

US EPA ARCHIVE DOCUMENT



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 B₂, 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 degrade 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 B₂, 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:

N 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.

N 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.

N 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.