



R.E.D. FACTS

Hexadecadienol Acetates

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 for hexadecadienol acetates, including the active ingredients (Z,E)-7,11-Hexadecadien-1-yl acetate and (Z,Z)-7,11-Hexadecadien-1-yl acetate, which are marketed under the trade name Gossyplure.

Use Profile

Hexadecadienol acetates are sex-attractant pheromones of the pink bollworm, Pectinophora gossypiella, Saunders, registered only for use on growing cotton to disrupt the male-female mating behavior. They are used in small quantities--less than 100 pounds of the active ingredients are applied each year, and only about 1% of the California cotton crop is treated with these biochemical pesticides.

Some products of this pheromone are applied in retrievably-sized polymeric matrix dispensers (twist ties and impregnated stakes). There are also end-use products which are microencapsulated and applied to foliage via broadcast, ground- and aerially-applications. These are water soluble formulations sprayed as either tank mixes or alone as emulsifiable concentrates or water dispersible granules.

Regulatory History

Hexadecadienol acetates were first registered as pesticides in the U.S. in 1978. Currently, 10 products are registered by six companies. The reregistration case contains four active ingredients, however two are not in any registered products.

The hexadecadienol acetate formulations classified as solid matrix dispensers soon may be exempted from regulation as pesticides because they pose little risk to human health or the environment.

Human Health Assessment

Toxicity

Hexadecadienol acetates generally are of low acute toxicity. They are placed in Toxicity Category IV, indicating the lowest level of acute toxicity, for acute oral and primary dermal effects. For acute dermal, acute inhalation and primary eye irritation effects, hexadecadienol acetates are placed in Toxicity Category III. Since the potential for human exposure to these pesticides is considered negligible, all other standard toxicology studies are waived.

Dietary Exposure

Hexadecadienol acetates may be present in the diet at low levels, but these residues are considered to be negligible and are not believed to pose human health risks. An exemption from the requirement of a tolerance has been established for residues of the active ingredient in or on the raw agricultural commodity cottonseed when applied to cotton from capillary fibers (see 40 CFR 180.1043). This exemption does not include the microencapsulated active ingredient.

Occupational and Residential Exposure

Since hexadecadienol acetates are contained, embedded or impregnated in a solid polymeric matrix or shell, cause little exposure, and do not pose significant toxicological concerns, no exposure data are required.

Human Risk Assessment

Based on their application methods, insignificant dietary and non-dietary exposure and relatively low toxicity, the hexadecadienol acetates' potential risks to humans are considered negligible.

Environmental Assessment

Environmental Fate

Hexadecadienol acetates are highly volatile and rapidly disperse into air. They are used in minute quantities in impregnated materials (stakes or twist ties) or as microencapsulated material which is applied to foliage via broadcast, ground- and aerially-applications. Because there is potential for the microencapsulated material to reach soil or water, soil or water contamination is possible. However, since the microencapsulated hexadecadienol acetate assumes the vapor state as it is released and rapidly

disperses, the amount which would actually be available in the ecosystem at any given time would be a small fraction of the amount applied.

Ecological Effects

Technical hexadecadienol is practically non-toxic to bobwhite quail, rainbow trout and honey bees. It is tentatively characterized as highly toxic to freshwater invertebrates. However, two aquatic studies are considered unacceptable and must be repeated as confirmatory data.

Ecological Effects Risk Assessment

Hexadecadienol acetate emulsifiable concentrate residues on treated food and forage items are expected to be below all levels of concern for both non-target and endangered avian species. A model used to calculate the expected environmental concentration (EEC) of hexadecadienol acetate emulsifiable concentrate in water indicates that adverse effects to aquatic species would be unlikely. Because it is highly volatile and is used in very small amounts, EPA believes that the risk to freshwater aquatic organisms will be minimal. However, the Agency is requiring acute toxicity data on both freshwater fish and aquatic invertebrates to confirm this assumption.

Additional Data Required

The generic data base for hexadecadienol acetates is substantially complete. However, EPA is requiring additional ecological effects studies as confirmatory data. 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 of pesticide products containing hexadecadienol acetates.

Product Labeling Changes Required

All hexadecadienol acetate end-use products must comply with EPA's current pesticide product labeling requirements. In addition:

Protection of Freshwater Invertebrates - All end-use products must bear the following precautionary statement:

"This product is highly toxic to freshwater invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate."

Application Rates - Product labels must include the amount of active ingredient to be applied per application, the maximum number of applications per year, and the minimum number of days between each application.

Worker Protection Standard (WPS) - Any product whose labeling permits use in the production of an agricultural plant on any agricultural establishment (farm, forest, nursery or greenhouse) must comply with the

labeling requirements of EPA's Worker Protection Standard (WPS). See PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7." Unless specifically directed in the RED, all statements required by the WPS and reflected in these two PR Notices must be included on product labeling.

Regulatory Conclusion

The use of currently registered pesticide products containing hexadecadienol acetates in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all currently registered products are eligible for reregistration. These products will be reregistered once the required confirmatory generic data, 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 hexadecadienol acetates 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.

Following the comment period, the hexadecadienol acetates 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 hexadecadienol acetates RED, or reregistration of individual products containing hexadecadienol acetates, 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, from 8:00 am to 6:00 pm Central Time, Monday through Friday.