



R.E.D. FACTS

Pesticide Reregistration

Triallate

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 (FQPA) 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 2695, triallate.

Use Profile

Triallate is a pre-emergent herbicide federally registered, but restricted to use in CO, ID, KS, MN, MT, NE, NV, ND, OR, SD, UT, WA, and WY on barley, lentils, peas (dried and succulent), triticale, wheat, and canary grass. The Agency has found that all currently registered uses of triallate, except canary grass, are eligible for reregistration, provided specified changes are made to the label. Canary grass is not being supported by the registrant for reregistration and the tolerance has been revoked. In addition, since completion of the RED, a tolerance has recently been established for a new use of triallate on sugar beets.

On average, about 2.3 million pounds of triallate are applied annually on 2.1 million acres. Depending on the crop, triallate formulations may be applied before or after planting, either by ground or aerial equipment. Application is typically made either in the fall or in the spring, before targeted weed species germinate.

Regulatory History

Triallate was first registered as a herbicide in the U.S. in 1961. Because triallate is a List B chemical, no Registration Standard was prepared. A Data Call-In (DCI) was issued in 1991 requiring the submission of additional data on product and residue chemistry, toxicity, environmental fate, and ecological effects. In 1993 and 1994, two additional DCIs were issued requiring the submission of a female mouse oncogenicity study at higher dose levels and a developmental neurotoxicity study.

Human Health Assessment

Toxicity

Triallate is a herbicide in the class of thiocarbamates, which includes pebulate, molinate, EPTC, butylate, vernolate, and cycloate. As with other chemicals in this class, neurotoxicity is the major toxic effect; however, other toxic effects, including carcinogenicity were also observed in toxicology studies for this compound.

Toxicity categories, which range from I (most toxic) to IV (least toxic), show that triallate has a low order of acute oral (Toxicity Category III); dermal (Toxicity Category IV); and inhalation (Toxicity Category IV) toxicity. In primary irritation studies, triallate produces slight irritation to the eye (Toxicity Category III) and skin (Toxicity Category IV), and is a skin sensitizer.

Triallate is classified as a Group C chemical (possible human carcinogen), based on hepatocellular carcinomas in male mice, with a positive trend and borderline significance in female mice, and increased incidence of renal tubular cell adenomas in rats.

Cumulative Risk

In accordance with the FQPA, the Agency is examining whether and to what extent some or all organophosphorous and carbamate (including, but not limited to, methyl carbamate, N-methyl carbamate, thiocarbamate, and dithiocarbamate) pesticides may share a common mechanism of toxicity. In contrast to other carbamates, the Agency has a less fully developed understanding of whether the thiocarbamates share a common mechanism of toxicity with other cholinesterase-inhibiting or carcinogenic chemicals. As a result, the Agency has not determined if it would be appropriate to include them in a cumulative risk assessment with other such chemicals (e.g., the organophosphorous and carbamate pesticides).

Therefore, for the purposes of this risk assessment, the Agency has assumed that triallate does not share a common mechanism of toxicity with cholinesterase-inhibiting chemicals.

Dietary Risks

Overall acute and chronic dietary (food only) risks associated with triallate use on all registered use sites, including the proposed use of triallate on sugar beets, are not of concern to the Agency. Acute and chronic drinking water concentrations were also estimated to evaluate the contribution of drinking water to dietary risk. These drinking water estimates are based on ground and surface water computer models that predict concentrations for both parent triallate and the metabolite TCPSA. Aggregating both food and drinking water acute and chronic (non-cancer) risks, the dietary exposures are not of concern to the Agency.

Triallate is classified as a Group C chemical (possible human carcinogen). Based on a linear low-dose (Q_1^*) approach for human cancer risk characterization, the cancer dietary risk is 7.1×10^{-8} , which is less than EPA's target of 1×10^{-6} (1 in 1 million) and, therefore, is not of concern to the Agency.

Although chronic (cancer) dietary (food only) risk is not of concern to the Agency, aggregating the cancer dietary risk (food) with model estimated drinking water concentrations is of concern. To address this, the registrant initiated a surface water monitoring program to measure parent triallate and metabolite TCPSA in high use areas with vulnerable soil conditions.

Tolerances

Tolerances [refer to 40 CFR 180.314 (c)] or maximum residue limits are summarized below:

- C Revoke 1 tolerance (lentils hay), since it is no longer considered a significant livestock feed item.
- C Add 3 new tolerances (barley hay; wheat forage; wheat hay), due to changes to OPPTS GLN 860.1000.
- C The tolerance for peas will apply to lentils.
- C All other tolerances are to be increased, except barley grain, which will remain the same.

Worker Risks

There are potential occupational exposures to pesticide handlers and to workers when applying triallate. For mixers/loaders, applicators, and flaggers, risks for all exposure scenarios are not of concern with either personal protective equipment (PPE) (i.e., gloves and dust/mist filtering respirators) or engineering controls (enclosed cockpits and trucks). The addition of some of these protective measures are necessary to reduce cancer risk to handlers.

Significant exposure to triallate during harvesting, or any other late season activity, is not likely since triallate is applied pre-emergence. Therefore, post-application exposure is not expected, provided that the current 12-hour restricted-entry interval (REI) is observed.

Environmental Assessment

Ecological Risks

The use of triallate is not likely to pose significant risk to birds, fish, large mammals, reptiles or nontarget insects. Levels of concern are slightly exceeded for endangered small mammals; however, this risk is dependent upon ingestion of large amounts of contaminated insects or seed in the diet. Levels of concern for acute risk, based on water modeling results, are slightly exceeded for endangered aquatic invertebrates. However, because the habitat of endangered aquatic organisms where triallate is registered are not likely to be exposed to the high modeled concentrations of triallate, effects to endangered aquatic invertebrates are not expected. Additionally, levels of concern for acute risk are exceeded for terrestrial and semiaquatic plants. Although risks to plants are greater than the level of concern, the overall ecological risk associated with the use of triallate is low; therefore, no additional mitigation measures to reduce estimated ecological risks are necessary.

Risk Mitigation

In order to support a RED for triallate, some risk mitigation measures are necessary and must be implemented. To address aggregate cancer dietary risk concerns (food and water), the registrant initiated a surface water monitoring program to measure parent triallate and metabolite TCPSA in high use areas with vulnerable soil conditions. A final report of this study is expected in late 2002. Interim results indicate that surface drinking water concentrations are not of concern to the Agency.

There are also potential occupational exposures to pesticide handlers and to workers when applying triallate. For mixers/loaders, applicators, and flaggers, risks for all exposure scenarios are mitigated with either personal protective equipment (PPE) (i.e., chemical resistant gloves and dust/mist filtering respirators) or engineering controls (i.e., enclosed cockpits and trucks).

Additional Data Required

EPA is requiring the following additional generic studies for triallate to confirm its regulatory assessments and conclusions: discussion of formation of impurities; stability to normal and elevated temperatures, metals, and metal ions; pH; UV/Visible absorption; partition coefficient; crop field trials (wheat hay); processed food/feed (barley); field accumulation in rotational crops; aquatic invertebrate life-cycle (21 day); aquatic plant growth; and surface drinking water monitoring.

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

All triallate end-use products must comply with EPA's current pesticide product labeling requirements, with the risk mitigation measures discussed above, and uses no longer eligible for reregistration should be excluded. For a comprehensive list of labeling requirements, please see the triallate RED document.

Regulatory Conclusion

The Agency has found that all currently registered uses of triallate, except canary grass, are eligible for reregistration, provided specified changes are made to the label. The use of eligible triallate products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to triallate will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for triallate 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 OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, 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> or <http://www.epa.gov/pesticides/>.

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 513-489-8695.

Following the comment period, the triallate RED 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 triallate RED, or reregistration of individual products containing triallate, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460; telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). 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 <http://ace.orst.edu/info/nptn/>.