United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-04-009 September 30, 2004

EPA R.E.D. FACTS

Cycloate

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 2125, cycloate (*S*-ethyl cyclohexyl(ethyl)thiocarbamate).

Use Profile

Cycloate is a broad-spectrum, pre-emergent herbicide registered for the control of annual grasses, certain perennial grasses and many broadleaf weeds on garden beets, spinach and sugarbeets. The Agency has found that the current uses of cycloate on garden beets, spinach and sugarbeets are eligible for reregistration, provided the changes specified in the RED are made to the cycloate labels. A new use on Swiss chard has been proposed by the IR-4 program. Cycloate is not for homeowner/garden use.

Sugarbeets account for more than 90% of cycloate usage. EPA estimates that approximately 679,000 pounds of active ingredient (a.i.) are used annually on a total of approximately 288,000 acres. Spinach accounts for almost 7% of cycloate usage with 45,000 pounds of a.i. applied per year on average. Garden beets receive about 17,000 pounds of a.i. annually on just under 8,000 acres treated, nearly 100% crop treated on garden beet acres.

Cycloate is formulated as an emulsifiable concentrate liquid (73.9% a.i.). Cycloate is typically applied using groundboom equipment and then incorporated into the soil mechanically or by sprinkler irrigation (chemigation).

Regulatory Hiistory

Cycloate was first registered in the United States on July 13, 1967, for use as a selective herbicide on sugarbeets and spinach by the Stauffer Chemical Company. The use of cycloate on garden beets was first approved on January 9, 1970. Stauffer Chemical Company transferred the cycloate registrations to ICI Americas, Inc. on December 23, 1987. On January 24, 1994, the registrant name was changed to Zeneca Agrochemicals. Zeneca Agrochemicals merged with Novartis Agribusiness in November 2000 to form Syngenta Crop Protection, Inc. Syngenta Crop Protection, Inc. sold all proprietary rights for cycloate to TRI AG, Inc. on December 1, 2000. Helm Agro US, Inc. is the agent for TRI AG, Inc.

Cycloate was the subject of a Registration Standard Guidance Document issued on December 7, 1988 and the Residue Chemistry Science Chapter of the Guidance Document (Phase 4 reviews of available residue chemistry data) was issued on December 20, 1990. These documents summarized the regulatory conclusions based on available residue chemistry data and specified the updated generic and product-specific chemistry data required by the Agency to support the continued use of cycloate. In addition to the data requirements in the 1988 Guidance Document, Data Call-In (DCI) notices were issued on April 5, 1991 and October 18, 1995. The data received in response to the DCIs were used to reach the reregistration eligibility conclusions for cycloate presented in the RED.

Human Health Risk Assessment

Toxicity

Cycloate has a low order of acute toxicity via the oral (Category III), dermal (Category IV) and inhalation (Category IV) routes of exposure. It is a moderate eye and dermal irritant (Category III) and is also a dermal sensitizer.

Cycloate is classified as "not likely to be a carcinogen to humans," therefore, no assessments were performed for cancer.

Cumulative Risk

The Agency has determined that some thiocarbamates (EPTC, molinate, pebulate and cycloate) share a common mechanism of toxicity, the inhibition of acetylcholinesterase. In September 2001, the Scientific Advisory Panel (SAP) concluded that there is insufficient evidence for grouping the thiocarbamate pesticides based on a common mechanism of toxicity for effects other than acetylcholinesterase inhibition.

The Agency conducted a preliminary "screening level" cumulative food risk assessment for the thiocarbamates. The results of this assessment, using very conservative Tier 1 exposure assumptions, is that MOEs exceed 310 for all population subgroups. Any MOE greater than 100 is deemed acceptable by EPA.

Therefore, at this time, EPA concludes that the potential cumulative risks from the thiocarbamates in general and cycloate in particular passes the "reasonable certainty of no harm" standard of the FQPA.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by OPP concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism at *http://www.epa.gov/pesticides/cumulative*.

Dietary Risks

No population subgroup, including infants and children, exceeded the Agency's level of concern for either acute or chronic dietary exposure to cycloate based upon aggregated exposure to food plus water.

Occupational and Residential Risks

The Agency has determined that there is a potential for short- and intermediate-term exposures in occupational settings from handling cycloate products during the application process (i.e., mixer/loader, applicator and mixer/loader/applicator). Short- and intermediate-term dermal risk estimates for most scenarios exceed the Agency's level of concern at baseline personal protective equipment (PPE). However, most of these exposures can be mitigated by some level of PPE and/or engineering controls. Risk estimates from inhalation exposures remain a concern for most scenarios, even with maximum PPE and/or engineering controls. Mitigation measures include the voluntary cancellation of the chemigation application of cycloate, requiring engineering controls (including closed cabs and closed mixing/loading systems), prohibiting on-farm impregnation of cycloate onto dry bulk fertilizer, and requiring use data to better characterize exposure from dry bulk fertilizer applications.

Post-application exposures are expected to be negligible because cycloate is incorporated into the soil either immediately or within a few hours after application, or it is injected into the soil. As a result, post-application scenarios were not assessed. However, due to the volatility of cycloate, the REI will be extended from the current 12 hours to 48 hours. However, workers will be allowed to enter the treated area during the first 48 hours following application to plant crops, provided they follow the early reentry language on the label.

Cycloate is not registered for any residential (home/garden) or other nonoccupational use, nor is it to be used in or around public buildings, schools or recreational areas where children or others might be exposed. Thus, there is no residential exposure to aggregate with the dietary exposure.

Environmental Risk Assessment

Ecological Risks

Cycloate use on garden beets, spinach and sugarbeets may cause adverse ecological effects at the current maximum application rate of 4 lbs. a.i./acre. Chronic risks are potentially a concern for small mammals, birds and estuarine/marine fish and invertebrates. Based on the Agency's screening level assessment, levels of concern have been exceeded for endangered species of small mammals (chronic risk) and potentially for birds (chronic risk). These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Currently, the Agency does not have data to determine the risk from cycloate use on spinach near estuarine areas to nontarget terrestrial plants. In addition, no acceptable chronic avian reproduction data were available, so chronic risks for avian species could not be assessed. Data are required to address these gaps in the ecological assessment.

Risk Mitigation

Pesticide mixer, loader and applicator risks will be mitigated by a combination of increased personal protective equipment, use of engineering controls and revised label language. Specifically, the following mitigation measures will reduce risks to agricultural workers:

- Voluntary cancellation of chemigation application of cycloate;
- Require engineering controls including closed cabs and closed mixing/loading systems;
- Prohibit on-farm impregnation of cycloate onto dry bulk fertilizer;
- Require use data to better characterize exposure from dry bulk fertilizer applications; and
- Extend the cycloate REI to 48-hours.

The registrant has agreed to submit data on cycloate that will allow the Agency to adequately assess the ecological effects of cycloate, thus refining these risk estimates. The Agency reserves the right to impose environmental risk mitigation strategies for cycloate, once these data have been reviewed**.**

Additional Data Required

EPA is requiring the following confirmatory data requirements for cycloate to confirm its regulatory assessments and conclusions: stability on TGAI; ultraviolet/visible absorption; solubility; field accumulation in rotational crops; terrestrial field dissipation; estuarine/marine fish and aquatic invertebrate acute toxicity studies on TGAI; freshwater fish early life stage test on TGAI; freshwater invertebrate life cycle test on TGAI; avian reproduction test (bobwhite quail and mallard duck) on TGAI; seedling germination/emergence and vegetative vigor, Tier 1 on TEP; aquatic plant growth, Tier 2 on TEP; multiresidue methods (3- and 4-HC metabolites); and developmental neurotoxicity study on rats.

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 cycloate end-use products must comply with EPA's current pesticide product labeling requirements, with the risk mitigation measures discussed above. For a comprehensive list of labeling requirements, please see the cycloate RED document.

Regulatory Conclusion

The use of currently registered products containing cycloate in accordance with approved labeling will not result in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing cycloate as the active ingredient are eligible for reregistration provided specified changes are made to the label and additional data identified above confirm this conclusion.

Cycloate 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 cycloate during a 60-day time period, as announced in a Notice of Availability published in the **Federal Register**. The public may access this **Federal Register** document electronically through the EPA Internet under the **"Federal Register"** listings at *http://www.epa.gov/fedrgstr/*. To obtain a copy of the RED and supporting documents for cycloate or to submit written comments, please contact the OPP Public Regulatory Docket, Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2002-0234. The docket telephone number is 202-305-5805.

To access electronic copies of the Agency's RED and supporting documents for cycloate, go directly to the REDs table on the EPA Office of Pesticide Programs Home Page, at *http://www.epa.gov/pesticides/reregistration/status.htm*. An electronic version of the public docket is also available to the public through EPA's electronic public docket and comment system, EPA Dockets. The public may use EPA Dockets at *http://www.epa.gov/edockets* to submit or view public comments, access the index listing of the contents of the official public docket and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in docket ID number OPP-2004-0234. Earlier information on cycloate, including public comments, can be found in EPA Dockets under docket ID number OPP-2004-0077.

For more information about EPA's pesticide reregistration program, the cycloate RED or reregistration of individual products containing cycloate, please contact the US EPA, OPP, Special Review and Reregistration Division (7508C), Washington, DC 20460-0001, 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://www.npic.orst.edu*.