United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-96-020
September 1996

Reregistration Eligibility Decision (RED)

Polyhedral Inclusion Bodies of GYPSY MOTH (*Lymantria dispar*) and DOUGLAS FIR TUSSOCK MOTH (*Orgyia pseudotsugata*) NUCLEAR POLYHEDROSIS VIRUSES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 4106 which includes the active ingredients polyhedral inclusion bodies of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*). The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. No additional data (generic) on the active ingredients are needed to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Biopesticide and Pollution Prevention Division representative, Glenn Williams, at (703) 308-8287.

Sincerely yours,

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division (7501W)

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**.

You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-BPPD)**
Office of Pesticide Programs (7501W)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-BPPD)**
Office of Pesticide Programs (7501W)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Polyhedral Inclusion Bodies of GYPSY MOTH (*Lymantria dispar*) and DOUGLAS FIR TUSSOCK MOTH (*Orgyia pseudotsugata*) NUCLEAR POLYHEDROSIS VIRUSES

LIST D

CASE 4106

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

TABLE OF CONTENTS

POLYHEDRAL INCLUSION BODIES OF GYPSY MOTH (*LYMANTRIA DISPAR*) AND DOUGLAS FIR TUSSOCK MOTH (*ORGYIA PSEUDOTSUGATA*) NUCLEAR POLYHEDROSIS VIRUSES

REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Ghulam Ali	Economic Analysis Branch
William Gross, Jr.	Biological Analysis Branch
Gabe Patrick	Biological Analysis Branch

Biopesticides and Pollution Prevention Division

Julie Fry	Microbial Pesticides Branch
John Kough	Microbial Pesticides Branch
Glenn Williams	Pollution Prevention Staff

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency has completed its reregistration eligibility decision (RED) for the biopesticide active ingredients (ais) Polyhedral Inclusion Bodies of *Lymantria dispar* and *Orgyia pseudotsugata* Nuclear Polyhedrosis Viruses (PIBs of LdNPV and OpNPV) for the products Gypchek ™, Lymantrin ™, and TM Biocontrol-1 ™. PIBs of LdNPV and OpNPV are viral insecticides used as aerial sprays on forest trees to manage gypsy moth and Douglas fir tussock moth, respectively.

These naturally occurring insect viruses belong to the family Baculoviridae, genus *Baculovirus*, subgenus A, and infect host insects, gypsy moth and Douglas fir tussock moth. Within the nuclei of the infected cells of the hosts, the viruses are occluded within polyhedrally shaped lattices of protein; i.e, polyhedral protein bodies that include virus particles within cell nuclei. Hence, the terminology is derived: nuclear polyhedral viruses (NPV) and polyhedral inclusion bodies (PIBs).

Although these two strains of NPVs are distinguishable by restriction endonuclease profiles, fragment profiles, and natural insect host range, biochemical characteristics and taxonomy indicate that both NPVs are closely related. For the purpose of assessing mammalian and ecological toxicity for reregistration of the ais, the PIBs of LdNPV and OpNPV may be considered the same. Study data on one strain are equally applicable for assessing the other strain. Consequently, the Agency determined that it would be appropriate in its assessment to bridge the test data between the two strains in determining the eligibility of the ais for reregistration.

This reregistration eligibility decision (RED) document includes a comprehensive reassessment of the required data and use patterns of the currently registered ais.

The Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment and, therefore, all appropriately labelled products are eligible for reregistration. The results of eye irritation testing indicate that a Toxicity Category I classification on the label is appropriate as defined in 40CFR156.10. The results of the other acute tests show no results that would cause undue concern for these ais. Acute toxic effects will be addressed by appropriate labeling. The Agency does not have subchronic or chronic concerns for the ais under the intended uses. Revised Precautionary, Personal Protective Equipment, Practical Treatment, and Note to Physician Label statements may be required depending on justifications and/or studies submitted and reviewed in the Reregistration Phase 5 review of pesticide products containing the ais.

At this time, submission of additional generic data are not being required to confirm the Agency's risk assessment and conclusions for the ais. The Agency does not expect any risk to humans or the environment from use of these biopesticides; therefore all uses are eligible for reregistration. The bases of this decision are:

o evaluation of the submitted data and published scientific literature for the RED indicate the bridged data base is complete and acceptable for all data requirements;

o the fact that PIBs of OpNPV and LdNPV are naturally-occurring pathogens of gypsy moth and Douglas fir tussock moth and are selective for Lymantriids with no known adverse effects to any species other than the hosts, gypsy moth and Douglas fir tussock moth; and

o the fact that in approximately 20 years of use, there have been no reports of adverse human health and ecological effects, with the exception of possible dermal sensitivity and eye irritation in exposed humans during manufacture.

Before reregistering the products containing the ais PIBs of LdNPV and OpNPV, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registrationand acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other ais will be eligible for reregistration only when the other ais are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances, but FQPA does not obligate the Agency to consider the factors set forth in the new section 408 of the FFDCA when making decisions under FIFRA with respect to pesticides that do not have any food uses. However, the FQPA did not amend any of the existing reregistration deadlines in section 4 of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of polyhedral inclusion bodies (PIBs) of *Lymantria dispar* and *Orgyia pseudotsugata* nuclear polyhedrosis viruses (NPVs). The document consists of six sections. Section I is the introduction. Section II describes PIBs of *Lymantria dispar* and *Orgyia pseudotsugata* NPVs, their uses, data requirements and regulatory histories. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision. Section V discusses the reregistration requirements. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** 1) Polyhedral inclusion bodies of *Lymantria dispar* nuclear polyhedrosis virus (PIBs of LdNPV)
  2) Polyhedral inclusion bodies of *Orgyia pseudotsugata* nuclear polyhedrosis virus (PIBs of OpNPV)

- **Biological Name:** 1) Polyhedral inclusion bodies of *Lymantria dispar* nuclear polyhedrosis virus
  2) Polyhedral inclusion bodies of *Orgyia pseudotsugata* nuclear polyhedrosis virus

- **Biological Family:** Baculoviridae

- **CAS Registry Number:** Not applicable

- **OPP Chemical Code:** 1) 107303
  2) 107302

- **Empirical Formula:** Not applicable

- **Trade and Other Names:**

  1) PIBs of LdNPV:
  Gypchek Biological Insecticide for the Gypsy Moth; and
  Lymantrin Insecticide.

  2) PIBs of OpNPV:
  TM Biocontrol-1.

- **Basic Manufacturer:** 1) PIBs of LdNPV:
  USDA Forest Service/Animal and Plant Health and Inspection Service (APHIS);
  American Cyanamid Company; and
  NPP Inc.

  2) PIBs of OpNPV:
  USDA Forest Service.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of **Polyhedral inclusion bodies of *Lymantria dispar* and *Orgyia pseudotsugata*** Nuclear Polyhedrosis Viruses (NPVs) are in Appendix A.

For polyhedral inclusion bodies of *Lymantria dispar* and *Orgyia pseudotsugata* Nuclear Polyhedrosis Viruses (PIBs of LdNPV and OpNPV):

Type of Pesticide: Microbiological pest control agent (viral insecticide)

Mode of Action: When PIBs of LdNPV and OpNPV are ingested by larvae of the hosts, chemical action in the gut releases viral rods from PIBs causing host-specific general viral infection and death of larvae.

Use Sites: 1) PIBs of LdNPV:

Forestry: Forest trees, including oak, hickory, basswood, birch, cherry, elm, blackgum, larch, sassafras, hemlock, cedar, spruce, black walnut, American chestnut, willow, poplar, ash boxelder, hawthorn, butternut, catalpa, American holly, locust, and sycamore.

2) PIBs of OpNPV:

Forestry: Forest trees, including Douglas fir, true fir, willow, and cedar.

Target Pests: 1) PIBs of LdNPV: Gypsy Moth
2) PIBs of OpNPV: Douglas Fir Tussock Moth

Formulation Types Registered: PIBs of LdNPV and OpNPV: End Use Product

1) PIBs of LdNPV:
   - o Wettable powder
   - o Soluble concentrate
   - o Flowable concentrate

2) PIBs of OpNPV
   - o Wettable powder

Method and Rates of Application:

Types of Treatment- PIBS of LdNPV and OpNPV: Low volume spray (concentrate); Spray

Equipment - PIBs of LdNPV and OpNPV: Aircraft with boom and nozzle systems designed to result in droplets 150-400mmd.

Method and Rate - 1) PIBs of LdNPV:

One application of at least 400 billion gypsy moth polyhedral inclusion bodies or two or more applications two to four days apart at the rate of 200 to 500 billion gypsy moth polyhedral inclusions bodies /per 1 gal finished spray per acre or

Two applications seven to ten days apart of 25 to 125 million gypsy moth potential units (MGMPU) per 1 gal finished spray per acre

2) PIBs of OpNPV:

0.31g product per 1-2 gals finished spray per acre or

.93 billion Activity Units (AU) per 1-2 gals finished spray per acre.

Timing - Spring foliar

C. Estimated Usage of Pesticide:

This section summarizes the best estimates available for the pesticide uses of polyhedral inclusion bodies ***Lymantria dispar*** **and** ***Orygia pseudotsugata*** Nuclear Polyhedral Viruses (NPVs). These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

For PIBs of LdNPV, federal and state cooperative applications to control gypsy moth, USDA Forest Service/Forest Pest Management estimates a total of 3000 acres treated in 1995 and an average annual total treatment from 1990 to the present of @ 3000 acres. (Rappaport, FS, 1996: Private communication based on: "Forest Health Technology Enterprise Team Update"). For federal applications, the U.S. Forest Service estimates @500 acres (less than 1% of forest acreage) were treated with 247 trillion polyhedral inclusion bodies (PIBs) applied/acre in 1994. (Thomas, 1995)

For PIBs of OpNPV, for federal applications, the U.S. Forest Service estimates @500 acres (less than 1% of forest acreage) are treated with 247 trillion polyhedral inclusion bodies (PIBs) applied/acre in 1994. (Thomas, 1995).

D. Data Requirements

In Phase 4 of the Reregistration Process data gaps for **polyhedral inclusion bodies of** ***Orgyia pseudotsugata*** **and** ***Lymantria dispar*** **Nuclear Polyhedrosis Viruses (NPVs)** were identified and Data Call-Ins (DCIs) were issued on September 1993 for studies on **ecological effects.** These test data were required to assure that the data base for reassessing the potential for unreasonable risks to human health and the environment is complete and supports the uses of the active ingredients. Appendix B includes all data requirements identified and reviewed by the Agency in determining eligibility for reregistration.

E. Regulatory History

1 Polyhedral inclusion bodies of *Orgyia pseudotsugata* Nuclear Polyhedrosis Viruses (PIBs of OpNPV)

On August 11, 1976, the EPA approved the U.S. Forest Services' (USFS) application for registration of PIBs of OpNPV as a viral insecticide for controlling the Douglas fir tussock moth. The PIBs of OpNPV are the ai of the product TM Biocontrol-1 [tm], EPA Registration Number 27586-1, used for aerial applications on forest lands.

During Phase 4 of the Reregistration Process, the data base for OpNPV was evaluated and determined to be inadequate in satisfying certain data requirements

for the ai. The following studies for assessing microbial pest control agents (MPCAs) were identified as data gaps, and a DCI was issued:

154A-16a	Avian oral tox/path--quail
154A-16b	Avian oral tox/path--duck
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
154A-24	Honey bee tox/path

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. (See Section III.C.1) The only remaining outstanding data requirement was for 154A-22 Nontarget plant studies for which a waiver was pending after the DCI response. 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.

On November 29, 1988, the USFS submitted studies to California Department of Food and Agriculture (CDFA) (information-only copies to EPA) supporting a request for registration of PIBs of OpNPV in California, where the product's registration had lapsed. The studies submitted were:

152A-10	Acute Oral tox/path--rat
152A-11	Primary Dermal Irritation study--rabbit
152-33	Intraperitoneal study--mouse

Additional mammalian toxicity studies for 152A-10 Acute Oral tox/path, 152-32 Acute Pulmonary (inhalation) tox/path and 152-39 Tissue culture were submitted to CDFA in July 1991. All submitted studies were determined unacceptable. In addition, study data indicated a Toxicity Category I for Eye Irritation. USFS has not yet addressed these issues with the state; PIBs of OpNPV has not been reregistered in California.

On April 18, 1996, the USFS submitted a label amendment for "Use

Practice Limitation," substituting the language "For use in only wide-area government sponsored pest control programs" for the original language on the label "For use by or under the supervision of U.S. Forest Service." On May 7, 1996, the amendment was accepted by EPA.

2. Polyhedral inclusion bodies of *Lymantria dispar* Nuclear Polyhedrosis Viruses (PIBs of LdNPV)

The U.S. Forest Service (USFS) developed PIBs of LdNPV, "Hamden strain," as a viral insecticide under EPA Experimental Use Permit (EUP) number 27856-EUP-8, and applied for registration December 22, 1976, while continuing research and testing in response to EPA's Data Requirements. EPA approved the USFS's application for registration of PIBs of LdNPV on April 11, 1978. The PIBs of LdNPV are the ai of the product Gypchek ™, EPA Registration Number 27586-2, used for aerial applications on forest lands to control gypsy moth.

During Phase 4 of the Reregistration Process, the data base for LdNPV was evaluated and determined to be inadequate in satisfying certain test data requirements for the ai. The following studies for MPCAs were identified as data gaps, and a DCI was issued:

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
154A-24	Honey bee tox/path

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. (See Section III.C.1.) 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 and waived because of the absence of toxicity in the "bridged" data set. LdNPV appears to not cause adverse effects on avian, mammalian, aquatic, insect and plant wildlife.

On January 8, 1990, the U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), initiated correspondence with EPA concerning the development of a more virulent strain "Abington strain"of LdNPV for use as an insecticide against gypsy moth. ARS intended to use a trivalent

pesticide containing three of the most virulent Abington isolates, which would replace the Hamden strain of PIBs of LdNPV. During March through June 1990, correspondence between EPA and ARS established Product Identity Data Requirements for demonstrating similarities between the Abington and Hamden strains that would support utilization of data already submitted for current registration of Hamden strain for an EUP, FIFRA Section 3 registration, or FIFRA Section 3 amendment applications for the Abington strain. As of the date of this RED, neither ARS nor USFS has submitted the Product Identity studies for the Abington strain or an EUP, registration, or amendment application. Therefore, this reregistration eligibility decision is only for NPV inclusion bodies from *L. dispar,* Hamden strain.

On September 25, 1990, NPP, Inc. submitted Application for Pesticide Registration for a "Me Too" registration of the ai of PIBs of LdNPV (Hamden strain), identical to the USFS registered product, EPA Reg. No. 27586-2. USFS authorized the complete use of all the necessary data base originally submitted by the USFS. The product, Lymantrin Insecticide [tm], was registered October 30, 1991, EPA Registration No. 62343-1. On January 10, 1994, NPP Inc. submitted a label Amendment to comply with PR Notice 93-7 (Worker Protection Standards), which was approved by EPA on March 22, 1994.

On March 27, 1992, American Cyanamid Company submitted Application for Pesticide Registration for a "Me Too" registration of the ai of PIBS of LdNPV (Hamden strain) identical to the USFS registered product, EPA Reg. No. 27586-2. USFS authorized the complete use of all the necessary data base originally submitted by the USFS. The product, Gypchek [tm], was registered June 5, 1992, EPA Registration No. 241-347.

On May 4, 1993, USFS submitted Application for Pesticide and Confidential Statement of Formula for amending its registration for Gypchek [tm] to include an alternative production facility, the Forest Pest Management Institute (FPMI) in Saulte Sainte Marie, Ontario, Canada--EPA Establishment Number #66989-CN-001. However, as of the date of this RED, this facility has not been used to manufacture Gypchek [tm] for the USFS.

On April 26, 1996, the USFS submitted a label amendment for changing "Use Practice Limitation," interval between treatments, and dosage. The amended label substitutes the language "For use in only wide-area government sponsored pest control programs" for the original language on the label "For use by or under the supervision of U.S. Forest Service." Interval between treatments changes from 7-10 days to 2-4 days; application rates change from "2 applications 7 to 10 days apart at the rate of 25.0 to 125.0 million gypsy moth potency units per acre" to "1 application of at least 400 billion gypsy moth polyhedral inclusion bodies per

acre," or "make 2 or more applications 2 days apart at the rate of 200 to 500 billion gypsy moth polyhedral inclusion bodies per acre. Percentages of ingredients change for ai from 20% to 14.6% and for inerts from 80% to 85.4%. On May 7, 1996, the label amendment was accepted by EPA.

F. Food Quality Protection Act

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

III. SCIENCE ASSESSMENT

EPA has thoroughly reviewed the scientific data base for polyhedral inclusion bodies of *O. pseudotsugata* and *L. dispar* Nuclear Polyhedrosis Viruses (PIBs of OpNPV and LdNPV). The review relied primarily on studies submitted by the registrant, including studies conducted by the registrant and studies published in the open literature. All studies were evaluated in relation to the various guideline requirements, and only those studies that were determined to be acceptable formed the data basis for this review. These studies are cited in Appendix B and the Bibliography. For the purpose of evaluating test data for health and ecological endpoints, the Agency's review of data indicates that both PIBs of OpNPV and LdNPV are so closely related that data from both ais may be considered interchangeable (see discussion below in section III.A.). Therefore, the combined database for both ai's may be used in determining the eligibility for reregistration of each NPV.

As forest use biopesticides, the PIBs of OpNPV/LdNPV qualify for a reduced set of generic data requirements for reregistration as specified in 40 CFR 158.740, Guidelines for Microbial Control Agents--Tier I--for non-food/feed uses, and *EPA Microbial Pesticide Test Guidelines 885.1000 series.*

The Agency concludes that the existing data base adequately satisifies the data requirements. No additional studies are required at this time. The Agency does not expect any risk to humans or the environment from use of these biopesticides; therefore, all uses are eligible for reregistration. The bases of this decision are:

o evaluation of the submitted data and published scientific literature for the RED indicate the data base is complete and acceptable for all data requirements;

o the fact that PIBs of OpNPV and LdNPV are naturally-occurring pathogens of gypsy moth and Douglas fir tussock moth and are selective for Lymantriids with no known adverse effects to any species other than the hosts, gypsy moth and Douglas fir tussock moth; and

o the fact that in approximately 20 years of use, there have been no reports of adverse human health and ecological effects, with the exception of possible dermal sensitivity and eye irritation in exposed humans during manufacture.

A. Physical Chemistry Assessment

1. Product Identity

The ais of the MPCAs are PIBs of OpNPV and LdNPV, naturally-occurring insect viruses belonging to the family Baculoviridae, genus *Baculovirus*, subgenus A. Baculoviruses are double-stranded DNA containing viruses that have no vectors and only infect arthropods, especially insects. The majority of baculoviruses characterized to date have been isolated from Lepidopteran hosts. PIBs of OpNPV and LdNPV are members of the morphological subgroup having multiple bacilliform shaped virions containing double-stranded DNA. The virions are embedded within a membrane and enclosed in a polyhedrin protein matrix, producing characteristic occlusion bodies, termed polyhedral inclusion bodies (PIBs), in the nuclei of infected host's cells. Both NPVs are described by the cryptogram D/2:50/15:U/(E):I/O.

While all NPVs have some conserved traits such as the polyhedrin protein, distinguishable traits include host range and responses to certain biochemical tests. The registrant has submitted biochemical data consisting of general product chemistry, restriction endonuclease (REN) profiles, protein analysis, serological tests and buoyant density and isopycnic centrifugation data that are specific to OpNPV and LdNPV (MRID numbers OpNPV: 49098, 49099, 49100, 49102, 49104; LdNPV: 68398, 68399, 68402, 66093, 66097). By employing these techniques, these NPVs may be distinguished from each other (REN analysis) and easily distinguished from other insect viruses, such as *Helicoverpa (Heliothis) zea* NPV reregistered by EPA in 1990. The *Helicoverpa zea* NPV has a different Lepidopteran host range and is a single embedded baculovirus.

PIBs of OpNPV and LdNPV can, therefore, be distinguished. Biological activity suggests, however, that both share more similarities than differences. First, both NPVs only infect species of forest pests in the Lymantriidae family.

Although the NPV of *L. dispar* has been shown incapable of infecting *O. pseudotsugata* larva, both strains of NPV have been shown to infect and replicate in embryonic and fat body cell lines of *L. dispar* (Barber *et al*. 1993; Lynn *et al*. 1988). Moreover, where studies on PIBs of OpNPV and LdNPV overlap in their test data, comparison of these data points demonstrates the same health or eco-toxicological responses. Consequently, for the purpose of evaluating health and ecological test data to make a reregistration eligibility decision, both PIBs of OpNPV and LdNPV are so closely related that the Agency considers data for one to be applicable for the other ai.

2. Other Physical and Chemical Characteristics

The physical and chemical characteristics of pesticides are usually requested to identify unique hazards of a synthetic chemical such as flammability and flash point. No such information regarding the physical and chemical parameters has been requested nor deemed necessary for assessing these baculoviruses for eligibility for reregistration.

3. Conclusion of Physical Chemistry Assessment

Product identification and chemistry data requirements were not subject to the Reregistration Phase 4 Data Call In. The Agency is not requiring any further information regarding product identity, physical and chemical characteristics. All product characterization data requirements have been satisfied.

B. Human Health Assessment

1. Toxicology Assessment

In general, the Agency's major toxicological concerns for microbial pest control agent (MPCA) ai's are the following endpoints:

- pathogenicity of the MPCA and of microbial contaminants;
- infectivity/unusual persistence of the MPCA and of microbial contaminants; and
- toxicity of the MPCA, of microbial contaminants, and of preparation by-products.

The Tier I battery of tests in CFR 158.740 (c) and the *EPA Microbial Pesticide Test Guidelines OPPTS 885.3000 series*, allow for a reasonable assessment of the potential risks of the MPCA for these three endpoints.

Adequate acute mammalian toxicology data for assessing the potential Tier I toxic effects of PIBs of OpNPV and LdNPV are available and support a reregistration eligibility decision.

a. Acute Mammalian Toxicity

The acute mammalian toxicity studies conducted with the two strains of NPVs adequately satisfy the data requirements. A summary of the bridged Tier I acute toxicity data for these NPV inclusion bodies is found in Table I below. The specific test results for each NPV inclusion body are not listed separately for each guideline; instead the most significant adverse response for each test guideline from the bridged data set is listed as the result of the test.

TABLE I: ACUTE MAMMALIAN TOXICITY REQUIREMENTS FOR THE NPVs OF *LYMANTRIA DISPAR* AND *ORGYIA PSEUDOTSUGATA*

GUIDELINE NO.	STUDY	RESULTS	TOX CATEGORY	MRID / AccessionNo.	PIBs of NPVs
152-30 / OPPTS 885.3050	Acute Oral Toxicity/ Pathogenicity	LD_{50} >5g/kg in rats	IV	49114 417387-01 49262 68401 60702	OpNPV LdNPV LdNPV LdNPV LdNPV
152-31 / OPPTS 885.3100	Acute Dermal Toxicity	LD_{50} >3.16 g/kg or >1 g/kg in rabbits	III	49116 49263 60703 66101	OpNPV LdNPV LdNPV LdNPV
152-32 / OPPTS 885.3150	Acute Pulmonary (Inhalation) Toxicity/ Pathogenicity	LC_{50} >6.12 mg/L or >0.68 mg/L	IV	54189 49266 60695 66102 66105	OpNPV LdNPV LdNPV LdNPV LdNPV
152-33 / OPPTS 885.3200	Acute I.V., I.C., I.P. Injection Toxicity/ Pathogenicity	LD_{50} >2.5 mg/kg (10^7 PIBs) in rats	N/A	49113 417387-03 66103 66109	OpNPV OpNPV LdNPV LdNPV
152-34	Primary Dermal Irritation	Not a dermal irritant	IV	49117 417387-02 49265 66104	OpNPV OpNPV LdNPV LdNPV
152-35 / OPPTS 885.3300	Primary Eye Irritation	Irritation with corneal involvement not cleared by day 14	I	49114 49264 91124 60696 68403 68404 60704	OpNPV LdNPV LdNPV LdNPV LdNPV LdNPV LdNPV
152-37 / OPPTS 885.3400	Hyper-sensitivity incidents	None Reported*	N/A	N/A	N/A

152-39 / OPPTS 885.3500	Tissue Culture	None submitted; Requirement has been waived	N/A	N/A	N/A

* All incidents must be reported to the Agency. However, see discussion.

Significant mortality was noted in the acute intraperitoneal injection tests (152-33) with OpNPV at a dose level of 10 mg per animal (MRID 417387-03). All animals injected with the 10 mg of material died within four hours of dosing, clearly indicating a toxic response. However, animals injected with smaller doses (1.0 mg or 0.1 mg) survived the 21 day duration of the test and showed no signs of lesions or toxicity at gross necropsy. The 1.0 mg dose represents a 10^7 PIB dose, which conforms to the dose level required by Guideline 152-33 / OPPTS 885.3200, and is adequate for addressing the infectivity endpoint. While the mortality at the 10 mg dose is significant, a high dose causing nonspecific toxicity is not unexpected, and is not relevant to the hazard assessment in compliance with the Guidelines. This nonspecific toxicity is also found, for example, in intraperitoneal injection assays with the bacterium, *Bacillus thuringiensis* when administered above the 10^7 CFU dose suggested in the Guidelines.

There have been no instances of hypersensitivity (152-37) reported to the Agency related to use of these active ingredients. The Agency believes the baculovirus particles by themselves are no more likely than any other proteinaceous substance to induce hypersensitivity. However, there are published reports in the medical literature (Shama *et al*. 1982) as well as anecdotal accounts of hypersensitivity relating to exposure to setae (hairs) of the larval stages of the target host insects. Since these active ingredients are produced using host larvae, it is incumbent on producers to insure that larval hairs are removed to a suitable level during processing. This method of larval processing will be examined during the product specific phase of reregistration.

The required data set for reregistration does not include immune response studies. The Agency reviewed supplemental studies conducted in immune-depressed animals. Oral, footpad injection and nasal and eye instillation studies were conducted with PIBs of LdNPV on immune-depressed mice, and dermal studies with the same ai were performed on immune-depressed guinea pigs (MRID Nos. 60700 and 60703). The studies showed no adverse reactions although the seriological response to

the virus varied with the level of immune suppression as would be expected. These negative results add further weight to the conclusions that PIBs of LdNPV and OpNPV are neither infective nor pathogenic to mammalian species.

Additionally, for current registration of baculoviruses, producers are required to submit studies examining the infectivity of the purified viral agent against mammalian cell lines in tissue culture assays (159-39). The OpNPV has been tested against amphibian and fish cell lines for infectivity and replication (Banowetz *et al.* 1976; Wolf 1975). While no effects were found against these vertebrate cell lines, these viral agents have not been tested against mammalian cell lines. Strictly following the OPPTS 885 series Guidelines, producers for both these active ingredients would be required to submit infectivity/toxicity tests with mammalian cell cultures. However, numerous baculoviruses have been tested against more than 50 cell lines without any detrimental effects (Groner 1986). In addition, the sum total of the toxicity/pathogenicity data on these NPVs and the subchronic and chronic feeding studies discussed below, which showed no adverse effects, can be used to satisfy the tissue culture study's requirement. These data do not indicate a concern for infectivity. Based on the available data, the tissue culture studies are considered satisfied and the requirement waived.

b. Subchronic Toxicity Studies

The Agency does not currently require the submission of subchronic studies for MPCAs that do not show adverse effects in the Tier I toxicology tests. Consequently, Tier II subchronic studies are not required but are reviewed and considered as supplementary studies in determining eligibility for reregistration.

Subchronic and chronic feeding studies (152-42 and 152-50) for LdNPV were reviewed in connection with the initial registration process (Accession Nos. 84340 and 84578, respectively). No adverse effects were noted in a 90-day feeding study with beagle dogs given daily oral doses of 0, 10^7, 10^8 or 10^9 PIBs of LdNPV. A two-year oncogenicity study (152-51) involving daily oral administration of 10^7 or 10^8 PIBs of LdNPV to Dublin rats showed no adverse effects. Since the longer-term studies were originally performed to assess the possible effects of repeated exposure to NPV, these tests provide information relevant to assessing mammalian cell culture endpoints currently required for viral pesticides. These longer-term studies demonstrate no infectivity/pathogenicity, cell transformation, or viral toxicity in mammals.

c. Conclusion of Toxicology Assessment

Tier I toxicology tests were not the subject of the Phase 4 Data Call In because the data base was considered satisfactory. In the evaluation of the toxicology data base for the reregistration eligibility decision for the PIBs of *Lymantria dispar* and *Orgyia pseudotsugata* NPVs, the guideline requirements have been fulfilled or adequately addressed by the studies already submitted. No further information for the active ingredients is required.

Eye irritation remains an area of concern for the final products. Irritation with corneal involvement did not clear by day 14 of the observation period, which indicates a Toxicity Category I response for the TGAI of PIBs of *L. dispar NPV*. Based on the available results of eye irritation studies, the clinical literature on irritation caused by larval hairs and the presence of microbial contaminants and added inerts in the final products, studies or a scientifically sound justification will be required prior to making final decisions on the Phase 5 reregistration of pesticides products containing these ais.

Dermal toxicity, primary dermal irritation and hypersensitivity are also areas of concern based on studies in the reregistration data base and the open literature. These issues and the appropriate Label statements will be examined in making final decisions on the Phase 5 reregistration of pesticide products.

2. Exposure and Risk Assessments

a. Dietary Exposure and Risk Assessment

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 toxicology data, there is no reason to expect any dietary risks from residues of the NPVs in these incidental exposures.

b. Occupational Exposure and Risk Assessment

Based on the application methods which involve spraying and aerial applications, the potential for dermal, eye and inhalation exposures

to the pesticide for pesticide handlers exists. However, spraying of the PIBs of OpNPV and LdNPV will not significantly increase exposure to larval hairs, microbes, or other by-products that occur in the preparation of the ais. Pest densities that necessitate spraying have a natural high background of these factors; moreover, dilution of the ais in the spraying preparation and its sticking to the forest foliage reduce the likelihood of exposure to a negligible level. Finally, the lack of human pathogenicity demonstrated by the test results on hand and the absence of any record that indicates human health effects from occupational exposures, leads the Agency to conclude that worker exposure data to the active ingredients are not required.

(1). Dermal

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 (Shama *et al*. 1982). (See Section V of this RED.) This label statement is necessary until proper quality control procedures are documented to reduce the likelihood that significant levels of insect hairs are present in the product. If production methods are employed which eliminate the use of larva and/or the potential exposure to larval hairs, these precautionary statements may be removed.

(2). Eye

The eye irritation studies submitted to date have produced equivocal results (Accession nos. 49114, 49264, 91124, 60696, 68403, 68404). Several animals in each test have shown corneal effects which did not clear by the end of the 14 day observation period (Accession No. 68404). These results would 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 (MRID No. 60704), nevertheless, until an acceptable eye irritation study is submitted to show otherwise, a label statement indicating the products are severe eye irritants and specifying appropriate eye protection is required. (See Section V of this RED.) Unlike the dermal sensitization where exposure to larval hairs is the likely cause, this effect may be tied to other factors such as bacterial contaminants or by-products. Therefore, this study cannot be waived based on altered manufacturing methods alone. Presently, a Toxicity Category I for primary eye irritation would require products containing the active

ingredients to be labeled with the signal word "Danger" and the appropriate Statements of Precaution and Personal Protective Equipment, Practical Treatment and Note to Physician.

C. Environmental Assessment

Part III. A. "Product Identity/Chemistry Assessment" and B. "Human Health Assessment" of this Reregistration Eligibility Decision Document discuss the biological similarities of the two NPVs, LdNPV and OpNPV, that allow the Agency to consider the data as one data set for both NPV active ingredients (ai). This approach holds true as well for ecological toxicity data assessment for non-target organisms, enabling the environmental assessment to bridge data between the two NPVs for evaluating their eligibility for reregistration.

Since their registration, PIBs of OpNPV and LdNPV have been used for approximately 20 years as MPCAs, and there have been no reported adverse ecological effects in that time period. Moreover, during natural outbreaks, when large numbers of these viruses are released into the environment, no adverse ecological effects are known to occur other than to the host species, gypsy moth and Douglas fir tussock moth. These facts support the evaluation of ecotoxicity studies summarized below in determining that the two ai's, PIBs of LdNPV and OpNPV, are eligible for reregistration without submission of any other environmental assessment data.

1. Ecological Toxicity to Terrestrial and Aquatic Organisms

The purpose of nontarget organism testing is to develop data necessary to assess potential hazards of MPCAs to terrestrial wildlife, aquatic animals, plants and beneficial insects. Tier I non-target organism and environmental expression data requirements, specified in CFR 158.740 (d) and in EPA's Microbial Pesticide Test Guidelines OPPTS Series 885, provide a battery of tests that allow the assessment of pathogenicity and toxicity to terrestrial and aquatic organisms exposed to MPCAs. The guidelines in Tier I reflect a maximum hazard approach to testing. Negative results provide a high degree of confidence that no unreasonable adverse effects are likely to occur from the actual use of the MPCA. The review of available data follows.

a. Summary of Ecotoxicity Studies

The available terrestrial and aquatic data and other relevant scientific information show that the PIBs of LdNPV and OpNPV do not cause adverse pathogenic or toxics effects on avian, mammalian and aquatic wildlife. They are host specific, infecting only forest insect pests

in the Lymantriidae family. Available data will support a Reregistration Eligibility Decision. The ecological effects data submitted in support of these NPVs are summarized in Table II.

In reviewing the Table, note that the studies identified by an asterisk next to the MRID, Acession number or literature citation were reviewed as supplemental studies since they do not follow protocols that would allow them to be substituted in their entirety for basic data requirements. However, the Agency believes that these studies provide sufficient information on the toxicity of direct exposure of NPVs to non-target species to make an environmental risk assessment and a reregistration decision.

TABLE II: NON-TARGET ORGANISM AND ENVIRONMENTAL EXPRESSION DATA SUPPORTING THE REREGISTRATION DECISION FOR THE NUCLEAR POLYHEDROSIS VIRUS OF *LYMANTRIA DISPAR* AND *ORGYIA PSEUDOTSUGATA.*

Guidelines	PIBs of NPVs	Study Type	Results	MRID, Accession # or Literature citation
154-16 / OPPTS 885.4050 Avian Acute Oral Pathogenicity/Toxicity test	OpNPV	English sparrow	LD_{50} > 1,969mg/kg	Hudson *et al*. (1984)*
154-16 / OPPTS 885.4050 Avian Acute Oral Pathogenicity/ Toxicity test	LdNPV	feeding study bobwhite quail	no signs of toxicity / pathogenicity 3.73 x 10^3 PIB/g/bird	00091447*
	LdNPV	8 -day dietary feeding study mallard	LC_{50} > 16000 ppm	accession # 231360
	LdNPV	feeding study black capped chickadee and house sparrow	birds fed larvae infected with 3 x 10^7 to 2 x10^8 PIBs: no short term effects found	accession # 231360*
154-17 / OPPTS 885.4100 Avian respiratory pathogenicity test	LdNPV OpNPV	Waived	Waived	Waived
154-18 / OPPTS 885.4150 Wild Mammal toxicity and pathogenicity test	LdNPV	mammal dietary study on white footed mouse, short tailed shrew, Virginia opossum	mammals fed larvae infected with 4 x 10^8 to 6 x10^8 PIBs: no short term effects found	00134314* 00060707* 00068412*

154-19 / OPPTS 885.4200 Freshwater fish toxicity and pathogenicity test (waived for OpNPV)	LdNPV	Brown Trout and Bluegill Sunfish 96hr LC_{50}	LC_{50} > 1.5 x 10^{9} PIB/g	0005465
154-20 / OPPTS 885.4240 Fresh H_2O aquatic invertebrate (waived for OpNPV)	LdNPV	an exposure study *w/ Daphnia magna*, *Notonecta undulata* , & *Chironomus thummi*	LC_{50} > 250 PIB/ml = to 10^{12} PIB/acre	00060709
154-22 / OPPTS 885.4300 Non-target Plants	LdNPV OpNPV	waived based on known insect species specificity	waived requirement	waived requirement
154-23 / OPPTS 885.4340 Non-Target Insects	LdNPV OpNPV	waived based on known host range	waived requirement	waived requirement
154-24 / OPPTS 885.4380 Honey Bee Toxicity, Pathogenicity Test	LdNPV OpNPV	4 month feeding study	no effects on egg laying, brood rearing and honey production 10,850 AU_{GL}/bee**	Knox, 1970*

* These studies were reviewed and are supplemental in that they do not follow protocols that would allow them to be substituted in their entirety for basic data requirements . However, the Agency believes that these studies provide sufficient information on the toxicity of direct exposure of NPVs to non-target species to make an environmental risk assessment and a reregistration decision.

** AU_{GL} = activity unit or the potency of each production lot and because the activity unit was based on the response of insect strain GL-1, its symbol is AU_{GL}

In addition to the studies cited above, PIBs of OpNPV has been tested against amphibian and fish cell lines for infectivity and replication. No effects were found against these vertebrate cell lines (Banowetz, G.M., J.L. Fryer, P.J. Iwai, and M. E. Martignoni. 1976. Effects of the Douglas-fir tussock moth nucleopolyhedrosis virus (baculovirus) on three species of salmonid fish. USDA For. Serv. Res. Pap. PNW-214, 6 p. Pac. Northwest For. and Range Exp. Stn., Portland, OR.)

Further studies were conducted and submitted to examine the effects of PIBs of LdNPV on wildlife following aerial application at the rate of 2.5×10^{12} PIBs/ha on woodland plots in Pennsylvania. Comparison of necropsy or organ weights and histopathological data taken on 297 mammals (including major gypsy moth predators) and seventy-six birds either free living or caged in the study plots indicated no significant difference between controls and treated mammals or birds. Further prespray and post spray censuses of the dominant mammals and resident songbirds taken on control and treated plots indicated no population changes could be attributed to NPV treatment. (MRID #s 00066108, 00060712, 00060711, 00060706). Mammals and birds are important natural predators of gypsy moth larvae, and natural occurrences of both mammals and birds passing NPV's through their alimentary tracts is documented (Groner. 1976). The negative results of these studies add further weight to the conclusions that this NPV is neither infective nor pathogenic to non-target species.

Avian respiration for baculovirus products are associated with inhalation of the larval setae (spiny hairs) which result from production *in vivo*. However, EPA has waived the Avian respiratory pathogenicity test, Subdivision M Guideline 154A-17/OPPTS 885.4100 for both PIBs of LdNPV and OpNPV. The Agency bases its decision on several considerations. Mammalian inhalation test for both NPVs showed no signs of toxicity or pathogenicity, and there is no reason to believe that the avian inhalation test would show different results. These products are typically applied by air. Natural dispersion as the product settles to the ground and foliage is not expected to result in high avian respiratory exposure. In addition, annual use of these baculoviruses is limited by their production *in vivo and in vitro* resulting in relatively low use and exposure compared to other products. To date, insect viruses have never been known to have any adverse avian effects.

b. Toxicity to Nontarget Plants

The NPVs of *L. dispar* and *O. pseudotsugata* are species-specific, infecting only insects. Therefore, all nontarget plant testing data requirements have been waived.

c. Toxicity to Nontarget Insects

Non-target insect testing was waived based on the known host specificity of both LdNPV and OpNPV to a limited number of related Lepidoptera, infecting and debilitating species of forest pests only in the Lymantriidae family. Groner (1986) in his review of

studies on susceptibility of alternativie hosts to NPVs found that infectivity is restricted to the family or at least to the order of the original host. The NPV of *L. dispar* has been shown incapable of infecting *O. pseudotsugata* larva (Barber *et al*. 1993). The NPV of *O. pseudotsugata* is known to infect three other species in the genus *Orygia* and has been shown to infect and replicate in embryonic and fat body cell lines of *L. Dispar* (Lynn *et al*. 1988).

2. Environmental Fate of NPV

Naturally occurring NPVs of *L. dispar* and *O. pseudotsugata* are important in bringing about the epizootic collapse of gypsy moth and Douglas fir tussock moth populations. During natural outbreaks of the moths, large amounts of these viruses are released into the environment with no known or reported adverse ecological effects to species other than the target insect host. An environmental fate study was reviewed in connection with the initial registration to determine NPV persistence after natural epizootics and how introduction of the virus as a MPCA affects its natural accumulation and persistence in the environment. Results from bioassays in leaf, bark, litter and soil showed that a much greater amount of virus is released into the environment by the collapse of the pest population than is released through application of NPVs as a biopesticide control measure (Podgwaite *et al*. 1979). Additional study results found that the natural levels of NPV did not increase after an application of 2.5×10^{12} PIBs/ha to a test plot already supporting high levels of naturally occuring NPV. Similarly, application of NPV at 5×10^{12} to a test plot supporting low levels of naturally occuring NPV did not result in a significant increase of virus levels over those in the control plot.

The Agency does not currently require the submission of environmental fate studies for microbial pesticides that adequately pass the Tier I tests; however, these data support the conclusion that PIBs of LdNPV and OpNPV are natural components of the hosts' environments and that pesticidal uses would not raise the levels of NPV above that which might naturally occur.

3. Environmental Exposure and Risk Assessment

The application of aerially applied NPVs to forest ecosystems can be expected to result in exposure to a wide variety of birds, mammals, fish and aquatic invertebrates. The available avian and aquatic data and other relevant literature and information show that PIBs of OpNPV and LdNPV do not cause adverse effects on avian, mammalian and aquatic wildlife. No mortalities were seen when these viruses were fed to mallard ducks, house sparrows, bobwhite quail and black-capped chickadees. No mortalities or other adverse effects were seen in brown trout, bluegill sunfish, and a variety of aquatic invertebrates. Similarly, tests with mule deer, Virginia opposums, short-tailed shrews and white-footed mice, resulted in no evidence of pathogenicity or toxicity. Known insect host range and scientific literature on honey bee mortality demonstrate that these baculoviruses do not have adverse effects on honeybees and should not pose a significant risk to nontarget insects (Cantwell *et al*. 1972; Knox 1970). NPV

effects on endangered species are considered a low risk based on the absence of threat to nontarget organisms.

4. Conclusion

Due to the lack of adverse effects on avian, mammalian and aquatic wildlife, plants and nontarget insects documented in the submitted studies and scientific literature after 20 years of use, the Agency finds that the PIBs of *L. dispar* and *O. pseudotsugata* NPVs pose minimal or no risk to nontarget wildlife, including endangered species. The toxicology data base for the reregistration eligibility decision for the PIBs of *L. dispar* and *O. pseudotsugata* NPVs are adequate for a risk assessment. The guideline requirements have been fulfilled or adequately addressed by the submitted studies. No further information is required.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing the active ingredients of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs. Product specific data required for reregistering products include product chemisttry and acute toxicity data. Generic data for these data requirements are satisfactory for product reregistration. Therefore the Agency expects the registrants to cite these previously submitted data in the "Eight-Month Response.' Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs, and lists the submitted studies that the Agency found acceptable.

In summary, the Agency concludes that the existing data base adequately satisfies the data requirements. No additional studies are required at this time. The Agency does not expect any risk to humans or the environment from use of these biopesticides; therefore, all uses are eligible for reregistration. The bases of this decision are:

o evaluation of the submitted data and published scientific literature for the RED indicate the data base is complete and acceptable for all data requirements;

o the fact that PIBs of OpNPV and LdNPV are naturally-occurring pathogens of gypsy moth and Douglas fir tussock moth and are selective for Lymantriids with no known adverse effects to any species other than the hosts, gypsy moth and Douglas fir tussock moth; and

o the fact that in approximately 20 years of use, there have been no reports of adverse human health and ecological effects, with the exception of possible dermal sensitivity and eye irritation in exposed humans during manufacture.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs and to determine that PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs are eligible for reregistration as specified in this RED, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs, the Agency has sufficient information on the health effects of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs for all uses are eligible for reregistration as specified in this RED.

2. Eligible and Ineligible Uses

The Agency has determined that all Forest Uses of PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs to manage gypsy moth and Douglas fir tussock moth, respectively, are eligible for reregistration and use as specified in this RED. No other uses are currently registered.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately.

EPA is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

2. Tolerance Reassessment

PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs are used exclusively for aerial spray control on Forests. This application is a non-food/non-feed use; therefore, neither a tolerance nor an exemption from tolerance is required.

3. Endangered Species Statement

Based on the Agency's assessment of health and environmental test data as well as studies in the literature, PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs, pose minimal to no adverse effects to plant and animal endangered species.

4. Labeling Rationale

a. Precautionary Labeling

The Agency has reexamined the data base for PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs and concludes that the current precautionary labeling (i.e., Signal Word, Statement of Practical Treatment, and other label statements associated with mitigating risks) require amendment as specified in Section V. Until acceptable studies, data, and/or written justifications show otherwise, it is prudent to label products containing PIBs of LdNPV and OpNPV in such a way as to assure mixers, loaders, applicators, and sensitive populations are adequately protected from both dermal sensitization (Toxicity Category III) and eye irritation (Toxicity Category I) health effects.

b. Directions for Use

The Agency has reexamined the label for PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs and concludes that the current use directions for the ais must be amended. The current label requires the identity of the use-site to be inferred. The label shall be amended to include the identity of the use site "Forest Trees," as specified in Section V.B.2.d. The RED recognizes the label amendments accepted by EPA on May 7, 1996. However, as the exposure and risk assessments indicate (See Section III.B.2.), the Agency has both dermal and eye irritation concerns, based on available data. Consequently, the pesticide must be applied in a manner to avoid spraying--either directly or through drift--sensitive, populated areas such as residential areas, schools, playgrounds, or similar sites where people or pets may be present.

Label statments for use directions are not required for "restricted-entry" or "notification-to-workers." Infestations of gypsy moth and Douglas fir tussock moth larval populations in forests that necessitate spraying PIBs of LdNPV and OpNPV have a

natural high background density of larval hairs and insect body parts--the inert elements which are currently found in the TGAIs and thought to cause the dermal and eye concerns (see Section III.2.b.). Spraying products containing the ais would not significantly increase exposures to these elements. Moreover, dilution of the ais in the spray preparation and the sticking of the preparation to forest foliage reduce the likelihood of exposures to these elements to a negligible level on the ground.

5. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Agency completes its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, the Agency may impose further refinements in spray drift management practices to further reduce off-target drift and risks associated with this drift.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of the active ingredients, PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs, for the above eligible uses has been reviewed and determined to be substantially complete. At this time, no additional data is required.

2. Labeling Requirements for Manufacturing-Use Products

The Agency reviewed and approved the labels for both ais/products on May 7, 1996. Statements for Environmental Hazard, and Storage and Disposal shall remain as approved on the May 7, 1996 label. Certain precautionary statements for the labels are to be amended to remain in compliance with FIFRA. Manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies.

To the Directions for Use statement, the MP labeling must add the following statement:

"Only for formulation into a biological insecticide for wide-area government sponsored pest control programs on Forest Trees."

In addition, because of acute dermal response and reports in the published literature of dermal sensitivity to the larval hairs of the host species, the Agency will require a product precautionary label statement that includes proper warning about the presence of insect parts being a potential dermal sensitizer. This label statement is necessary until proper quality control procedures are documented to reduce the likelihood that significant levels of insect hairs are present in the product. The statement shall read:

> "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."

Regarding primary eye irritation, until an acceptable eye irritation study is submitted that shows eye irritation is not a significant concern, a label statement is required indicating the products are severe eye irritants and specifying appropriate eye protection. 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 and Personal Protective Equipment, Practical Treatment, and Note to Physician.

> 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/application take place. Do not get pesticide in eyes or on clothing. Wear goggles or face shield. Wash thorougly 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."

Until acceptable studies, data, and written justification show that dermal sensitization and eye irritation are not a significant concern, both the dermal and eye irritation demonstrated by the test data make it prudent to avoid spraying the ais on sensitive populated areas. Consequently, products containing the ais must be labeled as follows:

> 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."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Worker Protection Standard

Worker Protection Standard (WPS) Labeling is not applicable to Gypchek (EPA Registration # 27586-2) and TM Biocontrol-1 (EPA Registration # 27586-1) because they are labeled "For use in only wide-area government sponsored pest-control programs" and are, therefore, according to PR Notice 93-7 exempt from the labeling provisions of the WPS. Lymantrin Insecticide (EPA Registration # 62343-1) is subject to the labeling provisions of the WPS.

Products that are controlled by the WPS and whose labeling permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse, must comply with the labeling requirements of 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, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

b. Effluent Discharge Labeling Statements

Refer to subsection A.2. above: "Labeling Requirements for Manufacturing-Use Products."

c. Statement of Precaution, Personal Protective Equipment, Practical Treatment, and Note to Physician.

Refer to subsection A.2. above: "Labeling Requirements for Manufacturing-Use Products" for Precautionary Statements.

d. Use Labeling

The Agency's review conducted in preparation of the Reregistration Eligibility Decision Document indicates that the Use Sites on the product labels for PIBs of LdNPV and OpNPV are not clearly specified. The Directions of Use section on the label shall be amended to indicate the following:

For PIBs of LdNPV: "This product is registered only for the management of gypsy moth and shall only be used on forests trees, including oak, hickory, basswood, birch, cherry, elm, blackgum, larch, sassafras, hemlock, cedar, spruce, black walnut, American chestnut, willow, popular, ash, boxelder, hawthorn, butternut, catalpa, American holly, locust, and, sycamore."

For PIBs of OpNPV: "This product is registered only for the management of Douglas fir tussock moth and shall only be used on forest trees, including Douglas-fir, true fir, spruce, larch, pine, hemlock, willow, and cedar."

C. Tolerance Revocation and Import Tolerances

Not applicable for PIBs of LdNPV and OpNPV for forestry use.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell PIBs of gypsy moth (*Lymantria dispar*) and Douglas fir tussock moth (*Orgyia pseudotsugata*) NPVs products bearing old

labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

Report Run Date: 08/29/96) Time 10:18 LUIS 3.02 - Page: 1
PRD Report Date: 09/14/95

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107302[Inclusion bodies of Douglas fir tussock moth nucleopolyhedrosi]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Tex. @ Max. Dose	# Apps Max. Rate unless noted Max. /crop /year otherwise)/A]	Max. Dose [(AI /crop /year cycle	Min. Interv (days)	Re-Entry Intv.	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED											
FOREST TREES (SOFTWOODS, CONIFERS)									Use Group: FORESTRY		
Low volume spray (concentrate), Foliar, Aircraft	WP	NA	.93 billion	*	NS	NS	NS	NS	NS NS AU A		C79
WIDE AREA/GENERAL OUTDOOR TREATMENT (QUARANTINE/ERADICATION USE)									Use Group: TERRESTRIAL NON-FOOD CROP		
Low volume spray (concentrate), Foliar, Aircraft	WP	NA	.93 billion	*	NS	NS	NS	NS	NS NS AU A		C79, CAC

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107302[Inclusion bodies of Douglas fir tussock moth nucleopolyhedrosi]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS
Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Re-Entry Intv. : Reentry Intervals
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
WP : WETTABLE POWDER

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"
AU : Activity Units
USE LIMITATIONS CODES
C79 : For use by or under the supervision of U.S. Forest Service.

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107302[Inclusion bodies of Douglas fir tussock moth nucleopolyhedrosi]

USE LIMITATIONS CODES (Cont.)

CAC : Keep out of lakes, streams, and ponds.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107303[Polyhedral inclusion bodies of gypsy moth nucleopolyhedrosis v]

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI Tex. @ Max. Rate unless noted otherwise)	Soil Max. # Apps Max. Dose [(AI Max. /crop /year otherwise)/A]	Min. Interv (days)	Re-Entry Intv. Dose	Geographic Limitations Allowed /crop	/year cycle	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION										
NON-FOOD/NON-FEED										
FOREST TREES (ALL OR UNSPECIFIED)							Use Group: FORESTRY			
Low volume spray (concentrate), Foliar, Aircraft	WP	NA	125 MGMPU A	* NS	2/1 yr	NS	NS	7	NS	
FOREST TREES (HARDWOODS, BROADLEAF TREES)							Use Group: FORESTRY			
Spray, Foliar, Aircraft	FM/S	NA	125 MGMPU A	* NS	2/1 yr	NS	NS	7	NS	CAC
	FlC	NA	125 MGMPU A	* NS	2/1 yr	NS	NS	7	.5	CAC

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107303[Polyhedral inclusion bodies of gypsy moth nucleopolyhedrosis v]
4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

LEGEND
444444

Sort: Uses Eligible or Ineligible for Re-registration, Food/Feed or Non-Food/Non-Feed Uses, Alpha Site Name, Use Group Name, Alpha Application Type/Timing/Equipment Description, Formulation, Maximum Application Rate Unit/Area Quantity, Minimum Application Rate

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days) : Minimum Interval between Applications (days)
Re-Entry Intv. : Reentry Intervals
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
FM/S : FORM NOT IDENTIFIED/SOLID
FlC : FLOWABLE CONCENTRATE
WP : WETTABLE POWDER

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"
MGMPU : Million Gypsy Moth Potency Units

APPENDIX A REPORT

Case 4106[NPV inclusion b] Chemical 107303[Polyhedral inclusion bodies of gypsy moth nucleopolyhedrosis v]

4444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444444

USE LIMITATIONS CODES

CAC : Keep out of lakes, streams, and ponds.

* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

REENTRY INTERVAL ABBREVIATIONS

.5 : day

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 4106 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 4106 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

APPENDIX B

Data Requirements for Reregistration of *Lymantria dispar NPV* and *Orgyia pseudotosugata NPV*

DATA REQUIREMENTS BY GUIDELINES	USE PATTERNS	CITATIONS: MRID, ACCESSION #, LITERATURE CITATION	BACULO-VIRUS	PHASE III STATUS
PRODUCT CHARACTERIZATION GUIDELINES:				
151-20 / 885.1100 Product identity	J	00066097	LdNPV	ACCEPT
151-21 / 885.1200 Manufacturing process	J			ACCEPT
151-22 / 885.1300 Discussion of formation of unintentional ingredients	J			ACCEPT
151-23 / 885.1400 Analysis of samples	J			ACCEPT
151-25 / 885.1500 Certification of limits	J			ACCEPT
151-25 Analytical Methods	J			ACCEPT
151-26 Physical and chemical properties	J	00049098 00049099 000490100 000490102 000490104 00068398 00068399 00068402 00066093	OpNPV OpNPV OpNPV OpNPV OpNPV LdNPV LdNPV LdNPV LdNPV	ACCEPT
TOXICOLOGY TIER I:				

152-30 / 885.3050 Acute oral Toxicity / Pathogenicity	J	00049114 000417387-01 00049262 00068401 00060702	OpNPV LdNPV LdNPV LdNPV LdNPV	ACCEPT
152-31 / 885.3100 Acute dermal Toxicity	J	00049116 00049263 00060703 00066101	OpNPV LdNPV LdNPV LdNPV	ACCEPT
152-32 / 885.3150 Acute Pulmonary (inhalation) Toxicity / Pathogenicity	J	00054189 00049266 00060695 00066102 00066105	OpNPV LdNPV LdNPV LdNPV LdNPV	ACCEPT
152-33 / 885.3200 I.V., I.C., I.P. injection Toxicity / Pathogenicity	J	00049113 00417387-03 00066103 00066109	OpNPV OpNPV LdNPV LdNPV	ACCEPT
152-34 Primary dermal Irritation	J	00049117 000417387-02 00049265 00066104	OpNPV OpNPV LdNPV LdNPV	
152-35 Primary eye Irritation	J	00049114 00049264 00091124 00060696 00068403 00068404 00060704	OpNPV LdNPV LdNPV LdNPV LdNPV LdNPV LdNPV	ACCEPT
152-36 Hypersensitivity study	J			
152-37 / 885.3400 Hypersensitivity incidence	J	NA	NA	ACCEPT
152-38 Immune response	J	NA	NA	NA
152-39 Tissue culture	J	NA	NA	NA
Supplemental Studies: Immune depressed animals	J	00060700 00060703	LdNPV LdNPV	NA
Supplemental Studies: Subchronic feeding study	J	00084340	LdNPV	NA

Supplemental Studies: Chronic feeding study	J	00084578	LdNPV	NA
ECOLOGICAL EFFECTS TIER I				
154-16 / 885.4050 Avian oral Pathogenicity / Toxicity Tests	J	000231360	LdNPV	WAIVED
Supplemenatal Studies: Avian oral Pathogenicity/Toxicity Tests	J	Tucker/Crabtree 1979 Tucker 1967 00091447 000231360	OpNPV OpNPV LdNPV LdNPV	
154-17 Avian injection	J			
154-18 / 885.4150 Wild Mammal Testing	J			WAIVED FOR LdNPV
Suppelmental Studies: Wild mammal toxicity and pathogenicity test	J	Tucker/Crabtree 1970 00134314 00060707 00068412	OpNVP LdNPV LdNPV LdNPV	
154-19 / 885.4200 Freshwater fish toxicity and pathogenicity test	J	0005465	LdNPV	WAIVED FOR OpNPV
154-20 / 885.4240 Freshwater aquatic invertebrate test	J	00060709	LdNPV	WAIVED FOR OpNPV
154-22 / 885.4300 Nontarget plant	J	NA	NA	WAIVED
154-23 / 885.4340 Nontarget insect	J	NA	NA	WAIVED
154-24 / 885.4380 Honey bee toxicity / pathogencity test	J	Knox 1970	OpNPV / LdNPV	ACCEPT FOR OpNPV

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

Polyhedral Inclusion Bodies
Gypsy Moth (Lymantria dispar)
Nuclear Polyhedrosis Viruses (NPVs)
References in Open Literature

Banowetz, G.M., J.L. Fryer, P.J. Iwai & M.E. Martignoni, 1976, Effects of the Douglas-fir tussock moth nucleopolyhedrosis virus (Baculovirus) on three species of salmonid fish. USDA For. Ser. Res. Pap. PNW-214, 6p. Pac. Northwest For. and Range Exp. Stn., Portland, OR.

Barber, K.W., W.J. Kaupp & S.B. Holmes, 1993, Specificity testing of the nuclear polyhedrosis virus of the gypsy moth, Lymantria dispar (L.) (Lepidoptera: Lymantriidae), Canadian Entomologist 125: 1055-1066).

Cantwell, G.E., T. Lehnert, and J. Fowler. 1972. Are biological insecticides harmful to the honey bee? Am. Bee J. 112(7):255-258, (8): 294-296.

Groner, A. 1986, Specificity and safety of baculoviruses. In eds. Granados, R.R., Frederici, B.A. The Biology of Baculoviruses. Vol. II. CRC Press: Boca Raton , FL. pp. 117-202).

Hudson, H., R.K. Tucker, M.A. Haegle. 19984. Handbook of toxicity of pesticides to wildlife. U.S. Dept. of Inter., U.S. Fish and Wild. Serv., Resource Publ. 153, 90pp.

Knox, D.A. 1970. Tests of certain insect viruses on colonies of honeybees. J. Invertebr. Pathol. 16(1):152).

Lynn, D.E., E.M. Doughetry, J.T. McClintock and M. Loeb. 1988. Development of cell lines from various tissues of Lepidoptera, In: invertebrates and Fish Tissue Culture, Y. Kuroda, E. Durstak & K. Maramorosch (eds.) Japan Scientific Societies, Tokyo.

Podgwaite, J.D., K. S. Shields, R.T. Zerillo, and R.B. Bruen. 1979. Environmental persistence of the nucleopolyhedrosis virus of the gypsy moth, Lymantria dispar L. Environ.Entomol. 8:523-536.

Shama, S.K., P.H. Etkind, T.M. Odel, A.T. Canada, A.M. Finn, and N.A. Soter, 1982, N.E. J. of Med. 306:1300-1301.

Thomas, D.F. 1995. Biopesticides in the Forest Service: research, development and application. USDA Forest Service. Washington, DC.
Tucker, R.K. 1967. Subacute oral treatment, mallard hens. Virus (Hemerocampa pseudotsugata). U.S. Dep. Inter. Fish and Wildl. Serv., Denver Wildl. Res. Cent., Denver, Colo. Intern. Rep. Supplement1, 1p.. (unpublish)

Wolf, K. 1975, Evaluation of the exposure of fish and wildlife to nuclear polyhedrosis and granulosis viruses In Baculoviruses for Insect Pest Control: Safety Considerations, p. 109-111, M. Summers, R. Engler, L.A. Falcon and P.V. Vail, eds. Am. Soc. Microbiol., Washington, D.C.

00049262 Hart, E.R.; Thornett, H.D. (1975) Final Report: Acute Oral Toxicity--Rats: LBI Project No. 2515. (Litton Bionetics, Inc. for U.S. Dept. of Agriculture, Forest Service, NEFES, Forest Insect and Disease Laboratory, unpublished study; CDL:223573-C)

00049263 Hart, E.R.; Thornett, H.D. (1975) Final Report: Acute Dermal Toxicity--Guinea Pigs: LBI Project No. 2515. (Litton Bionetics, Inc.for U.S. Dept. of Agriculture, Forest Service, NEFES, Forest Insect and Disease Laboratory, unpublished study; CDL:223573-D)

00049264 Hart, E.R.; Thornett, H.D. (1975) Final Report: Eye Irritation-Rabbits: LBI Project No. 2515. (Litton Bionetics, Inc. for U.S. Dept. of Agriculture, Forest Service, NEFES, Forest Insect and Disease Laboratory, unpublished study; CDL:223573-E)

00049265 Hart, E.R.; Thornett, H.D. (1975) Final Report: Primary Skin Irritation--Rabbits: LBI Project No. 2515. (Litton Bionetics, Inc.for U.S. Dept. of Agriculture, Forest Service, NEFES, Forest Insect and Disease Laboratory, unpublished study; CDL:223573-F)

00049266 Thornett, H.D. (1975) Final Report: Inhalation Toxicity Study-Rats: Contract No. 12-14-110-4145-33; LBI Project No. 2241. (Litton Bionetics, Inc. for U.S. Dept. of Agriculture, Forest Service, NEFES, Forest Insect and Disease Laboratory, unpublished study; CDL:223573-G)

00054565 Moore, R.B. (1977) Determination of the Effects of Nuclear Polyhedrosis Virus in Trout and Bluegill Sunfish under Laboratory Conditions: Cooperative Agreement No. 42-213. (Unpublished study received Aug 18, 1977 under 27582-2; prepared by Essex Marine Laboratory, Inc. and U.S. Forest Service, Northeastern Area, State and Private Forestry, submitted by Parker Livestock Supply, Inc., Fremont, Nebr.; CDL:231361-A)

00060695 Brown, R.M. (1976) Acute Inhalation Toxicity of~L. dispar~NPV Lot # 33 (Insect Virus): Laboratory No. 6E-2619. (Cannon Laboratories, Inc. for U.S. Forest Service; unpublished study; CDL:230162-F)

00060696 Becker, J.; Parke, G.S.E. (1976) Report: The Effects of Insect Virus~L. dispar~N.P.V. Bioserv Lot # 33 on the Eye Mucosa of New Zealand Albino Rabbits: Laboratory No. 6E-2616. (Cannon Laboratories, Inc. for U.S. Forest Service, Insect & Disease Laboratory; unpublished study; CDL:230162-G)

00060703 Hart, E.R.; Thornett, H.D.; Valerio, M.G. (1975) Final Report:Acute Dermal Toxicity--Guinea Pigs: LBI Project No. 2515.(Litton Bionetics, Inc. for U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect and Disease Laboratory; unpublished study; CDL:230162-O)

00060704 Hart, E.R.; Thornett, H.D. (1975) Final Report: Eye Irritation-Rabbits: LBI Project No. 2515. (Litton Bionetics, Inc. for U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect and Disease Laboratory; unpublished study; CDL:230162-P)

00060706 Galipeau, P.R. (1975) A Progress Report on the Effect of Nuclear Polyhedrosis Virus (NPV) on Selected Avian Predators of the Gypsy Moth. (Unpublished study received Jan 11, 1977 under 7586-EX-8; submitted by U.S. Dept. of Agriculture, Forest Service; CDL:230162-S)

00060711 Lautenschlager, R.A.; Rothenbacher, H.; Podgwaite, J.D. (1976) The Response of Small Mammals to an Aerial Application of the Nuclear Polyhedrosis Virus of the Gypsy Moth,~Lymantria dispar~L. (Unpublished study received Jan 11, 1977 under 27586-EX-8; prepared by Northeastern Forest Experiment Station, Forest In-sect and Disease Laboratory in cooperation with Pennsylvania State Univ., Dept. of Veterinary Pathology, submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL: 230162-Z)

00060712 Lautenschlager, R.A.; Rothenbacher, H.; Podgwaite, J.D. (1976) The Response of Birds to Aerially Applied Nuclear Polyhedrosis Virus of the Gypsy Moth,~Lymantria dispar~L. (Unpublished study received Jan 11, 1977 under 27586-EX-8; prepared by Northeastern Forest Experiment Station, Forest Insect and Disease Laboratory in cooperation with Pennsylvania State Univ., Dept. of Veterinary Pathology, submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:230162-AA)

00066093 Mazzone, H.M.; Tignor, G.H.; Shope, R.E.; et al. (1974?) A Serological Comparison of the Nucleopolyhedrosis Viruses of the Gypsy Moth and the European Pine Sawfly with Arthropod-Borne and Other Viruses. (U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect and Disease Lboratory and others for USFS; unpublished study; CDL:227336-F)

00066097 U.S. Department of Agriculture, Forest Service (19??) Complete Composition Including Impurities. (Unpublished study; CDL:227336-J)

00066101 Becker, J.; Parke, G.S.E.; Offenkrantz, F.M. (1976) Dermal Toxicity Study of Insect Virus (L~dispar~N. PV Bioserv Lot 33) in New Zealand Rabbits: Laboratory No. 6E-2617. (Cannon Laboratories, Inc. for U.S. Forest Service; unpublished study; CDL:227336-Q)

00066102 Brown, R.M. (1976) Acute Inhalation Toxicity of L.~dispar~NPV Lot #33: Laboratory No. 6E-2619. (Cannon Laboratories, Inc. for U.S. Forest Service; unpublished study; CDL:227336-R)

00066103 Terrell, Y.; Parke, G.S.E. (1976) Report on Acute I.P. Single Dose Toxicity in Mice: Laboratory No. 6E-2873. (Cannon Laboratories, Inc. for U.S. Forest Service, Insect & Disease Laboratory; unpublished study; CDL:227336-T)

00066104 Hart, E.R.; Thornett, H.D. (1975) Final Report: Primary Skin Irritation--Rabbits: LBI Project No. 2515. (Litton Bionetics, Inc.for U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect and Disease Laboratory; unpublished study; CDL:227336-U)

00066105 U.S. Department of Agriculture, Forest Service (19??) Persistence of~L. dispar~Nucleopolyhedrosis Virus following Inhalation to Rats: Bioassay of Lung and Tracha [sic]. (Unpublished study; CDL:227336-Y)

00066108 Lautenschlager, R.A.; Rothenbacher, H.; Podgwaite, J.D. (1976) The Response of Birds to Aerially Applied Nuclear Polyhedrosis Virus of the Gypsy Moth,~Lymantria dispar~L. (U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect and Disease Laboratory and Pennsylvania State Univ., Dept. of Veterinary Pathology for USFS; unpublished study; CDL:227336-AN)

00066109 Terrell, Y.; Parke, G.S.E. (1976) Report on Acute I.P. Single Dose Toxicity in Mice: Laboratory No. 6E-2874. (Cannon Laboratories, Inc. for U.S. Forest Service, Insect & Desease Laboratory; unpublished study; CDL:227336-AO)

00068398 Mazzone, H.M.; Breillatt, J.; Bahr, G. (19??) Studies on the Rod Forms and Isolated Deoxyribonucleic Acid from the Nucleopolyhedrosis Virus of the Gypsy Moth (~Porthetria dispar~L.). (U.S. Forest Service, Oak Ridge National Laboratry and Armed Forces Institute of Pathology; unpublished study; CDL:231360-B)

00068399 McCarthy, W.J.; Liu, S.Y. (19??) The Structural Proteins of~Por-µ~thetria dispar~Nuclear Polyhedrosis Virus. (Unpublished study received Aug 18, 1977 under 27582-2; prepared by Pennsylvania State Univ., Pesticide Research Laboratory and Graduate Study Center, submitted by Parker Livestock Supply, Inc., Fremont, Nebr.; CDL:231360-C)

00068402 Parker Livestock Supply, Incorporated (1976) Serological Investigations of~L. dispar~NPV--Methods. (Unpublished study received Aug 18, 1977 under 27582-2; CDL:231360-F)

00068403 Becker, J.; Parke, G.S.E. (1976) Report: The Effects of Insect Virus~L. dispar~N.P.V. Bioserv Lot #33 on the Eye Mucosa of New Zealand Albino rabbits: Laboratory No. 6E-2872. (Cannon Laboratories, Inc. for U.S. Forest Service, Insect & Disease Laboratory; unpublished study; CDL:231360-H)

00068404 Gordon, E.B.; Kinsel, D.A. (1977) Final Report: Primary Eye Irritation and Corrosiveness Study in Rabbits: LBI Project No. 2802. (Litton Bionetics, Inc. for U.S. Forest Service, Northeastern Forest Experiment Station, Forest Insect & Disease Laboratory; unpublished study; CDL:231360-I)

00091124 Imlay, P.; Terrell, Y. (1978) The Effects of LDP 53 on the Eye Mucosa of New Zealand Albino Rabbits: Laboratory Nos. 7E-9563 & 7E-9562. (Cannon Laboratories, Inc. for U.S. Forest Service; unpublished study; CDL:232889-A)

00091447 Roberts, S. (1978) Acute Oral Toxicity of LDP 53 (3.75 x 10^3**4**/g)in Bobwhite Quail: Laboratory No. 7E-9564. (Cannon Laboratories, Inc. for U.S. Forest Service; unpublished study; CDL:232890-A)

41893401 Adamson, A. (1991) Gypchek: Product Identity; Manufacturing Process and Quality Control. Unpublished study prepared by Espro, Inc. 7 p.

Polyhedral Inclusion Bodies
Douglas fir tussock moth (Orgyia pseudotsugata)
Nuclear polyhedrosis viruses (NPVs)
References in Open Literature

Banowetz, G.M., J.L. Fryer, P.J. Iwai & M.E. Martignoni, 1976, Effects of the Douglas-fir tussock moth nucleopolyhedrosis virus (Baculovirus) on three species of salmonid fish. USDA For. Ser. Res. Pap. PNW-214, 6p. Pac. Northwest For. and Range Exp. Stn., Portland, OR.

Barber, K.W., W.J. Kaupp & S.B. Holmes, 1993, Specificity testing of the nuclear polyhedrosis virus of the gypsy moth, Lymantria dispar (L.) (Lepidoptera: Lymantriidae), Canadian Entomologist 125: 1055-1066).

Cantwell, G.E., T. Lehnert, and J. Fowler. 1972. Are biological insecticides harmful to the honey bee? Am. Bee J. 112(7):255-258, (8): 294-296.

Groner, A. 1986, Specificity and safety of baculoviruses. In eds. Granados, R.R., Frederici, B.A. The Biology of Baculoviruses. Vol. II. CRC Press: Boca Raton , FL. pp. 117-202.

Hudson, H., R.K. Tucker, M.A. Haegle. 19984. Handbook of toxicity of pesticides to wildlife. U.S. Dept. of Inter., U.S. Fish and Wild. Serv., Resource Publ. 153, 90pp.

Knox, D.A. 1970. Tests of certain insect viruses on colonies of honeybees. J. Invertebr. Pathol. 16(1):152).

Lynn, D.E., E.M. Dougherty, J.T. McClintock & M. Loeb, 1988, Development of cell lines from various tissues of Lepidoptera, In: Invertebrate and Fish Tissue Culture, Y. Kuroda, E. Kurstak & K. Maramorosch (eds.) Japan Scientific Societies, Tokyo).

Podgwaite, J.D., K. S. Shields, R.T. Zerillo, and R.B. Bruen. 1979. Environmental persistence of the nucleopolyhedrosis virus of the gypsy moth, Lymantria dispar L. Environ.Entomol. 8:523-536.

Shama, S.K., P.H. Etkind, T.M. Odel, A.T. Canada, A.M. Finn, and N.A. Soter, 1982, N.E. J. of Med. 306:1300-1301.

Thomas, D.F. 1995. Biopesticides in the Forest Service: research, development and application. USDA Forest Service. Washington, DC.
Tucker, R.K. 1967. Subacute oral treatment, mallard hens. Virus (Hemerocampa pseudotsugata). U.S. Dep. Inter. Fish and Wildl. Serv., Denver Wildl. Res. Cent., Denver, Colo. Intern. Rep. Supplement1, 1p.. (unpublish)

Wolf, K. 1975, Evaluation of the exposure of fish and wildlife to nuclear polyhedrosis and granulosis viruses In Baculoviruses for Insect Pest Control: Safety Considerations, p. 109-111, M. Summers, R. Engler, L.A. Falcon and P.V. Vail, eds. Am. Soc. Microbiol., Washington, D.C.

00049098 Hughes, K.M.; Addison, R.B. (1970) Two nuclear polyhedrosis viruses of the Douglas-fir tussock moth. Journal of Invertebrate Pathology 16(2):196-204. (Also~In~unpublished submission received May 9, 1974 under 27586-EX-2; submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:223569-A)

00049099 Hughes, K.M. (1972) Fine structure and development of two polyhedrosis viruses. Journal of Invertebrate Pathology 19(2):198-207. (Also~In~unpublished submission received May 9, 1974 under 27586-EX-2; submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:223569-B)

00049100 Martignoni, M.E. (1972) A rapid method for the identification of nucleopolyhedron types. Journal of Invertebrate Pathology 19(2):281-283. (Also~In~unpublished submission received May 9,1974 under 27586-EX-2; submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:223569-C)

00049102 Carnegie, J.W. (1970) Isolation and Characteristics of the DNA from Nuclear Polyhedrosis Virus. Doctoral dissertation, Oregon State Univ. (Abstract; unpublished study received May 9, 1974 under 27586-EX-2; submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:223569-E)

00049104 Martignoni, M.E.; Iwai, P.J.; Breillatt, J.P. (1971) Heterogeneous buoyant density in batches of viral nucleopolyhedra. Journal of Invertebrate Pathology 18(2):219-226. (Also~In~unpublished submission received May 9, 1974 under 27586-EX-2; submitted by U.S. Dept. of Agriculture, Forest Service, Washington, D.C.; CDL:223569-G)

00049113 U.S. Department of Agriculture (1971) Acute Tests: Intramuscular, Intravenous, and Intradermal Injections in Rabbits and Guinea Pigs. (Forest Service, Forestry Sciences Laboratory, unpublished study; CDL:223569-P)

00049114 Weir, R.J. (1967) Final Report: Acute Oral Administration--Rats; Acute Eye Application--Rabbits: Projects No. 183-119 and No. 183-140. (Hazleton Laboratories, Inc. for U.S. Dept. of Agriculture, unpublished study; CDL:223569-Q)

00049116 Weir, R.J. (1967) Final Report: Acute Dermal Application--Rabbits: Project No. 183-163. (Hazleton Laboratories, Inc. for U.S. Dept. of Agriculture; CDL:223569-S)

00049117 Weir, R.J. (1968) Final Report: Primary Skin Irritation--Rabbits: Project No. 183-169. (Hazleton Laboratories, Inc. for U.S. Dept. of Agriculture, unpublished study; CDL:223569-T)

00054189 Thornett, H.D. (1975) Final Report: Inhalation Toxicity--Rats: LBI Project No. 2492; Contract No. 527-COR-72. (Litton Bionetics for U.S. Forest Service, Forestry Sciences Laboratory, CDL: 226053-J)

00054193 Tucker, R.K. (1966) Virus (~Hemerocampa pseudotsugata~). (U.S.Fish and Wildlife Service, Denver Wildlife Research Center, Section of Chemical, Physiological & Pesticide-Wildlife Studies, unpublished study; CDL:226053-N)

41738701 Lilja, H. (1989) Acute Oral Limit Study: TM-Biocontrol-1: [on Rats]: Lab Project Number: 89G-0387. Unpublished study prepared by Toxikon Corp. 9 p.

41738702 Lilja, H. (1989) Primary Dermal Irritation Study: TM-Biocontrol-1:[on Rabbits]: Lab Project Number: 89G-0386. Unpublished study prepared by Toxikon Corp. 13 p.

41738703 Lilja, H. (1980) Acte Toxicity/Pathogenicity Study with Microbial Pesticide: TM-Biocontrol-1: [on Mice]:Lab Project No: 90G-0355. Unpublished study prepared by Toxikon Corp. 12 p.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your

product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms

as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing

problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails

to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from

NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division (7501W)

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

4106 DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing 4106.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 4106. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this 4106 Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for 4106 are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on 4106 are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible 4106 products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Glenn Williams at (703) 308-8287.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Glenn Williams
Chemical Review Manager Team 81
Biopesticides and Pollution Prevention Division (H7501W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **4106**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement** I understand that this option is available **only** for acute toxicity or certain efficacy data and

only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or

Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you

have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

No toxicology batching is required for this case.

Attachment a. List of All Registrants Sent This Data Call-In (insert) Notice

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for 4106 that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies 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., or contact glenn williams at (703)-308-8287.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for 4106.

The following documents are part of the Administrative Record for 4106 and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1.Health and Environmental Effects Science Chapters.

2.Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria