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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 0014, endosulfan.

Use Profile

Endosulfan is a broad spectrum contact insecticide and acaricide registered for use on a wide variety of vegetables, fruits, cereal grains, and cotton, as well as ornamental shrubs, trees, vines, and ornamentals for use in commercial agricultural settings. Total average annual use of endosulfan is estimated at approximately 1.38 million pounds of active ingredient (lbs. ai), according to Agency and registrant estimates. Crops with the highest average percent drop treated are: squash (40%), eggplant (41%), cantaloupe (31%), sweet potato (31%), broccoli (26%), pears (20%), and pumpkins (20%). Crops with the highest sales in 2001 include: cotton (14.2%), cantaloupe (13.2%), tomatoes (12.2%), and potatoes (8.15%).

Endosulfan is formulated as a liquid emulsifiable concentrate (9-34% ai) and wettable powder (1-50% ai). The wettable powder formulation is frequently packaged in water soluble bags. Endosulfan can be applied by groundboom sprayer, fixed-wing aircraft, chemigation (potatoes only), airblast sprayer, rights-of-way sprayer, low pressure handwand sprayer, high pressure handwand sprayer, backpack sprayer and dip treatment.Regulatory

History

Endosulfan was first registered as a pesticide in the U.S. in 1954 to control agricultural insect and mite pests on a variety of field, fruit, and vegetable crops. A Registration Standard dated September 17, 1981, and a Guidance Document dated April 1982 were issued for endosulfan, which required additional generic and product-specific data for the manufacturing products of the technical registrants. Since the Guidance Document was issued, there have been seven DCIs generated: 10/23/85, 5/19/86, 5/27/86, 1/30/87, 6/19/87, 9/02/92, and 5/10/94 concerning the potential formation of chlorinated dibenzo-p-dioxins and dibenzofurans in technical endosulfan products. An additional DCI was issued in October 1994, which primarily concerned residue

chemistry data deficiencies.

Further, in 1991, the technical registrants amended labels to incorporate a 300-foot spray drift buffer for aerial applications between treated areas and water bodies. This setback was adopted in order to address concerns about contamination of water and risks to aquatic organisms. In 2000, the technical registrants amended technical product labels to remove all residential use patterns. Currently, there are 94 endosulfan products registered.

Human Health Assessment

Toxicity

Endosulfan generally has been shown to have high acute oral and inhalation toxicity as well as slightly toxic dermal toxicity. It is an irritant to the eyes and is not a dermal sensitizer. Endosulfan is neither mutagenic nor carcinogenic. Endosulfan primarily affects the nervous system. Toxic effects observed in animals from acute, subchronic, developmental neurotoxicity, and chronic/carcinogenic toxicity studies found that endosulfan causes neurotoxic effects, which are believed to result from over-stimulation of the central nervous system. Further, there is evidence (effects observed in a submitted chronic oral toxicity study in rats) that endosulfan acts as an endocrine disruptor. However, further investigation is necessary to determine the relevance and impact of such findings on public health.

Dietary Exposure

EPA has assessed dietary risk by estimating exposure to endosulfan residues from consumption of food and drinking water that can occur over a single-day (acute) or longer (chronic). Generally, a dietary (food) risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concern. Acute risk estimates from exposures to food, associated with the use of endosulfan exceed the Agency's level of concern for some population subgroups. For example, for exposure resulting from applications of endosulfan, for the most exposed population subgroup, children 1-6 years old, the percent acute PAD value is 150% at the 99.9^{th} percentile of exposure from consumption of food alone. The crops that contributed the most to the risks of concern are succulent beans and peas. Chronic dietary (food) exposure estimates are below the Agency's level of concern for all subpopulations. For the most highly exposed subpopulation, children 1-6 years old, the percent chronic PAD value is 17% from consumption of food alone.

Drinking water exposure to endosulfan can occur through ground and surface water contamination. EPA used modeled Tier 2 estimates of endosulfan and endosulfan sulfate to estimate risk for acute exposures. Taking into account the supported uses of endosulfan, the Agency concluded that residues of endosulfan in drinking water are of concern. Drinking water estimates for chronic exposures, based on models, from both ground and surface water are not of concern.

Risk from All Registered Pesticide Endosulfan Exposures

To assess risks from all endosulfan exposures, the Agency combined risk from food and drinking water exposure only. The technical registrants are not supporting residential or other non-occupational uses of endosulfan. As a result, these use patterns have not been considered for regulatory purposes at this time. The acute estimated drinking water concentrations for endosulfan are above the acute drinking water level of comparisons (DWLOCs) for infants <1 year and the most sensitive population subgroup, children 1-6 years old. The chronic estimated drinking water concentrations for the U.S. general population and all population subgroups are below the chronic drinking water levels of comparisons (DWLOCs) for the U.S. general population and all population subgroups and, therefore, are not of concern.

Occupational Exposure

Occupational handlers can be exposed to endosulfan through mixing, loading and/or applying a pesticide or re-entering treated sites. Occupational handlers of endosulfan include individual farmers or growers who mix, load and/or apply pesticides and professional or custom agricultural applicators. The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture.

Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE),

which determines how close the occupational exposure comes to a NOAEL. Generally, MOEs greater than 100 are not of concern. Restricted Entry Intervals (REIs) are 24 hours on current endosulfan labels. The Agency has determined that there are potential mixer, loader, applicator as well as post-application exposures to occupational handlers. Based on current use patterns, there are some short-term dermal and inhalation risks of concerns for workers who mix, load and apply endosulfan to agricultural sites as well as to those workers who re-enter a treated area following application of endosulfan.

Environmental Assessment

Ecological risks are also of concern to the Agency. The environmental risk assessment suggests that exposure to endosulfan could result in both acute and chronic risks of concern for terrestrial and aquatic organisms. Exposure to endosulfan has resulted in both reproductive and development effects in nontarget animals, particularly birds, fish and mammals.

Risk Mitigation Measures

To mitigate human health and ecological risks of concern for endosulfan, the following measures will be implemented:

Dietary (Food) Risk

- Delete use on succulent beans, succulent peas, spinach, and grapes

Dietary (Drinking Water) and Ecological Risk

Several mitigation measures are needed to reduce the potential for contamination of drinking water.

- Delete use on pecans;
- Reduce maximum seasonal application rates from 3lbs./ai/A to 2.5 lbs./ai/A for pome fruit, stone fruit, and citrus;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 2 lbs./ai/A for melons, cucurbits, lettuce, tomatoes, sweet potatoes, cotton (ground), broccoli, cauliflower, cabbage, kohlrabi, brussels sprouts, strawberries, filberts, walnuts, almonds, macadamia nuts, peppers, eggplant, potatoes, carrots, dry beans, dry peas, and tobacco;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1.5 lbs./ai/A for sweet corn, cotton (aerial) and blueberries;
- Reduce maximum seasonal application rate from 3 lbs./ai/A to 1 lb./ai/A for celery;
- Require 100 ft. spray buffer for ground applications between a treated area and water bodies;
- Require 30 ft. maintained vegetative buffer strip between a treated area and water bodies;
- Require all products to be Restricted Use;
- Restrict use on cotton to AZ, CA, NM, OK and TX only; and
- Restrict use on tobacco to IN, KY, OH, PA, TN and WV only.

Occupational Risk

- Require all wettable powers to be packaged in water soluble bags;
- Cancel use of wettable powders on tomatoes, sweet corn, sweet potatoes, cotton, small grains, alfalfa (seed), carrots, dry beans, dry peas, pineapples, and tobacco;
- Cancel aerial application using the wettable powder formulation on pome fruits, stone fruits, citrus, blueberries, strawberries, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), filberts, walnuts, almonds, and macadamia nuts;
- Require closed mixing/loading systems for aerial application using the EC formulation on pome fruits, stone fruits, citrus, sweet corn, sweet potatoes, cotton, collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed), broccoli, (seed), cauliflower (seed), kohlrabi (seed), cabbage (seed), blueberries, small grains, alfalfa (seed), filberts, walnuts, almonds and macadamia nuts;
- Require closed cabs for airblast applications on pome fruits, stone fruits, citrus, filberts, walnuts, almonds and macadamia nuts;
- Prohibit use of high pressure handwands with rates greater than 0.005 lbs/ai/gal;

Increase REI to 48 hours for all crops except as noted in the following bullets;
- Increase REI for WP products to 3 days for melons and cucurbits;
- Increase REI for WP products to 4 days for lettuce, celery, pome fruit, stone fruit, citrus, collard greens, kale, mustard greens, radish, turnip, rutabaga, ornamental trees and shrubs;
- Increase REI for WP products to 5 days for collard greens (seed), kale (seed), mustard greens (seed), radish (seed), turnip (seed) and rutabaga (seed);
- Increase REI for WP products to 9 days for blueberries, broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts;
- Increase REI for WP products to 12 days for broccoli (seed), cauliflower (seed), kohlrabi (seed), and cabbage (seed);
- Increase REI for EC products to 3 days for sweet potatoes
- Increase REI for EC products to 4 days for broccoli, cauliflower, kohlrabi, cabbage, and brussels sprouts;
- Increase REI for EC products to 6 days for blueberries;
- Increase REI for EC products to 7 days for broccoli (seed), kohlrabi (seed), and cabbage (seed); and
- Increase REI for EC products to 17 days for sweet corn.

Stakeholder Process

Given the toxicity and persistence of endosulfan and potential risks to aquatic organisms, the Agency has developed a number of mitigation measures in order to reduce the risks to aquatic organisms outlined in this document.

While the Agency believes that these measures will reduce the potential for exposures to aquatic organisms and reduce the overall environmental loading of endosulfan, it also believes that in specific geographic areas where conditions exist that make aquatic organisms especially vulnerable (e.g., shallow, leaky aquifers, highly erodible lands, the presence of especially sensitive organisms and high use of endosulfan) additional measures may be identified. In order to more fully evaluate the risks in these vulnerable areas; the risk management strategies that may be in place or could potentially be implemented in such areas (e.g., use of retention ponds) to reduce exposure; and the benefits of the use of endosulfan in those areas, the Agency is planning to conduct a stakeholder process to accomplish this objective. Further, the impacts of atmospheric transport may require additional evaluation during this time period.

Additional mitigation measures may be needed following the completion of this process.

Additional Data Required

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

- Harmonized Test Guideline 850.2100: Avian acute oral toxicity of bobwhite quail and mallard ducks
- Harmonized Test Guideline 850.2200: Avian subchronic oral toxicity of bobwhite quail and mallard ducks
- Harmonized Test Guideline 850.2300: Avian reproduction study
- Harmonized Test Guideline 850.1075: Freshwater fish acute toxicity study of bluegill sunfish
- Harmonized Test Guideline 850.1300: Early life stage fish
- Harmonized Test Guideline 850.1350: Life cycle invertebrate
- Harmonized Test Guideline 850.1500: Freshwater fish full life cycle using rainbow trout
- Harmonized Test Guideline 850.1075: Estuarine/marine fish acute toxicity study
- Harmonized Test Guideline 850.1035: Estuarine/marine invertebrate acute toxicity study of
- mysid shrimp
- Harmonized Test Guideline 850.1735: Whole sediment acute toxicity testing using a freshwater invertebrate
- Harmonized Test Guideline 850.1740: Whole sediment acute toxicity testing using a estuarine/marine invertebrate
- Harmonized Test Guideline 850.1735S: Whole sediment chronic toxicity testing using a freshwater invertebrate
- Harmonized Test Guideline 850.1740S: Whole sediment chronic toxicity testing using an estuarine/marine invertebrate

- 164-2 (Special Study): Vegetative buffer effectiveness study
- Harmonized Test Guideline 835.7100: Groundwater monitoring study
- Harmonized Test Guideline 835.7200: Surface drinking water monitoring study
- Harmonized Test Guideline 870.6200: Subchronic Neurotoxicity - Rat
- Harmonized Test Guideline 870.6300: Developmental Neurotoxicity Toxicity Study - Rat
- Harmonized Test Guideline 860.1380: Storage stability (oils seed, non-oily grain and processed commodities)
- Harmonized Test Guideline 860.1500: Crop field trials for the following raw agricultural commodities: barley hay, and pearled barley; oat forage, hay, and rolled oats; rye forage; wheat forage, and hay
- Harmonized Test Guideline 860.1500: Crop field trials for tobacco and a pyrolysis
- Harmonized Test Guideline 860.1520: Magnitude of residue in processed food/feed commodities
- Harmonized Test Guideline 875.1100: Dermal outdoor exposure for applying dip treatments to trees and roots or whole plants
- Harmonized Test Guideline 875.1700: Product use information for applying dip treatments to trees and roots or whole plants

The Agency is also requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Regulatory Conclusion

The Agency has assessed all 80 tolerances for endosulfan and can make a FQPA safety determination based on a review of the dietary (food and drinking water), ecological and occupational risks associated with the supported uses of currently registered pesticides containing endosulfan.

Agricultural uses of endosulfan based on approved labeling pose occupational risks of concern and ecological risks that constitute unreasonable adverse effects on the environment. However, the Agency believes these risks can likely be mitigated to levels below concern through changes to pesticide labeling and formulations. Accordingly, the Agency has determined that endosulfan is eligible for reregistration provided that: (1) additional required data will confirm this decision for occupational exposures associated with the application of dip treatment to roots or whole plants and ecological risks; and (2) the risk mitigation outlined in the RED are adopted, and label amendments are made to reflect these measures. Further, if vulnerable areas in specific geographic areas are identified as a result of the stakeholder process, additional ecological risk mitigation measures may be necessary to protect especially sensitive organisms. The endosulfan RED document includes guidance and time frames for complying with any label changes for products containing endosulfan.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for endosulfan 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 number 703-305-5805.

Electronic copies of the RED, this Fact Sheet, and all supporting documents are available on the Internet. See http://www.epa.gov/REDs.

The Agency has also established an official record for this action under docket control numbers OPP-34242 and eDocket OPP-2002-0262.

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 endosulfan 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 endosulfan RED, or reregistration of individual products containing endosulfan 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.

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