



R.E.D. FACTS

Polyhedral Inclusion Bodies of Gypsy Moth (*Lymantria dispar*) and Douglas Fir Tussock Moth (*Orgyia pseudotsugata*) Nuclear Polyhedrosis Viruses

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce 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 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 4106, Polyhedral inclusion bodies of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) nuclear polyhedrosis viruses, also referred to as PIBs of LdNPV and OpNPV.

Use Profile

Polyhedral inclusion bodies of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) nuclear polyhedrosis viruses, PIBs of LdNPV and OpNPV, are viral insecticides used to control gypsy moth and Douglas fir tussock moth on Forest Trees.

PIBs of LdNPV are used on: oak, hickory, basswood, birch, cherry, elm, blackgum, larch, sassafras, hemlock, cedar, spruce, black walnut, American chestnut, willow, poplar, ash, box elder, hawthorn, butternut, catalpa, American holly, locust, and sycamore.

PIBs of OPNPV are used on: Douglas fir, true fir, willow, and cedar.

Formulations include for PIBs of LdNPV: wettable powder, soluble concentrate, and flowable concentrate, and for PIBs of OpNPV, the formulation is wettable powder.

PIBs of LdNPV and OpNPV are applied by aerial spray from aircraft.

Use practice limitations: PIBs of LdNPV and OpNPV are limited to wide-area government sponsored programs to control gypsy moth and Douglas fir tussock moth on forest trees. Only non-food uses are permitted by labeling.

Regulatory History

PIBs of OpNPV were first registered as a viral insecticide in the U.S. in August, 1976. During Phase 4 of the Reregistration Process, the database for PIBs of OpNPV was evaluated and determined to be inadequate in satisfying certain data requirements for microbial pest control agents (MPCAs). In September 1993, a Data Call-In (DCI) required additional ecological effects data to fill data gaps: Avian oral toxicity/pathogenicity in quail and duck; freshwater fish toxicity/pathogenicity in trout; freshwater invertebrate toxicity/pathogenicity in benthic organism; nontarget plant; nontarget insect toxicity/pathogenicity; and honey bee toxicity/pathogenicity.

Based on the 90-day response to the DCI and additional publicly available literature provided by the USFS, the Agency determined the following: 1) the data requirements had been acceptably met for 154A-23 Nontarget insect tox/path and 154A-24 Honey bee tox/path, and 2) data requirements should be waived for 154A-16a Avian oral path/tox--quail, 154A-16b Avian oral path/tox--duck, 154A-19a Freshwater fish tox/path--trout, 154A-20 Freshwater invertebrate tox/path--benthic. The only remaining outstanding data requirement was for 154A-22 Nontarget plant studies. During the analysis and development of the reregistration eligibility decision (RED), wherein the databases for OpNPV and LdNPV were combined, the data requirement of non-target plant studies was reexamined and waived because of the absence of toxicity in the "bridged" data set. OpNPV appears to not cause adverse effects on avian, mammalian, aquatic, insect and plant wildlife.

PIBs of LdNPV were first registered as a viral insecticide in the U.S. in April 1978. During Phase 4 of the Reregistration Process, the database for PIBs of LdNPV was evaluated and determined to be inadequate in satisfying certain data requirements for microbial pest control agents (MPCAs). In September 1993, a Data Call-In (DCI) required additional ecological effects data to fill data gaps: freshwater fish toxicity/pathogenicity in trout; freshwater invertebrate toxicity/pathogenicity in benthic organism; nontarget plant; nontarget insect toxicity/pathogenicity; and honey bee toxicity/pathogenicity.

Based on the 90-day response to the DCI and publicly available literature, the Agency determined that the data requirements for 154A-19a Freshwater fish tox/path--trout, 154A-20 Freshwater invertebrate tox/path--benthic, 154A-22 Nontarget plant studies, 154A-23 Nontarget insect tox/path, and 154A-24 Honey bee tox/path may be waived. During the analysis and development of the reregistration eligibility decision (RED), wherein the databases for OpNPV and LdNPV were combined, these data requirements were reexamined in the "bridged" data set, and their waiver confirmed. LdNPV appears to not cause adverse effects on avian, mammalian, aquatic, insect and plant wildlife.

Currently, one product that has PIBs of OpNPV as the active ingredient is registered: TM Biocontrol-1™; two products that have PIBs of LdNPV as the active ingredient are registered: Gypchek™ and Lymantrin Insecticide™.

Human Health Assessment

Toxicity

In studies using laboratory animals, PIBs of OpNPV and LdNPV have generally been shown to be of low acute toxicity with the exception of primary eye irritation. Acute oral, acute pulmonary, and primary dermal irritation toxicity studies indicate Toxicity Category IV, the lowest of four Categories, and "practically non-toxic." The LD₅₀ for acute oral toxicity is > 5g/kg. Acute dermal has a LD₅₀ > 3.16 g/kg, a Toxicity Category III second lowest of the four Toxicity Categories and is characterized as "slightly toxic." However, primary eye irritation studies (perhaps because of the presence of larval hairs, microbial contaminants, or other inerts that currently are found with the active ingredient) demonstrate irreversible corneal damage, which warrants a Toxicity Category I, the highest toxicity rating that indicates the pesticide is "very highly or highly toxic."

Dietary Exposure

Since PIBs of OpNPV and LdNPV are applied to forested areas, the Agency considers these non-food uses which do not require a tolerance. Any exposures to wild food plants or adjacent croplands are incidental to the intended use and are not expected to present a significant dietary exposure. Given the lack of adverse effects presented by existing mammalian toxicological data, there is not reason to expect any dietary risks from residues of the NPVs in these incidental exposures.

Occupational and Residential Exposure

Based on spraying and aerial application methods that are used, the potential for dermal, eye and inhalation exposures to the pesticide exists. Because of the lack of human pathogenicity demonstrated by the test results on hand and the absence of reports of adverse human health effects after 20

years of manufacture and use of the AIs, worker exposure data on the active ingredients are not required.

However, due to the Acute Dermal response (Toxicity Category III) and reports in the published literature of dermal sensitivity to the larval hairs of the host species, the Agency will require product precautionary label statements that include proper warning about the presence of insect parts being a potential dermal sensitizer and the use of personal protective equipment. These label statements are necessary until proper quality control procedures are documented to reduce the likelihood that significant levels of insect hairs are present in the product.

In the eye irritation studies submitted to date, several animals in each test have shown corneal effects which did not clear by the end of the 14 day observation period. These results require that the labels have a toxicity rating of Toxicity Category I as a severe eye irritant. Although it was subsequently shown that the eye irritation was not associated with the virus particles themselves, nevertheless, until an acceptable eye irritation study is submitted to show otherwise, label statements are required that indicate the products are severe eye irritants and that specify appropriate eye protection.

Human Risk Assessment

For PIBs of OpNPV and LdNPV, applications of the insecticides are not expected to result in exposure and risk to workers. Potential exposures during mixing, loading, and spraying will be mitigated by compliance with the labeling requirements and use of personal protective equipment (PPE) as specified by this RED.

Environmental Assessment

Environmental Fate

Naturally occurring PIBs of OpNPV and LdNPV are important in bringing about the epizootic collapse of gypsy moth and Douglas fir tussock moth populations. Environmental fate studies indicate that collapse of the pest populations release a much greater amount of PIBs of OpNPV and LdNPV into the environment than their applications as a biopesticide; the natural levels of PIBs of OpNPV and LdNPV are not increased significantly by applications of the biopesticides. These data support the conclusion that PIBs of LdNPV and OpNPV are natural components of the hosts' environment and that pesticidal uses would not raise their levels above the range that naturally occurs.

Ecological Effects

The applications of aerially applied PIBs of OpNPV and LdNPV to forest ecosystems can be expected to result in exposure to a wide variety of birds, mammals, fish, aquatic invertebrates, and non-target insects.

Submitted studies, the scientific literature, target host specificity, and twenty years of use as biopesticides for controlling Douglas fir tussock moth and gypsy moth indicate no adverse effects on nontarget wildlife, including endangered species.

Ecological Effects Risk Assessment

No environmental or ecological toxicity data requirements are being required for PIBs of OpNPV and LdNPV in this RED. All data indicate that risks to non-target organisms are either non-existent or minimal.

Risk Mitigation

Until acceptable justifications and studies are submitted that show risks to be negligible, EPA is requiring modifications to the precautionary label statements for PIBs of OpNPV and LdNPV to protect against possible risk of dermal toxicity and eye irritation. See "Product Labeling Changes Required" below.

Additional Data Required

EPA is not requiring additional generic studies for PIBs of OpNPV and LdNPV to confirm its regulatory assessments and conclusions.

For reregistration of products containing the AIs of PIBS of OpNPV and LdNPV, 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

In the evaluation of the toxicological data base for PIBs of OpNPV and LdNPV, EPA determined that the AIs are severe eye irritants and thus require labels specifying appropriate eye protection. The Toxicity Category I for primary eye irritation requires products containing the AIs to be labeled with the signal word "Danger" and the appropriate Statements of Precaution, Personal Protective Equipment, Practical Treatment, and Note to Physician.

In addition, because of acute dermal response and reports in the published literature of dermal sensitivity to the larval hairs of the host species that contaminate the AIs, the Agency determined that the AIs have Toxicity Category III for acute dermal sensitivity. The EPA will require product precautionary label statements that include proper warning about the presence of insect parts being a potential dermal sensitizer and appropriate Statements of Precaution, Personal Protective Equipment, and Practical Treatment.

End-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the Polyhedral Inclusion Bodies of Gypsy Moth and Douglas Fir Tussock Moth Nuclear Polyhedrosis Viruses RED document.

Changes in the end use product labeling requirements specified in Chapter V of the RED are as follows:

"Avoid contact with skin, eyes or clothing, Wash thoroughly with soap and water after handling. Wear long-sleeved shirt and long pants, socks, shoes, and protective gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."

For eye irritation, label products with the signal word: "Danger."

Statements of Precaution and Personal Protective Equipment:

"Primary eye irritation studies indicate pesticide is a severe eye irritant and may cause irreversible eye damage. An emergency eye flushing apparatus shall be present where mixing/loading take place. Do not get in eyes or on clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse."

Statement of Practical Treatment: "If in eyes: hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

Note to Physician: "Product is a severe eye irritant, possibly causing irreversible damage to cornea."

Statement for aerial spraying: "Avoid spraying sensitive populated areas. This pesticide must be applied in a manner to avoid spraying--either directly or indirectly through drift--sites such as residential areas, schools, playgrounds, or similar sites where people or pets may be present."

Regulatory Conclusion

The use of currently registered products containing PIBs of OpNPV and LdNPV in accordance with approved labeling in the RED will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

PIBs of OpNPV and LdNPV 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

EPA is requesting public comments on the Reregistration Eligibility

Information

Decision (RED) document for Polyhedral Inclusion Bodies of Gypsy Moth and Douglas Fir Tussock Moth Nuclear Polyhedrosis Viruses 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 Polyhedral Inclusion Bodies of Gypsy Moth and Douglas Fir Tussock Moth Nuclear Polyhedrosis Viruses 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 RED Polyhedral Inclusion Bodies of Gypsy Moth and Douglas Fir Tussock Moth Nuclear Polyhedrosis Viruses, or reregistration of individual products containing PIBs of OpNPV and LdNPV, please contact the Biopesticides and Pollution Prevention Division (7501W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8712.

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 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.

