Interim Reregistration Eligibility Decision (IRED) Fact Sheet for Formetanate Hydrochloride

EPA 738-F-06-01

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 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 that describe the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act (FQPA) 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 current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

EPA has assessed the risks of formetanate hydrochloride (formetanate HCl) and reached an interim Reregistration Eligibility Decision (IRED) for this N-methyl carbamate pesticide. Provided that the risk mitigation measures are adopted, formetanate HCl's individual aggregate risks will be within acceptable levels, and the pesticide will be eligible for reregistration once EPA has considered the cumulative risks from the N-methyl carbamates.

Uses

Formetanate HCl is a miticide/insecticide used on alfalfa (grown for seed), apples, pears, peaches, nectarines, and assorted citrus crops. There are no residential uses for formetanate HCl products. Registered products containing formetanate HCl are intended for application on tree fruit and alfalfa grown for seed to control lygus bugs, mites, stink bugs, and thrips.

Currently, formetanate HCl is only available as a wettable powder formulation sold in water soluble bags which are considered to be engineering controls. Formetanate HCl can be applied with aerial or

ground equipment, such as groundboom sprayers and airblast sprayers. Formetanate HCl is labeled for use on tree fruits at 1.15 lb a.i. /A and for alfalfa grown for seed at a maximum of 0.92 lb a.i. /A.

Health Effects

Formetanate HCl has high acute toxicity via the oral route, moderate acute toxicity via the inhalation route and has low acute toxicity via the dermal route. It is not an eye or skin irritant but is a dermal sensitizer.

Formetanate HCl is a carbamate pesticide, and its primary mode of toxic action is through cholinesterase inhibition after single or multiple exposures. The clinical signs following acute and chronic exposure to formetanate HCl in rats (decreased body weight) and dogs (excessive salivation, wheezing, labored breathing, trembling, vomiting ,coughing, and abnormal quietness) are consistent with cholinesterase inhibition.

Formetanate HCl did not result in developmental toxicity in either rats or rabbits or in reproductive effects in the multi-generation rat reproduction study. There was no indication of increased offspring susceptibility in these studies.

Formetanate HCl is potentially neurotoxic because of its ability to inhibit cholinesterase. A Comparative Cholinesterase Assay (CCA) study in rats was submitted to EPA in lieu of a developmental neurotoxicity study to determine the susceptibility of the young compared to the adults. The endpoint of rat pup brain cholinesterase inhibition was derived from the CCA study.

Ecological Effects

Available acute toxicity data indicate that formetanate HCl is moderately to slightly toxic to freshwater fish and highly toxic to freshwater invertebrates on an acute basis. Chronic data for freshwater fish show that growth and development was the most sensitive endpoint. For estuarine/marine invertebrates, available acute toxicity data indicate that formetanate HCl is moderately toxic. No acute data for estuarine/marine fish or chronic data for invertebrates were available.

Formetanate HCl is classified as highly toxic to birds and mammals on an acute basis and slightly toxic to birds on a subacute basis. Chronic data indicate that use of formetanate HCl can potentially cause reproductive concerns in birds and cholinesterase inhibition in small mammals.

There are no indications that formetanate HCl is phytotoxic. Data indicate that formetanate HCl is practically nontoxic to bees on an acute contact basis.

Risks

Dietary Risk Assessment for Food + Water

Acute Dietary Risk

The resulting acute dietary exposure and risk estimates for food and water exceed EPA's level of concern for the U.S. population and all reported population subgroups. Most of the estimated acute exposure from food was determined to result from late season uses of formetanate HCl on apples. Deletion of the late season apple use results in an acute dietary (food + water) risk within an acceptable range of the level of concern. Drinking water is the largest contributor to acute dietary exposure when late season uses are excluded.

Chronic Dietary Risk

Chronic risk estimates are below EPA's level of concern for the U.S. population and all population subgroups.

Aggregate Risk

There are no residential uses for formetanate HCl. Therefore, when addressing aggregate exposures, only the dietary pathways of food and drinking water were considered.

Acute aggregate exposure estimates for food and water exceed EPA's level of concern with the inclusion of late season applications to apples, but are below the level of concern without this use. Chronic aggregate exposure estimates for food and water are below the Agency's level of concern.

Occupational Risk

Handler Risk

The Agency used a margin of exposure (MOE) approach to assess formetanate HCl. MOEs greater than 100 are not of concern. No scenarios resulted in MOEs above 100 for single layer personal protective equipment (PPE); however, after a respirator was added for applicators using groundboom equipment in alfalfa for seed production, the risk was below EPA's level of concern (MOE=130). Most scenarios for applicators had MOEs above 100 at maximum PPE (double layer clothing plus gloves and respirator) except for airblast applications to orchards (MOE=73). Scenarios for mixing and loading for aerial applications for both orchard crops (MOE=51) and for alfalfa grown for seed (MOE=69) had risks above the Agency's level of concern even with engineering controls of water soluble bags.

MOEs for flaggers are at an acceptable level with double layer PPE and a respirator. However, EPA has concerns with requiring additional protective clothing for these workers due to the potential for heat stress.

Postapplication Risk

For high-end activities, MOEs were acceptable for re-entry intervals (REI) by day 10 for evergreen fruit trees (citrus), day 8 for deciduous fruit trees (pome and stone fruits), and day 9 for alfalfa. It was determined that high exposure activities (hand harvesting) are not appropriate for alfalfa, and therefore, a 6-day REI is considered appropriate to protect post application workers performing medium-exposure activities.

Ecological Risks

From the screening level ecological risk assessment, risks to aquatic animals (both freshwater and estuarine/marine environments) were below the Agency's level of concern. Acute risks to birds are below the Agency's level of concern from formetanate HCl use. However, the Agency had concerns for chronic risks to birds. RQs ranged from 2 to 5. EPA also had concerns with acute and chronic risks to mammals (RQ's were as high as 28). Acute risks to birds are below the Agency's level of concern from formetanate HCl use. However, the Agency had concerns for chronic risks to birds. RQs ranged from 2 to 5. EPA also had concerns with acute and chronic risks to mammals (RQ's were as high as 28).

Risk Mitigation

The following risk mitigation measures are required for formetanate HCl to address risks of concern.

- To mitigate dietary risks:
  - Amend labels to prohibit late season applications to apples.
- To mitigate occupational risks to handlers:
  - Revise labels to prohibit aerial application for orchard crops.
  - Revise labels to require closed cabs for applicators using airblast sprayers on orchard fruit.
  - Revise labels to require closed cabs for human flaggers for aerial application
  - Revise labels by reducing the PPE to a single layer with a PF5 respirator for applicators using groundboom equipment for alfalfa for seed.

Although the Agency is concerned with the MOE for the mixing/loading scenario for aerial application on alfalfa grown for seed, EPA recognizes that the use provides high benefits to the grower community. In addition, EPA recognizes that the inputs used to calculate the inhalation assessment were based on conservative assumptions. The Agency is requiring additional data which will provide a more refined estimate of the inhalation risks for workers handling formetanate HCl. EPA believes these data will confirm the conclusion that no mitigation is appropriate for the mixer/loader scenario for aerial applications to alfalfa.

- To mitigate occupational risks to post-application agricultural workers:
  Revise labels to require a 10 day REI for citrus, an 8 day REI for pome fruit and stone fruits, and a 6 day REI for alfalfa.
- To mitigate ecological risk:
  No ecological specific mitigation is required. Some of the human health mitigation will result in lower non-target organism exposures.

Regulatory Conclusion

EPA has determined that all supported uses of formetanate HCl are eligible for reregistration (except for late season uses on apples) provided that registrants implement risk mitigation measures described in the IRED and that cumulative risks of the N-methyl carbamates do not exceed EPA's level of concern.

For More Information

Electronic copies of the formetanate HCl IRED and all supporting documents are available in Docket #EPA-HQ-OPP-2004-0032 at http://www.regulations.gov.

For more information about EPA's pesticide reregistration program, the formetanate HCl IRED, or reregistration of individual products containing formetanate HCl, please contact the Special Review and Reregistration Division (7508C), Office of Pesticide Programs, 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 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is http://npic.orst.edu. EXIT Disclaimer