

Oxyfluorfen RED Facts

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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 2670, oxyfluorfen.

Use Profile

Oxyfluorfen is a diphenyl-ether herbicide used for broad spectrum pre- and post-emergent control of annual broadleaf and grassy weeds in a variety of tree fruit, nut, vine, and field crops. The largest agricultural markets in terms of total pounds active ingredient are wine grapes and almonds. There are also non-agricultural ornamental and forestry uses. Oxyfluorfen is also used for weed control in landscapes, patios, driveways, and similar areas in residential sites.

Regulatory History

Oxyfluorfen was first registered in the United States in 1979 to control pre-emergent and post-emergent broadleaf and grassy weeds in a variety of field, fruit, and vegetable crops, ornamentals, as well as non-crop sites. It is manufactured by Dow AgroSciences and Makhteshim-Agan under the trade names Goal and Galigan. Data call-ins were issued in 1991, 1993, and 1995. In January 2002, the risk assessments were made publicly available for comment and a close-out conference call was conducted

on July 25, 2002, to discuss the risk management decisions and resultant changes to the oxyfluorfen labels.

Human Health Assessment

Toxicity

Oxyfluorfen is of low acute oral, dermal, and inhalation toxicity. The primary toxic effects are alterations in blood parameters (anemia) and in the liver. Oxyfluorfen is classified as a possible human carcinogen based on combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. A cancer potency factor (Q_1^*) was used to estimate human risk. The FQPA Safety Factor for protection of infants and children was reduced to 1X for all population subgroups as there was no increased susceptibility in animals due to pre- or post-natal exposure to oxyfluorfen.

Dietary Exposure

No adverse effects reflecting a single dose were identified in toxicological studies; therefore, no acute endpoint was selected and an acute dietary risk assessment was not conducted. EPA's dietary risk analysis for oxyfluorfen evaluated chronic (non-cancer) and cancer risk. For these chronic food risk assessments, anticipated residues were calculated using either USDA Pesticide Data Program (PDP) monitoring data or field trial data. Both data sets are consistent in that they show all non-detectable residues.

Based on this analysis, the percentage of cPAD utilized is expected to be less than 1 percent for the U.S. population and all subpopulations. Therefore, the chronic (non-cancer) dietary risk estimate from food alone is not of concern. Cancer risk from food is calculated by using a linear low-dose risk model (" Q_1^* ") to determine the lifetime cancer risk estimate. The Agency generally considers risks greater than 1×10^{-6} (1 in 1 million) to exceed its level of concern for cancer dietary exposure. Using the Q_1^* of 7.32×10^{-2} results in a maximum estimated lifetime cancer risk to the U.S. general population of 3.8×10^{-7} . Therefore, the cancer risk from food alone is also not of concern.

People may be exposed to residues of oxyfluorfen through the diet. Tolerances or maximum residue limits have been established for 33 fruits, vegetables and nut trees as well as meat commodities (please see 40 CFR 180.381). EPA has reassessed the oxyfluorfen tolerances and found that the majority are acceptable. New tolerances must be proposed/established for cotton gin byproducts, soybean forage, soybean hay, and grass forage, grass hay, and grass seed screenings.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to oxyfluorfen during and after normal use of liquid and granular formulations in agricultural and other

settings. Oxyfluorfen is used in the residential environment by homeowners to kill weeds on patios, driveways and similar surfaces. Oxyfluorfen homeowner products are intended solely for spot treatment; they are not used for broadcast treatment of lawns because they kill grass.

FQPA Considerations

Chronic (non-cancer) Aggregate Risk - This assessment addresses exposure to oxyfluorfen residues in food and water only, as there are no chronic residential scenarios identified. Comparison of the chronic DWLOCs with the environmental concentrations of oxyfluorfen shows that estimated surface and groundwater concentrations are substantially less than the DWLOCs for all populations. Consequently, the Agency concludes that residues of oxyfluorfen in food and drinking water do not result in a chronic aggregate risk of concern.

Short-term Aggregate Risk - Short-term DWLOCs were calculated based upon average food residues, and the residential handler exposure which resulted in the greatest risk (spot treatment of weeds using a RTU trigger pump sprayer). DWLOC calculations are for adults only since the residential exposure is to applicators. Surface and ground water concentrations estimated using conservative modeling are less than the short-term DWLOCs for oxyfluorfen. Consequently, there are no short-term aggregate risk concerns from food, drinking water and residential exposures.

Cancer Aggregate Risk - The chronic food cancer risk estimate of 3.8×10^{-7} , combined with the highest residential cancer risk estimate of 8.7×10^{-7} , results in a food + residential cancer risk of 1.3×10^{-6} . Since the Agency's level of concern is 1.0×10^{-6} , cancer risk slightly exceeds EPA's level of concern when considering both food and residential exposures. However, since PDP monitoring and field trial data showed all residues on food were non-detects, the food risk estimate is considered upper-bound. Screening-level surface water modeling indicates that there may be a concern for oxyfluorfen in drinking water, but this water modeling is also considered upper-bound.

Occupational and Residential Risk

Cancer risk to workers is of greater concern than non-cancer risk. Occupational cancer risks, when calculated without personal protective equipment or engineering controls, can range up to 1×10^{-3} . With the protection specified on several current labels, most scenarios result in cancer risks in the 10^{-5} range.

The residential assessment for oxyfluorfen only addresses the applicator, because negligible postapplication exposure is anticipated from spot treatment of weeds. None of the residential applicator scenarios are of concern because the short-term MOEs are greater than 100 and the cancer risks are less than 1.0×10^{-6} .

Environmental Assessment

Oxyfluorfen has the potential to affect terrestrial plants and aquatic ecological systems at all levels, as it is toxic to plants, invertebrates, and fish, and has been shown to drift from application sites to nearby areas. Birds and mammals may also experience subchronic and chronic effects from oxyfluorfen use.

Environmental Fate

Oxyfluorfen is persistent and relatively immobile in soil. The most likely route of dissipation is soil binding. Laboratory data suggest that once the soil-bound oxyfluorfen reaches deep or turbid surface water it will persist since it is stable to hydrolysis and since light penetration would be limited; however, it may degrade by photolysis in clear, shallow water. Oxyfluorfen can contaminate surface water through spray drift and runoff; however, it is unlikely to contaminate ground water because it is relatively immobile in the soil column; therefore, the likelihood of leaching is small. No degradates were identified, and therefore, only the parent, oxyfluorfen, is of toxicological concern for risk assessment.

Ecological Effects

For acute exposures, oxyfluorfen is practically non-toxic to birds, mammals, and bees, and the Agency has no risk concerns. However, subchronic and chronic risks to terrestrial birds and mammals do present a concern. These toxic effects may be manifested as reproductive, developmental, and hemolytic consequences. Assuming maximum residue values, the chronic level of concern is exceeded when oxyfluorfen is applied to crops at application rates greater than or equal to 0.25 lbs ai/acre/year for birds and greater than or equal to 2.0 lbs ai/acre for mammals. In addition, the potential of oxyfluorfen (as a light-dependent peroxidizing herbicide) to be more toxic in the presence of intense light may lead to the occurrence of more serious environmental effects that are not predicted by standard guideline toxicity tests. Oxyfluorfen is highly toxic to very highly toxic to fish and aquatic invertebrates. However, concentrations predicted by the Agency's surface water models from normal use are generally not high enough to cause an acute concern for fish. Chronic risk to fish and acute and chronic risk to aquatic invertebrates may occur from some uses of oxyfluorfen.

There are acute concerns for freshwater algal plants for all uses of oxyfluorfen. The risk to vascular aquatic plants cannot be assessed due to lack of data. Oxyfluorfen is expected and has been shown to negatively impact seedling emergence and vegetative vigor of terrestrial plants. Non-target terrestrial plants are exposed to oxyfluorfen as a result of spray drift and runoff and most incidents reported to the Agency are related to plants affected by spray drift. Acute levels of concern are exceeded for all uses of oxyfluorfen for terrestrial plants and semi-aquatic plants adjacent to treated areas.

Ecological Effects Risk Assessment

Generally, the Agency believes that oxyfluorfen presents the greatest risks to terrestrial plants and to aquatic organisms through spray drift of liquid formulations and runoff of dissolved and soil entrained oxyfluorfen.

Risk Mitigation

To lessen the risks of cancer from drinking water, occupational risks, and risks to wildlife posed by oxyfluorfen, EPA is requiring the following risk mitigation measures:

Lower the maximum rate to 1.5 lbs ai/broadcast acre/season for food crops and 2 lbs ai/acre/season for conifer seedlings.

For liquid formulations and granulars applied to field-grown ornamentals, registrants have agreed to lower this seasonal maximum rate to 4.5 lbs ai/A (1.5 lbs ai/A/application). For granulars applied to containerized ornamentals, the rate will be lowered to a seasonal maximum of 6 lbs ai/A (2 lbs ai/A/application).

Label language will be added to require 25 foot, no-spray, vegetative buffer zones around surface water bodies such as rivers, lakes, streams, and ponds.

To minimize oxyfluorfen drift, only use of a coarse, very coarse, or extremely coarse spray will be allowed according to the ASAE 572 definitions for standard nozzles, or a volume median diameter (VMD) of 385 microns or larger for spinning atomizer nozzles.

The maximum application rate on residential products will be reduced to 3 lbs ai/A or less unless efficacy data support the need for higher rates.

Closed mixing/loading systems to support applications to corn, cotton, soybeans, and aerial applications to fallow land.

Enclosed cab for applications to corn, and closed cockpit aircraft for applications to fallow land.

Double layer Personal Protective Equipment (PPE) for all other mixers, loaders, and applicators.

Additional Data Required

EPA is requiring the following additional generic studies for oxyfluorfen to confirm its regulatory assessments and conclusions: 21-day Dermal Toxicity Study in Rats; Crop Field Trials in Bananas and Cacao Beans; Estuarine/marine Fish Early-life Stage; Whole Sediment Invertebrate Freshwater Acute Toxicity; Whole Sediment Invertebrate Estuarine/marine Acute Toxicity; Seed Germination/Seedling

Emergence; Vegetative Vigor; Aquatic Plant Growth; Dislodgeable Foliar Residue Study in Conifers; Fish Phototoxicity Study; and Edge of Field Water and Sediment Monitoring.

Product Labeling Changes Required

All oxyfluorfen end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the oxyfluorfen RED document. The labeling requirements table is available as a separate document.

Regulatory Conclusion

The use of currently registered products containing oxyfluorfen in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

All 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 oxyfluorfen 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 oxyfluorfen 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 oxyfluorfen RED, or reregistration of individual products containing oxyfluorfen, 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 <http://npic.orst.edu>.