United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-002 January 1995

R.E.D. FACTS

Ethalfluralin

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 years ago 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. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2260, ethalfluralin.

Use Profile

Ethalfluralin is a selective herbicide used for the preemergence control of annual grasses and broadleaf weeds in certain food and feed crops. Marketed under the trade name Sonalan, ethalfluralin may be used in growing a variety of grain, seed, and cucurbit crops. The greatest amounts of ethalfluralin are used in growing soybeans, dry beans, and sunflower seeds. Granular, dry flowable, and emulsifiable concentrate formulations are registered. Products may be applied preplant, postplant prior to emergence, postemergence, or post-transplant as a soil incorporated, band, or broadcast application using ground equipment.

Ethalfluralin is used only outdoors, in agriculture--no residential uses are registered. Use practice limitations prohibit applying ethalfluralin to any body of water or wetland.

Regulatory History

Ethalfluralin was conditionally registered as a herbicide for use on dry peas, dry beans, soybeans, and cucurbits, from November 1983 until December 1, 1985. EPA determined that ethalfluralin's benefits outweighed its cancer risks during that time period. Tolerances, or maximum residue limits in food and feed commodities, were established. Later, data were

submitted that allowed full registration of ethalfluralin, and several new uses were added.

In December 1990, EPA issued a data call-in notice under phase IV of the accelerated reregistration program. At present, six products are registered containing the active ingredient ethalfluralin including one technical (manufacturing use) product and five end-use products.

Human Health Assessment

Toxicity

Ethalfluralin causes moderate eye irritation and moderate to severe skin irritation, and has been placed in Toxicity Category II (the second-highest of four acute toxicity categories) for these effects. It also is a skin sensitizer. Ethalfluralin otherwise is of relatively low acute toxicity. It has been placed in Toxicity Category III for inhalation effects, and Toxicity Category IV for oral and dermal effects.

Subchronic toxicity studies using mice and rats resulted in changes in liver and kidney weights, decreased weight gain, and changes in blood and enzyme activity. A study using beagle dogs resulted in changes in the liver, blood and cholesterol. A study using rabbits resulted in severe skin irritation.

A chronic toxicity and carcinogenicity study using rats resulted in mammary gland tumors in female rats at mid and high doses. EPA concluded on June 8, 1994, that ethalfluralin should be classified as a Group C, possible human carcinogen, based on the results of that study. A second study in mice caused liver cell, blood and enzyme changes, as well as increased liver, kidney and heart weights in females, and decreased body weight gain. A study using beagle dogs resulted in changes in the blood, bone marrow, enzymes and liver.

Although a developmental toxicity study in rats did not show effects, a study using rabbits resulted in maternal effects (abortions and decreased food consumption), and developmental toxicity effects including increased resorptions, abnormal skull development, and variations in the sturnum.

No treatment-related effects were noted on reproduction parameters in two reproductive toxicity studies using rats. Ethalfluralin was weakly mutagenic in two types of mutagenicity studies but negative for mutagenicity in two other studies.

Dietary Exposure

People may be exposed to residues of ethalfluralin through the diet. Tolerances or maximum residue limits have been established for ethalfluralin residues in/on plants (dry beans, cucurbit vegetables, peanuts, peanut hulls, dry peas, soybeans, and sunflower seeds) and in animal commodities (eggs, milk, and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep). (Please see 40 CFR 180.416.) All of these tolerances are established at 0.05 parts per million (ppm). Ethalfluralin residues are not likely to concentrate in processed food, so no

food or feed additive tolerances are established or required. Residues were not found in rotational crops so relevant tolerances need not be established.

EPA has assessed most existing ethalfluralin tolerances. Additional confirmatory data are required for the postplant-preemergence application use of ethalfluralin on cucurbits (cucumbers, melons, and squash) to reassess the adequacy of the tolerances established. New data also are required for the postemergence and posttransplant applications to cucurbits. These data are **not** considered confirmatory, however, since EPA lacks data which would allow an interim assessment of the residues. Thus, at this time, the postemergence and posttransplant uses of ethalfluralin on cucurbits **are not eligible** for reregistration. If data from cucurbit studies currently underway are not adequate, these uses will have to be removed from ethalfluralin product labels.

In addition, ethalfluralin tolerances for animal commodities must be revoked. Ethalfluralin residues in animals at up to ten times the usual dietary burden are not quantifiable. If it is not possible to determine finite residues with certainty, and if it is unlikely that there are any residues, the Agency's policy is not to establish tolerances, or to revoke existing ones.

Finally, since label restrictions on grazing, haying, and foraging generally are no longer permitted, such restrictions for beans, peas, soybeans, peanuts and alfalfa must be removed from all ethalfluralin labels.

EPA has assessed the dietary risk posed by ethalfluralin. In its analysis, the Agency included the existing tolerances for cucurbits (though adequate data are not available for reregistration) and animal commodities (though these tolerances must be revoked), to reflect a worst case scenario.

The upper bound dietary risk estimate for the U.S. population is 6.2×10^{-5} based on all the published tolerances for ethalfluralin. However, EPA is revoking the tolerances for meat, milk, poultry, and eggs, based on the presumption that there are undetectable, finite residues in these food items. When cancer risk is calculated without these tolerances, the upper bound dietary risk is 5.7×10^{-7}, a negligible risk.

For the overall U.S. population, chronic exposure from all existing ethalfluralin tolerances represents 2% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The Anticipated Residue Contribution (ARC), a more accurate estimate of dietary exposure which takes into account percent of crop treated and other chemical- and use-specific information, still represents only 2% of the RfD for the overall population. For the most highly exposed subgroup, non-nursing infants, chronic exposure from all existing tolerances represents 9% of the RfD, while the ARC is only 4% of the RfD. Therefore, chronic dietary risk appears to be minimal.

Acute exposure to the subgroup of greatest concern, females age 13 and older (women of childbearing age), results in a Margin of Exposure (MOE) of 25,000 for developmental toxicity. EPA believes MOEs of 100

or greater represent a negligible risk for that toxicological endpoint. Therefore, acute dietary risk to ethalfluralin is not of concern.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders and applicators) may be exposed to ethalfluralin during applications to agricultural crops. Because ethalfluralin is a possible human carcinogen, EPA assessed exposure and risk to workers in four major exposure scenarios. While workers in three of the scenarios have risks that are considered negligible, commercial mixers/loaders using the liquid/dry flowable formulation with ground application equipment are estimated to have an extra cancer risk of 1×10^{-5}.

To mitigate this worker risk, EPA is requiring use of minimum, baseline personal protective equipment (PPE), including coveralls and chemical resistant gloves, by all ethalfluralin handlers. To further reduce their risks, mixers and loaders must wear coveralls over long pants and long-sleeved shirts--a double layer of protection--as well as chemical resistant gloves and a chemical-resistant apron to protect against spills or splashing.

Post-application exposure to ethalfluralin should be minimal, as long as the pesticide is applied and incorporated into soil correctly, or unless the task involves contact with the soil subsurface. EPA is requiring a 24-hour restricted entry interval (REI), strengthening the interim 12-hour REI established by the Worker Protection Standard (WPS). However, if ethalfluralin has been incorporated correctly, workers may enter the treated area during the REI without PPE, if they are performing tasks that do not involve contact with the soil surface. When contact with the soil surface is necessary, early entry workers must wear appropriate PPE including coveralls over a short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and protective eyewear.

Human Risk Assessment

Ethalfluralin causes moderate eye and skin irritation but otherwise is of relatively low acute toxicity. However, it causes mammary gland tumors and is classified as a quantifiable Group C, possible human carcinogen. Ethalfluralin also is a developmental toxicant.

Although people may be exposed to residues of ethalfluralin through the diet, both acute and chronic dietary risks appear to be minimal. Risks to handlers (mixers/loaders/applicators) are of concern, but are being reduced by requiring minimum, baseline PPE for all handlers plus additional PPE for mixers and loaders. A more stringent, 24-hour REI is being imposed, as is early entry PPE.

Environmental

Environmental Fate

Assessment

Although the data submitted for reregistration are not complete, EPA has sufficient information at this time to provide an overall qualitative assessment for ethalfluralin.

Ethalfluralin is expected to dissipate by binding to soil particles and then degrading both aerobically and anaerobically. In the field, ethalfluralin did not leach, and it is not expected to contaminate ground water. Because ethalfluralin is structurally similar to trifluralin, which has been detected in ground water in 10 of 21 states, EPA cannot make a complete assessment of ethalfluralin until its assessment of trifluralin is finished.

There is some potential for ethalfluralin to reach surface waters on eroded soil particles. In surface waters, it is expected to photodegrade and to degrade rapidly in anaerobic sediments by electrochemical reactions. Ethalfluralin was not volatile in the laboratory; however, no assessment of its spray drift potential is possible from the submitted data.

Ecological Effects

Technical ethalfluralin is practically nontoxic to bobwhite quail on an acute oral basis, and to bobwhite quail and mallard ducks on a subacute dietary basis. It does not appear to cause reproductive effects in birds.

Ethalfluralin end-use products are practically nontoxic to slightly toxic to small mammals on an acute oral and dermal basis. Technical ethalfluralin also is practically nontoxic to honey bees.

Technical ethalfluralin is highly to very highly toxic to rainbow trout and bluegill sunfish. The formulated product also is highly toxic to bluegill sunfish. Since ethalfluralin persists in soils and is very highly toxic to fish, an acute toxicity sediment study was submitted. This study shows that ethalfluralin released from soil sediments can be lethal to sunfish when concentrations in water reach 17 to 58 parts per billion (ppb). In an early life stage toxicity test with freshwater fish, ethalfluralin affected larval length and weight in trout.

In invertebrate toxicity studies, technical ethalfluralin is very highly toxic and the formulated product is slightly toxic to *Daphnia magna* on an acute basis. In a life cycle study using daphnids, reproduction was the most sensitive parameter affected. Ethalfluralin is highly toxic to marine/estuarine fish, mollusks, and shrimp on an acute basis.

In terrestrial plant studies, ethalfluralin affected parameters including radicle length, plant height and weight, and shoot dry weight (in cotton).

Ecological Effects Risk Assessment

Wildlife may be exposed to ethalfluralin either by consuming contaminated food items (such as seeds, fruit, or insects), or by ingesting granules. Birds, for example, may ingest granules as a source of grit. However, no acute or chronic risks to endangered or nonendangered birds are expected to occur from eating food items, and no undue risk is expected from granular applications. Minimal risk to mammals is anticipated from the present ethalfluralin uses.

Ground applications of ethalfluralin could result in potential risks to aquatic organisms from runoff and drift. Although neither high acute risk nor chronic risk to aquatic organisms is anticipated, the restricted use trigger has been exceeded for freshwater organisms, and endangered species triggers are exceeded for freshwater organisms and estuarine/marine invertebrates.

For unincorporated applications, some risk is posed to nontarget semi-aquatic plants in the vicinity of treated fields. However, no risk to plants is posed from soil-incorporated applications. High risk to nontarget aquatic plants is not expected.

Endangered species levels of concern are exceeded for freshwater organisms and estuarine/marine invertebrates from unincorporated applications; for freshwater fish from incorporated applications; and for plants growing in wet areas receiving channelized runoff from treated sites (from unincorporated applications). Limitations may be imposed on the use of ethalfluralin to protect threatened and endangered species when EPA implements the Endangered Species Protection Program, later in 1995.

Risk Mitigation

Since ethalfluralin is considered a possible human carcinogen and a developmental toxicant, EPA is requiring the following risk mitigation measures, as discussed earlier:

- To reduce risks to workers, require all handlers to use minimum, baseline PPE, and require mixers and loaders to use additional PPE, as specified in the RED. Extend the REI from 12 to 24 hours and require early entry PPE, as detailed in the RED document.
- To reduce risks to freshwater fish, invertebrates, and certain nontarget plants from unincorporated granular and spray applications:
  - Prohibit alfalfa irrigation tail waters from entering aquatic habitats.
  - Recommend use of runoff controls such as vegetative buffer strips to filter water flow from recently treated cucurbit fields before it reaches aquatic habitats. EPA and the Natural Resources Conservation Service are developing guidance on such vegetative filters, and the Agency may require their use in the future.
  - Require compliance with the Endangered Species Protection Program, when it goes into effect.

Additional Data Required

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

Additional generic product chemistry studies;

Additional residue chemistry studies, confirmatory and new field trial data, and a third metabolism study for cucurbits (due by May 31, 1995);

Field trial data for alfalfa hay and forage, pea and bean hay and forage, soybean hay and forage, and peanut hay;

Nitrosamine content and analysis studies.

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 ethalfluralin end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection Standard

Personal Protective Equipment (PPE) Requirements

Products containing ethalfluralin may contain more stringent PPE, but in no case may require less stringent PPE than the following requirements. Producers must compare the PPE requirements in this section with those on current labeling and retain the more protective.

Handler PPE for Occupational Use Products - For all uses of ethalfluralin, which are within the scope of the WPS, the minimum or baseline PPE required for pesticide handlers (mixers, loaders, and applicators) is:

- coveralls, and
- chemical-resistant gloves.

The PPE required for mixers and loaders is:

- coveralls over long pants and long-sleeved shirt;
- chemical-resistant gloves; and
- chemical-resistant apron.

Early Entry PPE - The PPE required for early entry is:

- coveralls over short-sleeved shirt and short pants;
- chemical-resistant gloves;
- chemical-resistant footwear plus socks; and
- protective eyewear.

Entry Restrictions

WPS Uses - A 24-hour restricted entry interval (REI) is required for all currently registered ethalfluralin uses, all of which are within the scope of the Worker Protection Standard (WPS).

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Other Labeling Requirements

Grazing, foraging and haying restrictions must be removed from ethalfluralin labels, except sunflower forage.

Directions for Use - The labels of all ethalfluralin end-use products must be revised to bear the following statements under this section:

Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through spray drift. Only protected handlers may be in the area during application."

Engineering Controls:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides, 40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations:

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Precautionary Statements - Because ethalfluralin is classified as a skin sensitizer, the Agency requires that the following statement appear on all labels in the Hazards to Humans and Domestic Animals section of these statements:

"This product may cause skin sensitization reactions in certain individuals."

Environmental Hazard - The labels of all ethalfluralin end-use products must bear the following statement under this section:

"This product is toxic to fish and aquatic invertebrates. Do not apply directly to any body of water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do

not contaminate water when disposing of equipment washwaters or rinsate."

For application to alfalfa, the following statement is required:

"For flood or furrow irrigation, do not allow the tail waters from the first irrigation after application to enter aquatic habitats."

For applications to cucurbit fields, the following statement is required:

"Due to risk to plants and animals in aquatic habitats that receive run-off containing this product, use of controls such as a vegetative buffer strip to filter such water flow from recently treated fields is recommended."

Effluent Discharge Statements - All end-use and manufacturing-use products that may be contained in an effluent discharged to the waters of the U.S. or municipal sewer systems must bear the following labeling statement:

"This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Regulatory Conclusion

The use of currently registered products containing ethalfluralin, in accordance with labeling amended to reflect the risk mitigation measures imposed by this RED, generally will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products, except postemergence and posttransplant applications to cucurbits, are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision regarding the postemergence and posttransplant uses of ethalfluralin on cucurbits because the Agency does not yet have the residue chemistry data required to support these uses. A registrant is conducting the required studies, which are due to the Agency by May 31, 1995. Once EPA reviews and accepts the studies, these cucurbit uses also will be considered eligible for reregistration.

Ethalfluralin 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 ethalfluralin 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 can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV.*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

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 ethalfluralin RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the ethalfluralin RED, or reregistration of individual products containing ethalfluralin, 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 8:00 am and 6:00 pm Central Time, Monday through Friday.