



R.E.D. FACTS

Ancymidol

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 3017, ancymidol.

Use Profile

Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and other plant bedding areas for commercial production. Growth regulator effects produced by ancymidol are the result of inhibition of gibberellin biosynthesis. Since gibberellin promotes growth, treatment with ancymidol induces a more compact growth form by suppressing growth between nodes. The amount of active ingredient required for an optimum growth response depends on pot size, stage of growth, method of application, season, and varietal response.

Regulatory History

Ancymidol was first registered as a pesticide in the U.S. in 1973. In 1993 the Agency issued a Data Call-in (DCI) to the registrant for submission of additional data on ancymidol to support reregistration.

Currently there are two registered products, a technical formulation for manufacturing-use only and an end-use product containing 0.0264% ancymidol.

Human Health Assessment

Toxicity

Testing of ancymidol for acute toxicity on animals indicates that when inhaled, ingested, or applied to eyes, ancymidol is considered slightly acutely toxic (Toxicity category III). When applied to skin, it is practically non-toxic (Toxicity category IV). A subchronic 21-day toxicity study on rabbits showed no dermal irritation or systemic toxicity at the limit dose (1000 mg/kg) when applied dermally. A developmental toxicity study in rats did not indicate that ancymidol is a developmental toxicant. From that study, a lowest observed effect level for non-developmental toxic effects was determined to be 200 mg/kg/day, based on decreased body-weight gain and food consumption; while the no-effect level was considered to be 50 mg/kg/day. Finally, a battery of mutagenicity studies were negative for ancymidol. Long-term chronic toxicity testing of ancymidol has not been conducted but is not required since it is not found in food and other potential exposure to humans is very limited.

Dietary Exposure

No dietary exposure is expected from the pesticide uses of ancymidol since no food or feed uses are registered.

Occupational and Residential Exposure

Since ancymidol is used as a plant growth regulator for commercial purposes, there is potential exposure to pesticide handlers during use of the chemical and to persons entering treated sites after application is complete. At this time there are no products containing ancymidol intended for residential use. Therefore, the Agency did not conduct a residential risk assessment.

Human Risk Assessment

Since ancymidol has no food or feed uses, dietary risk is not expected. An acute toxicity inhalation study in rats treated with ancymidol shows what appeared to be neurotoxic effects. However, while spray applications may produce significant exposure, concentrations of ancymidol are low in formulated products (0.0264% a.i.), spray volatility is low, and current usage is very small. In consideration of this, the Agency believes that the potential risk to applicators is insignificant.

Ecological Effects Risk Assessment

Because environmental exposure to ancymidol is very limited and low toxicity is cited in all of the submitted studies, the Agency expects minimal adverse effects to birds, mammals, aquatic organisms and non-target plants.

Additional Data Required

The Agency 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 end-use products containing ancymidol must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the ancymidol RED document.

Regulatory Conclusion

The use of currently registered products containing ancymidol 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.

Ancymidol 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 ancymidol 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 ancymidol 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 ancymidol RED, or reregistration of individual products containing ancymidol, 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 8:00 pm Eastern Standard Time, Monday through Friday.