United States Environmental Protection Agency | Pesticides And Toxic Substances (7508W) | 738-F-90-101 January 1991

R.E.D. FACTS

Heliothis Zea NPV

Pesticide Reregistration

All pesticides sold or used 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 from pesticide producers and reviews a complete set of studies showing 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for Heliothis zea NPV.

Heliothis zea NPV

Heliothis zea nuclear polyhedrosis virus (Heliothis zea NPV), which is sold under the trade name Elcar, is a microbial insecticide made from a naturally-occurring virus of the cotton bollworm and tobacco budworm. It infects only organisms belonging to the genus Heliothis. It is used to control a variety of worms including the cotton bollworm, tomato fruitworm, soybean podworm, sorghum headworm, corn earworm and tobacco budworm.

The one registered product containing Heliothis zea NPV is sold as a wettable powder and is applied as a foliar spray. It is registered for use on the following crops, and all of these uses are eligible for reregistration:

Beans	Soybeans
Corn	Strawberries
Cotton	Tobacco
Lettuce	Tomatoes
Peanuts	Wild Clover
Sorghum	Wild Geraniums

Regulatory History

Heliothis zea NPV was first registered by EPA in 1975 for use on cotton and tobacco, to control the cotton bollworm and the tobacco budworm. EPA issued a Registration Standard for Heliothis zea NPV in June 1984.

Health Effects

Heliothis zea NPV is a microbial pesticide, and its health-related data base consists mainly of a group of screening studies designed to show the toxicity and infective properties of the virus. If these studies indicated potential adverse effects, further studies on environmental fate, ecological effects and food residues would be required.

The results of these screening tests and other available studies on Heliothis zea NPV indicate that it is virtually innocuous to people, wildlife and other non-target organisms. Therefore, no additional, environmental fate and residue data are being required.

Heliothis zea NPV caused no adverse effects in any acute oral, dermal, inhalation or intravenous toxicity test. Nor is the pesticide an eye irritant. It is, therefore, being placed in toxicity category IV (the least toxic category). Other studies show that Heliothis zea NPV will not replicate or infect mammals, and does not cause birth defects.

Several special toxicology studies on Heliothis zea NPV also were available to EPA. Heliothis zea NPV caused no adverse effects in these subchronic feeding and inhalation studies, in an oncogenicity study, a Rhesus monkey study, a developmental toxicity study, and even in a voluntary human feeding study.

Routes Of Exposure

Through the Diet

Heliothis zea NPV is used in growing several food crops, and residues of the pesticide could remain on food and animal feed. However, since the screening level and other studies show that it causes no toxic effects, no **tolerances** (or legal residue limits) have been established for Heliothis zea NPV. An exemption from the requirement of a tolerance was established for residues of Heliothis zea NPV on all agricultural commodities in 1980. After thoroughly reviewing and reassessing the available studies and literature on Heliothis zea NPV, EPA still believes that residue data are not needed for this microbial pesticide and that the existing tolerance exemption continues to be appropriate.

To update the terminology and better reflect current technology, EPA is proposing to amend the terms of the tolerance exemption for Heliothis zea NPV as set forth in the Code of Federal Regulations (40 CFR 180.1027). These changes will more clearly define the virus and will add specifications for its production.

During Application

Due to its low toxicity and its use pattern, Heliothis zea NPV poses no known risks to applicators.

Environmental Hazards

Environmental Fate

No environmental fate studies are required to support the reregistration of Heliothis zea NPV, since no toxic or pathogenic effects have been observed in the screening level ecological effects data for this microbial pesticide.

Ecological Effects

The available studies and other relevant information show that Heliothis zea NPV does not cause adverse effects on birds or fish. Due to its narrow host range, this pesticide does not harm honeybees or pose a significant risk to nontarget insects.

Since Heliothis zea NPV poses a minimal to non-existent risk to nontarget wildlife due to its narrow host range, no further ecological effects studies are required.

Additional Data Required

No additional generic or product-specific data are required for reregistration of Heliothis zea NPV.

Product Labeling Changes Required

So that it will meet current pesticide labeling requirements, the Heliothis zea NPV product label must be amended to include a water contamination warning and a more accurate, updated ingredients statement. Please see the Reregistration Eligibility Document for more detailed information on these required labeling changes.

Regulatory Conclusion

- Based on the studies available to EPA, Heliothis zea NPV appears to cause virtually no adverse effects in people, wildlife, or nontarget insects. Due to its narrow host range, this microbial pesticide poses a threat only to the insects that it is intended to control.

- EPA has sufficient data on Heliothis zea NPV to conduct a reasonable risk assessment and to determine that the pesticide can be used without causing unreasonable adverse effects in people or the environment. Therefore, Elcar, the only registered pesticide product containing Heliothis zea NPV, is eligible for reregistration. This product will be reregistered once revised labeling is submitted to and accepted by EPA.

For More Information

EPA will accept and consider public comments on the Reregistration Eligibility Document for Heliothis zea NPV for several months. To obtain a copy, or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-557-4436, or fax to 703-557-1884.

To obtain a copy of the Registration Standard for Heliothis zea NPV, please contact the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA. 22161. Call 703-487-4650, and request document #PB85134393.

For more information about Heliothis zea NPV or EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460. Call 703-308-8000, or fax your request to 703-308-8005.

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, 24 hours a day, seven days a week, or fax your inquiry to 806-743-3094.