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EPA R.E.D. FACTS

TRICLOPYR

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.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing or reassessing tolerances.

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. 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 2710, that includes triclopyr acid, triclopyr triethylamine salt (TEA) and triclopyr butoxyethyl ester (BEE).

Use Profile

Triclopyr TEA and BEE products are used as selective herbicides to control broad leaf weeds and brush on a variety of sites-- rights-of-way, pasture and rangelands, forests, rice, and turf, including home lawns. Triclopyr products are formulated as soluble concentrates, emulsifiable concentrates, liquids (pressurized and ready-to-use), granulars, wettable powders and pellets.

Regulatory History

Triclopyr TEA was first registered in 1979 as an herbicide on non-crop areas and in forestry use for the control of broadleaf weeds and woody plants. Triclopyr BEE was subsequently registered in 1980 for use on the same sites. Both formulations were registered for use on turf sites in 1984. In 1985, triclopyr BEE was registered for use on rangeland and permanent grass pastures. Most recently (1995), triclopyr TEA was registered for use on rice

to control broadleaf weed species. A Data Call-In Notice (DCI) was issued in August 1991 requiring the submission of product chemistry, residue chemistry, ecological and environmental fate data for both TEA and BEE and toxicological data for TEA. At the time of the RED assessments, there were 12 registered products containing triclopyr BEE and 24 products containing triclopyr TEA.

Human Health Assessment

Toxicity

Technical triclopyr acid was found to be slightly toxic by oral and dermal routes and has been placed in Toxicity Category III for these effects. Acceptable studies for acute inhalation, primary eye irritation, primary dermal irritation and dermal sensitization were not available for the technical grade of triclopyr acid. Available data indicate that both BEE and TEA are slightly toxic by oral (Toxicity Category III) and dermal (Toxicity Category III) routes of exposure, and practically non-toxic by inhalation (Toxicity Category IV) and do not cause dermal irritation. In a primary eye irritation study triclopyr TEA was found to be corrosive while BEE was found to be minimally irritating. Both TEA and BEE were found to cause dermal sensitization in test animals.

The Agency has classified triclopyr as a Group D chemical (not classifiable as to human carcinogenicity). This decision was based on increases in mammary tumors in both the female rat and mouse, and adrenal pheochromocytomas in the male rat, which were considered to be only a marginal response, and the absence of additional support from structural analogs or genotoxicity.

The Reference Dose (RfD), the amount of triclopyr residues that could be consumed daily over a lifetime without adverse effects, was established at 0.05 mg/kg/day, based on the 2-generation reproduction toxicity study in rats with a NOEL of 5.0 mg/kg/day, the lowest dose tested. At the next dose level (25 mg/kg/day), an increased incidence of proximal tubular degeneration of the kidneys was observed in P1 and P2 parental rats in this study.

For the acute dietary risk assessment, the endpoint of concern was the maternal and developmental NOEL of 30 mg/kg/day from a developmental toxicity study in rabbits based on a decreased number of live fetuses and other effects at the 100 mg/kg dose.

Because reliable pre- and post-natal data indicate no special sensitivity of young animals to triclopyr residues, EPA finds that an uncertainty factor of 100 (10 for interspecies differences in response, and 10 for intraspecies differences) is adequately protective of infants and children. Therefore, for risk assessment purposes the chronic dietary (RfD) calculations include a factor of 100, and the acute dietary risk assessments assume that a margin of exposure (MOE) of 100 or greater is acceptable.

Dietary Exposure/Risk

People may be exposed to residues of triclopyr through the diet. Triclopyr tolerances have been established for grass forage and hay, meat, meat byproducts, milk and eggs, and rice. EPA's tolerance reassessment indicates only minor changes to the current tolerance expression and tolerance values are needed, provided the label restrictions required by this RED are implemented limiting grazing and application rates.

Calculations using existing triclopyr tolerances result in a TMRC (theoretical maximum residue contribution) which represents < 1% of the RfD for the general population and < 3% of the RfD for children less than one year old, considering food only. These small percentages of the RfD generally indicate little concern for dietary risk.

Chronic aggregate dietary risk estimates, including both food and an upper bound estimate of triclopyr residues in drinking water, account for 16% of the RfD for females 13+ years, and 49% of the RfD for children ages 1 to 6.

The acute dietary (food only) MOE for the most sensitive subgroup, females of child bearing age, is 2500. The acute aggregate dietary MOE for the sub-population of greatest concern (pregnant females 13+) including food and drinking water is 1250.

Both triclopyr and the insecticide chlorpyrifos produce the metabolite 3,5,6-trichloro-2-pyridinol (TCP). TCP is similar in toxicity to triclopyr and less toxic than chlorpyrifos. EPA's aggregate assessment of the known, likely sources of exposure to TCP from both triclopyr and chlorpyrifos uses results in an acute MOE of 600 for females 13 + years. Aggregate chronic exposures could account for up to 90% of the provisional RfD for TCP for non-nursing infants less than 1 year old. Because these estimates include many upper bound exposure assumptions and still fall within acceptable limits, EPA believes that the risks posed by dietary exposure to the metabolite TCP are not of concern.

Occupational and Residential Exposure/Risk

Dermal absorption is calculated to be < 2% based on a study with human volunteers and a rabbit dermal absorption study. Neither occupational nor residential risk assessments for short-term and intermediate-term dermal exposure to triclopyr have been conducted because no adverse effects were seen at the highest dose tested of 1000 mg/kg/day in a 21-day dermal toxicity study in rabbits.

Because the acute inhalation LC_{50} was determined to be > 2.6 mg/L, significant toxicity resulting from inhalation exposure would not be expected, and a separate risk assessment for the inhalation route of exposure is not warranted.

Homeowner exposure to triclopyr is expected to be minimal because of low dermal and inhalation toxicity, and because methods typically used by homeowners do not provide significant exposure (e.g., weed stick), and

treatment areas are usually limited in size. Also, the percent active ingredient and the application rates of homeowner products are less than those for agricultural or industrial use products. No chronic residential or occupational exposures are anticipated.

EPA is working with other agencies and the Native American tribes in California to determine the potential exposure to forestry herbicides that may be occurring to Native Americans through their use of forest plant materials in the making of baskets, for medicinal purposes and in other activities. Work currently underway will characterize the dissipation rate and frequency of occurrence of three herbicides (glyphosate, hexazinone, and triclopyr) in plants of interest to Native Americans. Because this work is ongoing, these unique exposures are not reflected in the triclopyr RED assessments.

FQPA Summary and Findings

Reliable data indicate no special sensitivity of infants and children to triclopyr residues. An uncertainty factor of 100 has been applied in both the chronic and acute dietary risk assessments. Both acute and chronic aggregate dietary (food + drinking water) risks are well within the acceptable range for triclopyr and for the identified sources of TCP, a metabolite common to both triclopyr and chlorpyrifos. EPA has not made a final determination regarding a possible common mechanism of toxicity for triclopyr and other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of the tolerance reassessment in this RED, EPA considered only the risks of triclopyr and TCP in its assessments.

Environmental Fate/Ecological Risks

Triclopyr acid is somewhat persistent, and is mobile. The predominant degradation pathway for triclopyr in water is photodegradation. The predominant degradation pathway in soil is microbial degradation to the major degradate TCP, which is both persistent and mobile.

Triclopyr acid was found to be slightly toxic to birds and practically non-toxic to mammals, insects, freshwater fish and invertebrates. Triclopyr TEA was practically non-toxic to slightly toxic to birds and estuarine/marine invertebrates and practically non-toxic to freshwater fish, freshwater invertebrates and estuarine/marine fish. Testing with BEE indicated it to be slightly toxic to birds, moderately toxic to highly toxic to freshwater fish and estuarine/marine invertebrates, slightly to moderately toxic to freshwater invertebrates, and highly toxic to estuarine/marine fish.

Using current maximum permissible application rates (i.e., up to 12.12 lbs/ae/A), levels of concern (LOE) are exceeded for many species. However, calculating RQs at the revised, lower maximum rates established by the RED indicates that only chronic risk to mammals, acute risk to fish (BEE) and acute risk to non-target plants remain problematical.

Factors that lessen the Agency's concern for these LOC exceedances include several worst-case exposure assumptions that are unlikely under actual use conditions. For example: The screening level chronic assessment is based on 0-hour residues and does not take into account degradation--actual environmental concentrations would be less. Acute risks to fish were calculated assuming direct application to shallow aquatic habitat, which is not currently allowed--flowing water systems would result in rapid dissipation of triclopyr. Because triclopyr is an herbicide, risk to non-target plants is anticipated. However, potential damage to non-targets will be minimized by new spray drift management requirements and reduced application rates. Also, the registrant, Dow Agrosciences (formerly DowElanco), has provided the Agency with survey data indicating that typical application rates range from 0.5 to 4 lbs ae/A, generally much lower than the maximum rates allowed by current labels, and that more than 95% of triclopyr applications occur only once a year or less frequently.

EPA is concerned about the potential chronic toxicity and persistence of the triclopyr degradate, TCP, in the aquatic environment and is requiring additional confirmatory data to better characterize the fate of TCP and its chronic toxicity to fish, particularly salmonid species.

Risk Mitigation Measures

In order to reduce risk to non-target plants and animals, pesticide handlers and the environment, EPA is requiring the following changes to triclopyr use practices and labeling:

! The maximum application rate permitted on pasture and rangeland and all other sites where cattle can be grazed will be 1 lb/ae/A per year; for forestry applications the maximum will be 6 lbs/ae/A; for all other sites the maximum allowed rate will be 8 lb ae/A for the BEE and 9 lb/ae/A for the TEA.

! Labels must include best management practices for spray drift.

! A label statement warning users of the potential of triclopyr to leach to ground water in certain situations is required.

! A restriction against grazing lactating dairy animals until the following season is required. All conflicting grazing instructions must be removed. Labels must specify a 14 day PHI for grass hay, and retain the existing pre-slaughter interval of 3 days.

! An REI of 48 hours for triclopyr TEA, and 12 hours for triclopyr BEE is established for uses within the scope of the Worker Protection Standard; early entry PPE consisting of coveralls, chemical resistant gloves, protective eyewear--for TEA formulations, and shoes+sox) is required.

! Homeowner reentry is restricted until sprays have dried and dusts have settled.

! Additional confirmatory data are required to better characterize the fate of the degradate, TCP, in the aquatic environment and its chronic toxicity to fish. EPA is also requiring product-specific data including product chemistry and acute toxicity studies, and revised Confidential Statements of Formula (CSFs).

Regulatory Conclusion

EPA has determined that the reassessed tolerances for triclopyr meet the safety standard under the FQPA, and that there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to triclopyr or TCP residues. The use of currently registered products containing triclopyr in accordance with labeling required by this RED will not pose unreasonable risks of adverse effects to humans or the environment. Therefore, all currently registered uses of these products are eligible for reregistration.

Triclopyr products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. These products will be reregistered once any 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 triclopyr 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 triclopyr 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 and External Affairs 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 our website at 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 triclopyr RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-605-6000.

For more information about EPA's pesticide reregistration program, the triclopyr RED, or reregistration of individual products containing triclopyr, 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.