and/or the alcohol or acid degradates be detected at levels exceeding the Office of Water Health Advisory of 0.2 ppb, Dow AgroSciences has included, as part of the sampling program, risk reduction measures which would be in place before the next use season. EPA expects to use the results of the sampling program to better characterize risks with the 100' setback and to also see if the sampling program results can be extrapolated in order to characterize risks in other 1,3-D use areas.

The drinking water risk estimates using 1,3-D labels eligible for reregistration is 4×10^{-6}, calculated using on-site wells from the Florida study; the inhalation risk is 6×10^{-6} (using an average of levels monitored from NC, WA and AZ study sites at the 300 foot buffer). Thus the calculated aggregate risk estimate is 1×10^{-5}. This risk estimate does not take into account mitigation from lower application rates, soil sealing measures, increased depth of application, soil moisture and temperature requirements or potential reduction in exposure from the 100 foot drinking water well setback. EPA believes the risk estimates are likely to be in the 10^{-6} range and that risk concerns have been addressed when all of the mitigation measures as specified in this reregistration decision are taken into account.

EPA's risk assessment shows no short-term or acute risks of concern based on current 1,3-D use patterns and that there are no unacceptable developmental or reproductive effects. Infants and children do not appear to have heightened susceptibility to 1,3-D, thus, EPA has determined the extra 10X safety factor is not warranted. EPA looked at whether risks from 1,3-D should be cumulated with risks of a contaminant found in Telone products, 1,2-dichloropropane (1,2-D). For purposes of this reregistration action, EPA has assumed that 1,3-D and 1,2-D do not share a common mechanism of toxicity.

Risk Concerns - Environmental

EPA has received and reviewed all of the data required in the 1986 Registration Standard to assess the environmental risks posed by applications of 1,3-D. 1,3-D is a highly volatile compound, and once in soils, is mobile. 1,3-D's persistence appears to be inversely related to temperature (i.e. high persistence at low temperatures). EPA does not believe there are risks to birds or non-target insects, though there could be risk to aquatic invertebrates and fish, particularly if run-off were to occur. Models suggest that 1,3-D can be transported through run-

off, however, these models are not designed to track volatile soil fumigants. EPA is requiring additional data on the degradates, on estuarine environments and a study to see if 1,3-D enters surface water through runoff.

Based on the results of retrospective ground water monitoring studies and the two prospective studies, EPA believes that the conditions most likely to result in 1,3-D treatment-related ground water contamination are shallow water tables, cold temperatures and high soil permeability, though the studies do not provide enough information to rank these factors. In addition to the ground water monitoring studies, EPA reviewed the results of other sampling programs in 1,3-D use areas and the U.S. Geological Survey's recent water resource monitoring program results. The U.S.G.S. monitoring found no detections of 1,3-D, but did not look for 3-chloroallyl alcohol and 3-chloroacrylic acid.

Other Activities Related to 1,3-D's Reregistration

EPA will be reviewing new information on the carcinogenicity of 1,3-D, specifically, whether EPA will regulate 1,3-D as a non-linear carcinogen. EPA expects this review will take place sometime in 1999; however, no change in EPA's risk assessment, if needed, can take place until the Agency implements final policies on regulation of non-linear carcinogens. EPA also intends to issue a Position Document 2 (PD2) proposing to close out the Special Review for 1,3-D before the end of 1998.

Before reregistering products containing 1,3-D, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. 1,3-D <u>products</u> which also contain chloropicrin will be eligible for reregistration only when chloropicrin has been found to be eligible for reregistration.

I. INTRODUCTION

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

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

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

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 1,3-D, including risk to infants and children for any potential dietary, drinking water, dermal, or oral exposures, and cumulative effects as stipulated under FQPA. The document consists of six sections. Section I is the introduction. Section II describes 1,3-D, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for 1,3-D. Section V discusses the reregistration requirements for 1,3-D. Finally, Section VI contains the Appendices which support this Reregistration Eligibility Decision.

II. CASE OVERVIEW

Commercial 1,3-dichloropropene is a mixture of approximately equal proportions of the cis- and trans- isomers. The Telone II formulation contains 94% 1,3-dichloropropene and 6% inert ingredients. The Telone C-17 formulation, which is formulated with 16.5% chloropicrin, contains 77.9% 1,3-dichloropropene and 5.6% inert ingredients. A contaminant, 1,2-dichloropropane may also be present in small quantities (≤0.1%).

A. Chemical Overview

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

Common Name:	1,3-Dichloropropene
Chemical Name:	1,3-Dichloropropene
Trade and Other Names:	1,3-D, Telone®, Trilone, Pic-Clor, Tri-Form
Chemical Family:	Chlorinated Hydrocarbon
CAS Registry Number:	542-75-6
OPP Chemical Code:	029001
Empirical Formula:	$C_3H_4Cl_2$
Basic Manufacturer:	Dow AgroSciences

Multiple active ingredient products contain: 081501 (chloropicrin)

Registered "Me Too" Products Not Included in Appendix A: 8536-8; 8536-21; 8536-22; 11220-1; 11220-15; 11220-20; 11220-21; 11220-22

B. Use Profile

The following is general information on the current registered uses with an overview of use sites and application methods. A detailed table of these uses of 1,3-D is in Appendix A. Although the Appendix A information only reflects the basic manufacturer's products (i.e. DowAgro Sciences' Telone II and Telone C-17), the 1,3-D uses and use rates for the "me too" products are the same as those of the basic manufacturer's single and multiple active ingredient products, respectively.

TYPE OF PESTICIDE FOR SINGLE ACTIVE INGREDIENT:

Nematicide; Fungicide; Insecticide; Herbicide

MODE OF ACTION:

Soil fumigant, contact poison

USE SITES:

1,3-D is registered for use on all crops to be planted on 1,3-D-treated soils. Thus, the use sites include all vegetable, fruit and nut crops, all forage crops (grasses, legumes and other non-grass forage crops), tobacco, all fiber crops and all nursery crops (ornamental, non-bearing fruit/nut trees and forestry crops).

1,3-D is classified as a non-food use pesticide (and thus there are no tolerances or exemptions from the requirement of a tolerance).

TARGET PESTS FOR SINGLE ACTIVE INGREDIENT:
Plant-Parasitic Nematodes: all types

Plant Diseases: bacterial canker of peaches, sugar beet rhizomania, fusarium wilt of cotton, verticillium wilt of mint

Invertebrates: symphylans (garden centipedes), wireworms

Weeds: Canada thistle, field bindweed (perennial morning glory), quackgrass, and certain other deep-rooted perennial weeds in cropland

TYPES/FORMULATIONS REGISTERED:
End Use Products -

Liquid-Ready to Use - 78.3 to 94.0% (78.3%, and 94.0% multiple and single active ingredient products, respectively)

Note: single and multiple active ingredient "me too" products containing 37.6 to 94.0% 1,3-dichloropropene are also currently registered.

METHODS AND RATES OF APPLICATION:

Types of Treatment: Soil fumigation, broadcast and/or row treatments, and individual tree planting site treatments

Equipment: Soil injection equipment (chisel, Nobel plow, or plow-sole); Deep drip irrigation (6 or more inches deep)

Timing: Preplant (all crops); at planting (pineapple)
Application Rates: See rates listed in Appendix A for the Dow AgroSciences products (62719-12, 62719-32), which reflect the maximum rates of 1,3-D in single and multiple ingredient (i.e., with chloropicrin) formulations, respectively. Maximum rates for uses on vegetable and field crops varies with the soil type. Maximum rates for a given crop are typically slightly higher for the multiple active ingredient product than the single active ingredient product.

USE PRACTICE LIMITATIONS (APPLIES TO ALL 1,3-D PRODUCTS):

1,3-D is a restricted use pesticide (certified handlers only). Label statements include a 300 foot no-treatment buffer zone between treated fields and occupied structures, a five-day restricted entry interval for workers, closed loading, soil sealing immediately following application. In addition, labels suggest waiting at least one week for every gallon of 1,3-D applied before planting due to phytotoxicity.

See section IV. C. (3) for a list of detailed restrictions.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticidal uses of 1,3-D. These estimates are derived from a variety of published and proprietary sources available to the Agency, The estimates presented in Table 1 are primarily from a 1991 Data Call-In for use and usage.

All 1,3-D is used on agricultural crops; there are no residential uses. The following table estimates 1,3-D use by site:

Table 1. Major 1,3-D Usage Sites

Crop	Acres Treated (000)		% Crop Treated		lbs a.i. applied (000)		States where most usage occurs
	weighted average	estimated maximum	weighted average	estimated maximum	weighted average	estimated maximum	
Crucifers	10	22	4	8	2000	3500	AZ,TX,GA, SC, NC,CA
Peppers	5	10	4	8	400	800	NM,NC,CA
Cucurbits	13	27	2	4	600	1200	TX,AZ,SC, NC,GA,CA
Sugar Beets	45	55	3	4	4000	5500	NE,WY,CO, ID
Cotton	85	150	1	1	2000	6000	AZ,NC,GA, FL,CA
Tobacco	80	102	11	15	7200	9000	NC,SC,GA
Irish Potato	80	95	6	7	1350	1700	WA,ID,OR, CO,ND,MI
Sweet Potato	N/A	N/A	N/A	N/A	N/A	N/A	NC, GA, SC
Peanut	12	25	1	2	700	1900	AL,GA,TX
Fruit/Nut Trees and Grape Vines	27	54	6	13	2400	5000	CA,SC,NC, AZ,GA,NJ
Onions	5	10	5	10	1000	2000	OR,WA,ID
Tomato	2	5	0	1	200	800	GA,FL,AL
Carrots	2	4	2	4	150	250	CA,WA,TX
Pineapple	5	7	14	19	1300	2600	HI
Strawberries	1	4	1	3	80	170	CA,FL,NJ

Usage data covers 1990-1995 for most sites and as early as 1987 for other sites, primarily using data from the 1991 Use Usage and Product Performance DCI: California data is only available for 1994 and 1995 due to the 1991-1993 use permit suspension and limited re-entry program. "Weighted average" weights the more recent years' estimates because they tend to be more reliable estimates than for possibly outdated earlier estimates.

D. Data Requirements and Regulatory History

1,3-D was first registered in 1954 in the United States. A Registration Standard was issued in 1986, along with a Position Document announcing initiation of a Special Review (51 FR 36160) based on cancer concerns for workers. The Standard evaluated the available data with

other relevant information on 1,3-D and required the submission of additional data to maintain the existing registrations and to further refine the risk assessment for the Special Review.

On April 13, 1990, California suspended use permits for 1,3-D because unacceptably high levels of airborne 1,3-D were detected through its air monitoring program. After California suspended the 1,3-D use permits, EPA looked more closely at the risk posed to residents who live in the vicinity of treated fields. In 1992, Dow AgroSciences (at that time DowElanco), agreed to label measures to reduce the amount of 1,3-D that volatilizes into the atmosphere, including closed loading, shut-off valves to prevent 1,3-D from spilling at row turns, improved product stewardship, a phase-out of drum delivery, and reduced application rates. DowElanco also agreed to conduct studies to determine the mitigation value of these and other measures.

In 1996, other measures, including the Worker Protection Standard requirements for Personal Protective Equipment (PPE), were added to 1,3-D labels, including soil sealing, a 300-foot no-treatment buffer from occupied structures and other requirements designed to minimize the amount of 1,3-D that volatilizes (Gibson, 1996). These measures reduced exposures for both workers and anyone else who lives or works in the vicinity of treated fields.

On September 30, 1998, Dow AgroSciences requested modification of the terms and conditions of 1,3-D registrations to include use prohibition in certain northern tier states (ND, SD, MN, NY, ME, NH, VT, MA, UT, MT, WI), a 100-foot no-treatment buffer to drinking water wells, prohibition of use in areas overlying karst geologies and additional monitoring to confirm that use of 1,3-D does not pose unreasonable risks when used according to product labels (Roby, 1998). The benefits of these measures are to reduce risks for anyone who drinks water from wells in the vicinity of treated fields, particularly wells in unconfined aquifers.

Dow AgroSciences is developing confirmatory data for reregistration, to include tap water monitoring in certain 1,3-D use areas, a run-off study and data on the toxicity and environmental fate data for 3-chloroacrylic acid and chloroallyl alcohol.

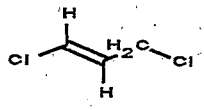
This Reregistration Eligibility Decision reflects an assessment of the data which were submitted in response to the 1986 Registration Standard and the 1991, 1992 and 1996 DCI's.

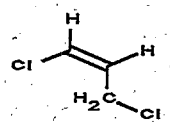
III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Identification of Active Ingredient

The active ingredient 1,3-dichloropropene (1,3-D, or Telone) is a soil fumigant used preplant to control root-knot nematodes and other soil pests and diseases. 1,3-D is a mixture of isomers; in the figures below, the trans isomer is on the left, and cis on the right.





Empirical Formula: $C_3H_4Cl_2$

Molecular Weight: 110.98

Physical State: liquid under pressure, volatile

Odor: sweet, pungent, penetrating

Water Solubility: 2,180 mg/L for cis isomer
2,320 mg/L for trans isomer

Vapor Pressure: 34.3 mmHg for cis isomer at 25°C
23.0 mmHg for trans isomer at 25°C

Boiling Point: 104°C for cis isomer
112.6°C for trans isomer

Specific Gravity: 1.209 g/mL at 25°C

2. Manufacturing and End-Use Product Chemistry

A search of EPA's Reference Files System conducted on September 9, 1998 identified no 1,3-D manufacturing-use products (MPs) under Shaughnessy No. 029001. Although the 1985 1,3-D Reregistration Standard dated identified a single 94% formulation intermediate registered to Dow Chemical Company (EPA Reg. No. 464-511), the product has since been transferred to Dow AgroSciences (EPA Reg. No. 62719-32) and is currently registered as an end-use product (EP). The product jackets for 1,3-D EPs confirms that the Dow AgroSciences 94% EP/MP is the source product for other formulations; therefore, generic (TGAI) and product-specific (MP) data are required to support its use as an MP. Dow AgroSciences has submitted an application to also market their 94% 1,3-D product as a manufacturing use product to reformulators; this application is under review.

3. Conclusions

All pertinent generic data requirements are satisfied for the 1,3-D TGAI except for the new data requirement concerning UV/visible absorption (OPPTS GLN 830.7050). All product-specific data requirements are satisfied for the 94% EP/MP; however, the ingredient certifications (OPPTS GLN 830.1750) must be submitted on EPA Form 8570-4. The data requirements for product chemistry are presented in Appendix D. In addition, the registrant must certify that the suppliers of beginning materials and the manufacturing processes have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Hazard Assessment

All toxicology guideline studies are fulfilled and the data base for 1,3-D is adequate to support reregistration eligibility. Across the battery of toxicology studies, the Telone test products contained various amounts of 1,3-D depending on the formulation available at the time of testing. Because of this, the toxicity tests were performed with varying percentages of the a.i. EPA does not believe the variations in levels warrants additional testing.

a. Acute Toxicity

The acute toxicity values and categories for 1,3-D are summarized below:

Table 2. Acute Toxicity of 1,3-Dichloropropene

OPP Guideline No.	OPPTS Guideline No.	Study Type	MRID #(S).	Results	Toxicity Category
81-1	870.1100	Acute Oral	40220901	LD_{50} = 300 mg/kg (M) 224 mg/kg (F)	II
81-2	870.1200	Acute Dermal - Rabbit	40220902	LD_{50} = 333 mg/kg	II
81-3	870.1300	Acute Inhalation	40220903	LC_{50} = 3.88 mg/L (M) 4.1 mg/L(F)	IV
81-4	870.2400	Primary Eye Irritation	40220904	Intermediate irritant	II
81-5	870.2500	Primary Skin Irritation	40220905	Slight irritant	III
81-6	870.2600	Dermal Sensitization	40220906	Sensitizer	--
81-8	870.6200	Acute Neurotoxicity	none	None required	--

The oral LD_{50} in the rat was 300 mg/kg in males and 224 mg/kg in females (Toxicity Category II). Clinical signs included diarrhea, lacrimation, chromodacryorrhea, palpebral closure, facial/perineal soiling, labored respiration and rough hair coat. Gross necropsy revealed gastric hemorrhage, watery contents and mucus in the cecum, thickened stomach wall and adhesions between the stomach and abdominal wall (MRID 40220901).

The dermal LD_{50} in the rabbit was 333 mg/kg. Animals exhibited restlessness, squealing, lethargy, transient anorexia, labored respiration and diarrhea. Skin findings were erythema, edema, necrosis and scabs. Gross necropsy revealed mottled skeletal muscles in hind limbs, multifocal erosions and/or ulcers of the stomach and fecal soiling of the perineal area (MRID 40220902).

The inhalation LC_{50} in the rat was 3.88-4.69 mg/L in males and 4.1 mg/L in females (Toxicity Category IV). Animals exhibited tremors, convulsions, salivation, lacrimation, diarrhea and lethargy. Gross necropsy revealed hemorrhaging in multiple lung lobes (MRID 40220903).

Instillation of Telone II (94% a.i.) in rabbit eyes resulted in intermediate irritation (Toxicity Category II). By day 14, all evidence of corneal opacity, iris irritation, conjunctival redness, chemosis and discharge had disappeared (MRID 40220904).

In a rabbit dermal irritation study, very slight erythema and edema were noted (Toxicity Category III). At 72 hours, 5 of 6 animals had well-defined erythema, 1 of 6 exhibited very slight erythema, 2 of 6 exhibited slight edema and 2 of 6 had very slight edema (MRID 40220905).

Telone II (94% a.i.) was a sensitizer in guinea pigs (MRID 40220906).

b. Subchronic Toxicity

(i) Oral

Telone II (96.0% a.i.) was administered to Fischer 344 rats (10/sex/group) at dietary levels of 0, 5, 15, 50 or 100 mg/kg/day for 13 weeks. Body weights and weight gains, as well as food consumption, were reduced at 50 and 100 mg/kg/day in both sexes (questionable reduction in male body weights/gains at 5 and 15 mg/kg/day). Doses of 15, 50 and 100 mg/kg/day caused hyperkeratosis and/or basal cell hyperplasia in the nonglandular portion of the stomach of both sexes. The NOEL was 5 mg/kg/day. The LOEL was 15 mg/kg/day based upon hyperkeratosis and/or basal cell hyperplasia in the nonglandular portion of the stomach of both sexes (MRID 42954802).

In a subchronic study, Telone II (96.0% a.i.) was administered to $B_6C_3F_1$ mice (10/sex/group) at dietary levels of 0, 15, 50, 100 or 175 mg/kg/day for 13 weeks. Body weights and weight gains were lower than the controls in males and females at 50, 100 and 175 mg/kg/day (27, 36, 39 and 58% in males and 7, 22, 30 and 32% in females). The NOEL was 15 mg/kg/day.

The LOEL was 50 mg/kg/day based on lower body weights and body weight gains compared with controls in males and females (MRID 42954801).

The data requirement for a subchronic dog study was waived because a one-year study had been conducted.

(ii) Inhalation

In a 30 day inhalation study, Fischer 344 rats (10/sex/group), were exposed to Telone II ("production grade" - no percentage of a.i. presented) at concentrations of 0, 3, 10 or 30 ppm (0, 0.0136, 0.045 or 0.136 mg/L), 6 hours/day, 5 days/week for 4 weeks. There was no mortality at any dose level. Body weights of male rats at all concentrations were similar to that of the controls. Females exhibited a slight decrease in body weights. There was an increase in the incidence of enlarged peribronchial lymph nodes in males at 3 and 10 ppm, but not at 30 ppm; the incidences were 1, 5, 6 and 2 at 0, 3, 10 and 30 ppm, respectively. Because there was no dose-response as well as lack of an effect on peribronchial lymph nodes at 30 ppm, the NOEL was considered to be 30 ppm (0.136 mg/L, highest dose tested) and the LOEL was > 30 ppm (0.136 mg/L) (MRID 00039685).

In a 30 day inhalation study, CD-1 mice (10/sex/group), were exposed to Telone II ("production grade"- no percentage of a.i. presented) at concentrations of 0, 3, 10 or 30 ppm (0, 0.0136, 0.045 or 0.136 mg/L), 6 hours/day, 5 days/week for 4 weeks. There was no mortality at any dose level. There were no test article related findings at any dose. The NOEL was 30 ppm (0.136 mg/L, highest dose tested) and the LOEL was > 30 ppm (0.136 mg/L) (MRID 00039685).

In a subchronic toxicity study, Fischer 344 rats (10/sex/group) were exposed to Telone II (90.9% a.i.) at concentrations of 0, 10, 30, 90 or 150 ppm (0, 0.045, 0.136, 0.408 or 0.680 mg/L), 6 hours/day, 5 days/week for 13 weeks. Both sexes at 90 and 150 ppm exhibited a significant decrease in body weights while rats at 30, 90 and 150 showed treatment-related histopathological lesions in the nasal turbinates. The NOEL was 10 ppm (0.045 mg/L) and the LOEL was 30 ppm (0.136 mg/L) (MRID 00146461).

In a subchronic toxicity study, $B_6C_3F_1$ mice (10/sex/group) were exposed to Telone II (90.9% ai) at concentrations of 0, 10, 30, 90 or 150 ppm (0, 0.045, 0.136, 0.408 or 0.680 mg/L), 6 hours/day, 5 days/week for 13 weeks. Both sexes at 90 and 150 ppm exhibited a significant decrease in body weights while females showed epithelial degeneration and hyperplasia of the nasal turbinates. The NOEL was 30 ppm (0.045 mg/L) and the LOEL was 90 ppm (0.136 mg/L) (MRID 00146461).

c. Chronic Toxicity/Carcinogenicity

(i) Oral

In a chronic toxicity/carcinogenicity study, Telone II (96% a.i.) was administered as microcapsules by dietary admix to Fischer 344 rats (60/sex/group with 10/sex/group sacrificed at 12 months) at levels of 0, 2.5, 12.5 or 25 mg/kg/day for two years. Body weight gains were decreased for males (8 and 21%) and females (15 and 25%) at 12.5 and 25 mg/kg/day compared to controls. Food consumption was decreased in females at 25 mg/kg/day. There was an increase in liver masses/nodules in males only at 12.5 and 25 mg/kg/day. There was an increased incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach of both sexes at the 12- and 24-month sacrifices at 12.5 and 25 mg/kg/day. For chronic toxicity, the NOEL was 2.5 mg/kg/day and the LOEL was 12.5 mg/kg/day based on a decrease in body weight gain compared with controls and an increase in the incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach. There was evidence of carcinogenicity. The incidences of rats with primary hepatocellular adenomas were as follows respectively (0, 2.5, 12.5 or 25 mg/kg/day): males = 2/50, 1/50, 6/50 and 9/50; females = 0/50, 0/50, 0/50 and 4/50. These data indicate that exposure to 1,3-D increases the incidence of these tumors in males at the two highest doses and in females at the highest dose. The highest dose tested in this study (25 mg/kg/day) was considered adequate to assess the carcinogenic potential of 1,3-D in rats (MRID 43763501). The results of this study were used to establish the oral reference dose (RfD).

In a study reported by the National Toxicology Program (NTP) in 1985, 1,3-D (89.0% a.i.) was administered in corn oil (with 1.0% epichlorohydrin) by gavage to Fischer 344 rats (52/sex/group) at doses of 0, 25 or 50 mg/kg/day three times per week for 104 weeks. Basal cell or epithelial hyperplasia of the forestomach was reported. At 0, 25 and 50 mg/kg/day, squamous cell papillomas of the forestomach (1/52, 1/52 and 9/52 in males respectively; 0/52, 2/52 and 3/52 in females respectively), squamous cell carcinomas of the forestomach (0/52, 0/52 and 4/52 for males) and neoplastic nodules of the liver (1/52, 6/52 and 7/52 for males respectively ; 6/52, 6/52 and 10/52 for females respectively) were seen. The NTP concluded that there was "clear evidence of carcinogenicity" for males and "some evidence" of carcinogenicity for females (MRID 00146469).

In a two-year toxicity/carcinogenicity study in $B_6C_3F_1$ mice (50/sex/group), Telone II (95.8% a.i.) was administered as microcapsules by dietary admix at levels of 0, 2.5, 25 or 50 mg/kg/day. There were no test article effects on clinical signs, mortality, ophthalmology, hematology parameters, organ weights, macroscopic pathology or microscopic pathology. For chronic toxicity, the NOEL was 2.5 mg/kg/day. The LOEL was 25 mg/kg/day for both sexes based on lower body weights and a decrease in weight gains compared with controls. There was no evidence of carcinogenicity (MRID 43757901).

In a study with $B_6C_3F_1$ mice (50/sex/group) reported by NTP in 1985, Telone II (89.0% ai) was administered in corn oil (with 1.0% epichlorohydrin) by gavage at doses of 0, 25 or 50 mg/kg/day three times per week for 104 weeks. The study in males was not considered to be

adequate because of the mortality of controls at weeks 48-51 (25/50, myocarditis) and the 104-week survival for males (8/50, 28/50 and 31/50). Squamous cell papillomas of the forestomach (0/50, 1/50 and 2/50 for females), squamous cell carcinomas of the forestomach (0/50, 0/50 and 2/50 for females), transitional cell carcinomas of the urinary bladder (0/50, 8/50 and 21/48 for females) and alveolar/bronchiolar adenomas (0/50, 3/50 and 8/50 for females) were seen. In males, the study was considered to be inadequate for carcinogenicity (due to mortality of controls). For females, there was "clear evidence of carcinogenicity" (MRID 00146469).

In a chronic toxicity study, beagle dogs (4/sex/group) were administered Telone II (95.8% a.i.) as a dietary admix at levels of 0, 0.5, 2.5 or 15 mg/kg/day for one year. At 15 mg/kg/day, there was: decreased body weight gain; hypochromic, microcytic anemia (increase in erythrocytes along with decreases in hemoglobin, hematocrit, mean corpuscular volume and mean corpuscular hemoglobin); hematopoietic activity in bone marrow and spleen; and a possible increase in absolute liver weights in males. For chronic toxicity, the NOEL was 2.5 mg/kg/day and the LOEL was 15 mg/kg/day based on a decrease in body weight gain compared with controls, microcytic anemia and an increase in hematopoietic activity. The study results also suggested a test-article related increase in absolute liver weights in males compared with controls at the LOEL (MRID 42441001).

(ii) Inhalation

In a chronic toxicity/carcinogenicity study, Fischer 344 rats (50/sex/group plus 10/sex/group to 6- and 12-month exposure groups) were exposed by whole-body inhalation to Telone II (92.1% a.i.) at aerosol concentrations of 0, 5, 20 or 60 ppm (equivalent to approximately 0, 0.023, 0.091 or 0.272 mg/L), 6 hours/day, 5 days/week for a total of 509 days over a two-year period. There was no effect of exposure to 1,3-D on the survival of males or females. Slight (approximately 5% in 60 ppm males and females, as well as 3% in 20 ppm males) decreases in body weight gains were observed (statistically significant, $p<0.05$) but generally only during the first year of the study. The olfactory region of the nasal cavity appeared to be the target tissue as determined by histopathological examination. Males and females having been exposed to 60 ppm (no evidence reported at lower concentrations of 20 or 5 ppm) showed decreased thickness and erosions of the epithelium as well as minimal submucosal fibrosis. For chronic toxicity, the NOEL was 20 ppm (0.091 mg/L)and the LOEL was 60 ppm (0.272 mg/L) based on histopathological changes in nasal tissue as well as the suggestion of decrease in body weight gain compared with controls during the first year of the study. There was no evidence of carcinogenicity (MRID 40312201). The results of this study were used to develop an intermediate residential/bystander inhalation NOEL (see sections III.C.5 and III.D.1).

In a chronic toxicity/carcinogenicity study, $B_6C_3F_1$ mice (50/sex/group plus 10/sex/group to 6- and 12-month exposure groups) were exposed by whole-body inhalation to Telone II (92.1% ai) at aerosol concentrations of 0, 5, 20 or 60 ppm (equivalent to approximately 0, 0.023, 0.091 or 0.272 mg/L) 6 hours/day, 5 days/week for a total of 510 days over a two-year period. There was no effect on survival (at least 80% in each group). There was a statistically significant decrease in body weight gain in 60 ppm males (3-9%) and females (2-11%). Urinary bladder

effects were noted primarily in females at 20 and 60 ppm (slight, moderate or marked roughened, irregular and opaque surfaces were reported in 20/50 at 20 ppm and 30/49 at 60 ppm compared with 3/50 slight in the control group). Hypertrophy and hyperplasia of the nasal respiratory mucosa (very slight/slight) were observed in most 60 ppm mice of both sexes and in 20 ppm females. Degeneration of olfactory epithelium (very slight/slight) was noted in most 60 ppm mice of both sexes. Hyperplasia of the epithelial lining of the nonglandular portion of the stomach was observed in 60 ppm males (0, 5, 20 and 60 ppm: males = 0, 3, 1 and 8; females = 0, 0, 0 and 2 respectively). For chronic toxicity, the NOEL was 5 ppm (0.023 mg/L) and the LOEL was 20 ppm (0.091 mg/L) based on urinary bladder hyperplasia and hypertrophy/hyperplasia of the nasal respiratory mucosa. Hyperplasia of the epithelial lining of the nonglandular portion of the stomach was observed in a higher incidence compared with controls in 60 ppm males and, to a lesser extent, 60 ppm females. There was evidence of carcinogenicity. Bronchioloalveolar adenomas appeared in a higher incidence in 60 ppm males only compared with controls (0, 5, 20 and 60 ppm = 9/50, 6/50, 13/50 and 22/50 respectively). Although the lung tumors noted in this mouse inhalation study were benign, the tumor induction was dose dependent, the tumor incidence was outside the range of historical controls and the tumor type was also seen in the mouse oral bioassay (MRID 40312300).

d. Developmental Toxicity

In a developmental toxicity study, Fischer 344 rats (30 females/group) were exposed during gestation days 6 through 15 to aerosol concentrations of Telone II (90.1% a.i.) at 0, 20, 60 or 120 ppm (equivalent to approximately 0, 0.091, 0.272 or 0.545 mg/L) 6 hours/day. The maternal NOEL was < 20 ppm (< 0.091 mg/L). The maternal LOEL was 20 ppm (0.091 mg/L) based on decreased body weight gains and food consumption compared with controls during the exposure days. The developmental NOEL was 60 ppm (0.272 mg/L). The developmental LOEL was 120 ppm (0.545 mg/L) based on increase in delayed ossification of the vertebral centra. No 1,3-D-related malformations were reported (MRID 00152848).

New Zealand rabbits (17-24 females/group) were exposed to aerosol concentrations of Telone II (90.1% a.i.) at 0, 20, 60 or 120 ppm (equivalent to approximately 0, 0.091, 0.272 or 0.545 mg/L), 6 hours/day during gestation days 6 through 18. The maternal NOEL was 20 ppm (0.091 mg/L). The maternal LOEL was 60 ppm (0.272 mg/L) based on decreased body weight gains compared with controls. The developmental NOEL was 120 ppm (0.545 mg/L). The developmental LOEL was >120 ppm (> 0.545 mg/L, HDT). No 1,3-D related malformations were reported (MRID 00152848).

e. Reproductive Toxicity

In a two-generation inhalation reproduction study, Fischer 344 rats (F_0 adults, 30 males and 40 females/group) were exposed to aerosol concentrations of Telone II (91.2% a.i.) at 0, 10, 30 or 90 ppm (equivalent to approximately 0, 0.045, 0.136 or 0.408 mg/L) 6 hours/day. The durations of exposure (6 hours/day) were as follows: F_0 males and females 5 days/week prior to breeding and 7 days/week during breeding at weeks 11 to 13, then during gestation and lactation;

F_{1a} and F_{1b} generations, dams from gestation day 20 until postpartum day 5; F_1 male and female parents, after weaning (about week 32 of the study) and continued for 12 weeks, but for 5 days per week, 6 hours/day; and F_0 to F_1 until adults were sacrificed. Pregnant females were not exposed to 1,3-D from gestation day 20 to postpartum day 4. Pups were not exposed to 1,3-D (dams separated from pups for 6 hours of exposure/day during lactation days 5 to 28). For parental/systemic toxicity, the NOEL was 30 ppm (0.136 mg/L). The LOEL was 90 ppm (0.408 mg/L) based on a decrease in body weight gain compared with controls, as well as microscopic nonglandular stomach lesions (mainly mucosa) and hyperplasia of the nasal respiratory epithelium with focal degeneration of the olfactory tissue. No reproductive toxicity was seen. For reproductive toxicity, the NOEL was 90 ppm and the LOEL was >90 ppm (HDT) (MRID's 40312401 and 40835301).

f. Mutagenicity

There was a positive effect in the Salmonella assay in strains G46, TA98, TA100 and TA1535 with and without activation and in strains TA1538 and TA1537 with activation. Responses up to approximately 100x and 10x background in strains TA1535 and TA100, respectively, were seen (MRID 00039688). 1,3-D, in the absence of metabolic activation, was positive in the B. subtilis rec-assay only at 1,250 µg/well (MRID 00039688). Up to a toxic concentration of 1,000 µg/plate, no positive results were reported in the E. coli reversion test with or without activation (MRID 00039688). A mouse host-mediated assay with Salmonella typhimurium strain G46 was negative. However, the oral gavage dosing of the mice up to 60 mg/kg may not have been high enough as adequate toxicity was not reported (MRID 00039680). Non-reproducible increases (just at 2x background) were reported in the nonactivated phase of the Chinese hamster ovary (CHO/HGPRT) gene mutation assay at 100, 150, 200, and 250 µM (MRID 00159679). 1,3-D was negative in an unscheduled DNA synthesis (UDS) assay with primary rat hepatocytes up to consistently cytotoxic doses (> 10^{-4} M) (MRID 00146467).

Data from the open literature also indicate that 1,3-D is mutagenic in Salmonella and cultured mouse lymphoma cells and induces chromosomal aberrations, sister chromatid exchange, and DNA strand breaks in several mammalian cell lines in vitro. Overall, the data from somatic cell assays are indicative of a mutagenic concern for 1,3-D and support the weight-of-the-evidence evaluation for carcinogenicity.

1,3-D was also positive for the induction of sex-linked recessive lethal mutations but not reciprocal translocations in Drosophila melanogaster (MRID 00146469). To confirm the results of the Drosophila sex-linked recessive lethal assay, a Data Call In (DCI) was issued for an in vivo alkaline elution assay in testicular cells (following inhalation administration) on June 17, 1996. The Registrant chose to perform an inhalation dominant lethal assay, which is an acceptable substitute. 1,3-D tested negative in this assay. Results from this study show that 1,3-D, administered by inhalation at concentrations up to 150 ppm (≈682 mg/m^3) 6 hours/day, 7 days/week for 10 weeks did not induce a dominant lethal effect in male rat germinal cells (MRID 44302801). The negative findings of this study lessen the concern for germ cell effects; therefore, no further mutagenicity testing is required. Dow AgroSciences is conducting additional

mutagenicity studies for the alcohol and acid degradates; for purposes of this reregistration, EPA is assuming equivalent mutagenic potential to the parent.

g. Metabolism

An oral pharmacokinetics study was conducted in Fischer 344 rats and $B_6C_3F_1$ mice. For the non-protein sulfhydryl studies, the following single oral non-radioactive doses were administered: 0, 1, 5, 25, 50 or 100 mg/kg. Single oral ^{14}C Telone II doses of 0, 1, 50 or 100 mg/kg were administered for the binding studies. The primary route of excretion for both species was the urine. The two major urinary metabolites were identified as 1,3-DCP-mercapturic acid and its sulfoxide (or sulfone) derivative. Following oral administration, most of the radio label was found in the stomach and gastrointestinal tract with lesser amounts in the kidneys, liver, urinary bladder, skin, fat, blood and carcass. Oral administration also depleted the non-protein-sulfhydryl contents of several tissues including the non-glandular stomach (both time- and dose-dependent). Dose-related increases in macromolecular bindings were noted in several organs with the highest binding sites being found in the non-glandular stomach (MRID 00155846).

In another study with Fischer 344 rats, gavage administration of Telone II at 5 mg/kg/day for 14 days resulted in rapid absorption from the gastrointestinal tract with distribution to all tissues examined. Highest concentrations appeared in the non-glandular stomach and urinary bladder. There was rapid elimination in the urine, feces, and as carbon dioxide in expired air. Nine metabolites were isolated from urine with two being identified as 1,3-D-mercapturic acid and the sulfoxide derivative. No parent compound was present in the urine (MRID 40959801).

h. Dermal Absorption

No dermal absorption studies were required. A waiver was granted for the 21-day dermal toxicity study. The current use-pattern does not indicate a concern for potential dermal exposure.

i. Epidemiological Data

The following data bases have been consulted for the poisoning incident data on the active ingredient 1,3-dichloropropene.

(i) OPP Incident Data System (IDS)

The incident data system contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies, and individual consumers, submitted to OPP since 1992. Reports submitted to IDS represent anecdotal reports or allegations, unless otherwise stated. Typically, no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, with enough cases and/or enough documentation risk mitigation measures may be suggested. No specific information on 1,3-D was found.

(ii) California Department of Food and Agriculture (superseded by the Department of Pesticide Regulation in 1991)

California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

(iii) National Pesticide Telecommunications Network (NPTN)

NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

(iv) Summary/Conclusions of Epidemiology Data

From the review of California data on suspected 1,3-D poisonings, it appears that a majority of incidents involved illnesses or injuries to workers who applied 1,3-D as a soil fumigant in fields. A large proportion of the cases occurred when workers were preparing, operating, cleaning, or repairing application equipment; however, label changes since 1992 have been adopted which may have prevented reported exposures. Some individuals with inhalation exposures have reported symptoms such as headache, chest pain, fatigue, irritability or difficulty concentrating, persisting for as long as two years after initial exposure.

Accidental ingestion of 1,3-D (concentration and amount unknown) has led to one reported fatality. In a cluster episode, two of nine firemen developed lymphoma six years after exposure to a 1,3-D spill. Other data or evidence from other epidemiologic studies would be needed before an association can be supported.

2. Dose-Response Assessment

a. Determination of Susceptibility to Infants and Children

Under the Food Quality Protection Act (FQPA), P.L. 104-70, which was promulgated in 1996 requires the EPA to "ensure that there is reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this "reasonable certainty of no harm," an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre-and

post-natal toxicity and completeness of data with respect to exposure and toxicity to infants and children. Notwithstanding this requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residues only if, on the basis of reliable data, such margin will be safe for infants and children.

1,3-D is a non-food use pesticide and therefore no tolerances or exemptions from the requirement of a tolerance are required. Although the FQPA's requirements are directed towards tolerance actions, the Agency has reviewed the requirements of FQPA as if 1,3-D were undergoing a tolerance review.

There are no data gaps for the assessment of increased susceptibility to infants and children from exposure to 1,3-D. The Agency has reviewed acceptable prenatal developmental toxicity studies in rats and rabbits and an acceptable two-generation reproduction study in rats following inhalation exposures. The data provided no indication of increased susceptibility in rat or rabbit fetuses following *in utero* exposure to 1,3-D. No developmental toxicity was observed at the highest concentration tested in the pre-natal developmental toxicity studies in rats and rabbits tested. No offspring toxicity was seen at the highest concentration tested in two generation reproduction toxicity study.

The Agency has determined that the 10X additional safety factor for the protection of infants and children (as required by FQPA) is not warranted and has been removed based on the following factors:

i. No evidence of developmental toxicity was seen in the prenatal studies in rats and rabbits and no offspring toxicity was seen in the postnatal toxicity study in rats following inhalation exposure to 1,3-D;

ii. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies submitted to the Agency;

iii. The toxicology database is complete;

iv. There is adequate data to conduct exposure assessments.

b. Acute Dietary

EPA has reviewed the available toxicological data for 1,3-D and concluded that the data do not indicate any evidence of significant oral toxicity from a single exposure event. Therefore, the acute dietary risk assessment for a single event high end dietary exposure is not required.

c. Chronic Reference Dose (RfD)

An RfD of 0.025 mg/kg/day was determined based on the NOEL of 2.5 mg/kg/day established in a 2-year dietary admix (microcapsules) study in rats (MRID 43763501) and using

an uncertainty factor of 100. The LOEL of 12.5 mg/kg/day was based on a decrease in body weight gain and an increase in the incidence of basal cell hyperplasia of the nonglandular mucosa of the stomach.

Once a study has been evaluated and the observed effect has been determined to be a threshold effect, EPA generally divides the NOEL from the most appropriate study by an uncertainty factor (usually 100) to determine the RfD. The RfD is a level at or below which daily aggregate exposure over a lifetime is not expected to pose appreciable risk to human health. An uncertainty factor (formerly called "safety factor") of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and also, that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive than other individuals or subgroups. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the studies and determines whether an additional uncertainty factor is warranted. An aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. Table 9 presents the aggregate exposure and percent RfD.

d. Classification of Carcinogenic Potential

EPA classifies 1,3-D as a Group B_2 (probable human) carcinogen based on oral and inhalation animal studies. This classification was based on NTP studies showing increased tumors in both sexes of rats (Fischer 344) and mice ($B_6C_3F_1$) after oral administration of 1,3-D (MRID 00146469). Tumor types noted included forestomach, liver, mammary, thyroid, adrenal, urinary, and lung. The carcinogenic potency factor (Q_1*) for humans via the oral route is 1.22×10^{-1} using the Multistage Model based on the incidence of combined forestomach, liver, adrenal, and thyroid tumors in male rats and using the 3/4 interspecies scaling factor (Fisher 1994).

EPA has also developed a potency factor (Q_1*) for humans via the inhalation route. This Q_1* is 5.33×10^{-2} based on increased bronchioloalveolar adenomas in male $B_6C_3F_1$ mice from inhalation studies using the linearized low dose extrapolation model and a 3/4 interspecies scaling factor (Fisher 1994; MRID's 40312201, 40312300).

The registrant submitted information as a rebuttal to a draft RED on January 15, 1998 proposing that 1,3-D should be regulated as a non-linear carcinogen (i.e., that there is a "threshold" dose below which there is no risk). While EPA does not believe it is appropriate to delay this reregistration decision, EPA has agreed to reconvene the Carcinogenicity Peer Review Committee sometime in 1999 to consider new information Dow AgroSciences submitted in 1998, particularly that related to whether 1,3-D should be regulated as a non-linear carcinogen. EPA is currently developing policies on regulating non-linear carcinogens and no change to the risk assessment can take place until those polices are officially adopted.

e. Occupational and Residential Exposure

EPA has identified the dose/end points to be used in the risk assessment for occupational and residential exposures. The current use-pattern does not result in exposure through foods grown in 1,3-D-treated soils; however, due to the potential contamination of ground water and consequently drinking water, the Committee has identified doses and endpoints for use in risk assessments for potential ground/drinking water exposures. The current formulations and application methods indicate a potential for occupational or residential exposure primarily via the inhalation route. Little dermal exposure is expected when 1,3-D is used according to label directions, and therefore dermal exposure is not a concern at this time. Doses and endpoints identified are for both drinking water and inhalation exposures (occupational and residential/bystander).

(i) Dermal Absorption

No dermal absorption studies were required. A waiver was granted for the 21-day dermal toxicity study. The current use-pattern does not indicate potential dermal exposure.

(ii) Inhalation Absorption

1,3-D has been tested extensively by the inhalation route. Therefore, inhalation endpoints are available for risk assessment and route to route extrapolation is not necessary. For this risk assessment, EPA assumes inhalation absorption to be 100 percent.

(iii) Acute Dietary

EPA has reviewed the available toxicological data for 1,3-D and concluded that the data do not indicate any evidence of significant oral toxicity from a single exposure event. Therefore, the acute dietary risk assessment for a single event, high-end dietary exposure is not required.

(iv) Short Term Occupational/Residential

EPA has reviewed the available 30-day inhalation studies for 1,3-D and concluded that the data do not indicate any evidence of significant toxicity from repeated exposure of up to 4 weeks duration. No effects were seen in either a rat or a mouse study. Therefore, no endpoint was identified. The short-term occupational/residential risk assessment for 1,3-D is not required.

(v) Intermediate Term Occupational and Residential/Bystander (1 week to several months)

For inhalation, the NOEL of 0.091 mg/L (20 ppm) will be used and is based on histopathological lesions in the olfactory region of the nasal cavity at the LOEL of 0.272 mg/L (60 ppm) in a 2-year combined chronic toxicity/carcinogenicity inhalation study in F344 rats (MRID 40312201). The 90-day (MRID 00146461) and 2-year inhalation studies were used in

conjunction to determine this endpoint. For intermediate term exposures, 90-day tests are generally used; however, the dose selection from the 90-day study (10 ppm, 30 ppm, 90 ppm, 150 ppm) did not allow for selection of an appropriate NOEL when compared to NOEL's seen in other studies. EPA concluded that had the 20 ppm dose been used in the 90-day study, this would likely have been the NOEL, and thus selected the NOEL of 0.091 mg/L (20 ppm) established in the 2-year chronic study.

(vi) Chronic - Occupational and Residential/Bystander

No chronic inhalation exposure is expected for 1,3-D. The current use pattern results in exposure for no more than 3 weeks at a time, generally only once a year. Therefore, no chronic non-cancer endpoint was selected and this risk assessment is not required.

(vii) Office of Water Health Advisory for 1,3-D

EPA's Office of Water has established a Health Advisory for 1,3-D at 0.2 ppb. This is the level that can be consumed daily over a lifetime that is associated with a 1×10^{-6} cancer risk. The Health Advisory, however, is only advisory in nature and is not enforceable. There is no Maximum Contaminant Level (MCL) for 1,3-D.

(viii) Risk Assessment Endpoints for 1,2-Dichloropropane (Impurity)

1,2-Dichloropropane (1,2-D) is of interest because it is an impurity found in Telone products (0.06 to 0.1% by weight) and has been shown to migrate to ground water and persist for many years. EPA has not conducted a formal evaluation of the toxicology database for 1,2-D at this time because 1,2-D is no longer registered as a pesticide. However, 1,2-D has been evaluated by the Office of Research and Development (ORD) to support development of the Drinking Water Criteria Document for the Office of Water (USEPA 1987). ORD evaluated the limited available database for 1,2-D and concluded that the liver was the principal target organ of toxicity. ORD also found effects from acute exposures; the effects were seen in the lungs, liver, kidneys central nervous system and eyes. A more detailed description is on EPA's IRIS data base.

Subchronic oral exposure to 1,2-D resulted in liver congestion, hepatic fatty changes, and liver necrosis in rats receiving 1000 mg/kg/day, 5 days/week for 13 weeks. Mice showed slightly depressed body weight after treatment with 500 mg/kg/day 1,2-D for 5 days/week for 13 weeks.

EPA's Office of Water has established a 10-day health advisory for children of 0.09 mg/L. This health advisory is based on the following assumptions: 10 kg child, consumption of one L/day of water, all exposure comes from water (i.e., no ambient inhalation exposure), and a health advisory value based on 7-30 days of exposure. There is also a Maximum Contaminant Level of 5 ppb established by EPA's Office of Water.

1,2-D has been classified as a Group B_2, probable human carcinogen, with a Q_1* of 3.69 $x10^{-2}$ $(mg/kg/day)^{-1}$ based on the statistically significant increased incidence of hepatocellular adenomas and carcinomas in male and female $B_6C_3F_1$ mice. In addition, a dose-related trend in mammary adenocarcinomas was noted in female F344 rats. This is considered significant because F344 rats have a relatively low background incidence of these tumors (FR 56(20):3540 (January 30, 1991). In addition, 1,2-D was mutagenic in the Salmonella and in Aspergillus nidulans. 1,2-D also induced sister chromatid exchange and chromosome aberrations in Chinese hamster ovary cells.

(ix) Endpoints for Degradates

Two degradates of 1,3-D have been found in groundwater: 3-chloroallyl alcohol and 3-chloroacrylic acid. EPA has determined that the degradates 3-chloroallyl alcohol and 3-chloroacrylic acid should be considered to have toxicological equivalence to the 1,3-D parent in the absence of toxicology data for the degradates (Abbotts 1997). For the water cancer risk assessment, the 1,3-D oral Q_1* will be used to estimate risk for combined exposure to parent and degradates. In addition, the levels of the degradates found in the ground water studies will be combined with 1,3-D levels to calculate non-cancer risks. The oral Q_1* for 1,2-D will be used to calculate cancer risk for this contaminant, but 1,2-D risks will not be added to 1,3-D risks to develop a cumulative risk assessment. A summary of toxicological endpoints for 1,3-D and its degradates of toxicological concern are presented below in Table 3.

Table 3. Summary of Toxicological Endpoints for 1,3-dichloropropene and Related Compounds			
1,3-D			
Exposure Scenario	Toxicological Endpoint for Risk Assessment	Endpoint	Study
Intermediate Residential/Bystander Inhalation Exposure	Inhalation NOEL = 0.091 mg/L	Histopathological lesions of nasal cavity (olfactory region)	2-year combined chronic/ carcinogenicity inhalation study in F344 rats MRID 40312201
Chronic Drinking Water Exposure	RfD = 0.025 mg/kg/day	Decreased body wt gain and increased incidence of basal cell hyperplasia of nonglandular mucosa of stomach	2-year combined chronic /carcinogenicity study in F344 rats (dietary admix, microencapsulated Telone)MRID 43763501
Lifetime Inhalation (Cancer)	$Q_1^* = 5.33 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Lung bronchioloalveolar adenoma tumor rates in male mice, 3/4 scaling factor, Multistage model	2-year combined chronic/ carcinogenicity inhalation study in mice MRID 40312300
Lifetime Drinking Water (Cancer)	$Q_1^* = 1.22 \times 10^{-1}$ $(mg/kg/day)^{-1}$	Combined forestomach, liver, mammary, thyroid, adrenal, urinary, lung tumors, Multistage Model, 3/4 scaling factor	2-year combined chronic/ carcinogenicity study in F344 rats MRID 00146469
Degradates: 3-chloroallyl alcohol and 3-chloroacrylic acid			
Acute Dietary	None	None	None
Lifetime Drinking Water (Cancer)	In lieu of data for degradates, assume potency equivalent to parent, $Q_1^* = 1.22 \times 10^{-1}$ $(mg/kg/day)^{-1}$	Based on combined forestomach, liver, mammary, thyroid, adrenal, urinary, lung tumors, Multistage Model, 3/4 scaling factor	2-year combined chronic/ carcinogenicity study in F344 rats MRID 00146469
1,2-Dichloropropane (Impurity)			
10-Day Health Advisory for Children MCL (adults)	0.09 mg/L 0.005mg/L	Office of Water Value	Office of Water Value
Lifetime Drinking Water (Cancer)	$Q_1^* = 3.69 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Based on incidence of hepatocellular adenomas and/or carcinomas in male mouse, Multistage Model, 3/4 scaling factor	2-year carcinogenicity study in mice and rats, B2 Carcinogen (described in EPA 1990)

3. Dietary Exposure Assessment

a. Dietary Exposure from Food Sources

(I) Directions for Use

All 1,3-D end-use products are registered for use as a preplant soil fumigation for soils to be planted to all vegetable crops, field crops, and fruit and nut crops. Broadcast applications for control of nematodes and garden symphylans can be made at rates up to 332.5 lb a.i./A for vegetable and field crops and up to 344.4 lb a.i./A for fruit and nut crops. Banded applications are permitted at rates not exceeding the per acre broadcast rate. Dow AgroSciences has applied for a new registration for 1,3-D application via sub-surface drip irrigation systems; this application is under review. Special Local Need Registrations (SLN's) OR940038 and WA940038 permit application to potatoes at a maximum rate of 380 lb a.i./A. The worker restricted entry interval (REI) is five days.

A tabular summary of the residue chemistry science assessments for reregistration of 1,3-D is included in Appendix B. The conclusions listed in Appendix A regarding the Reregistration eligibility of 1,3-D uses are based on the use patterns registered by the basic producer, Dow AgroSciences.

(ii) Nature of the Residue in Plants

The qualitative nature of the residue in plants is adequately understood based on soybean, tomato, and sugar beet metabolism studies, and consists of natural plant biochemicals. In studies with tomatoes and soybeans, no residues of the parent, 3-chloroallyl alcohol, or 3-chloroacrylic acid metabolites were detected.

(iii) Nature of the Residue in Livestock

The qualitative nature of the residue in animals is adequately understood based on adequate goat and poultry metabolism studies. The levels of radioactivity observed in tissues and milk at high dosing levels are negligible and suggest that it is unlikely that detectable levels of 1,3-D residues would occur in meat, milk, or eggs. Therefore, no feeding studies or tolerances are required for meat, milk and eggs when 1,3-D is used as a pre-plant soil fumigant in soils planted to feed crops.

(iv) Residue Analytical Methods

No tolerances are to be established for 1,3-D residues in/on plant or animal commodities. As a result of this determination, there is no requirement for the development of enforcement analytical methods for plant or animal commodities.

(v) Multiresidue Method Testing

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for multiresidue method testing is waived.

(vi) Storage Stability Data

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for storage stability data is waived.

(vii) Magnitude of the Residue in Crop Plants

Because metabolism data show ultimate breakdown of 1,3-D to non-toxic degradates and subsequent re-incorporation into natural plant constituents, tolerances are not to be established for plant commodities and residue data are not required for use as a preplant soil fumigant (Miller 1995).

(viii) Magnitude of the Residue in Processed Food/Feed

Because tolerances are not required for soil fumigation uses of 1,3-D, the requirement for processing studies is waived.

(ix) Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

No tolerances have been established for 1,3-D residues in animal commodities. The requirements for ruminant and poultry feeding studies have been waived.

(x) Magnitude of the Residue in Water, Fish, and Irrigated Crops

1,3-D is presently not registered for direct use on potable water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

(xi) Magnitude of the Residue in Food-Handling Establishments

1,3-D is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

(xii) Confined Accumulation in Rotational Crops

An acceptable confined rotational crop study was conducted with wheat, lettuce, and carrots and radishes. The results were in agreement with those from primary plant metabolism

studies, showing extensive incorporation of radiolabelled residues into natural plant biochemical constituents. No plant-back restriction is required.

(xiii) Field Accumulation in Rotational Crops

Given the results of the confined study, field rotational crop studies are not required for 1,3-D.

(xiv) CODEX Harmonization

No Codex MRLs are in effect for 1,3-D residues. Therefore, there are no questions regarding the compatibility of U.S. tolerances and Codex MRLs.

(xv) Conclusions

As noted above, all Reregistration data requirements for residue chemistry have been satisfied, and tolerances are not required for 1,3-D use as a pre-plant soil fumigant. No 1,3-D residues are expected to occur in plants.

b. Dietary Exposure from Drinking Water

(i) Factors Influencing Drinking Water Exposure

The amount of 1,3-D found in either ground or surface water is related to its physical and chemical properties, as well as a number of local environmental conditions, including soil temperature, soil type, and depth to ground water. 1,3-D, once applied, migrates through the soil profile. Transport can take 1,3-D down to ground water, laterally through the soil profile or up from the point of application through volatilization. 1,3-D that is not transported either degrades or is metabolized by soil bacteria.

1,3-D's mobility in soil is measured by soil adsorption coefficients (Kd's) which range from 0.23 in loamy sand to 1.09 in clay. 1,3-D has a low adsorption coefficient in a range of soils and tends to partition preferentially into water over soil (USEPA 1997). 1,3-D is considered to be a mobile chemical.

For this assessment, the half life of a chemical in the environment is presented as two different measurements: (1) the dissipation half-life, which reflects physical transport (i.e. volatilization) and degradation, and (2) the degradation half-life, which reflects degradation via biological and chemical mechanisms only. These measurements can be conducted in both the lab and field.

For 1,3-D, field dissipation studies show half-lives of 1 to 7 days, but laboratory measurements of aerobic soil metabolism show half-lives of up to 54 days. (Because of 1,3-D's high volatility, the aerobic soil metabolism is likely a more accurate measurement of 1,3-D's

degradation half-life in soil.) Hydrolysis studies of 1,3-D show that hydrolysis is independent of pH, but extremely variable with temperatures; longer half-lives are seen with low temperatures (USEPA 1997).

The major degradates of 1,3-D in soil are 3-chloroallyl alcohol and 3-chloroacrylic acid, both of which were detected in the prospective ground water monitoring studies (USEPA 1997). Information on the physical and chemical properties of 1,3-D's degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid, are limited; however, the degradates are not expected to be as volatile as 1,3-D.

1,3-D can migrate to ground water under certain conditions. Extensive ground water monitoring has been conducted for 1,3-D, and detections have been reported from several states. However, no information about past 1,3-D usage is available to correlate with retrospective ground water monitoring data. Results of the Florida ground water prospective monitoring study suggest that 1,3-D may also migrate to surface water via atmospheric transport, i.e., dissolution of 1,3-D vapors in surface waters. Surface water modeling suggests 1,3-D can migrate to surface water via runoff as well. Because of 1,3-D's volatility, it is not expected to persist in surface waters at high concentrations. The stability and persistence of its degradates in surface waters is unclear, but they are likely to be substantially less volatile than the parent, and therefore may be more persistent.

The contaminant 1,2-D has a different environmental fate profile than 1,3-D. 1,2-D is stable and highly persistent in the environment. The degradation of 1,2-D is not temperature dependent, unlike 1,3-D. Laboratory studies also indicate that 1,2-D is also very mobile, and that mobility is inversely proportional to the amount of soil organic matter.

(ii) Drinking Water Standards

1,3-D is not currently regulated under the Safe Drinking Water Act, however a Health Advisory level (HA) of 0.2 ppb has been established for 1,3-D. Because the HA is advisory in nature, public water supply systems are not required to sample and analyze for 1,3-D. The 0.2 ppb represents the level of daily consumption over a lifetime associated with a 1×10^{-6} cancer risk.

The Office of Pesticide Programs has developed drinking water Levels of Comparison (DWLOC's) to capture risk associated with exposure to pesticides in drinking water. A DWLOC, which is not an enforceable standard, is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). The DWLOC came about as part of EPA's review of pesticides under the 1996 passage of FQPA, which required EPA to develop a risk assessment tool to take into account these various exposures.

For 1,3-D, EPA has calculated two DWLOC's. For residents who live near treated fields, defined at the 300 feet buffer, the DWLOC for cancer is zero because the inhalation risk estimates are at or greater than 1×10^{-6} for this population. While the cancer risk estimates at distances

between 300 feet up to 800 meters are presented as greater than 1 x 10^{-6} (see Table 13), EPA believes these risks are overstated because the value of all mitigation measures has not been factored into the assessment, and thus a DWLOC of zero may be overly conservative.

For the general population, defined as residents who live at distances greater than 300 feet from 1,3-D treated fields, the DWLOC for cancer has been calculated to be 0.3, which is the level of daily consumption of a pesticide over a lifetime is associated with a 10^{-6} risk (see section vi of this chapter for detailed information on how this number was calculated and its relevance to the 1,3-D risk assessment).

The discrepancy between the Office of Water's HA of 0.2 ppb and OPP's DWLOC of 0.3 ppb is explained by the two offices different approaches to risk assessment. In general, the Office of Water assumes a different exposure level and a higher cancer potency estimate for 1,3-D. In addition, the DWLOC was generated using cancer data which was developed since the establishment of the 1987 HA. OPP, OW and EPA's Office of Research and Development are planning to share the information developed from the Cancer Peer Review (planned for 1999) in order to coordinate reviews based on the best and most up-to-date data on 1,3-D. OPP has, however, decided to use the 0.2 ppb HA as the trigger for implementation of risk mitigation in the tap water monitoring program because it is an established reference point and because it affords an extra level of protection should the monitoring program detect 1,3-D and/or the degradates.

The contaminant 1,2-D is regulated under the Safe Drinking Water Act. It has a maximum contaminant level (MCL) of 5 ppb, and a maximum contaminant level goal (MCLG) of 0 because it is a B_2 carcinogen (USEPA 1990). In addition, the Office of Water has established a Health Advisory for 1,2-dichloropropane: the 10-day Health Advisory for a 10-kg child is 0.09 mg/L. The drinking water concentration associated with a 10^{-6} cancer risk for a 70-kg adult is 0.06 mg/L (USEPA 1996).

The Office of Water did not establish a 1-day health advisory for 1,2-D because there were insufficient toxicological data on acute effects. In 1979, the National Academy of Sciences recommended an acceptable level of 0.3 mg/L for a 70 kg adult exposed to 1,2-D for a week.

(iii) Groundwater Monitoring

EPA has reviewed available groundwater monitoring data for 1,3-D (USEPA 1997). The Pesticides in Groundwater Database (EPA 1992) indicates detections of 1,3-D in Florida, New York, and Washington following normal field use. This database also reports detections in California due to point source pollution, and 1,3-D has also been detected in California following normal use. Small scale retrospective monitoring conducted by the registrant showed detections in studies conducted in Nebraska, but not in California or North Carolina. There was an unverified detection in a Washington study and a fifth study in Florida was terminated after a sink hole collapsed near the study site. More information on the Pesticides in Groundwater Database

and the retrospective studies can be found in section III. E.2. EPA believes that the best information for assessing human exposure through contaminated ground water is derived from two prospective ground water studies from Wisconsin and Florida, which are discussed below.

Prospective ground water study sites are located where a pesticide has never been used and follows a pesticide's movement from application forward in time through the unsaturated zone into ground water at a study site. The advantage over retrospective studies is that one can rule out detections from prior treatments and that application and environmental conditions can be tracked and evaluated against any detection (or lack of detection).

Wisconsin Site -- In Wisconsin, results show that 1,3-D was detected in an aquifer used for drinking water at concentrations ranging from 0.05 to 579 ppb. The Wisconsin study was still in progress as of printing of this RED, thus levels are presented up to 337 days following 1,3-D application of the two year study. In the Wisconsin study, ground water monitoring was conducted in on-site wells and one offsite well cluster following application of Telone II at a rate 28 gal/acre (283 lbs a.i./acre, typical rate). Depth to ground water ranged from 15-22 feet from the surface throughout the first 337 days of the study.

The study tracked results from eight on-site wells and the off-site well located 65 feet downgradient. The registrant requested that a 100 foot buffer from drinking water wells be added to labels after the study was well underway, therefore, the Agency was not able to modify the study to include how this buffer would affect human exposures with the 100 foot buffer. Although there was one off-site well, these levels can only be used as indicative of a trend, but cannot be used for quantitative risk assessment. For on-site wells, the peak 1,3-D concentration was 579 ppb, the time-weighted concentration (over an 11 month sampling period) was 134 ppb for 1,3-D alone and 357 ppb with 1,3-D plus the two degradates. The peak level of 1,3-D found in the downgradient offsite well was 173 ppb and a time-weighted average of parent plus degradates in this well was 26.6 ppb (Carleton 1998, Eiden 1998). The contaminant 1,2-D was found in all of the onsite shallow and deep wells at concentrations up to 3.9 ppb, and in the offsite well at concentrations up to 0.9 ppb.

Florida Site -- The Registrant volunteered to conduct small scale monitoring in southern Florida because of concerns for groundwater contamination due to the high water table and soil porosity, and in order to assess whether Telone products could be used without causing unreasonable adverse effects as an alternative to methyl bromide.

The Florida study design also evaluated on-site and off-site shallow and deep wells. In Florida, the majority of residents obtain drinking water from public supplies, which tap into the deep Floridian aquifer. However, approximately 20 percent of the population in Florida (up to 80% in certain Florida counties) tap private wells into the shallow, unconfined aquifers.

1,3-D was detected in the Florida prospective study at concentrations ranging from 0.05 to 21.6 ppb in shallow wells (screened at a 10 feet depth) not used for drinking water and up to one ppb in wells that tap into a confined aquifer (screened at a 70 feet depth) which could be

used for drinking water. In Florida, total 1,3-D residues (parent + degradates) in ground water were detected up to 43.9 ppb in the shallow wells (10 feet deep), and up to 8.9 ppb in the deeper wells (70 feet deep). The time-weighted averages (1,3-D plus degradates) were 1.15 ppb in wells at 10 feet from the surface and 0.17 ppb in wells 70 feet from the surface. For off-site wells, the time weighted average (1,3-D plus degradates) was 0.074 ppb.

(iv) Surface Water

Limited surface water monitoring data are available for 1,3-D. Ambient surface water monitoring was conducted concurrent with the Florida prospective ground water study. Monitoring was performed at four sampling sites along two perimeter ditches around a 1,3-D-treated field. 1,3-D was detected above a detection limit of 0.05 ppb in 14 of 20 samples collected from the two ditches in the first five days post-application (prior to the first runoff event). Concentrations ranged from 0.07 to 1.8 ppb. The maximum concentration of 1.8 ppb was the only detection > 1 ppb. No 1,3-D was detected in samples collected from the ditches after five days post-application. The degradate, 3-chloroacrylic acid, was detected in four of the 20 samples collected from the two ditches in the first five days post-application at concentrations ranging from 0.09 to 0.15 ppb. The degradate, 3-chloroallyl alcohol, was detected at a concentration of 0.78 ppb in one sample collected from the north ditch nine days post-application. No detections were noted after the first rainfall event. No rainfall events of sufficient magnitude to generate runoff occurred during the ditch water monitoring.

EPA believes that the 1,3-D found in surface water might have resulted from dissolution of volatilized compound from the air. A second possible pathway is that the levels in surface water resulted from a ground water-surface water interaction.

EPA also used computer modeling to see if 1,3-D use could contaminate surface water through runoff. EPA used Tier 2 (PRZM/EXAMS) modeling to estimate concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid in surface water in a small pond one hectare by 2 meters deep, adjacent to a 10-hectare field. EPA assumed that 1,3-D was incorporated to a depth of 25 cm below the soil surface. The model simulation included a decay rate from the parent compound (1,3-D) to the alcohol and acid degradates. Because the environmental fate data on the degradates is incomplete, EPA used assumptions based on 1,3-D's environmental fate in generating estimates in surface water through modeling.

EPA compared a variety of modeled and monitored results to test the veracity of the model. The maximum reported concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid detected in the Florida <u>ground water monitoring</u> study were: 21.6 ppb, 13.5 ppb, and 8.79 ppb, respectively. <u>Maximum surface water</u> concentrations of 1,3-D and 3-chloroallyl alcohol/ 3-chloroacrylic acid (combined) estimated from the PRZM/EXAMS model were: 1390, and 24 ppb, respectively. The <u>average annual surface water</u> concentrations (based on a 36 year mean) of 1,3-D and its degradates estimated from the PRZM/EXAMS model were 0.801 and 0.340 ppb, respectively. Average annual concentrations of 1,3-D and its degradates in

ditch water from the Florida small-scale prospective monitoring study could not be calculated from the limited monitoring duration (the maximum concentration of 1,3-D was 1.8 ppb).

The discrepancy between model estimates of the maximum concentrations in surface water and the monitoring data reflect, in part, the fact that they address different transport pathways. However, the larger problem with the models is that they are not well-suited to track volatile soil incorporated fumigants through the soil to air and water resources. Based on the data base as a whole, EPA believes once 1,3-D enters surface water, it degradess rapidly due to its chemical properties. Thus, the fate and concentrations of the degradates become of primary concern. EPA does not have a complete data base to determine whether run-off is a significant pathway, and thus Dow AgroSciences is conducting a run-off study to track whether 1,3-D is available for run-off. It should be noted that concentrations of the material in the ditch water fell below detection limits within five days after application in the Florida study; however, the presence of 1,3-D in the ditches was not reflective of the run-off process, since no run-off generating rainfall events occurred prior to its appearance in the ditch water.

(v) Drinking Water Exposure Estimates

EPA is using the results of the Florida and Wisconsin studies to derive ground water concentrations to quantify exposure to 1,3-D and its degradates in drinking water. EPA has estimated dietary exposure to 1,3-D via drinking water using these study results and a daily water consumption value of 2 L/day for adult males and females with bodyweights of 70 kg and 60 kg, respectively, and 1 L/day consumption for infants and children with a 10 kg bodyweight. The following equation used to estimate exposure to 1,3-D through drinking water for adult males is provided as an example of how EPA calculated exposure to 1,3-D and its degradates in drinking water:

$$\text{Exposure (mg/kg/day) (Adult male)} = \frac{(\text{conc'n, } \mu g/L)(2\ L/day)(0.001\ mg/\mu g)}{70\ kg\ \text{adult body weight}}$$

Chronic exposure estimates for 1,3-D, its degradates and 1,2-D based on time-weighted mean concentrations detected in ground water from small-scale prospective studies are provided in Table 4 below.

Table 4. Chronic Exposure Estimates for 1,3-D, Degradates, and 1,2-D based on Time-Weighted Mean Concentrations (TWMC) from Prospective Ground Water Studies. Exposures are presented in mg/kg/day.

Populations	Compound	FLORIDA PROSPECTIVE STUDY (365 days)						WISCONSIN PROSPECTIVE STUDY (after 337 days, on-site wells)	
		10-ft wells		70-ft wells		10-ft wells, 100' off-site		shallow aquifer (15-22 ft)	
		TWMC µg/L	Exposure	TWMC µg/L	Exposure	TWMC µg/L	Exposure*	TWMC µg/L	Exposure
Adult males	1,3-D	0.30	8.6×10^{-6}	0.04	1.1×10^{-6}	0.026		134	3.8×10^{-3}
Adult females			1×10^{-5}		1.3×10^{-6}				4.5×10^{-3}
Infants & Children			3×10^{-5}		4×10^{-6}				1.3×10^{-2}
Adult males	3-chloroacrylic alcohol	0.31	8.8×10^{-6}	0.11	3.1×10^{-6}	0.025		87	2.5×10^{-3}
Adult females			1×10^{-5}		3.6×10^{-6}				2.9×10^{-3}
Infants & Children			3×10^{-5}		1×10^{-5}				8.7×10^{-3}
Adult males	3-chloroacrylic acid	0.54	1.5×10^{-5}	0.03	8.6×10^{-7}	0.023		136	3.9×10^{-3}
Adult females			1.8×10^{-5}		1×10^{-6}				4.5×10^{-3}
Infants & Children			5.4×10^{-5}		3×10^{-6}				1.4×10^{-2}
Adult males	1,3-D + Degradates	1.15	3.3×10^{-5}	0.17	4.9×10^{-6}	0.074		357	1×10^{-2}
Adult females			3.8×10^{-5}		5.6×10^{-6}				1.2×10^{-2}
Infants & Children			1.2×10^{-4}		1.7×10^{-5}				3.6×10^{-2}
Adult males	1,2-D	0.22	6.3×10^{-6}	0.06	1.7×10^{-6}	NA		1.69	4.9×10^{-5}
Adult females			7.3×10^{-6}		2×10^{-6}				5.6×10^{-5}
Infants & Children			2.2×10^{-5}		6×10^{-6}				1.7×10^{-4}

* - note these wells were not used for risk assessment purposes, therefore, TWMC values are only presented to compare to levels found in other wells.

Limited surface water monitoring data from the Florida prospective study suggest that 1,3-D may migrate to surface water by transport pathways other than run-off. However, because information regarding potential 1,3-D migration to surface water is limited, and because 1,3-D is a volatile fumigant not well suited to the PRZM/EXAMS model, the concentrations of 1,3-D and its degradates derived from the model will be compared to drinking water levels of comparison. That is, they will not be used to quantify a drinking water risk associated with residues of 1,3-D and its degradates in surface water.

As noted previously, the Office of Pesticide Programs developed drinking water Levels of Comparison (DWLOC's) as a way to evaluate the concentration of a pesticide in drinking water that would be acceptable as an upper limit (i.e. no greater than 1×10^{-6} lifetime cancer risk or 100% RfD) in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). While there are no exposures from food or residential uses, EPA has decided it is

appropriate to aggregate inhalation and oral (drinking water) exposures. EPA calculated DWLOC values for chronic (RfD) and cancer (Q_1*) endpoints.

(vi) DWLOC/1,3-D plus Degradates

The RfD for 1,3-D (plus degradates) was used to calculate a Drinking Water Level of Comparison (DWLOC) for non-cancer, chronic effects. The $DWLOC_{chronic}$ is the concentration of 1,3-D in drinking water consumed daily over a lifetime that, as part of the aggregate chronic exposure from all sources (food, water and residential), occupies no more than 100% of the RfD. The $DWLOC_{chronic}$ for 1,3-D plus the degradates is 875 ppb for the total US population, 750 ppb for females 13+ years old, and 250 ppb for children. Note there is not an inhalation component because no chronic, non-cancer endpoint was identified and thus no risk assessment was required.

The **$DWLOC_{chronic}$** for 1,3-D plus degradates was calculated using the following formula:

$$DWLOC_{chronic} = \frac{\text{chronic water exposure (1,3-D + degradates) (mg/kg/day)(body weight,kg)}}{\text{(water consumption, L/day)}(10^{-3}\ \text{mg/µg})}$$

where chronic water exposure = RfD (because there is no exposure to 1,3-D via food); water consumption is two L/day for adults and one L/day for children; and body weight is 70 kg for total US population, 60 kg for females 13+ years old, and 10 kg for children 1 to 6 years old.

The oral Q_1* for 1,3-D was used to calculate a DWLOC for cancer effects associated with exposures to 1,3-D plus the degradates. The $DWLOC_{cancer}$ is the concentration of 1,3-D in drinking water consumed daily over a lifetime that is associated with a 1×10^{-6} cancer risk from all exposures. As noted previously in this document, EPA has developed two DWLOC's for 1,3-D (plus degradates). Because the cancer risk associated with inhalation exposures at the 300 feet buffer is above 1×10^{-6}, the DWLOC for water exposure is zero. Although calculated inhalation risk estimates for residents who live near treated fields are above 1×10^{-6}, EPA believes these estimates are overstated because all mitigation measures which are on 1,3-D labels have not been factored into the assessment.

For the general population (those living more than 300 feet from treated fields), the $DWLOC_{cancer}$ for 1,3-D is 0.3 µg/L (ppb). Because there is no dietary (food) exposure to 1,3-D, individuals could be exposed to 8.2×10^{-6} mg/kg/day of 1,3-D in drinking water before EPA's level of concern (1×10^{-6} cancer risk) would be exceeded. See section III.D. iv for an explanation of how EPA calculated risk estimates for cancer and how levels found in the ground water studies compare to the DWLOC for cancer. As explained in section III. B.3 b., there is an Office of Water Health Advisory of 0.2 ppb which differs from the DWLOC of 0.3 ppb.

The **$DWLOC_{cancer}$** for 1,3-D was calculated using the following formula:

$$DWLOC_{cancer} = \frac{\text{(chronic water exposure (1,3-D + degradates), mg/kg/day)(body weight)}}{\text{(µg/L)(water consumption, L/day)}(10^{-3}\ \text{mg/µg})}$$

where chronic water exposure = $\frac{1 \times 10^{-6}}{\text{oral } Q_1^* \text{ of } 1.22 \times 10^{-1} \text{ (mg/kg/day)}^{-1}}$,

water consumption is 2 L/day, and body weight is 70 kg.

(vii) DWLOC/1,2-D.

The oral Q_1^* for 1,2-dichloropropane was used to calculate a DWLOC for cancer effects caused by 1,2-D. The $DWLOC_{cancer}$ for 1,2-dichloropropane is 1 ug/L. The inhalation exposure studies did not monitor for levels of 1,2-D in air, therefore, the DWLOC only estimates oral exposures.

The **$DWLOC_{cancer}$ for 1,2-dichloropropane** was calculated using the following formula:

$$\underset{(\mu g/L)}{DWLOC_{chronic}} = \frac{\text{(chronic water exposure, mg/kg/day)(body weight)}}{\text{(water consumption, L/day)}(10^{-3}\text{ mg/}\mu\text{g})}$$

where chronic water exposure = $\frac{1 \times 10^{-6}}{\text{oral } Q_1^* \text{ of } 3.69 \times 10^{-2} \text{ (mg/kg/day)}^{-1}}$.

water consumption is 2 L/day, and body weight is 70 kg.

DWLOC's can also be compared to model estimates as a surrogate way to estimate and characterize risks. Using PRZM/EXAMS as a model, EPA devised three scenarios to give 36-year mean concentrations for 1,3-D and its degradates in pond water and compared those to the DWLOC's for chronic (RfD) toxicity endpoints. DWLOC values were calculated for chronic (non-cancer) effects for three subpopulations (U.S. population, adult females, and children and infants), and calculated for cancer effects for the general U.S. population. Table 5 below provides a comparison of the model estimates for three scenarios from Idaho, Mississippi and Georgia to the DWLOC values for the general population..

Table 5. Estimated Concentrations of 1,3-D, 3-chloroallyl alcohol, and 3-chloroacrylic acid in Pond Water (PRZM/EXAMS).

Subgroup	DWLOC chronic (ug/L)	36-Year Mean (ug/L)		
		Potatoes (ID)	Tobacco (GA)	Cotton (MS)
US Population	875	0.045	0.357	0.801
Females	750	0.016	0.081	0.340
Children & Infants	250	0.061	0.438	1.141

Note the DWLOC for the cancer endpoint is 0.3 ppb, which would be exceeded for all groups from the MS scenario and for all but females in the GA scenario.

However, EPA does not expect 1,3-D concentrations to persist in surface waters long enough to provide chronic exposures and recognizes that PRZM/EXAMS is not well suited to tracking volatile fumigants. Estimated average concentrations of 1,3-D and its degradates, alone or in total, are well below the DWLOC's for chronic, non-cancer effects for the subpopulations of concern. Estimated concentrations of 1,3-D, *per se*, are greater than the DWLOC for cancer effects in two of the scenarios modeled. EPA has some concern that the degradates, being less volatile than the parent compound, may persist in surface waters. Dow AgroSciences is developing environmental fate and run-off data to show whether the degradates persist to pose chronic risks.

C. Occupational and Residential Exposure

1. Summary of Use Pattern and Application Methods

There are no homeowner products containing 1,3-D. 1,3-D is a restricted-use pesticide and thus only certified handlers are allowed to load and apply 1,3-D.

1,3-D is applied by injection below the soil surface at least 12 inches. The liquid 1,3-D then diffuses through the soil spaces. 1,3-D may be degraded while in the soil or it may volatilize or migrate to groundwater. Occupational and residential/bystander inhalation exposure occurs as a result of 1,3-D volatilization. Inhalation is the primary route of exposure for workers. The rate of 1,3-D volatilization is affected by application method, soil sealing method, soil composition (e.g, amount of clay and organic matter), and soil moisture, temperature and a variety of other local environmental factors.

1,3-D is applied to soil by two methods: row and broadcast. With both methods, 1,3-D is injected 12-18 inches below the final sealed soil surface. The broadcast method uses one chisel, Nobel (sweep) plow or plow-sole application equipment with one or more fumigant outlets. The broadcast method requires the formation of a raised bed after the application. The row method consists of either one or two chisels per plant row to treat a band of soil where the crop is to be planted. The row method involves forming beds at the time of application so that the fumigant is placed at least 12 inches from the nearest soil/air interface.

1,3-D products do not require mixing, and are loaded into tanks which are attached to tractors or application rigs directly from a bulk or mini-bulk container. Bulk loading from tanker trucks is the predominant practice where custom applicators are the biggest users (e.g., the Pacific Northwest). Mini-bulk systems are portable 1000-gallon "traveler" cylinders with dry disconnects to prevent 1,3-D leaks. After applying 1,3-D, the user returns the mini-bulk container and any remaining 1,3-D to the local distributor, who then sells the remainder or returns the mini-bulk container for cleaning (note: cleaning and maintenance of bulk and mini-bulk containers are regulated by OSHA and are not included in this exposure assessment).

2. Exposure Mitigation Measures in Effect

Since 1992, numerous mitigation measures have been added to all 1,3-D product labels. Specific mitigation measures for workers and area residents are described below.

a. Workers

The following table presents label measures that are in effect to reduce exposures to workers through the dermal and inhalation routes of exposure. The largest sources of worker exposure, through leaks and spills, were addressed by the use of closed loading, equipment to shut off 1,3-D flow at row-turns and respirators.

Table 6. Summary of 1,3-D Label Restrictions that Impact **Worker** Exposures

Regulatory Action (effective date)	Label Requirements
Registration Standard (1986)	Precautionary Statements; Cancer Hazard Warning; Classification Change to Restricted Use Pesticide; Reentry increased to 72 Hours*; Clothing for Applicators and Handlers (Coveralls*, Chemical-resistant Gloves and Boots, Liquid-proof Hat).
1992 Label Amendments (1992/1993)	Lowered Maximum Rates; Deletion of Selected Use Sites; Revised Respirator Requirements*; Closed Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Improved Product Stewardship Materials
Worker Protection Standard (August 1992 see 57 FR 38102)	Coveralls Over Short-sleeved Shirt and Short Pants; Chemical-resistant Gloves and Footwear; Chemical-resistant Apron (for Direct Handlers).
1995 Label Amendments (1996)	A Respirator Requirement for All 1,3-D Handlers (Except Those in Certain Closed Cabs); Restricted Entry Increased to 5 Days; Soil Moisture and Soil Sealing Requirements; Modified Application Techniques and Lower Maximum Use Rates.

* Superceded or modified by later label measures.

b. Residents/Bystanders

1,3-D labels require a 300 foot buffer zone between treated fields and an occupied structure where 1,3-D applications are prohibited. Other measures listed in the table above, including use of the "traveler" mini-bulk loading system, reduced application rates, increased injection depth, soil sealing, and soil moisture requirements, are also expected to reduce exposure to residents and bystanders, although exposure reduction cannot be quantified (Carleton 1996a).

3. Factors Influencing 1,3-D Exposure

The label measures described above reduce, but do not do not completely prevent, 1,3-D releases into the atmosphere. EPA believes that the greatest potential for release under current labels is through the chisel trace that is left as 1,3-D is applied, and through off-gassing that occurs for several days after application. For this route, local environmental conditions greatly influence inhalation exposure to agricultural workers and residents/bystanders. Local soil conditions, such as soil type, moisture, organic content, and soil temperature all influence the rate of 1,3-D volatilization and subsequent exposure to workers or residents. 1,3-D product application methods, including soil sealing, injection depth, and placement of injection shanks influence the volatilization of 1,3-D. Local meteorological conditions, such as prevailing wind, also influence air concentrations and exposure potential. Application rates may also influence 1,3-D volatilization, although a quantitative relationship between application rate and air concentration has not been established. In addition, 1,3-D air concentrations may vary with time after application. Peak 1,3-D volatilization generally occurs over the first 72 hours following 1,3-D application, although detectable levels are still present 14 days following application.[1] 1,3-D exposure also varies with distance from treated fields. 1,3-D air concentrations measured 125 meters from treated fields were 45 to 72 percent lower than air concentrations measured five meters from treated fields (Carleton 1996).

4. Exposure Monitoring Studies

Dow AgroSciences performed exposure monitoring studies for both workers and for residents who live near treated fields. Most of these studies were required by the 1992 DCI. An additional worker study on 1000 gallon mini-bulk "travelers" was submitted by Dow AgroSciences in 1995, which was incorporated into the worker risk assessment, but not the residential assessment. Studies used for the EPA Worker and Resident/Bystander Risk Assessments are summarized below.

a. Worker Monitoring Studies

Personal air monitoring was conducted for product loaders, applicators, and re-entry workers (MRID's 42946201, 42845602, and 4880401). Air samples were drawn through activated carbon sorbent tubes, using battery operated pumps to collect air from the breathing zones of the workers at a measured flow rate. Samples were subsequently desorbed in an organic solvent and analyzed by GC-ECD or GC-FID. For the loaders and applicators, two kinds of samples were collected: four hour samples, and task-specific short duration (4 to 46 minutes) samples. The four hour samples provided inherently time-weighted average air concentrations over a major fraction of a work day, while the task-specific samples measured the air concentrations associated only with high-contact activities. For product loaders, these activities were the actual loading events. The 4-hour loader samples included the loading events, and the

[1] In two of three residential exposure studies, peak Telone air concentrations occurred within 72 hours of application.

time spent on site between loading events. In the Ainger, NC worker monitoring study, only short-term task specific samples were collected. Sampling occurred only when workers were actively engaged in loading. Worker monitoring studies are described below and the data from these studies are summarized in Tables 7 and 8.

- **Moses Lake, WA Worker Study**. October and November, 1992. Telone II was applied at the maximum application rate of 25 gal/acre (252.5 lbs a.i./acre) on a field used for potatoes; soil type was sandy loam. Bulk loading was used, with dry disconnects, which are common practice in the region. Application was by the broadcast method.

- **Buckeye, AZ Worker Study.** March 3-10, 1993. Telone II was applied by the row method at the maximum rate of 12 gal/acre (121.2 lbs a.i./acre) to a field used to grow cotton; soil type was loamy sand. Bulk loading was used, with dry disconnects. (The study also collected samples without dry disconnects, but these data were not used for Reregistration because dry disconnects are now a label requirement.)

- **Ainger, NC Worker Study.** April 3-5, 1995. Telone C-17 (1,3-D plus chloropicrin) was applied by the row method at a rate of approximately 10 gal/acre (82 lbs a.i./acre) to a field used to grow tobacco. Soil type was not specified. This study utilized the mini-bulk delivery system, Dow AgroSciences' portable 1000-gallon "traveler" cylinders, which utilize dry disconnects. End row spill control was also used in this study.

Not all available worker monitoring data were used for exposure assessment. Only data reflecting the label requirements current at the time of testing were used (e.g., respirators, dry disconnects, end-row spill control).

Biological exposure monitoring was also conducted on both sedentary human volunteers (controlled study) and on workers performing typical tasks. Urinalysis was used to detect the major 1,3-D metabolites (Levy 1993, McMahon 1993). These studies are described in detail in the worker exposure assessment for 1,3-D (Mehta 1994b). The biological monitoring data were not used in this risk assessment because an accurate correlation between urinary metabolite excretion and the air monitoring data could not be made to estimate absorbed dose (McMahon 1993). The biomonitoring data showed 1,3-D absorption in the range of 72-82 percent; these absorption estimates were determined to be minimum values after comparison with field trial data. Absorption via the inhalation route was assumed to be 100 percent for the purposes of this risk assessment.

b. Resident/Bystander Monitoring Studies

The NC, AZ and WA studies (MRID 42845601) included off-site monitoring to assess exposures to residents who live near treated fields. Residential/bystander monitoring studies

involved air sampling for 14 days at various stations 5, 25, 125, 500 and 800 meters from a 1,3-D-treated field (and additional sampling stations at 1200 and 1600 feet for the AZ site). Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment sites. The applications were conducted utilizing standard cultural practices and equipment at the time of the study. Fields that were selected and treated were isolated from all other known 1,3-D handling activities. Air sampling was conducted in all four compass directions. EPA analyzed data for samples taken downwind from treated fields, as well as for pooled data from all four directions (to account for shifts in wind direction). Air sampling was conducted around the clock to account for day and night exposures. Greater 1,3-D ambient air concentrations and volatilization rates were found at night (Mehta 1994a). However, only the 24-hour, time-weighted average air concentrations were used to estimate residential/bystander exposures, due to a lack of individual time activity data on time spent in and around the house at day and night.

Air monitoring was conducted directly above the treated field, and at distances of 5, 25, 125, 500, and 800 meters from the edge of the field, in each of four orthogonal directions (i.e. N,S,E,W). All samples were taken approximately five feet above the ground, using battery operated pumps to draw air through activated carbon sorbent tubes at a measured flow rate. Samples were collected during the 1,3-D application at all sampling locations, except directly above the fields. After the application was finished, sampling began at all locations, and continued for 14 days post application. The first 24 hour period following application was divided into six 4-hour samples. 1,3-D air concentrations were at their peak during the first 24-hours. The next 48 hours were divided into four 12-hour samples. The remaining 11 day period was divided into 24-hour samples, one for each day.

At the Washington study site, the presence of a nearby cattle stockyard prevented the collection of a sample 800 meters south of the treated field. However, at the Arizona site, samples were collected at 1200 and 1600 meters from the field in all four directions, in addition to the distances listed above.

Residential/bystander monitoring studies are described below.

- **Phase 1. Moses Lake, WA.** October 26 to November 9, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 20 acre plot treated with Telone II using the broadcast method at the maximum rate of 25 gal/acre (252.5 lbs a.i./acre). Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment site. The 800 meter south samples could not be collected because a cattle stockyard was located to the south of the treated field. The soil type was characterized as loamy sand.

- **Phase 2. Harquahala Valley, AZ.** February 16 to March 2, 1993. Telone II was applied using the row method at a rate of 12 gal/acre (121.2 lbs a.i./acre), imitating an application for a melon field. Air monitoring was conducted at 28 monitoring

locations surrounding the 20 acre plot treated with Telone II. The soil type was characterized as a sandy loam.

- **Phase 3. Hookerton, North Carolina**. December 7-21, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 12 acre plot that had been treated with Telone C-17. Telone C-17 was applied using the broadcast method at a maximum label rate of 20 gal/acre (164 lbs a.i./acre) for tobacco. The soil type was characterized as a sandy loam.

Monitoring data from these studies are summarized in Table 7 below. Off-site monitoring results are presented at various distances from treated fields. The monitoring data showed that 1,3-D air concentrations peaked during the first three days following treatment and then declined over a period of 14 days following treatment, which was the duration of the air monitoring. Data from the resident/bystander study are presented in a way that captures this peak. Data are presented as (1) the maximum 4-hour air concentration during the study, measured during the first few days of treatment, (2) mean 24 hour air concentrations, (3) mean 7-day air concentrations, and (4) mean 15-day air concentrations.

For each sampling station, the time weighted average (TWA) air concentration was calculated for the appropriate sampling period. This consisted of the arithmetic mean of the mean daily air concentrations. For all except the on-site samples, this calculation included the concentrations measured during the application process. For each distance from a treated field, the mean TWA over all four directions (N, S, E, W) was calculated for the appropriate monitoring period. The data for all three sites was then pooled, and an overall average for each distance was calculated for the entire data set.

Table 7. 1,3-D Air Concentration Monitoring Data for Agricultural Workers

Activity	Sample Duration	Study sites	Total reps.	Air Concentration ($\mu g/m^3$)		
				Range	Mean	Median
Loading [a]	4 hr	WA, AZ	10	177-5932	1,631	623
Loading [a]	task only	WA,AZ	10	526-32490	10,833	4,860
Loading [a]	task only	NC	12	52-1180	464	442
Application[b]	4 hr & task	WA, AZ, NC	28	43-6581	1,359	1,150

[a]With use of dry disconnects
[b]With use of end-row spill control

Table 8. Offsite Air Monitoring data

Distance from treated field (m)	Study Site	Max. 4-hour conc. (µg/m³)	Max conc. 24 hour TWA (µg/m³)	Mean conc. 7 day (µg/m³) **numbers in bold indicate mean levels at that distance for the 3 studies**	Mean conc. 15 day (µg/m³) **numbers in bold indicate mean levels at that distance for the 3 studies**
1600	AZ	90.9	23.3	3.2	2.4
1,200	AZ	157.7	46.0	5.6	3.8
800	AZ	215.9	62.9	9.7	6.5
	WA	171.9	79.7	21.0	14.6
	NC	63.2	10.8	1.4	1.3
				10.7	**7.5**
500	AZ	482.2	140.4	18.6	11.8
	WA	183.0	91.7	24.1	17.2
	NC	92.1	16.0	2.2	1.5
				15.0	**10.2**
125 Edge of buffer zone	AZ	1709.5	579.3	92.0	55.6
	WA	521.3	278.2	55.0	40.2
	NC	281.0	58.0	10.4	6.0
				52.5	**33.9**
25	AZ	3575.5	1807.0	196.0	112.4
	WA	311.7	212.2	74.9	62.1
	NC	394.3	222.9	26.2	15.1
				99.0	**63.2**
5	AZ	1592.6	1278.2	184.8	104.7
	WA	351.0	235.5	91.7	73.6
	NC	671.2	343.7	38.3	21.7
				104.9	**66.7**
onsite	AZ	2316.4	1067.1	315.4	171.1
	WA	351.0	266.2	151.3	115.5
	NC	339.9	261.9	75.6	40.4
				180.8	**109.0**

5. Exposure Estimates Used for Risk Assessment

EPA based its risk assessment on 1,3-D air concentrations measured in the monitoring studies described above. Only inhalation exposure was estimated; dermal exposure is expected to be negligible because of 1,3-D's volatility and the protective measures on 1,3-D product labels.

Because the number of monitored replicates at each site was small (5 to 13), EPA pooled the results from different sites to obtain the largest possible sample sizes for each exposure scenario. Tables 7 and 8 present a summary of the pooled data on air concentrations from these studies.

For intermediate-term worker exposure, the 4-hour samples were used to calculate the mean air concentrations over all pooled replicates. Separate inhalation exposure estimates are provided for custom loaders and applicators, because different individuals perform these tasks. However, for growers, EPA assumed that the same person conducts both loading and application of 1,3-D. Since growers presumably spend most of their work day engaged in application rather than loading, intermediate-term exposures estimates for growers were based on the air concentration for application rather than loading. All worker air concentration estimates were adjusted using a protection factor of 0.10 for respirators.

For intermediate-term residential/bystander exposure, a time weighted average (TWA) air concentration was calculated for the first eight days of exposure only (day of application and the first seven days of a 14-day study). These are the mean 7-day air concentrations in Table 8, which were used to calculate intermediate term MOE's.

For lifetime residential/bystander exposure, the TWA air concentration was calculated for the entire sampling period for each monitoring station. This time weighted average was the arithmetic mean of the mean daily air concentrations. For all but the on-site samples, this calculation included the air concentrations measured during the application process. This value was normalized over a 24 hour period, and incorporated into an overall 15 day TWA (the day of application plus the 14 days following). Since samples were not collected above the fields during the application process, the on-site TWA covered only the 14 day period after application.

For each distance from a treated field, the mean TWA over all four directions (N, S, E, W) was calculated for the entire monitoring period. The data for all three sites were then pooled, and an overall average for each distance was calculated for the entire data set. These values appear in Table 8 under the heading of "Mean conc. 15 day" air concentrations. Subsequent cancer calculations took account of the differing numbers of days used in calculating the mean air concentrations at the different distances, by assuming 14 days of exposure for the on-site concentration, and 15 days for all the others.

To calculate intermediate-term exposures, a similar calculation was performed, except that for each distance, a TWA air concentration was calculated for the first eight days only (day of application plus the seven days following). These values appear in Table 8 under the heading of "Mean conc. 7 day" air concentrations. Intermediate-term MOE's were estimated as the intermediate-term inhalation NOEL of 0.091 mg/L (see Table 3) divided by the "mean 7 day" 1,3-D air concentration.

Exposures to agricultural handlers entering treated fields after the five day REI were also calculated using the on-site air monitoring data from the residential/bystander studies. For each of

the three monitored sites, the TWA 1,3-D air concentration was calculated for the period consisting of days 6-14 post-application. The resulting concentration was used to estimate cancer risks to handlers entering treated fields.

Chronic, lifetime exposures to workers and area residents were expressed as lifetime average daily dose (LADD). The LADD of 1,3-D was calculated according to the following formula:

$$\text{LADD (mg/kg/day)} = \frac{[(\text{air concentration, } \mu g/m^3)(mg/1000\ \mu g)(\text{ventilation rate, } m^3/hr)(hr/day)(days/yr)(1\ yr/365\ days)(yrs\ exposed/70\ yrs)]}{70\ kg\ body\ wt}$$

using the following values for workers and residents/ bystanders:

	Workers	Residents/Bystanders
Ventilation rate	1.74 m^3/h (light work)	0.81 m^3/h
Lifetime Exposure	30 years, grower, 20 years, commercial	30 years
Average Lifetime	70 years	70 years
Exposure Duration	crop specific	16 h/day
Exposure Frequency	crop specific	15 days/event, 1 events/yr

LADD's for commercial "for-hire" handlers were calculated by first estimating average daily doses (ADD's) in mg/kg/day, from the air concentrations. Information on days per year and hours per day were obtained for each crop, state by state, from Dow AgroSciences' Use and Usage Summary Report. However, for loaders, the report lists only the total hours per day spent actively engaged in loading (0.5 to 1.25 hour/day), not total hours spent on site. To estimate ADD's, the Agency therefore assumed loaders to be on site for the same number of hours per day as the applicators (5 to 10 hour/day, depending on state and crop).

LADD's for growers assumed that the majority of the work day is spent applying 1,3-D, and only as much time as is required to load the tank is spent engaged in loading. Therefore, the 4-hour samples were used in the calculation of the portion of the exposure resulting from application, and the task-specific samples were used to calculate the exposure incurred while loading (because 4-hour samples were not collected for the mini-bulk study, the Agency made the assumption that for the use of mini-bulk cylinders, the task-specific loader air concentrations are experienced for the duration of a work cycle). The loading and application exposures were then added to estimate the total exposure for these individuals. Information on hours per day and days per year for each activity were obtained from the Dow AgroSciences' Use and Usage Summary Report. For growers, the Agency assumed that the same person conducts both loading and application of 1,3-D.

Exposure estimates for residents/bystanders were based on pooled data to account for random shifts in wind directions. For residents/bystanders, the Agency also assumed 16 hours/day spent in and around the house. EPA assumed 1,3-D air concentrations to be the same indoors and outdoors, in the absence of indoor air monitoring data. Exposure estimates for residents/bystanders are provided for individuals who remain at a fixed distance from a treated field. The LADD for workers was adjusted using a protection factor of 0.10 for respirators.

D. Risk Assessment

EPA expects both occupational and residential/bystander exposure from the use of 1,3-D. Residents and bystanders near Telone-treated fields are exposed via ambient air. Dietary exposure may occur through drinking water, but is not expected from food sources. Exposure can occur by the inhalation and oral (drinking water) routes, but not is not expected from the dermal route of exposure based on use patterns and label requirements for 1,3-D use.

1. Dietary Risk and Characterization

a. Food Source

No dietary risk assessment was performed for 1,3-D, because no residues are found in foods. Telone products are pre-plant fumigants which break down in the soil and thus are not available for uptake by plants. The at-plant treatment for pineapples shows that the fruit, which are borne three years later, do not contain 1,3-D treatment-related residues.

b. Drinking Water Source

(i) Acute Drinking Risk

No acute toxicological endpoints were identified for 1,3-D exposure for acute or subchronic time duration. Therefore, no acute or subchronic drinking water risk assessment was conducted.

For 1,2-D, EPA's Office of Water has a children's 10-day health advisory of 0.09 mg/L (90 µg/L or 90 ppb). The maximum concentration of 1,2-D found was 1.3 µg/L (0.0013 mg/L) in the Florida study and 3.9 µg/L (0.0039 mg/L) in the Wisconsin study. Because the maximum concentration of 1,2-D found in the prospective ground water monitoring studies does not exceed the 10-day health advisory for children, it is not considered to be of concern.

The Maximum Contaminant Level (MCL) for 1,2-D is 0.005 mg/L (5 µg/L). The maximum concentration of 1,2-D in the Florida study on-site wells was 1.3 µg/L in shallow wells and in the Wisconsin study was 3.9 µg/L. Therefore, the levels of 1,2-D found in the prospective studies do not exceed the MCL and are not considered to be of concern.

(ii) Short and Intermediate Term Drinking Water Risk

For 1,2-D, EPA's Office of Water has established a 10-day health advisory; the concentrations of 1,2-D in the water monitoring studies were compared to the 10-day health advisory for 1,2-D. Concentrations of 1,2-D in groundwater did not exceed the 10-day Health Advisory of 0.09 mg/L or the MCL of 0.005 mg/L and are not of concern. In the Florida study, the peak groundwater concentration in on-site wells of 1,2-D was 1.3 µg/L (0.0013 mg/L). In the Wisconsin monitoring study, the peak groundwater concentration of 1,2-D was reported to be 3.9 µg/L (0.0039 mg/L).

(ii) Chronic Drinking Water Risk as % RfD

For 1,3-D, EPA has determined that the oral RfD should be 0.025 mg/kg/day, based on a NOEL of 2.5 mg/kg/day from a 2-year chronic/carcinogenicity study in rats and an uncertainty factor of 100.

The chronic drinking water risk is calculated as a percent of the RfD taken up by drinking water. As stated previously, groundwater is expected to be the only source for chronic drinking water exposure to 1,3-D.

The following calculation was used:

$$\% \text{ RfD} = \frac{\text{(Drinking Water Exposure, mg/kg/day)}}{\text{RfD of 0.025 mg/kg/day}} \times 100\%$$

Time-weighted average ground water concentrations from the prospective ground water monitoring studies were used to estimate risk as a percentage of the RfD. Chronic drinking water exposure was compared to the RfD for the total U.S. population (as represented by adult males), adult females, and infants/children. For the exposure scenario using ground water monitoring data from the Wisconsin prospective ground water monitoring study, chronic exposure to 1,3-D for the total US population is 40 percent of the RfD, for adult females chronic exposure is 48 percent of the RfD, and for infants/children (the most highly exposed sub-population) chronic exposure is 144 percent of the RfD. Dietary and drinking water exposures below 100 percent of the RfD are generally considered not to be of concern. Chronic (non-cancer) risk estimates based on exposure to 1,3-D in drinking water are presented in Table 9 below.

Risk estimates for drinking water associated with chronic, non-cancer effects were not calculated for surface water because the available monitoring information on 1,3-D and its degradates in surface water is inadequate (does not provide a long-term average concentration value, i.e., a time-weighted mean concentration or information on whether run-off would contribute to surface water levels). No RfD was available for 1,2-D; therefore, a chronic drinking water risk assessment was not performed.

Table 9- Risk Estimates for Chronic Effects (non-cancer) of 1,3-D and 1,3-D + Degradates as a %RfD based on Maximum Exposure Calculated from the Wisconsin (up to day 337 from on-site wells of 2-Year Study) and Florida Prospective Ground Water Study Data.			
Wisconsin Prospective Ground Water Study (15-22 feet deep wells)			
Populations	Compound	Exposure (mg/kg/day)	% RfD
Adult males	Telone + degradates	1×10^{-2}	40
Adult females		1.2×10^{-2}	48
Infants & Children		3.6×10^{-2}	144
Florida Prospective Ground Water Study (10 feet deep wells on site)			
Populations	Compound	Exposure (mg/kg/day)	% RfD
Adult males	Telone + degradates	3.3×10^{-5}	<1.0
Adult females		3.8×10^{-5}	<1.0
Infants & Children		1.2×10^{-4}	<1.0
Florida Prospective Ground Water Study (70 feet deep wells on site)			
Adult males	Telone + degradates	4.9×10^{-6}	<1.0
Adult females		5.6×10^{-6}	<1.0
Infants & Children		1.7×10^{-5}	<1.0

(iv) Carcinogenic Risk from Drinking Water

The Agency estimated cancer risks associated with dietary exposure to 1,3-D via drinking water from ground water sources. Appropriate and reliable monitoring data for surface water were not available. Cancer risks were estimated for the total US population only, because the Agency has insufficient information to estimate lifetime drinking water consumption (or cancer risk) for subpopulations of varying ages and reproductive status.

Cancer risk estimates were calculated using the following equation:

Cancer risk = (chronic drinking water exposure, mg/kg/day) x Q_1*, $(mg/kg/day)^{-1}$

Chronic drinking water exposure values are derived from time-weighted mean concentrations of 1,3-D, its degradates, and 1,2-D detected in the Wisconsin and Florida prospective monitoring studies.

The oral Q_1* is 1.22×10^{-1} $(mg/kg/day)^{-1}$ for 1,3-D and 3.69×10^{-2} $(mg/kg/day)^{-1}$ for 1,2-D. Note there is a separate Q_1* for 1,3-D via the inhalation route of exposure, which is discussed in the following section.

Cancer risk estimates were derived from both the Florida and the Wisconsin study based on total concentration of 1,3-D and the degradates, 3-chloroallyl alcohol and 3-chloroacrylic acid (assuming that the degradates have cancer potency equivalent to 1,3-D). Lifetime cancer risk estimates from wells located on-site are estimated to be from 4×10^{-6} (Florida) to 1.2×10^{-3} (Wisconsin). The new 1,3-D labels prohibit use within 100 feet of a drinking water well, so these risks are likely overestimates.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. The studies were underway when the registrant proposed the 100' no-treatment buffer from drinking water wells, and as such, the study could not be modified to assess human exposures with this buffer. In the Florida study, time weighted average (TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 357 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures, results in both studies indicate that exposures were lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. EPA expects the sampling program will allow better characterization of risks including the 100' setback required from drinking water wells now required on the label.

Drinking water cancer risks were not calculated for surface water because the available monitoring information on 1,3-D and/or its degradates in surface water is inadequate (since it does not provide a long-term average concentration value, i.e., a time-weighted mean concentration) for use in a chronic exposure assessment to estimate cancer risks. The Agency believes that continued chronic exposure to 1,3-D is unlikely because 1,3-D is likely to dissipate rapidly from surface water via volatilization, making chronic surface water exposure unlikely. The potential for chronic exposure to the degradates is expected to be greater, since they are likely to be less volatile than the parent. As mentioned in the previous section, Dow AgroSciences is conducting a run-off study to investigate whether there is a potential for substantial exposures via surface water. Drinking water cancer risk estimates based on ground water data for the contaminant 1,2-D range from 6.3×10^{-8} to 1.8×10^{-6}. Cancer risk estimates for on-site drinking water wells are summarized in Table 10 below.

Table 10: Chronic Exposures and Cancer Risk Estimates for 1,3-D, its Degradates, and 1,2-D based on Time-Weighted Mean Concentrations from Prospective Ground Water Monitoring Studies

Compound	Florida Ground water Monitoring Data (on-site wells)						Wisconsin Ground water Monitoring Data (on-site wells)		
	10 ft deep wells			70 ft deep wells			shallow aquifer (15-22 ft)		
	Conc'n, µg/L	Estimated Exposure, mg/kg/day	cancer risk	Conc µg/L	Estimated Exposure, mg/kg/day	cancer risk	Conc µg/L	Estimated Exposure, mg/kg/day	cancer risk
1,3-D	0.30	8.57×10^{-6}	1.0×10^{-6}	0.04	1.1×10^{-6}	1.4×10^{-7}	134	3.8×10^{-3}	4.7×10^{-4}
3-chloroacrylic alcohol	0.31	8.86×10^{-6}	n/a	0.11	3.1×10^{-6}	n/a	87	2.5×10^{-3}	n/a
3-chloroacrylic acid	0.54	1.54×10^{-5}	n/a	0.03	8.6×10^{-7}	n/a	136	3.9×10^{-3}	n/a
1,3-D + Degradates	1.15	3.17×10^{-5}	4.0×10^{-6}	0.17	4.9×10^{-6}	5.9×10^{-7}	357	1.0×10^{-2}	1.2×10^{-3}
1,2-Dichloropropane	0.22	6.3×10^{-6}	2.3×10^{-7}	0.06	1.7×10^{-6}	6.3×10^{-8}	1.69	4.8×10^{-5}	1.8×10^{-6}

*Cancer risk estimates were calculated using the following equation:
Cancer risk = (drinking water exposure, mg/kg/day) X Q_1*, (mg/kg/day)-1
Where oral Q_1 * = 1.22×10^{-1} (mg/kg/day)$^{-1}$ for 1,3-D and 3.69×10^{-2} (mg/kg/day)$^{-1}$ for 1,2-D

c. Dietary Risk Characterization

The dietary risk assessment is based solely on exposures through levels in ground water; no exposure is expected from foods planted in 1,3-D-treated soils and there is insufficient data to quantify whether surface water could contribute to dietary risk. Based on the results of the prospective ground water studies in Florida and Wisconsin, the Agency believes that 1,3-D, its degradates, and 1,2-D can migrate to ground water under certain conditions. 1,3-D levels can persist in colder areas and levels of the degradates persist even in warmer areas. In estimating cancer risks, the Agency is making the assumption that Telone and its degradates' concentrations are of equal toxicity (and carcinogenicity).

The results of the prospective ground water study in Wisconsin confirmed EPA's hypothesis that 1,3-D could pose unreasonable risks under certain conditions where temperatures are low. The Wisconsin site was chosen based on its higher-end vulnerability characteristics (ground water less than 20 feet from the surface, porous soils and very cold climate). Levels of 1,3-D plus its degradates in wells located within the field were associated with lifetime cancer risk estimates of 1×10^{-3} and levels in the off-site well were elevated even after a year. Given this high estimate, EPA has determined that nothing short of a prohibition will protect areas similar to the Wisconsin site. As of October 1, 1999, all 1,3-D labels will bear prohibitions in certain northern tier states where ground water is less than 50 feet from the surface and where soils are porous (Hydrological Type A). Dow AgroSciences has committed to develop tap water monitoring in Michigan and Connecticut, which are cold areas, but with vulnerability characteristics that are less extreme than those at the Wisconsin site.

EPA believes that areas of Florida are also vulnerable to ground water contamination from 1,3-D use. Based on the prospective ground water study conducted in Florida, EPA believes that residents who tap wells into shallow aquifers in the vicinity of treated fields are most at risk. The study results show that on-site wells with levels of 1,3-D and its degradates were associated with risk estimates of 4×10^{-6} to 3×10^{-5} in shallow wells. The off-site well was located approximately 100 feet from the treated fields and showed levels considerably less than those found in the on-site wells (1.15 ppb onsite compared to 0.074 ppb off-site). To confirm the results of the prospective ground water monitoring studies, Dow AgroSciences has committed to conducting tap water monitoring in two distinct agricultural areas in Florida: northern Florida and in the Biscayne Aquifer (Dade and Broward counties) once use expands to that area.

EPA also looked at other sources of ground water monitoring to determine whether additional prospective ground water monitoring studies should be required. Based on the EPA Pesticides in Ground Water database and the USGS NAWQA study, EPA believes that 1,3-D does not present risk of widespread ground water contamination. Rather, the data base on ground water monitoring supports developing label restrictions to prevent localized contamination. Dow AgroSciences is conducting additional tap water monitoring in the Pacific Northwest, the Southeast, Nebraska and Florida to support 1,3-D registrations under labeling as specified in this document.

Based on 1,3-D's chemical properties and pattern of use (i.e. soil injected), exposure from surface water is not expected to be significant. However, various models, as well as the results of the Florida study showing detectable levels in nearby ditches, support the need for a run-off study. Dow AgroSciences is also conducting other data on the environmental fate and ecotoxicity of the degradates, together with the run-off study to confirm that surface water residues are not a concern, or to provide data that allows EPA to characterize and address any potential concerns.

The Agency notes that the models used to estimate surface water levels are not suitable for tracking volatile soil fumigants through the environment; thus, EPA views the model results as highly uncertain. See sections III.E. 1. and 2. for more details on these models and the water-related studies assessing 1,3-D levels in the environment.

d. Occupational and Residential/Bystander Inhalation Risk Characterization

Estimates of intermediate-term systemic risks and excess individual lifetime cancer risk for custom operators, growers, and area residents/bystanders are given in Tables 11, 12, and 13.

(i) Risks from Intermediate Term Inhalation Exposure

For intermediate-term worker MOE's, the 4-hour samples were used to calculate mean air concentrations over all pooled replicates. Tables 11 and 12 present commercial "for-hire" handlers and private handler (grower) exposure and risk estimates, respectively, derived using these values.

Table 11 presents the exposure and risk estimates for commercial handlers who handle 1,3-D, based upon the air concentration values listed in Table 7. Intermediate-term MOE's for commercial handlers were calculated as the ratio of the intermediate-term inhalation NOEL to the mean air concentration (adjusted by a 90 percent protection factor for wearing a respirator).

(ii) Cancer Risks from Lifetime Inhalation Exposure

Cancer risks for commercial "for-hire" handlers were calculated by first estimating average daily doses (ADD's) in mg/kg/day, from the air concentrations. Information on days per year and hours per day were obtained for each crop, state by state, from Dow AgroSciences' Use and Usage Summary Report. However, for loaders, the report lists only the total hours per day spent actually engaged in loading (0.5 to 1.25 hour/day), not total hours spent on site. Therefore, to estimate their ADD's, the Agency therefore assumed loaders to be on site for the same number of hours per day as the applicators (5 to 10 hour/day, depending on state and crop).

Table 12 presents exposure and risk estimates for growers who handle 1,3-D, based upon the air concentration values listed in Table 7. For growers, the Agency assumed that the same person conducts both loading and application of 1,3-D products. Since growers presumably spend most of their work day engaged in application, rather than loading, intermediate-term risks

(MOE's) for growers were estimated using the air concentration for application rather than loading.

Cancer risks for growers assumed that the majority of the work day is spent applying 1,3-D and only as much time as is required to load the tank is spent actually engaged in loading. Therefore, the 4-hour samples were used in the calculation of the portion of the exposure resulting from application, and the task-specific samples were used to calculate the exposure incurred while loading (because 4-hour samples were not collected for the mini-bulk study, the Agency assumed that the task-specific loader air concentrations are experienced for the duration of a work cycle). The loading and application exposures were then added to estimate the total exposure for these individuals.

Cancer risk estimates were calculated using the following formula:

Excess cancer risk = $Q_1^* \times LADE$

where $Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$

and $LADE = \frac{\text{exposure (mg/kg/yr)}}{\text{365 days/year}} \times \frac{\text{20 (custom) or 30 (grower) years}}{\text{70 years}}$

The excess individual lifetime cancer risk estimates for occupational exposure range from 7.0×10^{-6} to 6.1×10^{-5} for custom handlers and 5.1×10^{-6} to 5.0×10^{-5} for private growers. These values may be overestimates because they do not reflect certain mitigation measures which are expected to reduce risk, but can not be quantified. Generally, the Agency considers risks of 10^{-6} or lower not to be of concern and carefully examines risks in the range of 10^{-4} to 10^{-6} to seek ways of reducing risks prior to reregistration (Barolo, 1996). Risks that fall closer to 10^{-4} where no additional mitigation is available are judged against the benefits of the pesticide's use. For 1,3-D, worker risks have been mitigated to extent feasible and are considered to be overestimates given that some label measures' mitigation value cannot be quantified and included in the risk estimate. In addition, the Agency considers the benefits of 1,3-D use to be high. Based on EPA's policy, the cancer risks of 1,3-D use for workers under current labels are considered to be acceptable.

Table 11. 1,3-D Custom Handler Intermediate-Term and Cancer Risks

Delivery Method	Example Crop	Task	Conc. µg/m³	hr/d	d/yr	Doses (mg/kg/day)[a] ADD	AADD	LADD	Cancer Risk	Int.-Term MOE[a]
Bulk	Cotton, AZ	Loader	1631	10	36	0	4.0e-03	1.1e-03	6.1×10^{-5}	560
		Applicator	1359	10	20	3.4e-02	1.9e-03	5.3e-04	2.8×10^{-5}	670
Bulk	Potatoes, WA	Loader	1631	8	24	3.2e-02	2.1e-03	6.1e-04	3.2×10^{-5}	560
		Applicator	1359	8	24	2.7e-02	1.8e-03	5.1e-04	2.7×10^{-5}	670
Mini-bulk	Tobacco, NC	Loader	464	5	10	5.8e-03	1.6e-04	4.5e-05	2.4×10^{-6}	1960
		Applicator	1359	5	10	1.7e-02	4.6e-04	1.3e-04	7.0×10^{-6}	670

a Adjusted for wearing of respirator or use of enclosed tractor cab (PF= 0.1)

Table 12. 1,3-D Grower Intermediate-Term and Cancer Risks

Delivery Method	Example Crop	Loading Conc. µg/m³	hr/d	Application: Conc. µg/m³	hr/d	d/yr	Doses (mg/kg/day)[a] ADD	AADD	LADD	Cancer Risk	Int.-Term MOE[a]
Bulk	Cucurbits, TX	10833	0.25	1,359	6	15	2.7e-02	1.1e-03	6.3e-04	3.4×10^{-5}	670
Bulk	Pineapples, HI	10833	1.25	1359	6	11	5.4e-02	1.6e-03	9.3e-04	5.0×10^{-5}	670
Mini-bulk	Tobacco, NC	464	0.5	1359	5	3.5	1.7e-02	-2	-10	5.1×10^{-6}	670
Mini-bulk	Peanuts, GA	464	1	1359	3	5	1.1e-02	1.5e-04	8.8e-05	4.7×10^{-6}	670

a Adjusted for wearing of respirator or use of enclosed tractor cab (PF= 0.1)

Table 13 presents exposure estimates for residents who live near treated fields.

Table 13. Residential/Bystander Exposure

Distance from treated field (m)	Study Site(s)	Doses (mg/kg/day)		Cancer Risk	Int.-Term MOE
		ADD	LADD		
1600	AZ	7.6 e-07	-3	$1.7x\ 10^{-8}$	2800
1200	AZ	2.9e-05	-1	$6.6x\ 10^{-7}$	1600
800	overall	5.7e-05	-2	$1.3x\ 10^{-6}$	8500
500	overall	7.7e-05	-3	$1.8x\ 10^{-6}$	6100
125	overall	2.6e-04	-1	$5.9x\ 10^{-6}$	1700
25	overall	4.8e-04	-2	$1.1x\ 10^{-5}$	920
5	overall	5.1e-04	-2	$1.2x\ 10^{-5}$	870
onsite	overall	8.3e-04	-4	$1.9x\ 10^{-5}$	500

Shading denotes edge of buffer zone required 300 ft from an occupied structure.

A buffer zone of 300 feet (approximately 125 meters) is required between all occupied structures and any field where 1,3-D is used to mitigate cancer risks to area residents whose homes are adjacent to treated fields.

The resident/bystander cancer risks may represent overestimates because individuals are not likely to spend 16 hours/day at a fixed distance for 30 years. Most people in regions where 1,3-D is used are not part of this subpopulation (i.e. do not live at the edge of a buffer zone), and are therefore presumed to be at somewhat lower risk. Also, the population of area residents living at the edge of the buffer zone is expected to be small, according to limited 1992 population survey data from Dow AgroSciences (Mehta 1994c). The population survey of states comprising 95 percent of 1,3-D usage showed that there were approximately 1088 residences in the 17 states where 1,3-D is used within one mile of 1,3-D treated fields (Mehta 1994c). There are no data on the number of people actually residing within 300 feet of treated fields.

Other risk-mitigation measures, including reduced application rates, increased injection depth, mandatory soil sealing, and soil moisture requirements may also reduce exposure to residents and bystanders, although the magnitude of this reduction cannot be quantified and therefore cancer risk estimates are likely to be overstated.

(iii) Aggregate Exposure and Cumulative Risk

EPA has aggregated inhalation and oral exposures to 1,3-D. For 1,3-D, the aggregate risk estimate would be calculated as follows:

$$\text{cancer risk}_{\text{inhalation exposure}} + \text{cancer risk}_{\text{water exposure}} = \text{aggregate lifetime cancer risk}$$

In calculating aggregate risk, EPA has determined that a reasonable worst-case exposure scenario would be comprised of the inhalation risk at the 300 foot buffer, derived from the average of three air monitoring studies, and water exposure risk from the on-site concentrations from the Florida study. EPA did not use the Wisconsin study values because as of August 1, 1999, use in areas similar to this site will be prohibited. Thus the aggregate risk would be:

$$6 \times 10^{-6}{}_{\text{inhalation exposure}} + 4 \times 10^{-6}{}_{\text{water exposure}} = 1 \times 10^{-5}$$

This aggregate cancer risk estimate, however, is based on assessments which contain numerous uncertainties from both the inhalation and water routes of exposure. Those uncertainties are detailed in section e. below.

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

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides for which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude

that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether 1,3-D has a common mechanism of toxicity with 1,2-D or other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this reregistration decision, EPA has assumed that 1,3-D and 1,2-D do not have a common mechanism of toxicity.

e. Uncertainties in the Risk Assessment and Risk Characterization Summary for 1,3-D

The Agency estimated cancer risk to growers, custom loaders/applicators, and residents/bystanders exposed to 1,3-D. Exposures via the dermal route were assumed to be negligible due to 1,3-D's high volatility and PPE requirements. Inhalation data were available and deemed appropriate for quantitative risk assessment, and thus, route to route extrapolation was not necessary for risk assessment. Oral and inhalation exposures were aggregated to develop risk estimates for residents/bystanders.

There are numerous uncertainties associated with the studies used to develop exposure estimates. Although the air monitoring studies were designed to evaluate exposures under normal use conditions, the influence of local environmental conditions, such as wind, soil type and weather patterns coupled with 1,3-D's volatility, resulted in mixed results. Results varied widely not only between sites, but also within sites on a day-by-day basis. The inhalation exposure estimates provided in this assessment are derived from a limited number of monitoring studies per site, which further increases the uncertainty.

Where possible, the Agency has incorporated label mitigation measures into the risk assessment. However, not all mitigation measures can be quantified. For example, the following mitigation measures are likely to further reduce worker and residential exposures to 1,3-D and associated cancer risk: reduced maximum application rates by 30-65% depending on the crop, increased soil injection depth from 10" to 12", soil sealing, and shank placement. The actual impact of these specific mitigation measures on reducing risk cannot be quantified with the available data.

Some air monitoring data need to be considered carefully, since the results did not show a reduction in exposure levels with certain mitigation measures, including use of enclosed cabs and dry disconnects, measures which are known to reduce exposures. The monitoring data did not show enclosed cabs to provide any reduction in exposure, possibly because applicators frequently left the enclosed cab to perform various tasks during the application process. Therefore, the 1,3-D labels were modified to require a respirator if the worker leaves the enclosed cab during application for any reason.

Dry disconnects, which are couplers designed to prevent leaks and emissions during fumigant transfers, appear to offer some exposure mitigation. Exposure reduction with dry disconnects could be quantified with the short-term sampling data but not with the 4-hour sampling data. The 4-hour sampling data suggest an increase in exposure with the use of dry disconnects, which is counter-intuitive. The reasons are likely due to a low number of sampling replicates and inherent variability in the study conditions.

There are uncertainties regarding practices of commercial operators. Exposure and risk estimates provided assume that commercial operators treat only one crop. Risk may be underestimated for commercial operators treating specialty crops in the Pacific Northwest. However, the Agency also believes that custom operators are in a better position to train personnel and maintain and update equipment, which results in better control over exposures to 1,3-D.

Some use practices have changed since the early studies were conducted, as have the laws governing agriculture. Just as local environmental conditions affect 1,3-D volatilization, individual growers' decisions on application rate, application method, injection depth, and soil sealing measures vary. For example, some growers use different application rates from year to year depending on the level of nematode infestation. Actual land use is unpredictable, and is ultimately driven by weather conditions, pests, and market pressures. Therefore, the inhalation exposure estimates and assumptions used represent a simplification of real world exposures.

The residential risk assessment is based on an average for the three sites monitored (N.C., WA, AZ), though 1,3-D air levels were quite different among the three sites. In addition, the monitoring at the N.C. site was conducted using drum loading, which was the predominant use at the time of the study, but which has since been phased out in favor of mini-bulk containers. Air levels with drum loading are expected to be higher than the mini-bulk containers since closed loading and dry disconnects (to prevent release of vapors) were not used with drums and since loading 1,3-D into the tractor-drawn tank was more frequent because the 55-gallon drums were smaller than the 1000 gallon mini-bulk. A mini-bulk study was submitted in 1996, but was only designed to measure worker exposures. Although higher levels were seen at the AZ and WA sites, EPA expects that the levels from the N.C. site, and thus the average overall, would have been lower had the mini-bulk system been used in the off-site monitoring.

For the water exposure component of the aggregate risk estimate, levels monitored from on-site wells were used in the assessment. As of August 1, 1999, however, there will be a 100 foot no-treatment buffer between treated fields and drinking water wells. The prospective ground water monitoring studies included limited off-site monitoring, which showed decreasing levels with increasing distance from 1,3-D treated fields. However, studies with more sampling and a study design to look specifically at levels in off-site wells would have to be conducted in order to quantify any relationship between distance to treated field and levels in wells used for drinking water.

Despite the limitations discussed in this section, EPA believes that the air and ground water monitoring are suitable for risk assessment. The studies were specifically designed to assess exposures to 1,3-D, taking into account the unique chemical qualities of 1,3-D, as well as the specialized 1,3-D loading and application techniques. However, the influence of a variety of environmental factors, particularly in the air monitoring studies, confounded many results. Even if additional data were required to address some of the shortcomings discussed above, EPA believes it would be unlikely that the additional effort would significantly improve the assessment given that confounding factors, such as wind and precipitation, could not be controlled under actual field test conditions.

E. Environmental Assessment

1. Environmental Fate and Transport

1,3-D dissipates primarily through volatilization, leaching, abiotic hydrolysis, and aerobic soil metabolism. Field volatility studies have shown that approximately 25 percent of the applied 1,3-D volatilizes during the two weeks after an application. Hydrolysis is temperature dependent and there is an increase in stability at lower temperatures. At 2°C, for both pH 5.5 and 7.5, the half-life of the parent was 90 to 100 days. Under aerobic conditions, half-lives ranging from 12 to 54 days were reported for the parent. The 3-chloroallyl alcohol is expected to be the main hydrolytic degradation product and 3-chloroacrylic acid the major aerobic metabolite. Laboratory mobility data, in addition to ground-water monitoring information, has clearly demonstrated that 1,3-D is highly mobile in soil. The Freundlich adsorption coefficients for 1,3-D were: K_d= 0.23 in loamy sand, K_d= 0.32 in sand; and in clay, K_d= 0.42 and 1.09.

a. Environmental Fate Assessment of 1,2-D

The formulated 1,3-D product contains from 0.1 to 0.06 percent 1,2-D. 1,2-D has a vapor pressure of 42 mm Hg at 20°C, has a water solubility of 2700 ppm at 20°C, is fairly stable to hydrolysis with a half-life of 77 days at pH 5.5, and has variable aerobic soil half-lives (41 to 69 days on four soils but stable in a sandy loam and a loam). With 1,2-D, photoreactions are also minimal with a half-life of 313 days with respect to the (OH) radical and stable with respect to ozone. Mobility studies give a strong indication of the extreme mobility of 1,2-D. Freundlich adsorption coefficients for 1,2-D were K_d=0.12, K_d=0.16, K_d=0.05, K_d=0.87 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and the Wahiawa sandy clay loam soils, respectively. In column leaching experiments using a Fuquay loamy sand with 0.64% organic carbon, a total of 85.8% of the applied 1,2-D leached from the soil column. For the Wahiawa sandy clay loam column with 2.32% organic carbon, a total of 73.2% of the applied was found in the leachate. Thus, mobility was somewhat inversely proportional to organic matter content.

b. Degradation

Hydrolysis. In buffered solutions at pH values of 5, 7, 9, the half-life of 1,3-D was 13.5 days at 20°C. A supplemental study at pH's 5.5 and 7.5 showed that the half-life of 1,3-D was 90

to 100 days at 2°C; 11 to 13 days at 15°C; and 2 days at 29°C. The chloroallyl alcohol is expected to be the main hydrolytic product (MRID 00158442).

Another supplemental study gave these results: at pH values of 5, 7, and 9, the half-life of 1,2-D was 51 days at 10°C; 10 to 13 days at 20°C; and 3 to 5 days at 30°C. The chloroallyl alcohol reached maximum concentrations of 32%, 72%, and 78% at 10°, 20°, and 30°C, respectively, and appeared to be stable to further hydrolysis. Hydrolysis of 1,3-D is pH independent and temperature dependent (MRID 00117050).

Photodegradation in Air. Both cis and trans 1,3-D (purity $\geq$ 94.8%) at 0.035 to 0.050 μg/ml did not degrade in borosilicate glass vials irradiated continuously for 30 days with a xenon arc lamp at 25°C and ambient humidity. After 30 days of irradiation, 95% to 98% of the applied radioactivity was recovered, as 1,3-D and no degradates were detected. In the dark control at 30 days post-treatment, 86% to 92% of the applied was recovered as 1,3-D and no degradates were observed. The study indicates that under these conditions, direct photolysis in air is not an important degradative mode for 1,3-D (MRID 40390101).

Reactions of 1,3-D and 1,2-D with ozone (O_3) and OH radicals were studied. The half-lives of 1,3-D with respect to the OH radical were seven and 12 hours for the trans and cis isomers, respectively. The observed degradation products were formyl chloride and chloroacetaldehyde. The half-lives of the trans and cis isomers of 1,3-D with respect to ozone were 12 and 52 days, respectively. The observed products were formyl chloride and chloroacetaldehyde, chloroacetic acid, HCL, CO, CO_2 and formic acid. The rate of photolysis alone seems insignificant (as was shown in the above 161-4 experiment) relative to the reactions of 1,3-D with ozone and the OH radicals. For 1,2-D the experiments also indicated that the only significant loss in the atmosphere would be a reaction with the OH radical. The half-life with respect to the OH radical was 313 days. A half-life of 313 days for 1,2-D would indicate the compound is sufficiently stable for worldwide long-distance transport (Tuazon, 1984).

Aerobic Soil Metabolism. The reported half-lives were 12 days in Catlin silt loam soil and 54 days in Fuquay loamy sand soil. These major nonvolatile degradates were isolated from the soils: cis/trans-3-chloroprop-2-en-1-ol (3-chloroallyl alcohol) and cis/trans-3-chloroprop-2-enoic acid (3-chloroacrylic acid). Numerous naturally-occurring carboxylic acids were also identified as degradates (MRID 42642301).

Anaerobic Soil Metabolism. In a silty clay loam soil at 15°C, the half-life of 1,3-D was reported to be 9.1 days. In a sandy loam soil at 15°C, the half-life was 7.7 days. In both a silty clay loam and sandy loam soil, at 25°C, the half-life was 2.4 days. The observed degradates were chloroacrylic acid, propionic acid, and an unknown (MRID 40025901)

c. Mobility

Column Leaching. The calculated Freundlich adsorption coefficients for 1,3-D were: loamy sand K_d= 0.23; sand K_d= 0.32; clay K_d= 0.42 and 1.09. The average maximum K_{oc} values

were 20 for sand, 25 for loamy sand, and 41 and 42 for two clay soils. In 30-cm columns of sand, loamy sand, and Florida clay, 1-3-D leached when more than 25 inches of water were applied. A total of 1.9% to 4.6% of the applied (unaged) radioactivity remained in the soils and 70% to 84% was found in the leachate (MRID 40538901).

Aged Column Leaching. Aged (31 days) 1,3-D residues were very mobile, with 25.6% to 32.0% of the applied radioactivity in the leachates of 30-cm columns of loamy sand soil. 1,3-D and the degradates 3-chloroallyl alcohol, chloroacrylic acid, and composite carboxylic acids (including acetic acid, oxalic acid, and propionic acid) were detected in both the leachates and the upper 2-cm soil segment extracts.

Batch Equilibrium (1,2-D). Freundlich adsorption coefficients for 1,2-D were 0.12 (n=1.13), 0.16 (n=1.13), 0.05 (n=1.63), and 0.87 (n=1.07), with corresponding K_{oc}'s of 18.8, 23.5, 10.4, 37.5 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and the Wahiawa sandy clay loam, respectively. The Freundlich desorption coefficients were 1.54 (n=0.99), 0.93 (n=1.22), 0.45 (n=1.52), and 3.45 (n=1.13), with corresponding Koc's of 241, 137, 93.8 and 149 for the Fuquay loamy sand, Metz sandy loam, Hanford loam, and Wahiawa sandy clay loam (MRID 42868501).

Column Leaching (1,2-D). The column leaching experiments indicated that for the Fuquay loamy sand, a total of 85.8% of the applied 1,2-D leached from the soil column. 1,2-D was distributed evenly throughout the column. For the Wahiawa sandy clay loam column, a total of 73.2% of the applied was found in the leachate. 1,2-D was not evenly distributed throughout the column and concentrations were highest near the final soil segment. Sorption coefficients estimated from the column leaching studies were 0.09 and 0.43 for the Fuquay and Wahiawa soils with corresponding Koc's of 14.1 and 18.5 (MRID 42868501).

Field Volatility. The factors influencing the volatility of 1,3-D from a field plot include, but are not limited to, soil organic matter, wind speed, soil moisture content, depth of incorporation-injection, soil temperature and soil porosity. Approximately 25 percent of the applied 1,3-D had volatilized by 14 days post-treatment (the final sampling interval). The volatilization of 1,3-D increased to 35.1 $mg/m^2 \cdot hour$ by 3 days post-treatment using the aerodynamic flux method with 33- and 90-cm sampling levels at the plot center. Volatilization ranged from 8.13 to 22.3 $mg/m^2 \cdot hour$ at 4-6 days, 4.6 to 17.5 $mg/m^2 \cdot hour$ at 7-9 days, 3.31 to 7.78 $mg/m^2 \cdot hour$ at 10-12 days, and 1.28 to 4.93 $mg/m^2 \cdot hour$ at 12-14 days (MRID 42545101).

1,3-D was soil injected at 12-14 inches at 346 lb. a.i. per acre into fields of sandy loam, loamy sand, and muck soils. At six to 12 hours post-treatment, 1,3-D reached a maximum concentration of 0.09 to 4.4 ppm at the 0.5-foot height above the soil surface. 1,3-D concentrations decreased to $\leq$ 0.03 ppm in all air samples from all locations by seven days post-treatment. It was not detected above the loamy sand and sandy loam soils by 14 days or above the muck soil by 21 days. Volatilization rates appeared to be inversely proportional to the amount of soil organic matter and proportional to soil porosity (MRID 41057701).

Telone II was applied at approximately 12.8 gallons per acre (121 lbs a.i./acre) to a fallow plot in Nevada and monitored over 7 days for airborne concentrations directly above the field and at locations up to one-half mile away (no MRID, EFGWB #91-0910). The average value of 1,3-D at a 6-inch height above the field during 7 days was 465.31 $\mu g/m^3$; at a 5-foot height at the edge of the field it was 94.81 $\mu g/m^3$; at a 5-foot height 100 feet from the field it was 39.39 $\mu g/m^3$; at a 5-foot height 1/4 mile from the field it was 5.17 $\mu g/m^3$; and at a 5-foot height one-half mile from the field it was 3.88 $\mu g/m^3$. Wind was a major factor in the dispersion of 1,3-D as higher concentrations were measured at night. During the day, the increase in wind velocity also increased vapor dispersion and lowered the measurable amount of material (Houtman et al., 1991).

In general, it is difficult to correlate soil moisture content with volatilization but Glotfelty and Schomberg (1989) and Lyman et al. (1982) suggest that the extreme drying of soil during drought will greatly decrease volatilization. Addition of moisture to dry soils will generally increase volatilization rates to a point beyond which additional moisture may have little effect or may start to decrease volatilization. The effect of changes in soil moisture on the volatilization of organics from soils with intermediate moisture contents is difficult to predict and depends upon the chemical, soil type, and the initial soil moisture content. In general, soil chisel incorporation of 1,3-D is accompanied by capping off the soil injection cores and/or by covering the field with plastic to minimize volatilization. Deeper injection minimizes the total amount of material that volatilizes and maximizes the amount of time from injection until volatiles are observed at the soil/air interface because of the increased soil distance through which the pesticide must diffuse.

d. Field Dissipation

Terrestrial Field Dissipation. Cis and trans 1,3-D applied at 345 lb a.i./A dissipated with an observed initial half-life of approximately one day and a second half-life of approximately seven days in the surface 24-inches of a bare-ground loamy sand soil (MRID 40855501).

1,3-D was applied at 342 lb a.i./A to a sand soil field plot in California. 1,3-D residues declined from a maximum of 130,000 ppb in the 0.3- to 0.45-meter layer of soil immediately after treatment to less than 10 ppb (detection limit) in any soil layer at 71 days. The degradate 3-chloroallyl alcohol declined from a maximum of 410 ppb in the 0.66 to 0.81 meter layer of soil at seven days posttreatment to less than 10 ppb in any soil layer at 71 days (MRID 40403301); additional data 3/24/89). The half-life is approximately seven days assuming a linear dissipation rate.

2. Water Resources

a. Ground Water

High-quality data indicate that 1,3-D leaches to ground water as a result of normal agricultural use. The 1986 Registration Standard and Special Review position document both

noted that the Agency has concerns for the potential for ground water contamination based on limited ground water monitoring data and laboratory data on the mobility of 1,3-D.

(i) Occurrence of 1,3-D in Ground Water

Monitoring information collected since 1983 indicates that 1,3-D has been detected in ground water in seven states in different regions of the U.S. with detected levels up to 800 ppb. Note from the previous section that the average daily concentration associated with a 10^{-6} lifetime risk is 0.3 ppb. 1,3-D has also been detected in ground water in The Netherlands in potato and flower bulb fields. Because an MCL has not been established for 1,3-D, no monitoring for this chemical is required under the Safe Drinking Water Act.

1,2-D has been detected in ground water in California, Connecticut, Florida, Hawaii, Massachusetts, Maryland, Nebraska, New York, Oregon, Washington, and Wisconsin. The MCL for 1,2-D is 5 ppb. Dow AgroSciences's information indicates an estimated HAL of 1.2 ppb. This section describes the data base used by EPA in developing its human health and environmental risk assessment for 1,3-D

(ii) Small-Scale Retrospective Monitoring

In 1986, the Agency requested that the registrant evaluate the impact of 1,3-D on ground water in varied environments with different use patterns. From 1989 to 1992, Dow AgroSciences conducted retrospective ground-water monitoring studies in Grant County, Washington; Merced County, California; Monterey County, California; Wayne County, North Carolina; and Scotts Bluff County, Nebraska. A sixth study in Florida was terminated when a nearby sinkhole collapsed and interfered with monitoring. Although there were significant problems with the study designs and sampling, results indicated that 1,3-D can leach to ground water.

Nebraska. 1,3-D concentrations in ground water ranged from 0.23 ppb to 3.86 ppb using a detection limit of 0.05 ppb. In this sugar beet study, maximum residues were seen in ground water eight months after application. The cis isomer was detected fourteen months after the 1,3-D application.

Washington. In the Washington potato study, the cis isomer of 1,3-D was detected at 0.03 ppb in two ground-water samples from two of the 50-foot wells on the site approximately one month after application.

North Carolina and California. No residues of 1,2-D; 1,3-D or its degradates were detected in ground water in the North Carolina tobacco study, the Merced County, California sweet potato study or the Monterey County, California carrot study.

(iii) State Ground-Water Monitoring Studies

The Pesticides in Ground Water Database (EPA, 1992) indicates detections of 1,3-D in three states -- Florida, New York, and Washington -- because of normal field use. The database also reports detections of 1,3-D in California because of point source problems (i.e., misuse or a spill). Additional monitoring in Hawaii, Massachusetts, Mississippi, and Oregon has not yielded any detections of 1,3-D.

California. In 1987, 1988, and 1991, 1,3-D was detected in six wells in Del Norte, Fresno, and Santa Clara counties. Using a method detection limit of 0.5 ppb, concentrations ranged from 0.89 to 1.9 ppb. No information is available about the source of the detections. 1,3-D was not detected in 9,915 wells sampled from May 1979 to June 1996 using detection limits ranging from 0.02 to 100 ppb (Bartkowiak, 1997).

In Riverside, California, illegal use of 1,3-D in 1986 and 1987 resulted in six detections in one irrigation well ranging from 6.8 to 31 ppb (EPA, 1992).

Florida. From 1987 to 1996, a total of 9,505 wells were monitored for 1,3-D residues. The present detection limit is 0.0850 ppb, but has varied in the past (Fisher, 1997). Although 1,3-D was detected in three wells at concentrations ranging from 0.28 to 8 ppb, these are probably most likely 1,2-D detections (Riotte, 1997).

Hawaii. The Hawaii Department of Health monitors for 1,3-D in ground water because of its use as a soil fumigant in the pineapple industry. From 1979 to 1987, samples were analyzed from 54 wells and no residues were found (Giambelluca, 1988).

Massachusetts. In the summer and fall of 1985, several Massachusetts agencies analyzed samples from 239 wells in tobacco-growing areas. Using a detection limit of 1.0 ppb, no 1,3-D was found. No samples were analyzed for degradates (Massachusetts Interagency Task Force, 1986).

Mississippi. In Mississippi, a statewide drinking-water ambient monitoring survey was designed to sample for pesticides. 1,3-D is not widely used in Mississippi (Landreth, 1997), and the reported monitoring may not have been conducted in areas where 1,3-D has been used. To date, 348 deep wells have been sampled and analyzed for cis and trans 1,3-D. No residues have been detected using a detection limit of 0.10 ppb for the parent.

New York. Although monitoring for 1,3-D is not usually done by the State, several studies have been done by researchers to determine the leaching potential of 1,3-D in Suffolk County, New York. In one of the studies done in 1983, 1,3-D was detected in ground water at concentrations ranging from 37 to 270 ppb in one well over a period of three months. The detection limit used in this study was 2 ppb (Loria et al., 1986). In another study, no 1,3-D was detected in nine wells located near fields where 1,3-D was applied. The detection limit used here was also two ppb (Kotcon and Loria, 1987).

Oregon. In Oregon, a standard analytical screen that includes 1,3-D is performed for every well that is sampled. Many of these wells are not in agricultural areas or 1,3-D use areas. Some 1,3-D has been found using a detection limit of 0.5 ppb. However, problems with data retrieval make it impossible to determine how much or how many times 1,3-D has been detected (McLaughlin, 1997).

Washington. From 1990 through 1996, the Washington State Department of Ecology analyzed 196 wells for cis and trans 1,3-D. The trans isomer was found on April 30, 1991 in three wells at concentrations of 0.10, 0.11, and 0.11 ppb. The same three wells were re-sampled in February 1992 (10 months later) and no 1,3-D was detected (Larsen, 1997).

(iv) Small-Scale Prospective Monitoring

Wisconsin. The Agency required that Dow AgroSciences conduct a small-scale prospective ground-water monitoring study in a northern climate because of the concern for 1,3-D persistence in cold climates. Dow AgroSciences conducted site selection in Idaho, Nebraska, Wyoming, Michigan, Minnesota, North Dakota and Wisconsin. The site selection criteria required shallow ground water, porous soils, minimal slope, no impeding layer (such as a clay barrier) between the treatment zone and ground water, no prior usage of 1,3-D and no concurrent usage of 1,3-D in the vicinity of the test site. Potato-growing areas in these states were targeted since potatoes are a major use site for 1,3-D use. The site in Wisconsin met all of EPA and Dow AgroScience's selection criteria and was thus selected to represent a vulnerable site in a northern use area.

On September 9, 1997, Telone II was applied to a sugar beet field at 28 gallons per acre (266 lb ai/acre). Levels peaked at 579 ppb in on-site wells after one year of monitoring. In the off-site well located 65 feet down gradient, 1,3-D levels peaked at 173 ppb.

1,2-D was detected in all eight of the onsite shallow wells and four of the onsite deep wells at concentrations ranging from trace levels to 3.9 ppb using a quantitation limit of 0.05 ppb.

Dow AgroSciences also submitted, though with insufficient information to allow formal EPA review, results to predict 1,3-D levels at further distances off-site. Using the program ModFlow, which looked at concentrations of 1,3-D only, downgradient concentrations reached 0.3 ppb at 1100 feet after 2.5 years. The same model predicts a time-weighted concentration at 100 feet downgradient of 8.4 ppb after the first year and 13.4 ppb after the second year. Given the levels and trends seen in the modeling and monitoring, EPA does not believe that the 100 feet buffer alone would provide sufficient mitigation for human health risks.

Florida. In 1993, Dow AgroSciences initiated a small-scale prospective monitoring study in southern Florida. Because of concerns for potential ground-water contamination, EPA and the State of Florida became involved in the study design and review. On December 13, 1995, Telone C-17 was applied to a pepper field at approximately 22.5 gallons per acre. Study results showed

detections of 1,3-D, 1,2-D and both the 3-chloroacrylic acid and 3-chloroallyl alcohol degradates in ground water.

Most Floridian soils are porous with shallow water tables. While most residents of the state obtain water from public systems which tap aquifers that are not surficial, there are areas where 20% or more of the residents obtain water from private wells that tap surficial aquifers (in some counties up to 80%). Some areas have a spodic horizon between the surficial and deeper aquifers, while other areas overlay karst geology (highly permeable, rocky soils). Note that as of August 1, 1999, the 1,3-D labels prohibit use in areas of karst geology. In order to support agriculture in certain areas of Florida, perimeter ditches are used to either raise the availability of water serving the field, or to divert excess rainfall. There can be extensive interaction between these ditches, surface water and surficial ground water aquifers. Because of the warmer temperatures, EPA expected the rate of degradation to be relatively higher than in areas with lower temperatures.

In the uppermost part of the aquifer (one to two foot wells which were not used in the drinking water assessment) 1,3-D was detected in all eight of the onsite wells. Detections peaked at 833 ppb and declined to 0.19 ppb by 110 days after application. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 360 ppb and 3-chloroacrylic acid at concentrations ranging from trace levels to 424 ppb. 1,2-D was detected at concentrations ranging from trace levels to 11.5 ppb. Five offsite wells also contained 1,3-D residues at concentrations ranging from trace levels to 0.23 ppb.

At a depth of 10 feet from the surface, 1,3-D was detected in all eight of the onsite wells. Concentrations ranged from trace levels (0.05 ppb) to 21.6 ppb. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 13.5 ppb and 3-chloroacrylic acid at concentrations ranging from trace levels to 8.79 ppb. 1,2-D was detected at concentrations ranging from trace levels to 1.28 ppb.

Early in the study, 1,3-D was briefly detected in the deep part of the aquifer (70 feet), however, the concurrent water blanks from the bailers used to sample the deep wells contained similar 1,3-D concentrations. Also, the bromide tracer did not reach these deep wells during the study, suggesting these detections were the result of inadvertent sample contamination. However, the information submitted is as follows: 1,3-D was detected in two of the three onsite wells in the Lower Tamiami Aquifer with concentrations ranging from 0.05 to 1.03 ppb. These wells also contained 3-chloroallyl alcohol at concentrations ranging from trace levels to 7.85 ppb and chloroacrylic acid at trace concentrations. 1,2-D was detected at concentrations ranging from trace levels to 0.07 ppb. No 1,3-D residues were found in the offsite deep well; 1,2-D was detected in this well at trace levels in all but one sampling event.

(v) The National Water Quality Assessment Program

In 1991, the U.S. Geological Survey initiated the National Water Quality Assessment program (NAWQA) to study national water quality. The monitoring, which is being conducted in

four parts, will assess more than 50 of the largest river basins and aquifers (study units) and cover the drinking water sources of about 70 percent of the U.S. population.

NAWQA included 1,3-D (both isomers) and 1,2-D among the compounds tested. Areas of the country with the highest 1,3-D use are covered, at least in part, by 10 study units. None of the reports released to date have shown detections of 1,3-D in wells or other water resources. The summary reports, however, do not allow the Agency to assess whether 1,3-D use took place in the vicinity of water sampling locations and did not sample for the acid and alcohol degradates.

Nonetheless, the information in the NAWQA reports is useful. Although no information in the reports directly links 1,3-D use to the monitored wells, the absence of detections suggests that 1,3-D use does not result in widespread aquifer contamination.

b. Modeling and Occurrence of 1,3-D in Surface Water

A mixture of the cis and trans isomers of 1,3-D is typically applied at a rate of several hundred pounds per acre at a depth of approximately one foot below the soil surface. It then moves through the soil profile, with some escaping up through the treatment zone to the atmosphere. One study (MRID 42545101) showed that approximately 25 percent of applied 1,3-D volatilizes, however, environmental and soil conditions will affect the actual amount. The 1,3-D isomers undergo fairly rapid dissipation in soil via volatilization and to a lesser extent degradation. Also, only chemical molecules that have diffused into the top one to two centimeters of soil at the time a runoff event occurs would likely be susceptible to runoff. Such factors should somewhat limit the runoff potential of the 1,3-D isomers. However, extremely high application rates of several hundred pounds per acre coupled with low soil/water partitioning, indicate some potential for runoff.

In addition to runoff, another route of 1,3-D transport to surface water could be by dissolution of volatilized compound from the air. Dow AgroSciences has proposed this route to explain 1,3-D residues in perimeter ditches of a treated field in Florida (see previous discussion on the Florida prospective ground-water monitoring study) prior to any runoff events. Dow AgroSciences postulates that during conditions of low wind, volatilized 1,3-D will move close to the ground due to its higher density than air, and that some of the 1,3-D passing over surface water will be transported from the air to the water and dissolved. Another possibility is that in Florida, ground water may be contributing to residues in surface water through ground and surface water interactions. Both the 3-chloroallyl alcohol and 3-chloroacrylic acid were detected in surface water along with 1,3-D in the prospective ground-water monitoring study in Florida.

1,3-D will probably undergo rapid rates of dissipation in most surface waters due to volatilization and, to a lesser extent, by abiotic hydrolysis and possibly biodegradation. Volatilization rates will be highest for shallow turbulent water and decrease with increasing depth and decreasing turbulence. Isomer mixture soil/water partition coefficients of 0.23 in a loamy sand, 0.32 in a sand, 0.42 and 1.09 in two clay soils indicate that the concentration of 1,3-D in sediment pore water will be comparable to that adsorbed to suspended and bottom sediment.

Concentrations in the water column will be less than in the sediment pore water, but should still be somewhat comparable to concentrations adsorbed to sediment. The low octanol/water partitioning of 1,3-D indicates that its bioaccumulation potential is probably low.

c. Drinking Water Exposure Assessment

Please refer back to section III. B.3. for a full discussion of the levels used for the drinking water exposure and risk assessment.

3. Ecological Assessment

a. Toxicity to Terrestrial Animals

(i) Birds, Acute and Subacute

An acute oral (LD_{50}) study using the technical grade of the active ingredient (TGAI) were submitted to establish the toxicity of 1,3-D to birds. The result of the Northern bobwhite test is presented in Table 14.

Table 14. Avian Acute Oral Toxicity

Species	% ai	LD_{50} (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification[1]
Northern bobwhite *(Colinus virginianus)*	92	152	moderately toxic	00118938 Wildlife International /1982	Core

[1] Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)

Since the LD_{50} falls in the range of 51 to 500 mg/kg, 1,3-D is moderately toxic to avian species on an acute oral basis (MRID 00118938).

Two subacute dietary studies on the Mallard duck and Northern bobwhite using the TGAI were submitted to establish the toxicity of 1,3-D to birds. The avian acute dietary LC_{50} test is a subacute, eight-day dietary laboratory study designed to determine the dietary concentration of toxicant that is likely to cause 50 percent mortality in a test population of birds. The TGAI is administered to juvenile birds' diets for five days, followed by three days of "clean" diet. Results of these tests are presented in Table 15.

Table15 Avian Subacute Dietary Toxicity

Species	% ai	LC_{50} (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite *(Colinus virginianus)*	92	>10,000	Practically Nontoxic	STEODI03 Fink, 1975	Core
Mallard duck *(Anas platyrhynchos)*	92	>10,000	Practically Nontoxic	00120908 Fink, 1975	Core

The LC_{50} is higher than 2,000 ppm. This toxicity value indicates that 1,3-D is practically nontoxic to birds on a subacute dietary basis; however, this result is inconsistent with the acute oral test. The subacute dietary results could be explained by the fact that the length of time to perform the test is long and, because 1,3-D is highly volatile, it may not remain in the food. Therefore, the birds may have received an inadequate dose resulting in a low dose response. Field study data indicate that volatility is the primary route of 1,3-D dissipation with dispersal increasing to 35.1 mg/m^2/hour by three days. Therefore, the weight of evidence indicates that 1,3-D is moderately toxic to birds (LD_{50} = 157 mg/kg) (MRID's STEODI03 and 00120908).

(ii) Birds, Chronic

Avian reproduction studies using the TGAI were not required for 1,3-D in the 1986 Registration Standard. Since the field dissipation half-life is roughly one week and generally only one application is made per year, birds are not expected to be exposed to repeated or continuous residues of 1,3-D.

(iii) Mammals, Acute and Chronic

The toxicity values for mammals are presented in Table 16 (USEPA, 1997). Results indicate that 1,3-D is slightly toxic to toxic to small mammals on an acute oral basis (640 mg/kg) (MRID #0039693).

Table 16. Mammalian Toxicity

Species	Test Material	Test Type	Toxicity Value	Affected Endpoints	MRID No.
Laboratory mouse *(Mus musculus)*	Telone II	Acute Oral	LD_{50} 640 mg/kg (M&F)	Mortality	00039683
Laboratory rat *(Rattus norvegicus)*	1,3-dichloropropene	Acute Inhalation	LC_{50} 729 ppm/4 hours	Mortality	235350
Laboratory mouse *(Rattus norvegicus)*	1,3-dichlorpropene	Chronic Inhalation	NOEL Systemic 730 ppm	No systemic effects observed at 730 ppm	00039685
Laboratory rat *(Rattus norvegicus)*	90% ai cis + trans	Developmental - Inhalation	NOEL Maternal 20 ppm NOEL Developmental 60 ppm	Maternal - body weight loss and reduced food consumption Developmental - delayed ossification of vertebral centra	00144715 00152848
Laboratory rat *(Rattus norvegicus)*	96% ai cis + trans	13 Week Feeding	NOEL 5 mg/kg/day LOEL15 mg/kg/day	Body weight, hyperkeratosis and/or basal cell hyperplasia of the non-glandular portion of the stomach	42954802

(iv) Insects

A honeybee acute contact study using the typical end-use product was not required in the 1986 Registration Standard. The registered application method via soil injection prior to planting should not result in honeybee exposure. However, exposure in adjacent habitats could occur because of 1,3-D's volatility and the probability of the chemical drifting offsite.

Results from a study submitted for contact toxicity on honeybees are presented in Table 17, and indicate that 1,3-D is moderately toxic to bees on an acute contact basis (MRID's 00028772 and 00018842).

Table 17. Non-target Insect Acute Contact Toxicity

Species	% ai	LD_{50} (μg/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Honey bee *(Apis mellifera)*	TGAI	6.6	Moderately toxic	00028772/ Atkins/1972	Core
Honey bee *(Apis mellifera)*	Formulation	6.6	Moderately toxic	00018842/ Atkins/1969	Core

b. Terrestrial Field Testing

Based on the application method and use pattern, terrestrial field testing of 1,3-D has not been requested or submitted to support reregistration.

c. Toxicity to Freshwater Aquatic Animals

(i) Freshwater Fish and Amphibians, Acute

Freshwater fish toxicity studies using the TGAI were submitted to establish the toxicity of 1,3-D to fish and amphibians. Results of these tests are presented in Table 18. Since the LC_{50} falls in the range of 1 to 10 ppm, 1,3-D is moderately toxic to freshwater fish on an acute basis. (MRID's 00039692 and STE0DI02). The registrant is also conducting additional studies on the degradates as confirmatory data.

Table 18. Freshwater Fish Acute Toxicity

Species/ (Flow-through or Static)	% ai	96-hour LC_{50} (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Walleye *(Stizostedion vitreum)* static	100	1.08 (measured)	Moderately Toxic	40098001/ Mayer & Ellersieck/ 1986	Core
Largemouth Bass *(Micropterus salmoides)* static	100	3.65 (measured)	Moderately Toxic	40098001/ Mayer & Ellersieck/ 1986	Core
Rainbow Trout *(Salmo gairdneri)* static	92	3.9 (measured)	Moderately Toxic	00039692/ Bentley/ 1975	Core
Fathead Minnow *(Pimephales promelas)* static	100	4.1 (measured)	Moderately Toxic	40098001/ Meyer & Ellersieck/ 1986	Core
Rainbow Trout *(Salmo gairdneri)* static	92	5.9 (unknown)	Moderately Toxic	STE0DI01 USEPA 1977	Core
Bluegill Sunfish *(Lepomis macrochirius)* static	≥80	6.1 (nominal)	Moderately Toxic	00117043/ Buccafusco/ 1981	Supplemental[1]
Bluegill Sunfish *(Lepomis macrochirirus)* static	92	6.7 (unknown)	Moderately Toxic	STE0DI02 USEPA 1977	Core
Bluegill Sunfish *(Lepomis macrochirirus)* static	92	7.1 (measured)	Moderately Toxic	00039692/ Bentley/ 1975	Core

[1] Rated supplemental because the dose levels were not high enough to calculate an LD_{50}.

(ii) Freshwater Fish, Chronic

Dow AgroSciences will conduct a freshwater fish early life-stage study (72-4) using Rainbow trout as confirmatory data. As stated previously in this document, EPA believes that 1,3-D will undergo rapid rates of dissipation in most surface waters due to volatilization and, to a lesser extent, by abiotic hydrolysis and possibly biodegradation.. However, given the high acute

LC_{50} value and a half-life of 13.5 days, the Agency is interested in comparing the results to the run-off study to gage possible exposures to freshwater fish on a chronic basis.

(iii) Freshwater Invertebrates, Acute

Results of the freshwater invertebrate acute studies are presented in Table 19.

Table 19. Freshwater Invertebrate Acute Toxicity

Species/(Static or Flow-through)	% ai	48-hour LC50/ EC50 (ppm) (measured/nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea *(Daphnia magna)*	100	0.09	Highly Toxic	40098001/ Mayer & Ellersieck/ 1986	Core

Since the LC50/EC50 is less than 0.1 ppm, 1,3-D is considered very highly toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 40098001). The registrant is also conducting the 72-2(a) study on the degradates to compare to the assumption in the risk assessment that the degradates are of equal or less toxicity to 1,3-D.

(iv) Freshwater Invertebrate, Chronic

Dow AgroSciences has agreed to conduct a freshwater invertebrate chronic study (72-4(b)) using *Daphnia magna*.

The data at hand on acute levels show that the LC_{50} for aquatic invertebrates (0.09 ppm) is less than 0.1 ppm. Also, at all registered application rates, initial, 21-day, and 90-day surface-water EECs, as calculated by GENEEC, are less than one percent of the lowest LC_{50} for freshwater invertebrates. However, because GENEEC is not suitable for tracking soil fumigants and since EPA expects rapid rates of dissipation in most surface waters, EPA is less concerned about chronic risks than for acute risks for aquatic invetebrates.

(v) Freshwater Field Studies

A freshwater field study using the TGAI is not required for 1,3-D.

d. Toxicity to Estuarine and Marine Animals

(i) Estuarine and Marine Fish, Acute

The 1986 Registration Standard did not require estuarine and marine studies. Use of 1,3-D, however, is expected to expand into areas, namely Florida, that could impact estuarine and marine environments. The registrant has committed to submit by June 1, 1999 a study on 1,3-D for acute estuarine and marine fish using the sheepshead minnow. Studies on estuarine and

marine fish for the degradates are reserved pending the outcome of this 1,3-D acute study and other studies.

(ii) Estuarine and Marine Fish, Chronic

Chronic tests of estuarine/marine fish test using the TGAI are not required for 1,3-D at this time. This requirement will be re-evaluated after reviewing the freshwater fish toxicity information.

(iii) Estuarine and Marine Invertebrates, Acute

The registrant is conducting confirmatory studies on the mysid shrimp (72-3(c)) and Eastern oyster (72-3(b)) to test the toxicity of 1,3-D on estuarine and marine invertebrates. As noted above, 1,3-D use is expected to increase in areas and could impact estuarine and marine environments.

(iv) Estuarine and Marine Invertebrate, Chronic

Chronic tests of estuarine and marine invertebrates using the TGAI are not required for 1,3-D at this time. This requirement will be re-evaluated after examining the results of the chronic freshwater invertebrate, acute marine/estuarine studies and the run-off study.

(v) Estuarine and Marine Field Studies

A field study in estuarine/marine environments using the TGAI is not required for 1,3-D.

e. Toxicity to Aquatic and Terrestrial Plants

The registrant has committed to conducting Tier I and Tier II tests for aquatic and terrestrial plants using the TGAI. These studies are being conducted because 1,3-D is labeled for use as an herbicide and has phytotoxicity warnings. The registrant has also committed to conducting Tier I and Tier II tests for aquatic plants for the degradates (3- chloroacrylic acid and 3-chloroallyl alcohol).

f. Toxicity of Degradation Products and Manufacturing Impurities

No data were available to conduct a full ecological assessment for 1,2-D, 3-chloroallyl alcohol or 3-chloroacrylic acid. All of these chemicals are considered at least as toxic as the parent. As noted throughout this section, the registrant is conducting various environmental fate and ecotoxicity studies on the degradates.

4. Exposure and Risk Characterization

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

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The quotient method is used to integrate the results of exposure and ecotoxicity data. In this method, risk quotients (RQ's) are calculated by dividing exposure estimates by both acute and chronic ecotoxicity values.

RQ = EXPOSURE/TOXICITY

RQ's are then compared to EPA's levels of concern (LOC's). These LOC's are criteria used by EPA to indicate potential risk to non-target organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on non-target organisms. LOC's currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high and regulatory action may be warranted in addition to restricted use classification; (2) **acute restricted use** - the potential for acute risk is high but may be mitigated through restricted use classification; (3) **acute endangered species** - the potential for acute risk to endangered species is high and regulatory action may be warranted; and (4) **chronic risk** - the potential for chronic risk is high and regulatory action may be warranted. Currently, the Agency does not conduct assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: LC50 (fish and birds), LD50 (birds and mammals), EC50 (aquatic plants and aquatic invertebrates) and EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies assessing chronic effects are: LOEC (birds, fish, and aquatic invertebrates), NOEC (birds, fish and aquatic invertebrates) and MATC (fish and aquatic invertebrates). For birds and mammals, the NOEC value is used as the ecotoxicity test value in assessing chronic effects. Other values may be used when justified. Generally, the MATC (defined as the geometric mean of the NOEC and LOEC) is used as the ecotoxicity test value in assessing chronic effects to fish and aquatic invertebrates. However, the NOEC is used if the measurement endpoint is reproduction or survival. Risk presumptions, along with the corresponding RQ's and LOC's are listed in Table 20.

Table 20. Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items
[2] $\frac{\text{mg/ft}^2}{\text{LD50 * wt. of bird}}$ [3] $\frac{\text{mg of toxicant consumed/day}}{\text{LD50 * wt. of bird}}$

Table 21. Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = (ppm or ppb) in water

Table 22. Risk Presumptions for Plants

Risk Presumption	RQ	LOC
Terrestrial and Semi-Aquatic Plants		
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
	Aquatic Plants	
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

[1] EEC = lbs ai/A
[2] EEC = (ppb/ppm) in water

For pesticides applied as nongranular products (e.g., liquids, dusts applied via broadcast methods, etc.), the EECs on food items following product application are compared to toxicity values to assess risk (Fletcher et al., 1994). However, the Agency currently does not have routinely used methods for predicting EECs for soil fumigants. When available, risk determinations can be made when actual concentrations have been reported in terrestrial field dissipation studies or other studies submitted in support of reregistration.

b. Field Data Used for Risk Assessment

In this assessment, post-application 1,3-D residues detected in soil, water, and air samples are compared to toxicity values. It should be noted that this risk assessment relies on very little data, measured or predicted. It should also be noted that the reported field studies were conducted with lower application rates than allowed on some crops. 1,3-D concentrations in soil, water, and air will be higher with corresponding higher application rates. However, the risk quotients calculated from the environmental data do provide information about the potential risk of 1,3-D application to non-target species. In some instances, extrapolations were made to higher application rates, however, these levels are a simplification of what actual levels may be. Environmental fate and air monitoring study results have not established a correlation between the level of applied product and subsequent levels in the environment.

Two terrestrial field dissipation studies (MRID's 40403301 and 40855501) provided 1,3-D residue concentrations in treated soil and subsequent dissipation rates. A prospective ground-water monitoring study in Florida yielded 1,3-D concentrations in water collected from ditches adjacent to treated fields (MRID 44005201). Three field volatility studies evaluated atmospheric concentrations of 1,3-D under field conditions (MRID's 42545101, 41057701 and EFGWB 91-0910).

c. Exposure and Risk to Non-target Terrestrial Animals

1,3-D is used on over half a million acres of cropland each year (see Table 1). For orchard trees and grapevines, approved rates are as high as 556 lbs a.i./A. However, because the application method reduces terrestrial exposure and because of the relatively low toxicity to mammals, its use is not expected to result in large incidents of mortality. No avian mortality incidents have been reported in relation to 1,3-D applications. Telone C-17 contains chloropicrin, which is a contact irritant to humans and serves as a warning to applicators. It is assumed this product could affect birds and wild mammals in the same manner, resulting in avoidance and thereby reducing the risk of exposure.

The Agency does not have a standard protocol for conducting terrestrial risk assessments on terrestrial organisms when chemicals are applied via soil injection methods. Instead, in this risk assessment, animals were assumed to be exposed through dietary intake of contaminated soil. Beyer et al. (1994) analyzed scat samples from a variety of vertebrate species to determine the percent of soil in the diet. His work showed that the quantity of soil in animal diets can range from less than two percent up to 30 percent. Animals can ingest soil intentionally to provide

missing minerals or unintentionally through preening and grooming activities or by particles adhering to food items such as roots, tubers or foliage. Many species of birds also inadvertently ingest soil when probing soft soils for food. For the purpose of calculating risk quotients, it was assumed that 100 percent of the soil in an animal's diet comes from the treated field.

(i) Birds

Because of the application method, 1,3-D use in chemical soil fumigation operations is not expected to present a significant hazard to avian species. However, birds could be exposed through both dietary and inhalation routes. The available toxicity information allowed an acute risk determination through dietary routes. However, no information is available on acute inhalation toxicity to birds but the acute risk associated with this type of exposure is probably insignificant.

Risk quotients were calculated from the field dissipation residue data submitted to the Agency in support of reregistration. The Northern bobwhite LD_{50} was chosen to calculate the following risk quotients because of the wide range between the avian LD_{50} and the two avian LC_{50}'s determined for this chemical. The discrepancy between the two endpoints is believed to be the result of the difficulty of keeping 1,3-D concentrations constant on the test diets considering 1,3-D's volatility. The following equation was used to determine the avian acute risk quotients:

$$LD_{50}s/day = \frac{EEC * (\% \text{ daily food consumption} * \% \text{ soil in diet})}{LD_{50}}$$

The results of these calculations are presented in Table 23.

Table 23. Risk Quotients for Acute Avian Exposure --based upon an Avian LD_{50} of 152 mg/kg and a mean and range of soil consumption rates[1] of 10.6% (>2% to 30%) of the total daily food intake and a daily food consumption rate of 18% of total body weight. EECs are taken from a field dissipation study submitted to the Agency (MRID 40403301).

Application Rate and Injection Depth (MRID #)	EEC (ppm)	Avian LD_{50} (mg/kg)	Daily Soil Ingestion Rate[1]	RQ
342 lbs ai/acre (13-15 inches) (404033-01)	130	152	Mean = 10.6% Range = >2 to 30%	Mean =0.02 Range = <0.003 to 0.05

[1] Soil consumption values are taken from Beyer et al. 1995.

From Table 20, the LOC's for avian species are: 0.5 (acute high risk); 0.2 (acute restricted use); 0.1 (acute endangered species); and 1 (chronic risk). An evaluation of the above risk quotients shows that no LOC's are exceeded for avian species. If it assumed that the concentration in soil is directly proportional to the application rate, the EEC would be 208 ppm at the highest rate of 556 lbs a.i./acre. At this concentration, no LOC's were exceeded. At this soil concentration, a 100-gm bird with an LD_{50} of 152 mg/kg would need to consume 72 grams of soil to attain this equivalent dose. This evaluation indicates that 1,3-D use should not result in significant acute mortality to avian species under any application scenario.

No avian chronic test data were required to support reregistration. Since 1,3-D is generally only applied once per growing season and because it has a relatively short field dissipation half-life, it is not expected to result in long-term exposure or subsequent chronic effects.

(ii) Mammals

Because of the application method, the use of 1,3-D in chemical soil fumigation operations is not expected to present a significant hazard to mammals. However, exposure could occur through both dietary and inhalation routes. No incidents of mammalian mortality have been reported due to the application of 1,3-D.

Risk quotients were calculated from field dissipation data and laboratory mouse LD_{50} data using the following equation:

$$LD_{50}s/day = \frac{EEC * (\% \text{ daily food consumption} * \% \text{ soil in diet})}{LD_{50}}$$

The results of these calculations are presented in Table 24.

Table 24. Risk Quotients for Acute Mammalian Exposure -- based upon a mammalian LD_{50} of 640 mg/kg and a mean and range of soil consumption rates[1] of 4.4% (>2% to 17%) of the total daily intake and a daily food consumption rate of 95% of total body weight. EECs are from a field dissipation study submitted to the Agency (MRID 40403301).

Application Rate and Injection Depth (MRID #)	EEC (ppm)	Mammalian LD_{50} (mg/kg)	Daily Soil Ingestion Rate[1]	RQ
342 lbs ai/acre (13-15 inches) (404033-01)	130	640	Mean = 4.4% Range = >2 to 17%	Mean =0.008 Range = <0.003 to 0.03

[1] Soil consumption values are taken from Beyer et al. 1995.

From Table 20, the LOC's for mammal are as follows: 0.5 (acute high risk); 0.2 (acute restricted use); 0.1 (acute endangered species); and 1 (chronic risk). Evaluation of the above risk quotients show that no LOC's are exceeded for mammalian species. If it is assumed that the concentration in soil is directly proportional to the application rate, the EEC would be 208 ppm at the highest rate of 556 lbs a.i./acre. At this soil concentration, a 20-gram mouse with an LD_{50} of 640 mg/kg would need to consume 61 grams of soil (three times its body weight) to attain this equivalent dose. Therefore, 1,3-D use should not result in significant acute mortality to mammalian species via dietary exposure under any application scenario.

Acute inhalation toxicity was assessed by comparing mammalian inhalation data to the amount of volatilized chemical found above the treated fields. Using an application rate of 346 lbs a.i./acre, 1,3-D concentrations at a height of 6 inches above the soil surface never exceeded 4.4 ppm. This value is less than 0.01 percent of the mammalian inhalation LD_{50} of 713 mg/kg.

Even if 1,3-D concentrations in the air are directly proportional to the application rate, atmospheric concentrations are not expected to reach toxic levels. This result also indicates that 1,3-D use should not result in significant acute mortality to mammalian species via inhalation exposure under any application scenario.

Chronic toxicity is normally assessed through dietary routes of exposure and soil can be a substantial portion of the diet. Using the assumptions of the acute assessment and substituting the reproductive effect NOEL of > 90 ppm for the LD_{50}, the chronic LOC is not exceeded. Chronic risk can also be assessed by using the NOEL of 5 mg/kg/day derived in the 13-week rat feeding study. The following assumptions are used for this calculation:

- a mouse weighs approximately 20 grams, so the NOEL per mouse would be 0.1 mg/day;
- a mouse eats the equivalent of 18 percent of its body weight per day and a maximum of 17 percent of the diet is soil, which equates to 612 mg of soil per day;
- if soil 1,3-D concentrations were 208 mg/kg soils at an application rate of 556 lbs a.i./acre, each gram of soil would contain 0.208 mg. 1,3-D; and
- following these assumptions, a mouse would consume 0.127 mg of 1,3-D per day.

Using the above scenario, the chronic RQ is 1.3, which exceeds the LOC. However, this model uses maximum exposure condition. If factors such as the average concentration of 1,3-D over a 13 week period (32 ppm at a seven day field dissipation half-life) or soil consumption rates more typical of small mammals are used, the LOC is no longer exceeded. Since 1,3-D is applied generally only once per growing season and because it has a relatively short dissipation half-life, EPA does not expect long-term exposures.

(iii) Terrestrial Insects

The Agency currently does not assess risk to non-target insects. Results of acceptable studies are used for recommending appropriate label precautions.

d. Exposure and Risk to Non-target Freshwater Aquatic Animals

Exposure of pesticides to aquatic non-target organisms is possible through surface water runoff, soil erosion, off-target drift, and movement from ground water to surface water. Risk via exposure to 1,3-D concentrations in surface-water was assessed by using aquatic EEC's predicted using the program GENEEC (see Table 21) and from actual residues in ditch water found during a ground-water study. These estimates of environmental levels were then compared to known toxicity reference values.

(i) Freshwater Fish

Acute and chronic risk quotients are presented in Table 25.

Table 25. Risk Quotients for Freshwater Fish --Based on a (Walleye) LC50 of 1.08 ppm. Chronic risk quotients could not be evaluated due to the lack of chronic toxicity information.

Site/ Application Method/ Rate in lbs ai/A	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/Peak (ppm)	EEC 90-Day Ave.[1] (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
177	1.08	nd	0.685	0.006	0.63	nc
253	1.08	nd	0.980	0.008	0.91	nc
354	1.08	nd	1.380	0.012	1.27	nc
404	1.08	nd	1.570	0.013	1.45	nc
556	1.08	nd	2.160	0.018	2.00	nc

[1] 56 day concentration was not modeled.
nd = no data
nc = not calculated

From Table 21, the LOC's for aquatic animals areas follows: 0.5 (acute high risk); 0.1 (restricted use); 0.005 (acute endangered species); and 1 (chronic). The results of the GENEEC model indicate that aquatic acute high risk, restricted use, and endangered species levels of concern are exceeded for freshwater fish at application rates equal to or above 177 lbs a.i./acre. Chronic risk could not be determined because of the lack of chronic toxicity data.

Because GENEEC is not suitable for tracking soil fumigants, EPA believes that actual residues may be a better indicator of exposure and risk. The freshwater fish LC_{50} (1.08 ppm) was compared to actual residues detected in perimeter ditches adjacent to fields treated at an application rate of 182 lbs a.i./acre (MRID #44005201). Concentrations ranged from 0.34 ppb to 1.8 ppb. The resulting risk quotient ranges from 0.002 to 0.0003 which does not exceed any LOC. If residues in ditch water are assumed to be directly proportional to the application rate, then at 556 lbs ai/acre, concentrations in ditch water would reach 5.5 ppb. At this concentration no LOC's are exceeded.

Concentrations of 1,3-D in ground water four feet below the surface in Florida reached a maximum of 833 ppb. At this concentration, the acute high risk LOC for fish would be exceeded by 1,3-D alone by 1.5 times. This assessment does not account for the additional toxicity presented by the two degradates that were also found in ground water in Florida. Note that there can be considerable interaction between surface and ground water, thus, the levels found in ground water are relevant in a discussion of exposures to fish.

(ii) Freshwater Invertebrates

The acute and chronic risk quotients are presented in Table 26.

Table 26. Risk Quotients for Freshwater Invertebrates --Based on a Daphnia LC50 of 0.09 ppm. Chronic risk quotients could not be evaluated due to the lack of chronic toxicity information.

Site/ Application Method/ Rate in lbs ai/A	LC50 (ppm)	NOEC/ MATC (ppm)	EEC Initial/Peak (ppm)	EEC 21-Day Ave. (ppm)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOEC or MATC)
177	0.09	nd	0.685	0.025	7.61	nc
253	0.09	nd	0.980	0.035	10.89	nc
354	0.09	nd	1.380	0.05	15.33	nc
404	0.09	nd	1.570	0.055	17.44	nc
556	0.09	nd	2.160	0.080	24.00	nc

nd = no data
nc = not calculated

From Table 21, the LOC's for aquatic animals areas follows: 0.5 (acute high risk; 0.1 (restricted use); 0.005 (acute endangered species); and 1 (chronic). The results indicate that aquatic acute high risk, restricted use, and endangered species levels of concern are exceeded for freshwater invertebrates at application rates equal to or above 177 lbs a.i./acre from the GENEEC model. Chronic toxicity could not be determined due to a lack of toxicity information.

When the LC_{50} (0.09 ppm) is compared to actual residues (MRID #44005201) detected in perimeter ditches adjacent to fields in Florida treated at an application rate of 182 lbs a.i./acre ranged from 1.8 ppb to 0.34 ppb. The resulting risk quotients range from ranges from 0.02 to 0.004, which do exceed the endangered species LOC. If residues in ditch water are assumed to be directly proportional to the application rate, then at 556 lbs a.i./acre, concentrations in ditch water would reach 1.04 to 5.5 ppb. At concentrations above 4.5 ppb, endangered species LOCs are exceeded.

Concentrations of 1,3-D in ground water four feet below the surface at the application site in Florida reached a maximum of 833 ppb. At this concentration, the acute high risk LOC for invertebrates would be exceeded. This does not account for the additional toxicity presented by the two degradates that were also found in this ground water. Additionally, concentrations remained at potentially toxic levels for approximately 60 days. In addition to 1,3-D movement in aquatic environments through ground and surface water interaction, shallow ground water is itself inhabited by aquatic invertebrates.

e. Exposure and Risk to Estuarine and Marine Animals

No toxicity information for estuarine and marine animals were required in the 1986 Registration Standard. Consequently, no risk analysis could be conducted for these types of organisms.

The registrant is conducting several estuarine and marine studies on 1,3-D. The tests are estuarine/marine invertebrates with the mysid shrimp (72-3(c)) and the Eastern oyster (72-3(b)) and estuarine/marine fish using the Sheepshead minnow (72-3(a)). Should the results of these studies and other toxicity studies on the degradates show a potential for ecotoxicity from the degradates, EPA will also require studies on the degradates for estuarine and marine animals.

f. Exposure and Risk to Non-target Plants

No toxicity information for non-target plants were required in the 1986 Registration Standard. Consequently, no risk analysis could be conducted for these types of organisms. The registrant has committed to conducting Tier I and Tier II studies for 1,3-D (aquatic and terrestrial) and its degradates (aquatic). These studies are scheduled to be submitted by October 1, 2000.

g. Endangered Species

The Endangered Species Protection Program is expected to be finalized in the future. Limitations in the use of 1,3-D will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submissions of generic (i.e. active ingredient specific) data required to support reregistration of products containing 1,3-D. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of 1,3-D. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 1,3-D, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of 1,3-D. The Agency has determined that 1,3-D products, when used as specified in this document (i.e. only pre-plant soil fumigant uses and according to label requirements to include the pending restrictions listed in Table 31), do not result in unreasonable adverse effects to human health or the environment. Therefore, the Agency finds that products containing 1,3-D as the active ingredient are eligible for reregistration. The reregistration of

particular products is addressed in Section V. of this document. Note that products which also contain chloropicrin will not be deemed eligible for reregistration until the reregistration of that active ingredient has been completed.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. Although the Agency has found that all uses of 1,3-D are eligible for reregistration when used according to specifications in this document, it should be understood that the Agency may take appropriate regulatory action and/or require the submission of additional data to support the registration of products containing 1,3-D if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change. This includes the results of the studies now underway on the degradates, the run-off study, and the tap water monitoring program.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient 1,3-D, as well as other data generated for the 1,3-D Special Review, the Agency has sufficient information on the health effects of 1,3-D and on its potential for ground water contamination. The Agency has determined that 1,3-D products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable adverse effects to humans or the environment. Therefore, the Agency concludes that all products containing 1,3-D, when used under the conditions specified in this document, are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for managing risks associated with the use of 1,3-D. Where the registrant has committed to labeling revisions that are not yet on 1,3-D labels, specific language is set forth in Section V. of this document.

1. Summary of 1,3-D's Carcinogenicity

EPA has classified 1,3-D as a B_2 carcinogen by both the oral and inhalation routes of exposure. Dow AgroSciences has submitted information in support of having EPA regulate 1,3-D as a non-linear carcinogen. EPA conducted a preliminary review of the information and expects to reconvene the Cancer Peer Review sometime in 1999 to consider the information. EPA will not, however, reconsider the 1,3-D risk assessment until all EPA policies regarding the regulation of non-linear carcinogens are finalized.

2. Summary of EPA's Approach to the 1,3-D Risk Assessment

a. Tolerances, Codex Harmonization and Dietary Risk

EPA has determined that 1,3-D, when applied as a pre-plant soil fumigant, is a non-food use pesticide and therefore, tolerances or exemptions from the requirement of a tolerance, are not required. (There is one exception for pineapples, which are treated at plant but show no residues since fruit are not borne until three years later). Therefore, a review of tolerance actions under the safety standard established under section 408(b)(2)(D) of the Federal Food, Drug and Cosmetics Act, as amended by FQPA, is not required. 1,3-D is regulated under the safety standard established under Section 3 of FIFRA, which requires that no unreasonable adverse effects to human health or the environment be associated with use of a pesticide. Nonetheless, EPA has reviewed the data base for 1,3-D to determine whether infants and children are particularly susceptible to toxic effects from exposures to 1,3-D residues and whether aggregate and cumulative exposures pose unreasonable risks.

No tolerances or Codex MRLs have been established; therefore, there are no issues regarding the compatibility of MRLs and tolerances.

Although there is no dietary risk from foods, EPA's risk assessment assumes dietary exposures to come from water sources (ground water). Results from the Florida study suggest that 1,3-D may enter surface water as volatilized residues in the air, settle into surface water and then dissolve. This route, however, is considered insignificant and the registrant is conducting studies to confirm that surface water is not a significant source of exposure.

EPA also looked to see if infants and children have increased susceptibility to the toxic effects of 1,3-D. In making its determination, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed and other information. Based on the current data requirements, 1,3-D has a complete database for developmental and reproductive toxicity. Therefore, EPA has concluded that an extra uncertainty factor of 10 is not warranted in order to protect infants and children.

No acute toxicological endpoints were identified for 1,3-D exposure for any population sub-group under labeling as specified in this document. For 1,2-D, the levels found in the ground water studies were 20 to 30 times lower than the Office of Water's 10-day Health Advisory for children.

Dow AgroSciences is developing data for reregistration on the toxicological profile, including developmental toxicity, for the alcohol and acid degradates. For purposes of reregistration, the Agency assumed that the degradates possess the same toxicological profile as the parent.

b. Aggregate and Cumulative Risk

EPA considers the main sources of 1,3-D exposure to be inhalation and drinking water from contaminated wells, especially for residents who live near treated fields. Aggregated cancer risks (inhalation plus water) for residents who live near treated fields based only on the information that allowed quantification of exposure are approximately 1×10^{-5}. This estimate does not include all of the mitigation measures to reduce inhalation risk, nor does it take into account a 100 foot no-treatment buffer from drinking water wells. While there are no data to assess the potential for risk from surface water residues, EPA believes this would be an insignificant source of exposure. Based on use patterns, dermal exposure is considered to be insignificant. EPA also looked at whether the Agency should also provide estimates of cumulative risks with the contaminant, 1,2-D. EPA does not have available data to determine whether 1,3-D has a common mechanism of toxicity with 1,2-D or other substances. For purposes of this reregistration action, EPA has assumed that 1,3-D and 1,2-D do not have a common mechanism of toxicity. EPA has determined that exposures under the current use patterns meet the safety standards set by FFDCA and FIFRA.

c. Effects to the Endocrine System

EPA is required to develop a screening program to determine whether certain substances (including all active ingredient pesticides and inerts) "may have an effect in humans that is similar to an effect predicted by a naturally occurring estrogen, or such other endocrine effect." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed three years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end-use products.

In deciding to continue to make reregistration determination during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

EPA may determine, as a result of this later implementation process, that any of the determination described in this RED are no longer appropriate. In this case, the Agency will consider itself free to pursue whatever action may be appropriate including, but not limited to, reconsideration of any portion of this RED.

2. Summary of 1,3-D's Benefits

1,3-D is one of the few remaining registered soil fumigants used to control nematodes. Nematodes are microscopic soil worms that live in the soil spaces. Nematodes cause damage by damaging the roots themselves (thereby doing the most damage to root crops such as carrots and potatoes), by reducing yields and by creating opportunities for other soil pathogens to enter the plant. 1,3-D is also used to control wireworms and rhizomania. The combination product of 1,3-D and chloropicrin is also used to treat nematodes and fungi.

The benefits of 1,3-D use are expected to increase with the phase-out of methyl bromide, mainly for use on tomatoes and strawberries. Additional research may find alternative uses for 1,3-D, or it is possible that other nematicides are identified or developed to replace both methyl bromide and 1,3-D.

3. Summary of Risk Management Decisions

a. Human Health

(i) Dietary

The Agency has determined that dietary exposure and risk associated with the use of 1,3-D under current labeling are negligible.

Exposure through Foods Grown in Treated Soils. Data show that no residues of 1,3-D or its degradates of toxicological concern are found in crops grown in treated soils, as long as 1,3-D is applied as a pre-plant soil fumigant. 1,3-D labels suggest a waiting period of one week for every 10 gallons of 1,3-D applied between soil treatment and planting, based on phytotoxicity concerns. For fall fumigation, 1,3-D is applied several months before planting. 1,3-D either volatilizes, leaches below the root zone, or breaks down in the soil, and thus is generally not available for uptake.

Dow AgroSciences has indicated interest in at- and post-plant applications of 1,3-D to orchard crops and grapevines. Before acting on these registrations, the Agency will require data on whether there are residues in treated crops and whether tolerances, or exemptions from the requirement of a tolerance, will be needed to support these uses.

Exposure through Water. Based on ground water monitoring, the Agency has concluded there can be dietary exposure to 1,3-D through contaminated ground water. 1,3-D is mobile, and in some areas, persistent, though these properties vary according to environmental conditions such as temperature, soil type and soil porosity.

There are numerous ground water data bases available to the Agency, including a survey of EPA's own monitoring, the USGS NAWQA Program and state data. The best information for assessing human health impacts are two prospective ground water monitoring studies conducted

in Florida and Wisconsin. The Agency believes that these two study sites represent vulnerable environments for ground water contamination from 1,3-D use.

The Florida site is vulnerable in that the soils are porous and the water table is shallow. The Agency is particularly concerned about the potential for increased use in these vulnerable environments because 1,3-D has been identified by USDA as an adequate alternative to methyl bromide, which is used heavily in Florida tomato production. Dow AgroSciences has agreed to conduct tap water monitoring in both traditional 1,3-D use areas in the north of the state and in south Florida once 1,3-D use expands to that region. Risks associated with levels found in shallow, on-site wells were as high as 4×10^{-6} (though the labels which are to take effect in August of 1999 will prohibit 1,3-D use within 100' of drinking water wells).

The Wisconsin site is also vulnerable. The ground water level is high and soils are porous; in addition, risk appears to be exacerbated by low soil and water temperatures. In the Wisconsin study, risks associated with lifetime exposures to levels found in on-site wells were in the 10^{-3} range, and measurable levels persisted for more than 12 months.

Both prospective ground water monitoring studies included limited monitoring in off-site wells located down gradient from the treated fields. In the Florida study, time weighted average (TWA) concentrations of 1,3-D plus its degradates in the on-site wells (10' deep) were 1.15 ppb. TWA concentrations of 1,3-D plus degradates measured in wells located 100 feet down gradient from the treated field were 0.074 ppb. In the Wisconsin study, on-site wells yielded TWA concentrations of 1,3-D and its degradates of 357 ppb while concentrations in a well 65' down gradient from the treated field were 26.6 ppb. Although neither of these studies was designed to quantify offsite exposures; results in both studies indicate that exposures were considerably lower with increasing distance from treated field.

Dow AgroSciences has agreed as a condition of reregistration to conduct tap water monitoring studies to better estimate current concentrations of 1,3-D and degradates in drinking water. Sampling will be targeted to high-use areas and will be initiated once the new labels are in effect in August of 1999. Should residues of 1,3-D and/or the alcohol or acid degradates be detected at levels exceeding the Office of Water Health Advisory of 0.2 ppb, Dow AgroSciences has included, as part of the sampling program, risk reduction measures which would be in place before the next use season. EPA expects to use the results of the sampling program to better characterize risks with the 100' setback and to also see if the sampling program results can be extrapolated in order to characterize risks in other 1,3-D use areas.

The Agency has evidence that degradation of 1,3-D is temperature dependent. For this reason, the Agency believes that once 1,3-D contaminates ground water in certain colder areas, residues can persist for long periods of time at levels that pose unreasonable risks. For this reason, Dow AgroSciences amended their labels to prohibit use in certain northern tier states where soils are porous and water tables are 50 feet or less. Although 1,3-D is used infrequently, or not at all in these areas, the Agency believes the label statement is appropriate. Based on the levels and persistence seen in the Wisconsin study, one application could result in unreasonable

lifetime risks. Dow AgroSciences is also conducting tap water monitoring in Michigan and Connecticut to confirm that the label prohibition to be added as of August 1, 1999 covers all vulnerable cold environments.

EPA is also aware of other data bases which show only a few detects out of tens of thousands of samples nationwide. The NAWQA sampling showed no detections of 1,3-D out of 21 study units, the locations of which coincide with some of the counties with heaviest 1,3-D use. The main weakness in interpreting these data is that there is no information in the summary reports to determine whether 1,3-D was used in proximity of tested wells. A second weakness is that NAWQA did not test for the presence of the two degradates of toxicological concern (3-chloroacrylic acid and 3-chloroallyl alcohol). Nonetheless, the NAWQA summary reports do provide a qualitative sense that 1,3-D use does not result in widespread aquifer contamination.

In summary, the Agency believes it has mitigated risks in the most vulnerable areas and is focusing resources now on developing confirmatory data in additional areas of high 1,3-D use. All 1,3-D labels bear a ground water advisory to alert users to ground water contamination risk and as of August 1, 1999, there will be a 100 foot buffer between drinking water wells and treated fields. Although the buffer is expected to provide some protection to drinking water, the actual mitigation on a site-by-site basis cannot be quantified since this will depend on a variety of local factors (such as soil type, subsurface hydrogeology, etc.). The tap water monitoring will be designed to allow EPA to take further regulatory action if study results indicate a problem. EPA is also committed to following trends in usage should 1,3-D use increase significantly, especially in areas which may be vulnerable.

(ii) Residential Exposure

The Agency has determined that exposures and risk to residents who live near 1,3-D-treated fields has been mitigated to the extent feasible. Data developed for reregistration and the Special Review show that about 25 percent of applied 1,3-D volatilizes from treated soils into the atmosphere and that atmospheric levels decrease with increasing distance from treated fields. These studies were less clear as to the value of a variety of measures added to 1,3-D labels.

In 1994, 1,3-D labels were modified to add a 300 foot buffer between occupied structures and treated fields. Three air monitoring studies in different environments show an approximate 30 percent overall reduction in air levels at this distance, however, the amount varied by site. In addition, there are label measures designed to minimize the amount of 1,3-D that volatilizes out of treated fields, such as soil sealing, engineering controls for loading and application and lowered rates. As mentioned above, the risk reduction value of several of these measures cannot be quantified with the data available, and would be difficult to obtain based on numerous uncontrollable variables that ultimately influence exposure to 1,3-D.

In addition to not including (in a quantitative sense) all mitigation measures, there are also uncertainties related to the data used to derive the residential exposure estimates. For example, although levels are generally expected to decrease with increasing distance, at the Washington

site, levels at 125 meters were approximately 70% **higher** than at 25 meters (see Table 8). Although the studies were carefully designed to assess actual exposures, the variety and influence of local environmental factors (such as wind, soil type, temperature) were quite large. These factors not only varied from test site to test site, but even day by day at the individual test sites. In addition, the small number of replicates per site are likely to have contributed to the mixed results. The assessment also assumes that a person is 300 feet from the edge of the field for 16 hours a day, 15 days a year for 30 years. EPA believes it is reasonable to use this as a "worst-case" exposure scenario, though this is likely to overstate most residents' exposure.

In addition, a weakness in the residential exposure assessment is in the use of the North Carolina data using 55-gallon drums of Telone C-17. While a later study using the mini-bulk system was used to replace the worker exposures, that study could not be used for residential exposure assessment. The N.C. data was combined with the Washington state and Arizona data to get an average exposure, so the contribution of the N.C. values is expected to overstate exposures because of the higher air levels associated with drum loading.

Dow AgroSciences has indicated interest in developing systems that apply 1,3-D at sub-surface soil depths, instead of at the 12 inch depth required by current labels. The Agency believes that this new method could provide lower exposures since the delivery system would not leave a chisel trace. This chisel trace is thought to be the main path for 1,3-D movement to the atmosphere. The Agency will require air monitoring with any registration application which requests depth of application of less than 12 inches.

There are no residential uses of 1,3-D; thus, there is no exposure from home-based applications.

(iii) Aggregate and Cumulative Risks

The calculated drinking water risk estimates using 1,3-D labels eligible for reregistration is 4×10^{-6} (using on-site wells from the Florida study); the inhalation risk is 6×10^{-6} (using an average of levels monitored from NC, WA and AZ study sites at the 300' buffer). Thus the calculated aggregate risk estimate is 1×10^{-5}. This risk estimate does not take into account mitigation from lower application rates, soil sealing measures, increased depth of application, soil moisture and temperature requirements or potential reduction in exposure from the 100 foot drinking water well setback. EPA believes the risk estimates are likely to be in the 10^{-6} range and that risk concerns have been addressed when all of the mitigation measures as specified in this reregistration decision are taken into account. The Agency has not cumulated risks with the impurity 1,2-D or other chemicals since no determination has been made that these chemicals share a common mode of toxicity.

(iv) Occupational Exposure

The Agency has determined that existing label measures are sufficient to mitigate worker exposures to 1,3-D. Several label changes have been made since the 1986 Registration Standard,

including closed loading systems, engineering controls to prevent 1,3-D spillage at row-turns, the phase-out of drum delivery, respiratory requirements, the use of closed cabs, increasing the restricted entry interval from three to five days and protective clothing.

While the data developed for estimating worker risks is of high quality, there are uncertainties. From Table 7, the studies used to test the efficacy of dry disconnects (shut-off valves for closed loading systems) gave mixed results, even suggesting that exposures were higher with the dry disconnects. Another uncertainty is assessing the potential risk to workers based on the methyl bromide phase-out. Increased 1,3-D risks would occur if a worker who currently applies methyl bromide replaces that methyl bromide use with 1,3-D. Based on conversations with grower groups and the registrant, this is unlikely since there is very little, if any, tandem use of the two fumigants. The phase-out of methyl bromide will likely increase the numbers of workers who are exposed to 1,3-D, but will not likely increase the lifetime cancer risk of an individual worker.

According to data developed for the Special Review and reregistration, the risks for custom applicators, custom loaders and for growers (who are assumed to both load and apply 1,3-D) is in the 10^{-5} to 10^{-6} range. Note that 1,3-D is a restricted use pesticide based on cancer concerns for worker risks. Because of this there are certain training and reporting requirements. The 1,3-D product stewardship goes beyond this training to provide manuals, videos and technical support in the field.

EPA's policy on worker risk sets a goal of no greater than 10^{-6} lifetime risks for workers. If, however, there are not measures available to do so, then risks that are somewhat higher will be considered acceptable. Risks that are higher than 10^{-4} are generally not seen as acceptable unless extremely high benefits of the use of the pesticide outweigh these risks.

In summary, the Agency believes that worker risks have been adequately mitigated with current label measures and are in accordance with current worker risk policies. The Agency's determination takes into account expected increases in usage of 1,3-D with the methyl bromide phase out.

b. Environmental/Ecological Effects

The Agency believes that use of 1,3-D as specified in this document will not pose unreasonable risks to the environment. However, certain properties of 1,3-D and its degradates justify the on-going monitoring program underway to confirm this position.

Specifically, 1,3-D and its degradates have been detected in both retrospective and prospective ground water monitoring studies. 1,3-D is considered mobile and persistent, with these properties varying depending on environmental conditions. Studies show that the rate of 1,3-D degradation is proportional to temperature, and thus 1,3-D is expected to be more persistent in colder environments. Limited data suggest that the degradates of 1,3-D, in particular 3-chloroacrylic acid, are more persistent than 1,3-D and the influence of temperature on

persistence is less than for the parent. For this reason, the registrant is generating data on the toxicity and environmental fate of the degradates. For this RED, the Agency has assumed that the degradates' toxicity and exposure parameters are equal to the parent; this is considered a conservative estimate.

The results of the prospective studies and information developed by USGS demonstrate that 1,3-D levels in ground water decrease with increasing distance from treated fields. The NAWQA found no detections of 1,3-D in any of its 21 Phase 1 monitoring study units around the country, suggesting that 1,3-D does not pose a widespread contamination risk to aquifers. Rather, the Agency believes the highest risks to the environment are in localized areas close to treated fields. The label statement to prohibit use in areas similar to the Wisconsin study site (i.e., cold climates with shallow ground water and permeable soils) is expected to lessen the potential for environmental risk as well as risks to human health.

For ecological effects, the available acute toxicity data on the TGAI indicate that 1,3-D is slightly toxic on an acute oral basis to small mammals, moderately toxic on an acute oral basis to birds, moderately toxic to acutely toxic to freshwater fish and bees, and very highly toxic to freshwater invertebrates. Toxicity testing has not been conducted on estuarine or marine organisms.

Because 1,3-D degradation appears to be related to temperature, organisms living in cooler climates (where degradation is slower) would be at greater risk than those in warm climates. Applications to cool climate crops may pose the greatest acute and chronic risks. Alternatively, although use in Florida may present a substantial risk to freshwater and estuarine organisms, the potential for chronic effects may be shortened because of the rapid degradation in warm climates.

1,3-D application methods (soil injection and subsurface drip irrigation) greatly reduce the risk to terrestrial birds. Since application is primarily to bare fields prior to planting, terrestrial organisms could be at risk through three routes of exposure: ingestion of contaminated soil, ingestion of contaminated water or inhalation of 1,3-D vapors.

Birds. Soil residue levels found in field samples were used to estimate risk to birds. Acute risk quotients did not exceed any LOC even at the maximum application rates. No data are available to conduct a chronic risk assessment. However, given the relatively short field dissipation half-life, chronic exposure is not anticipated.

Mammals. Using soil and air concentrations from field studies, acute risk quotients did not exceed any LOC. These results indicate the use of 1,3-D should not result in significant acute mortality to mammalian species via dietary or inhalation exposure under any application scenario. The chronic LOC was not exceeded based on reproductive effects data. It was exceeded slightly in a rat feeding study, but given 1,3-D's relatively short dissipation half-life and one application per year, EPA does not expect chronic effects.

Aquatic Organisms. Using GENEEC information, application rates equal evaluated (at or above 177 lbs. a.i. per acre) exceed the acute high risk LOC's for freshwater fish and freshwater invertebrates. Using measured residues found in ditch water adjacent to treated fields at 182 lbs. ai/acre, the LOC for endangered species was exceeded. Concentrations in four foot deep ground water in Florida were higher than the LOC for aquatic invertebrates. No data were available to assess chronic risk.

It should be noted again that the computer model GENEEC is a screening model designed only to help determine if substantial risks are unlikely. It should not be used to determine if substantial risks are likely. The determination of whether risks actually exceed the LOC's depends on data generated from higher-tier exposure and risk assessments and/or additional monitoring information.

Estuarine and Marine Organisms. No estuarine or marine toxicity data were required for reregistration in the 1986 Registration Standard, and as such, no acute or chronic risk analysis could be conducted. The registrant is generating acute data for estuarine and marine organisms since 1,3-D use is expected to expand to these areas.

Plants. No toxicity information for non-target plants has been submitted. Consequently, no risk analysis has been conducted. However, 1,3-D is registered as a herbicide and has phytotoxicity warnings and, therefore, is a candidate for both terrestrial and aquatic plant testing.

c. Restricted Use Classification

Based on 1,3-D's high acute inhalation toxicity, potential carcinogenicity and its use patterns, the Agency is maintaining the Restricted Use classification for all 1,3-D products that are currently so classified.

d. Endangered Species Statement

The Agency has developed a program (the "Endangered Species Protection Program") to identify pesticides which may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanism as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency is not imposing label modifications through this RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

e. Labeling Rationale

The Agency is maintaining its current label restrictions and is basing its reregistration eligibility decision on these measures and other label measures that will be added as of August 1, 1999. There are on-going studies, reviews and data collection which are being conducted to confirm the Agency's position that 1,3-D, when used as specified in this document, does not pose unreasonable adverse effects to humans or the environment. Should the results of those confirmatory data provide information to change the Agency's current risk assessment and position, EPA will consider further label changes to maintain the registration of products containing 1,3-D.

(i) Labeling Requirements for Handlers (Including Re-Entry)

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) and changes to 1,3-D labels in 1992 and 1996 established worker protection requirements to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries and greenhouses to produce agricultural plants (including food, feed and fiber plants, trees, turf grass, flowers, shrubs, ornamentals and seedlings). Uses within the scope included not only uses on plants but also uses on the soil or planting medium the plants are (or will be) grown in.

The Personal Protective Equipment (PPE) requirements under the WPS, as well as the process for complying with the WPS are found in PR notice 93-7. For products containing 1,3-D, a supplement, entitled, "Supplement Four-D, Labeling Guidance for 1,3-Dichloropropene Fumigant Products" was issued with specific working for all 1,3-D product labels. A separate supplement, "Supplement Four-E, Labeling guidance for 1,3-Dichloropropene Plus Chloropicrin Fumigant Products" was also issued.. Some of the PPE requirements in the WPS were further refined in 1995. The requirements for 1,3-D handlers are specified below (note these are requirements for 1,3-D only):

Handlers Performing Direct Contact Tasks (e.g., includes equipment repair and calibration, fumigant transfers, clean-up of small spills) -

- Coveralls over short-sleeved shirt and short pants,
- Chemical-resistant gloves (barrier laminate (EVAL) or viton)
- Chemical resistant footwear plus socks
- Face-sealing goggles, unless full face respirator is worn
- Chemical resistant headgear for overhead exposure
- Chemical-resistant apron
- Respirator with organic-vapor-removing cartridge or canister approved for pesticides

Handlers in Enclosed Cabs

- Coveralls
- Shoes and socks

- A half-face respirator with an organic-vapor-removing cartridge or canister approved for pesticides
- A respirator is NOT required if occupants are within an enclosed cab equipped with a vapor-adsorptive filter (activated charcoal). HOWEVER, PPE for direct handlers must be worn if applicator within cab leaves the cab and re-enters.

Post Application/Re-entry Handlers in Treated Area within REI - Five Days after Application
- Coveralls
- Chemical-resistant gloves (barrier laminate (EVAL) or viton)
- Chemical-resistant footwear and socks
- Respirator with organic-vapor-removing cartridge or canister approved for pesticides

Handlers Exposed to High Concentrations (e.g., clean-up of large spills)
- Chemical resistant suit
- Chemical resistant gloves (barrier laminate (EVAL) or viton)
- Chemical-resistant footwear plus socks
- Chemical-resistant headgear
- Supplied air respirator

The Agency is retaining the WPS requirements, as well as all other PPE and engineering controls which are as follows:

Table 27. Summary of 1,3-D Label Restrictions that Affect Worker Exposures

Regulatory Action (effective date)	Label Requirements
Registration Standard (1986)	Precautionary Statements; Cancer Hazard Warning; Classification Change to Restricted Use Pesticide; Reentry increased to 72 Hours*; Clothing for Applicators and Handlers (Coveralls*, Chemical-resistant Gloves and Boots, Liquid-proof hat).
1992 Label Amendments (1992/1993)	Lowered Maximum rates; Deletion of Selected Use Sites; Revised Respirator Requirements*; Closed Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Improved Product Stewardship Materials
Worker Protection Standard (August 1992 see 57 FR 38102)	Coveralls over short-sleeved shirt and short pants; Chemical-resistant gloves and footwear; Chemical-resistant Apron (for direct handlers).
1995 Label Amendments (1996)	A Respirator Requirement for all 1,3-D handlers (except those in certain closed cabs); Restricted Entry increased to 5 days; Soil moisture and soil sealing requirements; Modified application techniques and Lower maximum use rates.

* - measures which were superceded or modified by subsequent label changes

(ii) Labeling Requirements that Affect Residential Exposure

There are no residential uses of 1,3-D. However, the Agency has concerns for inhalation risks to residents who live near 1,3-D treated fields, and an additional concern for residents who obtain drinking water from private wells in the proximity of treated fields.

Residential risks were not included in the 1986 Registration Standard. In 1990, California suspended 1,3-D use permits based on unexpectedly high levels of 1,3-D in the atmosphere following treatment. EPA used the Special Review process to obtain additional data and risk mitigation (through label amendments) to mitigate inhalation exposures.

EPA is also retaining requirements for measures to mitigate risks from exposure through ground water. The following table summarizes label statements which are required for 1,3-D labels to protect residents who live near treated fields.

Table 28. Measures to Reduce Risks to Residents who Live Near Treated Fields

	Label Measures
Measures Designed to Reduce Inhalation Risk	300' No-treatment Buffer; Lowered application rates; Loading Requirements; Technology to Minimize 1,3-D Spillage during Application, Soil moisture and soil sealing requirements; Modified application techniques
Measures to Reduce Dietary Risk via Potential Ground Water Exposure	100' buffer between drinking water wells and treated fields (as of 8/1/99); lowered application rates, ground water advisory; prohibition of use in certain states with shallow ground water and vulnerable soils (as of 8/1/99); prohibition in areas overlying karst geology (as of 8/1/99)

(iii) Other Labeling Requirements

Because the end-use product Telone II is also reformulated into other products, EPA is requiring that any product containing 1,3-D bear a label statement to require that all measures on the Telone label are also required on any other product containing 1,3-D. This measure is designed to cover <u>all</u> reformulated products, whether the 1,3-D source is Dow AgroScience's Telone product or from some other producer or reformulator.

V. ACTIONS REQUIRED OF REGISTRANTS

A. Amendments to Current 1,3-D Registrations

This section specifies the data requirements and responses necessary for the reregistration of products containing 1,3-D.

B. Requirements for 1,3-D Products

1. Additional Generic Data Requirements

On September 30, 1998, Dow AgroSciences requested changes to the terms and conditions of their 1,3-D registrations to include modified labels and study requirements (Roby, 1998). All 1,3-D products must be relabeled by August 1, 1999 to include the amended labeling.

In addition to the label changes, the registrant has agreed to conduct the following studies:

a. Studies to be performed as a result of modified terms and conditions of registration – Studies on 3-chloroacrylic acid and 3-chloroallyl alcohol

Table 29 - Study on 3-chloroacrylic acid and 2-chloroallyl alcohol	OPP Guideline Number	Study Due Date
Acute oral-rat	81-1	June 1, 1999
Acute dermal toxicity - rabbit/rat	81-2	June 1, 1999
Primary eye irritation - rabbit	81-4	June 1, 1999
Primary dermal irritation	81-5	June 1, 1999
dermal sensitization	81-6	June 1, 1999
mutagenicity (Ames assay)	84-2A	October 1, 1999
mouse micronucleus	84-2	October 1, 1999
pharmacokinetics/balance of metabolism	85-1	October 1, 2000
mouse lymphoma	84-2	October 1, 1999
in vitro chromosomal aberration in Chinese Hamster lung	84-2	October 1, 1999
developmental toxicology	83-3A	January 1, 2000
subchronic 90-day feeding study	82-1A	January 1, 2000
aquatic aerobic metabolism	162-4	October 1, 1999

Table 29 - Study on 3-chloroacrylic acid and 2-chloroallyl alcohol	OPP Guideline Number	Study Due Date
adsorption/desorption	163-1	October 1, 1999
hydrolysis	161-1	October 1, 1999
vapor pressure	68-9	October 1, 1999
Henry's Law Constant	NA	October 1, 1999
acute fish toxicity- rainbow trout	72-1	June 1, 1999
acute aquatic invertebrate toxicity-Daphnia magna	72-2(a)	June 1, 1999
Tier I and Tier II aquatic plant	122-2/123-2	June 1, 1999

b. Studies to be performed as a result of modified terms and conditions of registration - 1,3-D

Table 30 - Study on 1,3-D	Guideline Number	Due Date
Freshwater fish early life stage - rainbow trout	72-4(a)	October 1, 1999
Freshwater aquatic invertebrate life cycle - Daphnia magna	72-4(b)	October 1, 1999
Estuarine/marine fish LC 50-sheepshead minnow	72-3(a)	June 1, 1999
Estuarine/marine invertebrate LC50-mysid shrimp	72-3(b)	June 1, 1999
Estuarine/marine invetebrate LC50-eastern oyster	72-3(b)	June 1, 1999
Tier I and Tier II aquatic plant	122-2/123-2	June 1, 1999
Seed germination and seedling emergence	122-1(a)	October 1, 1999
Vegetative vigor	122-1(b)	October 1, 1999
Tier I and Tier II terrestrial plants	122-1 and 123-1	October 1, 2000
Aerobic aquatic metabolism	162-4	October 1, 1999

c. Studies to be performed as a result of modified terms and conditions of registration with tiered requirements - Run-off Study and Studies on Ecotoxicity

Dow AgroSciences will conduct a run-off study to assess whether run-off is a significant pathway for movement of 1,3-D in the environment. If studies show that 1,3-D and/or its degradates can enter surface water in unacceptably high amounts as a result of run-off, then the battery of studies for 3-chloroacrylic acid and 3-chloroallyl alcohol for estuarine/marine animals (sheepshead minnow, mysid shrimp, eastern oyster) will be required.

In addition, EPA may require an avian acute oral study on the degradates pending the results of the environmental fate studies on the degradates. As noted in section E.4.c., the application method, of 1,3-D is not expected to result in high exposures to birds. If, however, the environmental fate study results show that concentrations of concern may be present, then EPA will require an acute avian oral study.

d. Product Chemistry Requirements

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

2. Formulation Changes

There are no requirements for formulation changes to products containing 1,3-D at this time.

3. Time frames

Revised labeling is scheduled to be borne by all products by August 1, 1999. The time frames for the additional studies are listed in the Tables 29 and 30 above.

4. Labeling Requirements for End-Use Products

All end-use products should have clear, concise and complete labeling instructions. Proper labels can improve reader understanding, thereby reducing misuse and the potential for incidents. Towards this end, the Agency is requiring the following:

Table 31: Summary of Required Labeling Changes for 1,3-Dichloropropene		
Description	**Required Labeling**	**Placement on Label**
All Products Containing the Active Ingredient 1,3-Dichloropropene		
This statement must be added to 1,3-D labels to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	FORMULATOR USE OF 1,3-DICHLOROPROPENE: Labeling for end use products containing 1,3-Dichloropropene that are prepared and sold by formulators must comply with all labeling for precautionary statements, use precautions, environmental hazards, handling and protective equipment requirements, maximum application rates, and other exposure mitigation measures specified in this product labeling.	General Use Precautions in Directions for Use
On labels as of August 1, 1999	"Do not apply within 100 feet of any well used for potable water." "Do not apply in areas overlying karst geology." "The following restriction applies only in North Dakota, South Dakota, Wisconsin, Minnesota, New York, Maine, New Hampshire, Vermont, Massachusetts, Utah and Montana: Where ground water aquifers exist at a depth of 50 feet or less from the surface, do not apply this product where soils are Hydrologic Group A."	

C. Existing Stocks

The existing stocks time frames have been set for products containing 1,3-D. The label changes which are referred to above in Table 32 are to be on all products which are sold or distributed by Dow AgroSciences or any reformulator by August 1, 1999.

VI. APPENDICES

Appendix A - Table of Use Patterns Subject to this RED

Appendix A is 23 pages long and is not being included in this RED. Copies of Appendix A are available upon request per the instructions in Appendix E.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 0328 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 0328 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

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

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

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	all	40163301
61-2A	Start. Mat. & Mnfg. Process	all	40163301
61-2B	Formation of Impurities	all	40163301
62-1	Preliminary Analysis	all	40398501
62-2	Certification of limits	all	40504201, 40398501
62-3	Analytical Method	all	40504201, 40398501
63-2	Color	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806,40163301
63-3	Physical State	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806,40163301
63-4	Odor	all	40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-5	Melting Point	all	40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-6	Boiling Point	all	40163301, 40163301, 40483801, 404838702, 40483803, 40483804, 40483805, 40483806
63-7	Density	all	40163301, 40163301, 40483801, 40483802, 40483803, 40483804, 40483805, 40483806

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
63-8	Solubility	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-9	Vapor Pressure	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-10	Dissociation Constant	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-11	Octanol/Water Partition	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-12	pH	all	40483801, 40483802, 40483803, 40483804, 40483805, 40483806
63-13	Stability	all	40483804, 40483801, 40483802, 40483803, 40483805, 40483806
63-17	Storage stability	all	00162145
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C	261149
71-1B	Acute Avian Oral - Quail/Duck TEP	A,B,C	waived
71-2A	Avian Dietary - Quail	A,B,C	00120908
71-2B	Avian Dietary - Duck	A,B,C	STEOD103
71-3	Wild Mammal Toxicity	A,B,C	waived
71-5B	Actual Field Study	A,B,C	waived
72-1A	Fish Toxicity Bluegill	A,B,C	STOD102
72-1B	Fish Toxicity Bluegill - TEP	A,B,C	waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
72-1C	Fish Toxicity Rainbow Trout	A,B,C	00039692
72-1D	Fish Toxicity Rainbow Trout- TEP	A,B,C	waived
72-2A	Invertebrate Toxicity	A,B,C	40098001
72-2B	Invertebrate Toxicity - TEP	A,B,C	waived
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	see footnote
72-3B	Estuarine/Marine Toxicity - Mollusk	A,B,C	see footnote
72-3C	Estuarine/Marine Toxicity - Shrimp	A,B,C	see footnote
72-4A	Early Life Stage Fish	A,B,C	see footnote
122-1A	Seed Germination/Seedling Emergence	A,B,C	see footnote
122-1B	Vegetative Vigor	A,B,C	see footnote
122-2	Aquatic Plant Growth	A,B,C	see footnote
123-1A	Seed Germination/Seedling Emergence	A,B,C	see footnote
123-1B	Vegetative Vigor	A,B,C	see footnote
123-2	Aquatic Plant Growth	A,B,C	see footnote
124-1	Terrestrial Field	A,B,C	waived
124-2	Aquatic Field	A,B,C	see footnote
141-1	Honey Bee Acute Contact	A,B,C	00028772
141-2	Honey Bee Residue on Foliage	A,B,C	000188423

TOXICOLOGY

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
81-1	Acute Oral Toxicity - Rat		40220901
81-2	Acute Dermal Toxicity - Rabbit/Rat		40220902
81-3	Acute Inhalation Toxicity - Rat		40220903
81-4	Primary Eye Irritation - Rabbit		40220904
81-5	Primary Dermal Irritation - Rabbit		40220905
81-6	Dermal Sensitization - Guinea Pig		40220906
82-1A	90-Day Feeding - Rodent		42954801, 42954802
82-1B	90-Day Feeding - Non-rodent		43763501
82-2	21-Day Dermal - Rabbit/Rat		waived
82-4	90-Day Inhalation - Rat		00039685
83-1A	Chronic Feeding Toxicity - Rodent		40312201, 40312301
83-1B	Chronic Feeding Toxicity - Non-Rodent		42922301, 42441001
83-2A	Oncogenicity - Rat		434653501, 40312201
83-2B	Oncogenicity - Mouse		40312301
83-2B	Oncogenicity - Mouse		40312301
83-3A	Developmental Toxicity - Rat		00152848
83-3B	Developmental Toxicity - Rabbit		00152848
83-4	2-Generation Reproduction - Rat		40835301
84-2A	Gene Mutation (Ames Test)		44302801

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
84-2B	Structural Chromosomal Aberration		00259101
85-1	General Metabolism		40959801, 161151
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
133-3	Dermal Passive Dosimetry Exposure		waived
133-4	Inhalation Passive Dosimetry Exposure		waived
ENVIRONMENTAL FATE			
161-1	Hydrolysis		00158442, 262730
161-4	Photodegradation		40330101
162-1	Aerobic Soil Metabolism		42642301
162-2	Anaerobic Soil Metabolism		40025901
162-3	Anaerobic Aquatic Metabolism		waived
162-4	Aerobic Aquatic Metabolism		see footnote
163-1	Leaching/Adsorption/Desorption		42868501, 425155501, 40538901
163-3	Volatility - Field		42845601, 42845602, 42545101, 42774201
164-1	Terrestrial Field Dissipation		41385701, 40155501
164-2	Aquatic Field Dissipation		waived
164-5	Long Term Soil Dissipation		waived
165-1	Confined Rotational Crop		43140201
165-2	Field Rotational Crop		waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
166-1	Ground Water - Small Prospective		44227701, 44318701, 44258901, 44226901, 44270201, 44005201
166-2	Ground Water - Small Retrospective		43428301, 42914301, 42452901, 42536401, 42354201
166-3	Ground Water - Irrigated Retrospective		inapplicable
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants		42845401, 42894201, 42784201, 42760801, 42709401
171-4B	Nature of Residue - Livestock		43083301, 42946401
171-4C	Residue Analytical Method - Plants		waived
171-4D	Residue Analytical Method - Animal		waived
171-4E	Storage Stability		42354201
171-4F	Magnitude of Residues - Potable H2O		waived
171-4G	Magnitude of Residues in Fish		waived
171-4H	Magnitude of Residues - Irrigated Crop		waived
171-4I	Magnitude of Residues - Food Handling		waived
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		waived
171-4K	Crop Field Trials		waived

Data Supporting Guideline Requirements for the Reregistration of 1,3-Dichloropropene

REQUIREMENT		USE PATTERN	CITATION(S)
171-4L	Processed Food		waived
171-5	Reduction of Residues		waived
171-6	Proposed Tolerance		waived
171-7	Support for Tolerance		waived
171-13	Analtyical Reference Standard		waived

Note- Requirements for these studies were not included in the 1986 Registration Standard, however, based on expected increases in usage to sensitive environments, the registrant is conducting these studies, which are to be submitted by October 1, 1999 (except for 122-1 and 123-1, which are due October 1, 2000).

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as

(19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

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MRID	CITATION

Table 1 - Citations with MRID Numbers Assigned

00030385 Glas, R.D. (1979) Determination of Residues of Cisand Trans 1,3Dichloropropene in Plant Materials: ACR 79.15. Method dated Nov 30, 1979. (Unpublished study received Feb 7, 1980 under 464511; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 241761-B)

00033255 McKinney, W.J.; Wendt, M.B.; Abbott, R.; et al. (1978) [Residues in Sugarbeets]: TIR-24-355-76. (Unpublished study including TIR24-355-76-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-A)

00033256 McKinney, W.J.; Wendt, M.B.; Fries, F.A.; et al. (1978) [Residues in Cabbage]: TIR-24-160-78-A. (Unpublished study including TIR24-195-78B and TIR-24-195-78, received Jun 25, 1980 under 464511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-B)

00033257 McKinney, W.J.; Wendt, M.B. (1978) [Residues in Potatoes]: TIR-24172-78-A. (Unpublished study including TIR-24-172-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 242726-C)

00033258 McKinney, W.J.; Fries, F.A.; Wendt, M.B.; et al. (1978) [Residues in Cauliflower]: TIR-24-180-78. (Unpublished study including TIR-24-180-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-D)

00033259 McKinney, W.J.; Fries, F.A.; Wendt, M.B.; et al. (1978) [Residues in Lettuce]: TIR-24-191-78A. (Unpublished study including TIR24-191-78-B, TIR-24-192-78A and TIR-24-192-78-B, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-E)

00033260 McKinney, W.J.; Fries, F.A.; Bierman, B.; et al. (1979) [Residues in Watermelon]: TIR-24-227-78B. (Unpublished study including TIR-24-227-78, TIR-24-244-78-B and TIR-24-244-78, received Jun 25, 1980 under 464-511;

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MRID	CITATION
	prepared by Shell Development Co. and others, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 242726-F)
00033261	McKinney, W.J.; Brown, L.J.; Doern, B.L.; et al. (1979) [Residues in Various Crops]: TIR-24-642-78. (Unpublished study including TIR-24-614-79, received Jun 25, 1980 under 464-511; prepared by Shell Development Co., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-G)
00033262	Dutson, N.J.; Seager, S.V.; Wallace, B.G.; et al. (1977) Residues of the Major Components of D-D and Primary Metabolites in Lettuce from Germany: Group Research Report BLGR.0024.77. (Unpublished study received Jun 25, 1980 under 464-511; prepared by Shell Research, Ltd., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-H)
00033263	Bosio, P.G.; Granier, R. (1977) Residues of D-D in Potatoes from France--1976/77 Trials: Group Research Report BEGR.0086.77. (Unpublished study received Jun 25, 1980 under 464-511; prepared by Shell Chemie, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-I)
00033264	Sherren, A.J.; Murray, S.M.; Wallace, B.G.; et al. (1978) Residues of the Major Components of D-D and Primary Metabolites in Pineapples from South Africa: Group Research Report BLGR.0071.78. (Unpublished study received Jun 25, 1980 under 464-511; prepared by Shell Research, Ltd., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:242726-J)1
00036894	Osborne, W.W. (1974) Prevent/limit pod rod with two-phase chemical control. Peanut Farmer 10(4):12. (Also~In~unpublished submission received Sep 13, 1976 under 400-129; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:225604-H)
00039680	Dow Chemical U.S.A. (1980) [Metabolism, Mating Behavior, Fertility and Toxicity in Male and Female Rats]. Summary of studies 099515-R and 099515-S. (Unpublished study received Jul 22, 1980 under 464-EX-63; CDL:099515-G)
00039683	Toyoshima, S.; Sato, R.; Sato, S. (1978) The Acute Toxicity Test on Telone II in Mice. (Unpublished study received Jul 22, 1980 under 464-EX-63; prepared by Keio Univ., Drug Chemistry Institute, Chemotherapy Div. and Japan

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MRID	CITATION
	Experimental Medical Research Institute Co., Ltd., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-J)
00039685	Coate, W.B.; Keenan, D.L.; Hardy, R.J.; et al. (1978) Final Report: Telone^(R)= II (Production Grade): Project No. 174-126. (Unpublished study received Jul 22, 1980 under 464-EX-63; prepared by Hazleton Laboratories America, Inc., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-L)
00039688	Sudo, S.; Nakazawa, M.; Nakazono, M.; et al. (1978) The Mutagenicity Test on 1,3-Dichloropropene in Bacteria Test System: Project No. NRI-78-2819. (Unpublished study received Jul 22, 1980 under 464-EX-63; prepared by Nomura Sogo Research Institute, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-P)
00039692	Bentley, R.E. (1975) Acute Toxicity of M-3993 to Bluegill (µ~Lepomis macrochirus~µ) and Rainbow Trout (µ~Salmo gairdµ~neri~µ). (Unpublished study received Jul 22, 1980 under 464EX-63; prepared by Bionomics, EG&G, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-T)
00039693	Dow Chemical U.S.A. (19??) Summary of Residue Analyses of 1,3-Dichloropropenes in Crops Treated Post-plant with Telone II. (Unpublished study received Jul 22, 1980 under 464-EX-63; CDL: 099515-W)
00039694	Glas, R.D. (1980) Determination of Resudies [sic] of Cisand Trans1,3-Dichloropropene in Fruit: ACR 80.9. Method dated Jul 9, 1980. (Unpublished study received Jul 22, 1980 under 464-EX63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 099515-X)
00039695	Glas, R.D. (1980) Determination of Residues of Cisand TransChloroallyl Alcohols in Fruit by Gas Chromatography Using and Electrolytic Conductivity Detector: ACR 80.10. Method dated Jul 9, 1980. (Unpublished study received Jul 22, 1980 under 464-EX63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 099515-Y)
00039696	Lembright, H.W.; Hart, W.; Rough, D. (1980) Residues of 1,3-Dichloropropenes and Chloroallyl Alcohols in Green Almonds Grown in Soil Fumigated with Telone II Soil Fumigant. (Unpublished study received Jul 22,

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MRID	CITATION
	1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-Z)
00039697	Glas, R.D.; Turner, G.O. (1980) Analysis of Oranges and Peaches for Residues of Dichloropropenes and Chloroallyl Alcohols after Postplant Application of Telone II Soil Fumigant: GH-C 1312. (Unpublished study received Jul 22, 1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-AA)
00039698	Glas, R.D.; VanGundy, S. (1980) Analysis of Peel, Pulp, Leaves and Soil from an Orange Grove for Residues of Dichloropropenes and Chloroallyl Alcohols after Post Plant Injection of Telone II Soil Fumigant: GH-C 1308. (Unpublished study received Jul 22, 1980 under 464-EX-63; prepared in cooperation with Univ. of California--Riverside, submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-AB)
00039699	Glas, R.D.; Turner, G.O. (1980) Analysis of Grapes for Residues of Dichloropropenes and Chloroallyl Alcohols after Postplant Application of Telone II Soil Fumigant: GH-C 1281. (Unpublished study received Jul 22, 1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-AC)
00039700	Lembright, H. (1980) Residues of 1,3-Dichloropropenes and Chloroallyl Alcohols in Grapes Grown in Soil Fumigated with Telone II Soil Fumigant. (Unpublished study received Jul 22, 1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099515-AD)
00040721	Bauriedel, W.R.; Craig, L.F. (1973) A Study of the Residue Present in Sugar Beets Grown in Soil Treated with 14C-Labeled~Cis~µand µ~Trans~µ-1,3-Dichloropropene. (Unpublished study received Jul 22, 1980 under 464-EX-63; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:099516-L)
00040722	Berry, D.L. (1973) Absorption, Translocation and Metabolism of 1,3Dichloropropene in Selected Plants. Doctoral dissertation, Utah State Univ. (Unpublished study received Jul 22, 1980 under 464EX-64; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 099516-M)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

DEC 22 1998

CERTIFIED MAIL

Dear Sir or Madam:

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

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or

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

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

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-99).

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

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

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form (Insert B). Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

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

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

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

2. **Satisfying the Product Specific Data Requirements of this Notice** There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 5 on the Requirements Status and Registrant's Response Form(Insert A) and item numbers 7a and 7b on the Data Call-In Response Form(Insert B). Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. **Request for Product Specific Data Waivers.** Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status

and Registrant's Response Form (Insert B). If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

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

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced here in and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines(PAG), and be in conformance with the requirements of PR Notice 86-5.

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

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline

remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form (Insert A) and a Requirements Status and Registrant's Response Form (Insert B) committing to develop and submit the data required by this Notice.

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

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

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

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

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

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

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

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

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

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

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

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

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

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

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

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form (Insert A) and the Requirements Status and Registrant's Response Form (Insert B), as appropriate.

III-D. REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to

FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

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

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

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

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

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

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

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

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

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

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

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

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

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

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

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute,

or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Ivois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form (Insert A)
3 - Requirements Status and Registrant's Response Form (Insert B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice

1,3-DICHLOROPROPENE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 1,3-Dichloropropene.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 0328. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), and (5) a list of registrants receiving this DCI (Attachment 5).

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 1,3-Dichloropropene are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 1,3-Dichloropropene are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible 1,3-Dichloropropene products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Karen Jones at (703) 308-8047.

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

Karen Jones
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **1,3-Dichloropropene**

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

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

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	0328 1,3-DICHLOROPROPENE	PRODUCT SPECIFIC

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

8. Certification

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

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option** 7 (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

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

1. Company name and Address
SAMPLE COMPANY
NO STREET ADRESS
NO CITY, XX 00000

2. Case # and Name
0328 1,3-DICHLOROPROPENE
EPA Reg. No. NNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNN-RD-NNNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern		7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical									
61-1	Product identity & composition (1)					C	J	MP/EP	8 mos.	
61-2(a)	Descriptn starting materials, (1,2) productn & formulatn process					C	J	MP/EP	8 mos.	
61-2(b)	Discussion of formation of impurities (1,3)					C	J	MP/EP	8 mos.	
62-1	Preliminary analysis (1,4,50)					C	J	MP/EP	8 mos.	
62-2	Certification of limits (1,5)					C	J	MP/EP	8 mos.	
62-3	Analytical method (1)					C	J	MP/EP	8 mos.	
63-2	Color (17)					C	J	MP/EP	8 mos.	
63-3	Physical state					C	J	MP/EP	8 mos.	
63-4	Odor (17)					C	J	MP/EP	8 mos.	
63-7	Density					C	J	MP/EP	8 mos.	
63-12	pH (9)					C	J	MP/EP	8 mos.	
63-13	Study not required for product (51)					C	J	MP/EP	8 mos.	

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

Signature and Title of Company's Authorized Representative _____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 03-31-99

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

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
0328 1,3-DICHLOROPROPENE
EPA Reg. No. NNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNN-RD-NNNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern		7. Test Substance	8. Time Frame	9. Registrant Response
	specific reregistration.									
63-14	Oxidizing or reducing action (10)					C	J	MP/EP	8 mos.	
63-15	Flammability (11)					C	J	MP/EP	8 mos.	
63-16	Explodability (12)					C	J	MP/EP	8 mos.	
63-17	Storage stability (18)					C	J	MP/EP	8 mos.	
63-18	Viscosity (13)					C	J	MP/EP	8 mos.	
63-19	Miscibility (14)					C	J	MP/EP	8 mos.	
63-20	Corrosion characteristics					C	J	MP/EP	8 mos.	
63-21	Dielectric breakdown voltage (15)					C	J	MP/EP	8 mos.	
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat (1,36,37)					C	J	MP/EP	8 mos.	
81-2	Acute dermal (1,2,37)					C	J	MP/EP	8 mos.	
	toxicity-rabbit/rat									
81-3	Acute inhalation toxicity-rat (3)					C	J	MP/EP	8 mos.	
81-4	Primary eye irritation-rabbit (2)					C	J	MP/EP	8 mos.	
81-5	Primary dermal irritation (1,2)					C	J	MP/EP	8 mos.	
81-6	Dermal sensitization (4)					C	J	MP/EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0328 Telone

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product, registrants are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).

2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.

3 If the pesticide is not already under full scale production and an experimental use permit is sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

4 To support registration of an MP or EP, whether produced by an integrated system or not, the technical grade of Active Ingredient must be analyzed. If the technical grade of Active Ingredient cannot be isolated, a statement of composition of the practical equivalent of the technical grade of Active Ingredient must be submitted. Data on EPs or MPs will be required on a case-by-case basis.

5 Certified limits are not required for inert ingredients in products proposed for experimental use.

9 Required if test substances are dispersible with water.

10 Required if product contains an oxidizing or reducing agent.

11 Required if product contains combustible liquids.

12 Required if product is potentially explosive.

13 Required if product is a liquid.

14 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

15 Required if end-use product is liquid and is to be used around electrical equipment.

17 Not required unless efficacy data are required.

18 Required for MP and EP but should not be submitted for EP unless (a) efficacy data are required to be submitted, (b) the storage stability data show that the active ingredient(s) is (are) not within the certified limits or toxicologically significant degradates are detected, or (c) product instability is suspected or incidents of instability are reported. Refer to PR Notice 92-5 for more information.

50 This includes MPs/EPs that are technicals, MPs/EPs manufactured from registered or non-registered sources, or MPs/EPs formulated from non-registered sources.

51 Guideline Reference No. 830.7050 UV/Visible Absorption
This study is a new requirement for all technicals, MPs and EPs, but could not be added under 830.7050 until the PDCI program is updated. Therefore, we have included it under Guideline Reference No. 63-13 until the PDCI system can be updated.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0328 Telone

Footnotes (cont.):

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.
36 Special testing (acute, subchronic, and/or chronic) is required for organophospates, and may be required for other cholinesterase inhibitors and other pesticides which have demonstrated a potential to adversely affect the visual system. Registrants should consult with the agency for development of protocols and methodology prior to initiation of studies.
37 Testing of the EP dilution in addition to the EP or MP is required if it can be reasonably anticipated that the results of such testing may meet the criteria for restriction to use by certified applicators specified in 40 CFR 152.170(b) or the criteria for initiation of special review specified in 40 CFR 154.7 (a)(1).

INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM (INSERT B) FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also

submit: (1) a completed **"Certification with Respect to Citations of Data (in PR Notice 98-5)" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data " (EPA Form 8570-32)**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-34)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

EPA'S BATCHING OF TELONE (1,3-DICHLOROPROPENE) PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing **Telone** (1,3-dichloropropene) as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not

to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Ten products were found which contain Telone as the active ingredient. These products have been placed into four batches in accordance with the active and inert ingredients and type of formulation.

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	62719-32	94.0	LIQUID
	11220-01	94.0	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
2	8536-21	1,3-dichloropropene ... 79.9 chloropicrin ... 15.0	LIQUID
	11220-20	1,3-dichloropropene ... 79.9 chloropicrin ... 15.0	LIQUID
	62719-12	1,3-dichloropropene ... 78.3 chloropicrin ... 16.5	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
3	8536-22	1,3-dichloropropene ... 65.8 chloropicrin ... 29.7	LIQUID
	11220-21	1,3-dichloropropene ... 65.8 chloropicrin ... 29.7	LIQUID
	11220-22	1,3-dichloropropene ... 61.1 chloropicrin ... 34.65	LIQUID

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
4	8536-08	1,3-dichloropropene ... 37.6 chloropicrin ... 59.4	LIQUID
	11220-15	1,3-dichloropropene ... 35.3 chloropicrin ... 58.8	LIQUID

The following summarizes acute data requirement by batch:

- Registrants with products in Batch 1 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 2 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 3 need to cite/submit all acute data on one of the subject products.
- Registrants with products in Batch 4 need to cite/submit all acute data on one of the subject products.

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0328 Telone

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
008536	SOIL CHEMICALS CORPORATION PRODUCT	D/B/A SCC PRODUCTS AND SOIL CHEMIC	BOX 782	HOLLISTER CA	95024
011220	TRICAL		BOX 1327	HOLLISTER CA	95024
062719	DOW AGROSCIENCES LLC		9330 ZIONSVILLE RD 308/3E	INDIANAPOLIS IN	46268

LIST OF AVAILABLE RELATED DOCUMENTS AND ELECTRONICALLY AVAILABLE FORMS

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.
   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

Forms Required for Responding to the RED:		
8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Restraints for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Other Pesticide Registration Forms:		
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.
3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
   a. Registration Division Personnel Contact List
   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   c. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information.

These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at 1-800-858-7378 or through their Web site.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
the Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following is a list of available documents for 1,3-Dichloropropene that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies are available on our website at www.epa.gov/REDs, or contact Lisa Nisenson at (703) 308-8031.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for 1,3-Dichloropropene.

The following documents are part of the Administrative Record for 1,3-Dichloropropene and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

3. Appendix A - Table of Use Patterns Subject to Reregistration

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria.