

SEPA R.E.D. FACTS

(Z)-9-Tricosene

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 4112, (Z)-9-tricosene.

Use Profile

(Z)-9-tricosene is the sex-attractant pheromone of the female housefly. This biochemical pesticide is used in a number of places where fly control is necessary including food/feed handling establishments, livestock premises and residential areas. However, these are considered non-food/feed uses because label restrictions prohibit use near food and feed. (Z)-9-tricosene is formulated as an impregnated material or pest strip, as well as a granular and crystal. Products are applied by hand, using rubber gloves or a cup or scoop.

Use restrictions for products containing (Z)-9-tricosene include: use granules and crystals in bait stations or only in places inaccessible to birds; strips containing the chemical may not be placed in areas where birds, pets or children can accidentally come in contact; products are not permitted in food areas of food handling establishments, or where milk is processed or stored; and products must be kept out of reach of food producing animals.

Regulatory History

Pesticide products containing (Z)-9-tricosene were first registered in the United States in 1975. Currently, there are twelve products registered, several also containing other pesticide active ingredients.

Human Health Assessment

Physical Chemistry

(Z)-9-tricosene is classified as a biochemical pesticide because even though it is chemically synthesized, it is identical to the sex pheromone of the female house fly Musca domestica.

There are certain technical chemistry issues to be resolved, including the method used to quantify the percent active ingredient. This leads to a deficiency in the Certification of Ingredient Limits and also the validation of the method used to verify certified limits. These deficiencies are considered minor to the Agency's ability to assess the risks associated with the current uses of (Z)-9-tricosene products. However, the Agency is requiring confirmatory data to correct these deficiencies and accurately characterize the technical chemistry of the (Z)-9-tricosene.

Toxicity

Other than slight eye and dermal irritation effects, and possibly moderate dermal sensitization, (Z)-9-tricosene showed no significant signs of acute toxicity. Because of its use patterns, no further toxicology studies are required.

Dietary Exposure

There are no established tolerances or tolerance exemptions for (Z)-9-tricosene. All labels bearing directions for use in food or feed handling establishments must carry restrictions to keep products containing this chemical away from food and feed areas and out of reach of livestock. These uses are classified as non-food uses and thus, there are no dietary exposure concerns.

Occupational and Residential Exposure

Based on the registered uses of products containing (Z)-9-tricosene, there are no worker or residential exposure concerns.

Human Risk Assessment

The potential risks to humans from both non-dietary and dietary routes are considered negligible. Because the active ingredients are impregnated or embedded in a solid polymeric matrix shell, there is low potential for exposure and there are no toxicological concerns.

Environmental Assessment

Environmental Fate

The major routes of dissipation in the environment for (Z)-9-tricosene are volatilization and microbial mediated degradation.

Ecological Effects

(Z)-9-tricosene has low toxicity to mammalian species that may come in contact with this pesticide in the environment. The chemical is practically non-toxic to birds or freshwater fish on an acute oral basis. On a subacute dietary basis, it is practically non-toxic to upland game birds and waterfowl.

(Z)-9-tricosene is very highly toxic, even in low doses, to waterfowl for reproductive effects and is also highly toxic to freshwater invertebrates.

Ecological Effects Risk Assessment

For products which contain impregnated materials and solid matrix forms (bait stations and strips), it is assumed that exposure to terrestrial and aquatic species will be minimal. For products formulated as crystals or granules, minimal acute effects to terrestrial species can be expected. Effects to aquatic invertebrates may occur if direct application of the chemical accidentally occurs.

Endangered Species

Based on the current use pattern for products formulated as crystals and granules, the potential risk of adverse acute effects to avian, aquatic and mammalian endangered species would be minimal. However, there could be a risk of reproductive effects to endangered avian species.

Additional Data Required

EPA is requiring confirmatory generic product chemistry data on the method used to quantify the percent of the active ingredient. Product-specific data including product chemistry, revised Confidential Statements of Formula (CSFs) and revised product labeling also are required for reregistration of products containing (Z)-9-tricosene.

Product Labeling Changes Required

The labels of all registered end use products containing (Z)-9-tricosene must comply with EPA's current labeling requirements, and with the following:

Avian Risk Mitigation: To mitigate the avian reproduction toxicity concern for broadcast products and the accessibility to birds, the Agency is requiring registrants to modify their products in a manner that would significantly reduce the exposure potential to birds, such as bait stations.

Regulatory Conclusion

The use of registered products containing (Z)-9-tricosene will not pose unreasonable risks or adverse effects to humans or the environment, provided that these products are used in accordance with the restrictions on product labeling. Therefore, all uses of these products are eligible for reregistration. Products containing (Z)-9-tricosene will be reregistered once required confirmatory generic data, product-specific data, 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 (Z)-9-tricosene during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. 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.

Following the comment period, the (Z)-9-tricosene RED document 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 (Z)-9-tricosene RED, or reregistration of individual products containing (Z)-9-tricosene, 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 6:00 pm Central Time, Monday through Friday.