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EPA R.E.D. FACTS

EPTC

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 0064, EPTC (S-Ethyl dipropylthiocarbamate).

Use Profile

The following active ingredient is covered by this Fact Sheet:

- **Common Name:** EPTC
- **Chemical Name:** S-Ethyl dipropylthiocarbamate
- **Chemical Family:** Thiocarbamate
- **Type of Chemical:** Herbicide

- **CAS Registry Number:** 759-94-4
- **OPP Chemical Code:** 041401
- **Empirical Formula:** $C_9H_{19}NOS$
- **Basic Manufacturer:** Zeneca Ag Products

EPTC is a pre-emergence and early post-emergence thiocarbamate herbicide used to control the growth of germinating annual weeds, including broadleaves, grasses, and sedges. It is used in every region of the United States in the agricultural production of a wide variety of food crops. The heaviest usage is in the Corn Belt, Northeastern and Mid-Atlantic states, Coastal and Northern Great Plains and in the Pacific Northwest. Highest use states are California, Michigan, Oregon, Pennsylvania, North Dakota, Minnesota, and Arizona. The largest markets in terms of total pounds of active ingredient are corn, potatoes, dry beans, peas, alfalfa, and snap beans. Usage ranges from about 10 to 20 million pounds a.i. annually**.** EPTC is also available to the residential home gardener for use in vegetable and ornamental gardens.

As with other thiocarbamate herbicides, EPTC exerts its herbicidal action through inhibition of cuticle formation at the early stages of seedling growth. Formulated products include emulsifiable concentrate (EC) liquids containing up to 87.8% active ingredient and granular (G) formulations containing up to 25% active ingredient. EPTC is typically applied annually in one to three applications, with each application ranging from about 2 to 6.1 lbs a.i./acre (maximum rate 7.5 to 12.2 lbs a.i./acre for alfalfa and potatoes). EPTC can either be applied by aerial or ground equipment or through chemigation. Because of its chemical properties, however it is applied, it must be incorporated into the soil immediately after application to prevent volatilization.

Regulatory History

EPTC was registered in the United States in 1958 for use as a selective preemergent herbicide, and was originally owned by Stauffer Chemical Company. Chemiolimpex, a technical EPTC (TGAI), was manufactured in Hungary, and was imported into the United States by PPG Industries of Pittsburgh, Pennsylvania. Zeneca Ag Products currently holds registrations for several end-use products, and holds the only registration for the technical product.

A Registration Standard for EPTC was issued in September 1993. The Agency determined that additional generic data would have to be submitted for evaluation in order to maintain registration. This RED reflects a reassessment of all data which were submitted in response to the Registration Standard.

Human Health Assessment

Toxicity results of acute toxicity, primary eye and dermal irritation, and dermal sensitization studies with EPTC technical material are summarized in the RED. EPTC is moderately toxic (Toxicity Category III) via the oral and dermal routes, and in a primary eye irritation study in rabbits, the technical was found to be slightly irritating (Toxicity Category III). EPTC is most toxic via the inhalation route (Toxicity Category II).

There was an increased incidence and severity of cardiomyopathy and neuronal necrosis/degeneration in studies performed in the central and peripheral nervous systems of both rats and dogs. The neurotoxic effects of EPTC are consistent with effects seen in other thiocarbamates. Because of these effects (neuronal necrosis/degeneration), and the potential for residential exposure to infants and children from use of EPTC, the Agency's FQPA Safety Factor Committee recommended that the 10x FQPA safety factor be retained for all population subgroups for acute, chronic and residential exposure assessments.

Although it appears that EPTC did not produce any significant reproductive or developmental toxicity, there is still uncertainty regarding the effects on the developing fetal nervous system This uncertainty is being addressed by the requirement of a developmental neurotoxicity study in rats. EPTC effects were also negative in two oncogenicity studies.

Occupational and Residential Exposure

Occupational and residential exposure to EPTC residues via dermal and inhalation routes can occur during handling activities such as mixing, loading, and applying; however, the potential for postapplication occupational exposure is minimal. Because EPTC is applied as a soil directed spray and immediately incorporated, or as a soil injection well before plants are mature, the potential for postapplication dermal exposure during harvest activities is minimal. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules. Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for the occupational and residential handler, and for residential postapplication inadvertent oral ingestion soil/granulars exposure to children.

Potential EPTC residential use sites may include a variety of shade trees, evergreens, and annual or perennial ornamentals. EPTC is typically applied only to bare soil once before planting or after weeding under ornamentals followed by soil incorporation. Examples of typical usage of a granular formulation in the home garden would include pre-planted application and

incorporation with a rototiller, post-plant application incorporated into the soils to a depth of 2-3 inches using a hand rake or hoe, and weed control in established trees and shrubs by incorporation into the top 6 inches of soil In contrast to occupational workers, individuals in residential settings are more likely to transplant seedlings and plant seeds by hand. In addition, there is a potential for inadvertent oral exposure to children from eating EPTC-treated soil and/or granules.

Human Risk Assessment

Dietary Exposure

Risk from food and water combined are acceptable. And the Tier 1 acute dietary exposure analysis of EPTC, exposure (food consumption) was compared to an acute population adjusted dose of 0.067 mg/kg/day. The acute dietary risk analysis estimates the distribution of single day exposures for the overall U.S. population and certain subgroups. The analysis evaluates exposure to the chemical for each food commodity, and assumes uniform distribution of EPTC in the food supply.

The acute dietary residue contribution at the 95th percentile occupied less than 100% of the aPAD for any population subgroup, and therefore does not exceed the Agency's level of concern. For non-probalistic acute dietary exposure the Agency uses the 95th percentile. For the most highly exposed subgroup, children 1-6, residue contribution occupied 87.5% of the aPAD. This Tier 1 acute analysis for EPTC is a conservative upper-bound estimate with all input residues equal to the reassessed tolerance value and the assumption that 100% of the crop is treated nationwide.

Environmental Fate

The environmental fate data indicates that EPTC would not be persistent under many environmental conditions, which is supported by relatively short half-lives observed in terrestrial and low aquatic concentrations. Monitoring data suggests that concentrations of EPTC in ground water will be less than those found in surface water. However, the persistence of EPTC in ground water would probably be greater than in surface water because losses due to volatilization would be expected to be much less.

The low affinity for binding to soil and water solubility also suggest a potential to leach, but since EPTC generally does not persist long in surface soils, the potential to leach is greatly reduced.

Environmental

Ecological Effects

Assessment

EPTC is practically non-toxic to birds and bees; slightly toxic to mammals and fish, and moderately toxic to aquatic invetebrates, algae and an aquatic vascular plant. Toxicity studies are unavailable for estuarine species. Reproduction studies are not available for any species, except laboratory mammals. Due to lack of data, acute risks to estuarine species, and reproductive risks to birds, fish and aquatic invertebrates were not assessed. The registrant will be required to provide additional data in order to evaluated the potential effects of bird, aquatic and estuarine species.

EPTC is toxic to both monocot and dicot plant species. Although EPTC is a pre-emergent herbicide, it may cause some phytotoxic damage and growth effects on established plants. Risk quotients for granular and spray applications suggest that EPTC poses adverse effects on non-target plants for all uses.

Environmental Risk Characterization

Residue levels of EPTC on vegetation exceed levels of concern for high acute risks and effect on endangered species for small mammals. Soil incorporation reduces the amount of vegetation exposed, but the vegetation remaining at the surface poses a potential risk to small mammals. Given the low probability of EPTC dietary exposure to small mammals, any mortality is unlikely to have any serious effect on the local populations of small mammals, with the exception of an endangered species.

The level of concern is exceeded for endangered and terrestrial plants species such as monocots and dicots. Non-target terrestrial plants in adjacent fields or habitats are potentially at risk from spray drift from some uses and from runoff for all registered uses. EPTC also appears to have the potential to be transported off site via the vapor phase as it was one of a number of residues found in more than 25 percent of the rain samples collected in three water sheds in Minnesota. In addition, being a herbicide, EPTC may also have an indirect effect on endangered insects by adversely affecting the plants on which they depend.

The levels of EPTC that are likely to be atmospherically deposited into soils or on vegetation is uncertain. The absence of reported atmospheric deposition incidences does not preclude the occurrence of such events. The registrant will be required to provide additional data on field volatility and atmospheric dissipation in order to further evaluate the environmental fate of EPTC.

Although the EPTC data base is sufficient to render a reregistration eligibility decision, additional confirmatory data such as developmental neurotoxicity, residue analytical methods-plant, and Multiresidue method

studies are needed to further assess the chemical's toxicity. In addition, ecological effects and environmental fate studies are needed to fully assess the impact of EPTC and its primary degradates on the environment.

Risk Mitigation

To lessen the risks posed by EPTC, EPA is requiring the following risk mitigation measures:

- The exposure assessments indicate that occupational handlers are at risk to dermal and inhalation exposure, and that additional protective measures are necessary to reduce these risks. Therefore, various forms of additional personal protective equipment (PPE) (e.g., double layer clothing and respirators) and engineering controls (e.g., enclosed cockpits) are necessary for certain handler scenarios to reduce the risks to below the Agency's level of concern.

- In order to mitigate risks to homeowners, the registrant will be required to add label language which prohibit use of the belly grinder, which contributes to the highest level of exposure, for home owner products. The registrant will also be required to delete all residential emulsifiable concentrate formulation uses from the EPTAM 7E label. In addition, the registrant will be required to change the maximum rate of 15 lbs per acre for the Eptam 2.3 granular products to the typical rate of 5 lbs per acre for residential products.

- Risk quotients for granular and spray applications suggest that EPTC poses adverse effects to small herbivorous and insectivorous mammals for most uses and adverse effects on non-target terrestrial plants for all uses. EPTC use could also cause adverse effects on endangered species. As a member of the Endangered Species Task Force, the registrant will be required to obtain information which identifies endangered and threatened species of concern which may be found in areas adjacent to crops treated with EPTC.

Additional Data Required

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

Guideline:	**Study:**
870.6300	Developmental neurotoxicity study in the rat
860.1340	Residue Analytical methods-Plant
860.1360	Multiresidue Method
860.1380	Storage Stability Data

860.1520	Processed Food/ Feed
860.1500	Crop field Trials
Guideline:	**Study:**
850.2100	Acute Avian Oral(quail/duck)
850.2300	Avian Reproduction Quail/Duck
850.1400	Fish Early Life Stage
835.4100	Aerobic Soil
835.4200	Anaerobic Soil
835.4300	Aerobic Aquatic Metabolism
835.8100	Field Volatility
835.6100	Field Dissipation
850.1730	Aquatic Organism Accumulation

Product Labeling Changes Required

Before reregistering the products containing EPTC, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF), and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration. All EPTC end-use products must comply with EPA's current pesticide product labeling requirements and. For a comprehensive list of labeling requirements, please see the EPTC RED document.

The use of currently registered products containing EPTC 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.

Regulatory Conclusion

EPA has determined that products containing EPTC are eligible for reregistration. The use of eligible EPTC 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 EPTC 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 EPTC 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 513-489-8695.

Following the comment period, the EPTC 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 EPTC RED, or reregistration of individual products containing EPTC, 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 Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm, Pacific Standard Time, or 9:30 am to 7:30 pm, Eastern Standard Time, seven days a week.

Their internet address is ace.orst.edu/info/nptn.