

Propargite RED Facts

EPA 738-F-01-012

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0243, propargite.

Use Profile

Propargite is an insecticide used to control mites on a variety of field, fruit, and vegetable crops, as well as ornamentals. It is manufactured by Uniroyal Chemical, under the trade names Omite and Comite. It is sold in both liquid and wettable powder formulations. Propargite is applied by aerial application, chemigation, airblast sprayer, and high pressure handwand.

Regulatory History

Propargite was first registered as a pesticide in the U.S. in 1969. EPA issued a Registration Standard for Propargite in September, 1986. (PB 87-139358). An October 1995 Data Call-In (DCI) required additional foliar residue and worker exposure data.

In April 5, 1996, the Agency and the registrant signed an agreement under which the registrant voluntarily canceled certain uses of the pesticide. The uses canceled under the agreement included those for apricots, apples, peaches, pears, plums, figs, cranberries, strawberries, green beans, and lima beans. Based on Agency analysis of submitted residue monitoring data, those uses were believed to pose an unacceptable carcinogenicity dietary risk. Tolerances for these 10 uses were subsequently revoked (64 FR 39068; July 21, 1999).

Human Health Assessment

Toxicity

Propargite generally has been shown to have low acute toxicity via the oral and dermal routes of exposure. However, it is considered to be severely irritating to both the skin and eyes, and dermal sensitization effects have been observed. Toxicity Categories used by EPA range from 1 (most toxic) to 4 (least toxic); for propargite, the categories are 3 for acute oral and dermal toxicity, and 1 for eye and dermal irritation.

Propargite is classified as a probable human carcinogen based on the appearance of intestinal tumors in test animals. The cancer concern was based on a 2-year cancer bioassay conducted on Sprague Dawley rats. In that study, propargite caused fatal tumors of the intestine in both male and female rats.

Dietary Exposure – Food

People may be exposed to residues of Propargite through the diet. Tolerances or maximum residue limits have been established for 42 crops and/or commodities. EPA has reassessed the propargite tolerances and found that no changes in tolerances are necessary due to risk concerns, therefore all tolerances will remain in effect, except those for dried citrus pulp and poultry meat/meat by-products, which are no longer needed. The Agency will establish new tolerances for aspirated grain fractions, cotton gin by-products, and citrus oil.

EPA has assessed the dietary (food) risk posed by propargite and has determined that it is not of concern. Specifically, for the sub-population judged to be most sensitive to propargite (females age 13 – 50 years), exposure from all current propargite tolerances represents 2% of the acute population adjusted dose (aPAD) (the amount believed not to cause adverse effects if consumed on any given day). For chronic exposure to the general U.S. population and all sub-populations, propargite dietary exposure is expected to be less than 1% of the chronic population adjusted dose (cPAD) (the amount believed not to cause adverse effects if consumed daily for 70 years.) Similarly, the estimated dietary exposures for the general population does result in a significant risk of cancer. The cancer risk for the general population is estimated to be 1.8×10^{-7} .

Dietary Exposure – Drinking water

EPA has assessed exposure via drinking water and has determined that there is not a risk of concern. Estimated ground and surface water concentrations of propargite are below the Agency's concern levels for acute and chronic effects. Although the cancer risk from drinking water appear to be of concern for surface water sources, the Agency believes that the monitoring and modeling analyses for propargite have over-estimated exposures in the present case. Moreover, establishing spray buffers around surface waters, as set forth in the RED, is expected to further reduce drinking water exposures. The Registrant has also agreed to conduct a monitoring study to confirm propargite use does not result in residues of concern in surface water sources of drinking water.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to propargite during and after application. Several exposure scenarios exceed the Agency's level of concern for short term health effects. Also, the cancer risk to certain pesticide mixers and loaders, when calculated without personal protective equipment or engineering controls, exceed the Agency's level of concern. Those exposures can be reduced to acceptable levels by the mitigation measures described below. To prevent unreasonable cancer risks to harvesters, weeders, scouts, and other post-application workers, all such workers will observe Restricted Entry Intervals ("REIs") of 1 to 36 days, depending on crop and activity. In most cases, these REIs are more stringent than that set by the Worker Protection Standard.

There are no propargite exposures via residential applications because no residential uses of propargite are approved.

FQPA Considerations

As part of the FQPA tolerance reassessment process, EPA assessed the various risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to propargite is within its own "risk cup." In other words, EPA has concluded that the tolerances for propargite meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the acute and chronic food exposure. An aggregate assessment was conducted for exposures through food and drinking water exposure (there are no residential uses of propargite with which to further aggregate exposure). Results of this aggregate assessment indicate that the human health risks from these combined exposures are within acceptable levels. The FQPA also 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 does not believe that propargite shares a common mechanism of toxicity with other chemicals. Therefore, propargite is not subject to any cumulative risk assessment as required by the FQPA.

Environmental Assessment

In water or in moist conditions, propargite degrades rapidly under alkaline conditions and is rated as "moderately persistent" to "persistent" under neutral and acid conditions. Soil and aquatic photolysis and aerobic and anaerobic metabolism occur at moderate rates. Because of its high affinity for soil and sediment, propargite has the potential to move off the site of application during rainfall, irrigation, erosion, runoff on soil particles and by drift. Given the moderate to slow degradation rates for metabolism and photolysis, and the high Koc values, propargite will probably be adsorbed to sediments and organic material if transported to surface waters.

Ecological risks are of concern to the Agency. Based on toxicity studies submitted by the Registrant, propargite poses a potential for adverse effects on reproduction in birds and mammals. Risk to aquatic organisms and plants is generally lower than the risk for birds and mammals; however, the chronic risk concern levels for freshwater invertebrates and freshwater fish are either approached or exceeded for over 60 days from multiple propargite applications. Propargite is also expected to be highly toxic to

amphibians. To address these ecological risks, the registrant has agreed to the risk reduction measures described below.

Risk Mitigation

EPA found that certain risk reduction measures were necessary in order to re-register propargite. The registrant has agreed to implement these label changes. To reduce risks to agricultural workers who may be exposed to propargite, EPA finds that the following measures are necessary:

- Closed mixing/loading systems for corn and cotton applications;
- Enclosed cockpits for all aerial applications;
- Water soluble packaging for all wettable powder formulations;
- Enclosed cabs for all airblast spray applications;
- Personal protective equipment (socks, shoes, long-sleeved shirts, long pants, and gloves) for all other applications; and
- Longer restricted entry intervals for most crops after propargite application.

To reduce the risk to birds, mammals, and aquatic organisms, EPA finds that the following measures are necessary:

- Decreasing seasonal maximum rates for beans, citrus cotton, corn, jojoba, mint, oranges, grapefruit, lemons, potatoes, and walnuts;
- Adding spray intervals of 21 days for most food crops (28 days for citrus);
- Decreasing the number of annual applications for cotton from 3 to 2.
- Prohibiting application of propargite by ground within 50 feet or by air within 75 feet of aquatic areas.
- Adding label requirements to minimize spray drift exposures.
- Conducting testing to better characterize exposure and risk to birds.

In addition to the above measures, EPA will reclassify propargite as a restricted use pesticide (RUP) to ensure that all persons who handle this pesticide are properly trained in the necessary worker safety and ecological protection precautions. The manufacturer has also agreed, as listed below, to conduct a surface water monitoring study to confirm that human exposures to propargite via drinking water are below the EPA concern levels.

Additional Data Required

EPA is requiring the following additional generic studies for Propargite to confirm its regulatory assessments and conclusions:

- Harmonized Test Guideline 860.1380 - Storage stability data for peanut, walnut, corn and tea.
- Harmonized Test Guideline 860.1520 - Residue data for cotton gin byproducts.
- Harmonized Test Guideline 840.1100 - Droplet size spectrum
- Harmonized Test Guideline 840.1000 - Drift field evaluation
- Harmonized Test Guideline 850.1350 - Estuarine/marine life cycle (mysid)
- Harmonized Test Guideline 850.1500 Freshwater fish full life cycle
- Special Study - Surface Source Drinking Water Monitoring Study.
- Special Study - Avian Dietary Exposure Study.

The Agency is also 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

All propargite end-use products must comply with EPA's current pesticide product labeling requirements and with the label changes described in the RED document for additional worker protection requirements, engineering controls, application intervals, spray buffers around surface waters, spray drift controls, and decreases in certain application rates. For a comprehensive list of labeling requirements, please see the propargite RED document.

Regulatory Conclusion

The use of currently registered products containing propargite in accordance with approved labeling, coupled with the risk reduction measures described in the RED, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all use of these products identified in the RED are eligible for reregistration.

Propargite products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information


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

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

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 301-604-3408.

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

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

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is npic.orst.edu .