REREGISTRATION ELIGIBILITY DOCUMENT

POLYHEDRAL INCLUSION BODIES OF *HELIOTHIS ZEA* NUCLEAR POLYHEDROSIS VIRUS

(REFERRED TO AS *HELIOTHIS ZEA* NPV)

LIST A

CASE NUMBER 151

DECEMBER 1990

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	1
I. INTRODUCTION	3
II. ACTIVE INGREDIENTS COVERED BY THE REREGISTRATION DECISION DOCUMENT	
A. IDENTIFICATION OF ACTIVE INGREDIENT	5
B. USE PROFILE	5
C. REGULATORY HISTORY	6
III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT	
A. PRODUCT IDENTIFICATION	8
B. HUMAN HEALTH ASSESSMENT	
1. TOXICOLOGICAL DATA	8
a. ACUTE TOXICITY/PATHOGENICITY	9
b. PRIMARY EYE IRRITATION	10
c. HYPERSENSITIVITY INCIDENTS	10
d. CELL CULTURE	10
e. SPECIAL STUDIES NOT REQUIRED BY TIER I TESTING	11
2. DIETARY EXPOSURE	12
3. NON-DIETARY EXPOSURE	14
C. ENVIRONMENTAL ASSESSMENT	
1. ENVIRONMENTAL FATE ASSESSMENT	14
2. ECOLOGICAL EFFECTS ASSESSMENT	14

TABLE OF CONTENTS

		PAGE
IV.	**REREGISTRATION DECISION FOR HELIOTHIS ZEA NPV**	
	A. DETERMINATION OF ELIGIBILITY	15
	B. ADDITIONAL GENERIC DATA REQUIREMENTS	16
	C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING HELIOTHIS ZEA NPV	16
V.	**PRODUCT REREGISTRATION**	
	A. DETERMINATION OF ELIGIBILITY	16
	B. PRODUCT-SPECIFIC DATA REQUIREMENTS	16
	C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HELIOTHIS ZEA NPV	16
VI.	**APPENDICES**	
	A. APPENDIX A - GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF HELIOTHIS ZEA NPV AND DATA CITATIONS SUPPORTING REREGISTRATION[1]	
	1. GUIDE TO APPENDIX A	19
	2. PRODUCT IDENTIFICATION	20
	3. TOXICOLOGY	21
	4. ENVIRONMENTAL EXPRESSION	23
	B. APPENDIX B - BIBLIOGRAPHY	
	1. GUIDE TO APPENDIX B	25
	2. BIBLIOGRAPHIC CITATIONS	27

[1] The product specific data requirements for products containing Heliothis zea NPV are the same as those required in the Generic Data Requirements Table.

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
LC50	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 or feed, e.g., mg/l or ppm.
LD50	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.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPT	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS CONT'D

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

Heliothis zea NPV or the single embedded nuclear polyhedrosis virus (HzSNPV) is a microbial pesticide registered in the United States to control a wide variety of pests on cotton, tomatoes, soybeans, corn, tobacco, sorghum, peanuts, lettuce, strawberries, beans, wild geraniums, and wild clover. Nuclear polyhedrosis virus (NPV), classified in the family Baculoviridae, are structurally large and complex DNA-containing viruses infecting insects. Heliothis zea NPV is a specific naturally occurring insect virus of the cotton bollworm and tobacco budworm which infects organisms belonging only to the genus Heliothis. The only registered product is a wettable powder end-use product, Elcar, which is applied by foliar spray. This product which contains Heliothis zea NPV as its active ingredient is eligible for reregistration for the uses mentioned above.

In June of 1984 a Registration Standard was issued for Heliothis zea NPV entitled "Guidance for the Reregistration of Pesticide Products Containing Nuclear Polyhedrosis Virus of Heliothis Zea as the Active Ingredient"[2] (NTIS PB85-134393). The Registration Standard summarized the available data supporting the registration of Heliothis zea NPV and required additional data to assure that the proper use of the pesticide poses no potential adverse effects to human health or the environment.

Recently, the Agency conducted a thorough review of the scientific data base and all relevant information supporting the reregistration of Heliothis zea NPV, including the data submitted in response to the Registration Standard. The data base consists of Tier I microbial testing as described in the 1989 revision of Subdivision M, Guidelines for Testing Microbial and Biochemical Pesticides (NTIS PB89-211676), and additional higher tier data not originally required in the Standard. The effects indicated by the Tier I testing do not trigger additional higher tier testing. These higher tier testing requirements, which were not triggered, include environmental fate and residue data. No further generic or product-specific data are required. An exemption from the requirement for a tolerance was previously established for Heliothis zea NPV on all agricultural commodities. The Agency concludes, as a result of reregistration review, that the exemption continues to be appropriate.

The data are sufficient to allow the Agency to conduct a

---

[2]Copies of the Registration Standard and Guidelines for Testing Microbial and Biochemical Pesticides may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Telephone (703) 487-4650.

reasonable risk assessment for all registered uses of Heliothis zea NPV. The Agency has determined for all registered uses that Heliothis zea NPV can be used according to label directions without resulting in unreasonable adverse effects. Based on the data reviewed, the numerous materials available from the public literature for Heliothis zea NPV, and the narrow host range of Heliothis zea NPV, the Agency has determined that the microbial pesticide Heliothis zea NPV poses no unreasonable adverse effect to human health and the environment and declares that the one product containing Heliothis zea NPV as its active ingredient is eligible for reregistration. The product containing Heliothis zea NPV as its active ingredient will be reregistered when appropriate labels are submitted.

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.

Section 4(g)(2)(A) of FIFRA 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 risks 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.

This document presents the Agency's decision regarding the reregistration of Heliothis zea NPV or the single-embedded nuclear polyhedrosis virus (HzSNPV). Nuclear polyhedrosis virus (NPV), classified in the family Baculoviridae, are structurally large and complex DNA-containing viruses infecting insects. Following the infection of the target insect pest, NPVs produce either a single nucleocapsid per envelope (SNPV) or one to many nucleocapsids per envelope (MNPV). The enveloped nucleocapsids are occluded in a crystalline protein matrix called polyhedron during the late phase of the viral replicative cycle. Since Heliothis zea NPV is a single-embedded NPV it differs from other types of baculoviruses by the number of virions (i.e. enveloped nucleocapsids) occluded in the polyhedron resulting in a viral progeny phenotypes called polyhedral inclusion bodies (PIB).

This document consists of five sections. Section I is the introduction. Section II describes Heliothis zea NPV, its uses, and regulatory history. Section III discusses the Agency's human health and environmental assessment based on

the available data. Section IV discusses the reregistration decision for Heliothis zea NPV and Section V discusses product reregistration. Additional details concerning the Agency's review of available data are available on request.[3]

[3] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St., S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENT COVERED BY THIS REREGISTRATION DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

The following active ingredient is covered by this Reregistration Eligibility Document:

Chemical Name: polyhedral inclusion bodies of *Heliothis zea* single-embedded nuclear polyhedrosis virus

Common Name: *Heliothis zea* NPV, nuclear polyhedrosis virus (NPV) of *Heliothis zea* (HzSNPV or HzNPV)

CAS Number: 2401-948-01

Office of Pesticide Programs Chemical Code Number: 107301

Empirical Formula: N/A

Trade Name: Elcar

Basic Manufacturer: Sandoz Crop Protection Corp.

B. USE PROFILE

Type of Pesticide: Biological Agent (Insecticide)

Pests Controlled: cotton bollworm, tomato fruitworm, soybean podworm, sorghum headworm, corn earworm, and tobacco budworm

Registered Use Sites:
- Terrestrial Food Crop: cotton, sorghum, soybeans, tomatoes, corn, peanuts, lettuce, strawberries, beans
- Terrestrial Feed Crop: cotton, sorghum, soybeans, tomatoes, corn, peanuts, beans
- Terrestrial Non-Food Crop: tobacco, wild geraniums, wild clover
- Residential Outdoor: wild geraniums, wild clover

Formulation Types Registered: formulation - wettable powder

Methods of Application: foliar spray with aircraft or ground equipment

C. REGULATORY HISTORY

Heliothis zea NPV was first registered by the Agency in 1975 as a microbial pesticide for use on cotton and tobacco to control the cotton bollworm and the tobacco budworm. In June 1984 the Registration Standard entitled " Guidance for the Reregistration of Pesticide Products Containing Nuclear Polyhedrosis Virus of *Heliothis Zea* as the Active Ingredient" (NTIS No. PB85-134393) was issued for *Heliothis zea* NPV which summarized the available data supporting its registration and concluded that additional scientific data were needed to evaluate this microbial pesticide. The following data were required in 1984 for reregistration:

Product Identity	
151A-10	Product Identity
151A-11	Manufacturing process
151A-12	Discussion of formation of unintentional ingredients
151A-13	Analysis of samples
151A-15	Certification of limits
151A-16(a)	Color
151A-16(c)	Odor
151A-16(e)	Density
151A-16(j)	Corrosion characteristics
151-16	Analytical methods (This study is no longer required in Subdivision M testing. The number 151-16 is the old guideline number used at the time the Standard for *Heliothis zea* NPV was issued.)
Toxicology	
152A-14	Primary eye irritation
Ecological Effects	
154A-16(a)	Avian oral pathogenicity/toxicity - quail
154A-16(b)	Avian oral pathogenicity/toxicity - duck
154A-19(a)	Freshwater fish toxicity/ pathogenicity -trout
154A-19(b)	Freshwater fish toxicity/ pathogenicity -sunfish
154A-20	Aquatic invertebrate toxicity/ pathogenicity
154A-23	Insect predators/parasites toxicity/pathogenicity

Ecological Effects (continued)

154A-24	Honey bee toxicity/pathogenicity
154-17	Avian injection test (This study is no longer required in Subdivision M testing. The number 154-17 is the old guideline number used at the time the Standard for *Heliothis zea* NPV was issued.)

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

The Agency has conducted a thorough review of the scientific data base for Heliothis zea NPV. Based on the evaluation of these data, the Agency has no reason to change the major findings made in the "Guidance for the Reregistration of Pesticide Products containing the Nuclear Polyhedrosis Virus of Heliothis zea as the Active Ingredient." Appendix A lists the generic data supporting the Agency's assessment of this active ingredient. The Agency's assessment is summarized below:

A. PRODUCT IDENTIFICATION

In the 1984 Registration Standard additional data were required on the product identity of Heliothis zea NPV. Recently, the registrant was required to submit data on the identity of Heliothis zea NPV by providing either restriction endonuclease (REN) profiles or SDS-polyacrylamide gel electrophoresis (SDS-PAGE) protein profiles of Heliothis zea NPV. The registrant submitted REN profiles of Heliothis zea NPV DNA which were adequate for the proper identification of Heliothis zea NPV. Heliothis zea NPV is a unique virus that can easily be identified by restriction analysis and the Agency sees no reason to require any additional studies at this time.

Although the physical and chemical characteristics (i.e., color, odor, density, and corrosion characteristics) of the technical grade active ingredient (TGAI) were requested in the Standard and were not submitted, sufficient data and information were available from other studies which adequately described the biophysical and chemical properties of Heliothis zea NPV. The Agency is not requiring any additional information regarding the physical and chemical characteristics. All product identity data requirements are satisfied.

B. HUMAN HEALTH ASSESSMENT

1. DATA BASE PERTAINING TO TOXICITY/PATHOGENICITY AND VIRAL REPLICATION

The only toxicity/pathogenicity study required in the 1984 Standard was a primary eye irritation study. This study was submitted, reviewed, and found acceptable. Based on a review and evaluation of all available data and other relevant information on Heliothis zea NPV, the Agency is not requiring any additional toxicological studies

or studies on viral replication in nontarget hosts to support the reregistration of Heliothis zea NPV.

Toxicology requirements are set forth in three tiers. The Tier I tests serve as a starting point for the hazard assessment and serve to indicate whether further testing (Tier II and Tier III) are needed. As stated in the Executive Summary, the results of the toxicological tier I tests did not indicate the need for higher tiered studies at this time.

The results of the reviews of the toxicological data base to support the reregistration of Heliothis zea NPV have been reviewed or reassessed and are presented below:

a) Acute Toxicity/Pathogenicity

Data from acute oral, dermal, inhalation, intravenous toxicity/pathogenicity, and acute-infectivity studies conducted in mammals have been reviewed to determine the relative toxicity of Heliothis zea NPV. No adverse effects were observed in any acute oral, dermal, inhalation, and intravenous test conducted with Heliothis zea NPV. A summation of the results for each type of acute test is found in the following four sections:

Acute Oral

In an acute oral toxicity study the oral dose of 2.96×10^{11} PIB/kg of Heliothis zea NPV produced no treatment-related effects in the test rats.

Acute Dermal

The results of a dermal allergenicity study of free virus particles in guinea pigs indicated that no detectable allergenicity reaction was found in test animals at a maximum dose of 4.8×10^{8} polyhedral inclusion bodies (PIB) equivalent/ guinea pig. (i.e. PIB equivalent=alkaline-released free virus particles (i.e virions) obtained from the alkaline treatment of Heliothis zea NPV PIBs.)

Acute Inhalation

When guinea pigs were subjected daily to either an aerosol treatment of purified PIBs (purified of

host and bacterial contaminants) or free virus particles (alkaline-released) for three consecutive weeks no abnormal clinical symptoms, or change in food consumption and body weight were observed in the treated guinea pigs when compared to the control animals. The results of another inhalation study using free virus particles in guinea pigs showed no adverse effects in treated animals at a maximum dose of 3×10^{10} PIBs/day/guinea pig. No other observable effects were reported following treatment with either the purified PIBs or the free virus particles.

Acute Intravenous

Test animals (mice, rats, and guinea pigs) were injected intravenously with either polyhedral inclusion bodies or with free virus particles (alkaline-treated PIBs) of *Heliothis zea* NPV at doses ranging from 6×10^{7} to 5.25×10^{10} PIBs/animal. All animals remained healthy with normal weight gains during the observation period of three weeks to two months after injection.

b) Primary Eye Irritation

An acceptable primary eye irritation study in rabbits, submitted in response to the Registration Standard, shows *Heliothis zea* NPV is not an eye irritant and is classified as Toxicity Category IV.

c) Hypersensitivity Incidents

There were no deleterious effects observed in any of the five different health monitoring tests performed on various employees of several different companies over periods of as long as 4 1/2 years.

d) Cell Culture

The tissue culture study received and reviewed in the 1984 Standard was not based on the method recommended by the 1989 revision of Subdivision M, Guidelines for Testing Microbial and Biochemical Pesticides (NTIS PB89-211676). The specific data requirements for the study of inhibition of cell division, bioassay of culture fluid, the decay of input virus inoculum, and potential appearance of viral nucleic acid and proteins were not included in the study. However, the toxicological data

obtained from the teratology test, the chronic feeding study in rats, the oncogenicity test in mice, the human feeding study, and the Rhesus monkey study support the negative response of viral replication, pathogenicity, and infectivity in mammals. In addition, based on developmental toxicity data received by the Agency, Heliothis zea NPV has not been shown to cause birth defects (fetotoxic effect) or treatment related effects in offspring of pregnant female rats (see the Developmental Toxicity summary below). Thus, the Agency concludes, as originally noted in the Standard, that there are sufficient toxicological data to satisfy this requirement without requesting a tissue culture study.

e) Special Studies Submitted But Not Required

Subchronic Feeding

The Agency has received and reviewed three 90-day feeding studies conducted in the rat and one in the dog. No treatment-related effects were noted in the rat 90-day feeding study following the administration of $6x10^9$ Heliothis zea NPV PIBs/100g (feed) in the diet.

Subchronic Inhalation

In two 13-week inhalation studies, no difference in the clinical appearance, hematology values, blood chemistry parameters, and histopathological findings were observed between the treated and untreated control groups of rats and dogs.

Oncogenicity

Oncogenicity data were not required in the 1984 Standard since the information and data on Heliothis zea NPV did not trigger the additional tier III testing. The Agency had reviewed an acceptable two-year mouse carcinogenicity study conducted with Heliothis zea NPV. The virus material was administered by the oral and subcutaneous route at a dosage of 1.94×10^7 PIBs/kg/day three times a week until weaning. At the level tested no treatment-related effects regarding tumor formation were observed in treated mice by either the oral or subcutaneous route.

Rhesus Monkey Study

Rhesus monkeys were treated with Heliothis zea NPV through subcutaneous injection, inhalation, and oral gavage. No viral infectivity was found in lymph node tissues and blood samples of the treated monkeys. In addition, body temperature and blood chemistry values from the treated monkeys remained normal throughout the course of the study.

Developmental Toxicity

A teratology study was conducted to determine the potential of Heliothis zea NPV to induce structural and/or other abnormalities in pregnant female rats. In this study no abnormalities in the internal organs of the rats were observed, no significant differences in the maternal body weight gain and the mean fetal weight were found between the treated and control groups, and no teratogenic response to the administration of the Heliothis zea NPV in the rat during the critical period of organogenesis was observed. No treatment-related effects were observed at 0.1 mg/kg/day/virus.

Human Feeding Study

A human feeding study was carried out by volunteers (10 men and women) from the Entomology Research Division, Agricultural Research Service, USDA in 1967. The volunteers were each fed 5.82 x 10^9 Heliothis zea NPV PIBs over the course of five days. There were no significant changes in the condition of any individual in the test or control group, nor were there any differences in clinical effects noted between the two groups. This examination gave no suggestion of viral inflammation, allergy, or side effects to the human volunteers.

2. DIETARY EXPOSURE

The Agency established an exemption from the requirement for a tolerance for Heliothis zea NPV on all agricultural commodities under 40 CFR 180.1027 (45 FR 78688, Nov. 26, 1980). The Agency grants an exemption if the Tier I toxicological data do not indicate any toxic effects. After a thorough review and reassessment of the Heliothis zea NPV scientific data base and the available literature on this

microbial pesticide, the Agency still believes residue data are not required and an exemption from the requirement for a tolerance continues to be appropriate. A wide variety of studies which are outlined in the toxicological data base portion of the human health assessment have been used in support of this exemption.

To agree with the language of the reregistration document, and to better reflect the current identification and testing technology, the Agency is at this time proposing to amend 40 CFR 180.1027 as follows:

> (a) For the purposes of this section, the viral insecticide must be produced with an unaltered and unadulterated inoculum of the single-embedded Heliothis zea nuclear polyhedrosis virus (HzSNPV). The identity of the seed virus must be assured by periodic checks.
>
> (b) Each lot of active ingredient of the viral insecticide shall have the following specifications:
>
> (1) The level of extraneous bacterial contamination of the final unformulated viral insecticide should not exceed 10^7 colonies per gram as determined by an aerobic plate on trypticase soy agar.
>
> (2) Human pathogens, e.g., Salmonella, Shigella, or Vibrio, must be absent.
>
> (3) Safety to mice as determined by an intraperitoneal injection study must be demonstrated.
>
> (4) Identity of the viral product, as determined by the most sensitive and standardized analytical technique, e.g., restriction endonuclease and/or SDS-PAGE analysis, must be demonstrated.
>
> (c) Exemptions from the requirement of a tolerance are established for the residue of the microbial insecticide Heliothis zea NPV, as specified in paragraphs (a) and (b) of this section, in or on all agricultural commodities including: corn, cottonseed, beans, lettuce, okra, peppers, sorghum, soybeans, and tomatoes.

3. NON-DIETARY EXPOSURE

Based on the current use pattern and because no adverse effects were observed in the Tier I toxicological data, non-dietary exposure data are not required to support the reregistration of Heliothis zea NPV.

C. ENVIRONMENTAL ASSESSMENT

1. ENVIRONMENTAL FATE

Environmental Fate data are only required when toxic or pathogenic effects are observed in the ecological effects Tier I data on non-target plants and animals. No adverse effects have been observed in the ecological effects studies for Heliothis zea NPV; therefore, environmental fate data are not required.

2. ECOLOGICAL EFFECTS

The available avian and aquatic data and other relevant information show that Heliothis zea NPV does not cause adverse effects on avian and aquatic wildlife. No mortalities were seen when Heliothis zea NPV was fed to mallard ducks, english sparrows, and valley quail. No mortalities or other adverse effects were seen in sheepshead minnow, white sucker, shrimp, and black bullhead. Also, extensive scientific literature on honey bee mortality and insect host range demonstrated that this product does not have adverse effects on honeybees and should not pose a significant risk to nontarget insects because of its narrow host range.

Due to the lack of adverse effects on avian and aquatic wildlife documented in the submitted studies, the numerous studies in the literature documenting no adverse effects on honeybees, and a narrow host range, the Agency finds Heliothis zea NPV poses a minimal to non-existent risk to nontarget wildlife. Therefore, the Agency has reassessed the data requirements needed, and has determined that all of the studies required in the Standard, excluding avian injection test, (i.e. avian oral, freshwater fish, freshwater invertebrate, non-target insect and honeybee toxicity studies) are waived. The avian injection test, originally required in the 1984 Standard, is no longer required under the Subdivision M (Guidelines for Testing Microbial and Biochemical Pest Control Agents) target data base.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

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 ingredient are eligible for reregistration. The Agency has previously identified and required submission of all the generic (i.e., active ingredient specific) data required to support reregistration of products containing Heliothis zea NPV as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing Heliothis zea NPV. Appendix A identifies the generic data that the Agency reviewed as part of its determination of the reregistration eligibility of Heliothis zea NPV, and lists the submitted studies which fulfilled the guideline requirements.

The data identified in Appendix A were sufficient to allow the Agency to conduct a reasonable risk assessment for all registered uses of Heliothis zea NPV and to determine for all such uses that Heliothis zea NPV can be used according to label directions without resulting in unreasonable adverse effects on the environment. The Agency therefore finds that all products containing Heliothis zea NPV as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

The Agency made its reregistration eligibility determination based upon the target data base for reregistration, the current guidelines for conducting acceptable studies to generate such data, and the data identified in Appendix A. Although the Agency has found that products containing Heliothis zea NPV are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support registration of products containing Heliothis zea NPV, if new information comes to the Agency's attention or if the data requirements for registration (or if the guidelines for generating such data) change. The Agency may also require submission of additional data before establishing any new uses.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing Heliothis zea NPV has been reviewed and determined to be complete for reregistration. No further generic data are required.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING HELIOTHIS ZEA NPV

Currently there are no registered manufacturing-use products containing Heliothis zea NPV as the active ingredient.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

All currently registered products containing the active ingredient Heliothis zea NPV are eligible for reregistration. 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.

The Agency has previously identified and required the submission of all product-specific data required to support the reregistration of the one currently registered product containing Heliothis zea NPV as an active ingredient in the 1984 Registration Standard. Because these data are the same as the generic data required for the active ingredient, they are sufficient to support the reregistration of the single product containing Heliothis zea NPV. The product containing Heliothis zea NPV as its active ingredient will be reregistered when appropriate labels are submitted.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

No additional product-specific data are required for the one product for Heliothis zea NPV.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HELIOTHIS ZEA NPV

1. All products must bear appropriate labeling as specified in 40 CFR 156.10. Specific instructions regarding label requirements are included in the Pesticide Reregistration Handbook.

2. The ingredient statement for end-use products must list the active ingredient as:

   Nuclear Polyhedrosis Virus of *Heliothis zea** - xx%

   *Contains at least 4 billion Polyhedral Inclusion Bodies per gram of product.

   The current ingredient statement on the label needs to be amended.

3. All end-use products are to bear the following statements:

   "Do not contaminate water when disposing of equipment washwaters." This change must be made in order to agree with the current statement required for chemical pesticides. The current label needs to be amended to include this statement.

   "Do not apply this product through any type of irrigation system." This statement is currently found on the label and no change is needed.

   "Do not contaminate water, feed or food by storage or disposal." This statement is currently found on the label and no change is needed.

   The label for the currently registered product must be amended as noted in Section 5(c) of this document and submitted within eight months of the date of issuance of the Reregistration Eligibility Document as described in the Product Reregistration Handbook.

APPENDIX A

Generic Data Requirements for Reregistration of *Heliothis zea* NPV and Data Citations Supporting Reregistration

GUIDE TO APPENDIX A

Appendix A contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in the 1989 revision of Subdivision M, Guidelines for Testing Microbial and Biochemical Pesticides. The guidelines are available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. The NTIS reference number is NTIS PB89-211676.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. 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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Any other designations will be defined in a footnote to the table.

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 Appendices for a complete citation of the study.

APPENDIX A
GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF *Heliothis zea* NPV AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION (EPA Master Record Identification Number)
PRODUCT IDENTIFICATION: MICROBIAL AGENTS			
151A-10	Product Identity	ABCK	41556401
151A-11	Manufacturing Process	ABCK	see footnote[4]
151A-12	Discussion of formation of unintentional ingredients	ABCK	see footnote 4
151A-13	Analysis of samples	ABCK	see footnote 4
151A-15	Certification of limits	ABCK	see footnote 4
151A-16(a)	Color	ABCK	see footnote 4
151A-16(c)	Odor	ABCK	see footnote 4
151A-16(e)	Density	ABCK	see footnote 4
151A-16(j)	Corrosion Characteristics	ABCK	see footnote 4

[4] Information to satisfy the physical and chemical characteristics requirements was extracted from various sources, including the following studies and the open literature submitted in conjunction with those studies: 00070484, 00081452, 00082094, 00072677, 00101024, 00062599, 00062595, 00101019, 00072668, 00072677, 00082092, 00082218, 0101002, and 00101017.

APPENDIX A
GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF *Heliothis zea* NPV AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION (EPA Master Record Identification Number)
TOXICOLOGY: MICROBIAL AGENTS			
TIER I			
152A-10	Acute oral toxicity/pathogenicity	ABCK	00067550[5] 00075281 00056871 00089268
152A-11	Acute dermal toxicity	ABCK	00082221[6] 00075283 00056871
152A-12	Acute pulmonary tox/pathogenicity	ABCK	00081440 00075283 00056871 00089268
152A-13	Acute intravenous tox/pathogenicity	ABCK	00089268 00081436
152A-14	Primary eye irritation	ABCK	study # I-2851.701 (Microbiological Associates)

[5] The identical study is found in MRID 00091306.

[6] The identical study is found in MRID 00081441.

APPENDIX A
GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF Heliothis zea NPV
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION (EPA Master Record Identification Number)
TOXICOLOGY: MICROBIAL AGENTS			
TIER I			
152A-15	Hypersensitivity incidents	ABCK	00081450 00062582 00070481[7] 00065898
152A-16	Cell Culture	ABCK	Submittal of an acceptable cell culture study is waived.[8]

There are numerous studies considered to support the target data base for the reregistration on Heliothis zea NPV which were not triggered by Tier I testing and/or required in the 1984 Guidance Document. A summary of some of these studies is found on page 11 in Sect III.B(1)(e) and the citations are in the accompanying bibliography.

---

[7] The identical study is found in MRID 00081449 and MRID 00082091.

[8] Due to the overall results of Tier III toxicology testing and the additional toxicology data which support the negative response of viral replication in mammals, the agency concludes there are sufficient data to satisfy this requirement without requesting a cell culture study.

APPENDIX A
GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF Heliothis zea NPV
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE REFERENCE NUMBER	TITLE OF STUDY	BIBLIOGRAPHIC CITATION (EPA Master Record Identification Number)

ENVIRONMENTAL EXPRESSION: MICROBIAL AGENTS
TIER I

EPA waived these guideline requirements due to lack of adverse effects on avian and aquatic wildlife documented in the following studies, which were found supplemental, the numerous studies in the literature documenting no adverse effects on honeybees, and a narrow host range:

Master Record Identification Number (MRIDs)

- 00100998
- 00100999
- 00049121
- 00082222[9]

[9] MRID 00082222 also contains studies found in the following MRIDS: 00081443, 00081444, 00081445, 00081446, 00081447, 00081456, 0081457 and 0081459.

APPENDIX B

HELIOTHIS ZEA NPV BIBLIOGRAPHY

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX B

1. CONTENT 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, will be 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 attempted also 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 at any time 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, 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

author. As a last resort, the Agency has shown the first submitter as author.

b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00044040	Heimpel, A.M.; Buchanan, L.K. (1965) Human Feeding Tests Using the Nuclear Polyhedral Virus of Heliothis Zea:. (U.S. Agricultural Research Service, Insect Pathology Laboratory, unpublished study including letter dated Sep 7, 1966 from R.S. Roe to M.W. Parker; CDL:104333-A)
00047582	Woodard, G. (1969) Proposed Protocol: NPV-Virus-Technical: Polyhedrosis Virus Safety Evaluation by a Single and Repeated Subcutaneous Injection, by a Single and Repeated Oral Administration and by Single and Repeated Inhalation Exposure in Rhesus Mon-Keys. (Unpublished study including letter dated Jul 7, 1970 from G. Woodard to Michael F. Markel, received on unknown date under 8G0722; prepared by Woodard Research Corp., submitted by Nutrilite Product, Inc., Buena Park, Calif.; CDL:093032-A)
00047589	Totman, L.; Bleiberg, M.J.; Cronin, M.T.I. (1968) Polyhedral Virus: Evaluation of the Carcinogenic Potential in Mice: Addendum to the Final Report. (Unpublished study received on unknown date under 8G0722; prepared by Woodard Research Corp., submitted by Nutrilite Product, Inc., Buena Park, Calif.; CDL:093032-I)
00049121	Knox, D.A. (1970) Tests of certain insect viruses on colonies of honeybees. Journal of Invertebrate Pathology 16(1):152. (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-Z)
00056871	Ignoffo, C.M. (1973) Effects of entomopathogens on vertebrates. Pages 141-164, in Annals of the New York Academy of Sciences: Volume 217. By ? N.P. (Also in unpublished submission received Feb 7, 1977 under 275-18; submitted by Abbott Laboratories, North Chicago, Ill.; CDL:231528-E)
00062579	Cronin, M.T.I. (1966) Polyhedral Virus: Summary of Histopathological Observations in Dogs. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-B)
00062580	Woodard Research Corporation (19??) Polyhedral Virus: A Summary Evaluation of Observations on 20 Day Old Rat Fetuses. (Unpublished study received Oct 2, 1968 under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-C)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00062581	Durloo, R.S.; Bleiberg, M.J. (1967) Polyhedral Virus: Evaluation of the Carcinogenic Potential in Mice: 57 to 78-week Interim Rept. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-D)
00062582	Rostenberg, A., Jr. (1967) Report on the Investigation to Determine the Skin Irritancy and Potential Sensitizing Ability of the Heliothis Nuclear Polyhedrosis Virus on Humans. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Univ. of Illinois, Dept. of Dermatology, submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-E)
00062583	Rafajko, R.R. (1967) Final Report: In Vitro Tissue Culture Studies with Nuclear Polyhedrosis Virus of Heliothis. (Unpublished study received Oct 2, 1968 under 8G0697; prepared by Medical Research Consultants, Inc., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-F)
00062584	International Minerals & Chemical Corporation (1967) Published and Unpublished Studies Demonstrating Specificity of Heliothis Virus to Other Insects, Invertebrates and Vertebrates Including Humans. (Unpublished study received Oct 2, 1968 under 8G0697; CDL:091209-G)
00062588	Heimpel, A.M.; Buchanan, L.K. (1967) Human feeding tests using a nuclear-polyhedrosis virus of Heliothis Zea. Journal of Invertebrate Pathology 9(1):55-57. (Also in unpublished submission received Oct 2, 1968 under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL: 091209-L)
00062591	Ignoffo, C.M.; Heimpel, A.M. (1965) The nuclear-polyhedrosis virus of Heliothis zea (Boddie) and Heliothis virescens (Fabricius): V. Toxicity-pathogenicity of virus to white mice and guinea pigs. Journal of Invertebrate Pathology 7(3):329-340. (Also in unpublished submission received Oct 2, 1968 under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091209-O)
00062594	International Minerals & Chemical Corporation (1967) Analytical Method: Quantitative Microscopic Determination of Polyhedral Inclusion Body Concentration. Method no. 67184 AM dated Aug 2, 1967. (Unpublished study received Oct 2, 1968 under 8G0697; CDL:091209-R)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00062595	International Minerals & Chemical Corporation (1967) Analytical Method: Bioassay of Cotton Bollworm (Heliothis) Virus. Method no. 67185 AM dated Aug 2, 1967. (Unpublished study received Oct 2, 1968 under 8G0697; CDL:091209-S)
00065851	Beliles, R.P.; Benson, B.W.; Scott, W.J., Jr.; et al. (1967) Polyhedral Virus for Insect Control. (Unpublished study received Oct 5, 1968 under 8F0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091215-A)
00065898	Jeffords, F.W. (1971) Health Monitoring of Personnel Associated with H. Zea Virus Production. (Unpublished study received on unknown date under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091212-B)
00065900	Durloo, R.S.; Totman, L.; Bleiberg, M.J.; et al. (1968) Polyhedral Virus: Evaluation of the Carcinogenic Potential in Mice. Final rept. (Unpublished study received on unknown date under 8G0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:091212-D)
00066815	International Minerals & Chemical Corporation (1973) Quality Control Data on Viron/H (TM): Shipped during 1972. (Compilation; unpublished study received Jun 15, 1973 under 3F1304; CDL:092206-D)
00067550	Ignoffo, C.M.; Batzer, O.F.; Barker, W.M.; et al. (1970) Fate of Heliothis nucleopolyhedrosis virus following oral administration to rats. Pages 357-362, in Proceedings, IV International Colloquium on Insect Pathology; Aug 25-28, 1970, College Park, Maryland. N.P. (Also in unpublished submission received Jun 15, 1973 under 3F1304; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:092206-A)
00067551	Shapiro, M.; Ignoffo, C.M. (1970) Serological characterization of the Heliothis nucleopolyhedrosis virus. Pages 147-151, in Proceedings, IV International Colloquim on Insect Pathology; Aug 25-28, 1970, College Park, Maryland. N.P. (Also in unpublished submission received Jun 15, 1973 under 3F1304; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:092206-C)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00067552	Batzer, O.F.; Huang, H.T. (1973) Attempted Detection of Antibodies Specific to Heliothis zea Nucleopolyhedrosis Virus in Human Serum by Hemagglutination-inhibition. (Unpublished study received Jun 15, 1973 under 3F1304; submitted by International Minerals & Chemical Corp., Libertyville, Ill.; CDL:092206-E)
00070480	Nutrilite Products, Incorporated (1965) Introduction: [Biotrol VHZ]. (Unpublished study received Mar 13, 1981 under 6296-EX-2; CDL:127376-A)
00070481	Halverson, G.R.; Dulmage, H.T. (1965) Human Testing Program. (Unpublished study received Mar 13, 1981 under 6296-EX-2; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:127376-B)
00070482	Nutrilite Products, Incorporated (19??) Planned Carcinogenicity Tests. (Unpublished study received Mar 13, 1981 under 6296-EX-2; CDL:127376-C)
00070484	Nutrilite Products, Incorporated (19??) Production Methods of Manufacture of Biotrol VHZ. (Unpublished study received Mar 13, 1981 under 6296-EX-2; CDL:127376-E)
00070487	Heimpel, A.M.; Buchanan, L.K. (1965) Human Feeding Tests Using the Nuclear Polyhedral Virus of Heliothis zea. (U.S. Agricultural Research Service, Entomology Research Div., Insect Pathology Laboratory and Office of Personnel, Employee Health Div.; unpublished study; CDL:127379-C)
00072668	Sandoz, Incorporated--Crop Protection (1971?) Bioassay of Heliothis NPV Preparations. (Unpublished study received Mar 6, 1981 under 11273-EX-23; CDL:099943-C)
00072677	Sandoz, Incorporated--Crop Protection (1978?) Microbial Examination of Production Batch Preparation of Elcar. (Compilation; unpublished study, including published data, received Mar 6, 1981 under 11273-EX-23; CDL:099944-F)
00075280	Barnes, R.W.; Meinecke, C.F.; McLane, W.C.; et al. (1970) Long-term feeding and other toxicity-pathogenicity studies on rats using a commercial preparation of the nuclear-polyhedrosis virus of Heliothis zea. Journal of Invertebrate Pathology 16(1):112-115. (Also in unpublished submission received Feb 28, 1971 under 6296-EX-2; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:127382-A)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00075281	Chauthani, A.R.; Murphy, D.; Claussen, D.; et al. (1968) The effect of human gastric juice on the pathogenicity of Heliothis Zea nuclear-polyhedrosis virus. Journal of Invertebrate Pathology 12(2):145-147. (Also in unpublished submission received Feb 28, 1971 under 6296-EX-2; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:127382-B)
00075283	Meinecke, C.F.; McLane, W.C.; Rehnborg, C.S. (1970) Inhalation and dermal allergenicity studies of a nuclear-polyhedrosis virus of Heliothis Zea in guinea pigs. Journal of Invertebrate Pathology 15(2):207-210. (Also in unpublished submission received Feb 28, 1971 under 6296-EX-2; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:127382-D)
00081436	Nutrilite Products, Incorporated (1968) Acute Toxicity Studies in Small Rodents. (Unpublished study received on unknown date under 8G0722; CDL:091244-A)
00081437	Nutrilite Products, Incorporated (1965) Ninety-day Feeding Study Using Sprague-Dawley Rats. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-B)
00081438	Nutrilite Products, Incorporated (1967) Two-year Feeding Study Using Sprague-Dawley Rats to Assess Carcinogencity Potential of Biotrol VHZ--a Continuation of 90-day Study. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-C)
00081439	Nutrilite Products, Incorporated (1967) Eighteen (18) Month Mouse Test to Assess Carcinogenicity Potential of Biotrol VHZ by Repeated Subcutaneous Injections. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-D)
00081440	Nutrilite Products, Incorporated (1967) Inhalation Studies using Guinea Pigs To Test for Possible Allergenicity of Biotrol VHZ. (Unpublished study received Mar 3, 1968 under 8G0722; CDL: 091244-E)
00081441	Nutrilite Products, Incorporated (1967) Dermal Exposure Studies on Guinea Pigs to Test for Possible Allergenicity of Biotrol VHZ. (Unpublished study received Mar 3, 1968 under 8G0722; CDL: 091244-F)
00081442	Nutrilite Products, Incorporated (1966?) Completed and Planned Antibody Tests. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-G)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00081443	Nutrilite Products, Incorporated (1966) Toxicology--Related to Safety of Animals. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-H)
00081444	Nutrilite Products, Incorporated (1966) Tests Evaluating the Effects of Biotrol VHZ on the Following Species of Fresh Water Fish: (1) Rainbow Trout, (2) Black Bullhead, and (3) White Sucker. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-I)
00081445	Nutrilite Products, Incorporated (1966) Tests Evaluating the Effects of Biotrol VHZ on Bluegill Fish. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-J)
00081446	Nutrilite Products, Incorporated (1966) Tests Evaluating the Effects of Biotrol VHZ on 3 Species of Native Birds: (1) English Sparrows, (2) Valley Quail, and (3) Mallard Duck. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-K)
00081447	Nutrilite Products, Incorporated (1966) Tests Designed To Study the Possible Mutability of Biotrol VHZ When Passed through the Gut of the Mallard Duck. (Unpublished study received Mar 3, 1968 under 8G0722; CDL:091244-L)
00081449	Dulmage, H.T.; Halverson, G.R. (1968?) Report of Clinical and Physical Examinations of Laboratory Personnel Heavily Exposed to the Nuclear Polyhedrosis Virus of Heliothis zea. (Unpublished study received Mar 3, 1968 under 8G0722; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:091244-O)
00081450	Rehnborg, C.S.; Westall, E.B.; Halverson, G.R. (2967) Report of Clinical and Physical Examinations of Laboratory Personnel Heavily Exposed to the Nuclear Polyhedrosis Virus of Heliosis zea since December, 1965. (Unpublised study received Mar 3, 1968 under 8G0722; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:091244-P)
00081452	Nutrilite Products, Incorporated (1964?) Production of Biotrol VHZ. (Compilation; unpublished study received Mar 3, 1968 under 8F0722; CDL:091244-R)
00081453	Heimpel, A.M. (1964?) Preliminary Discussions on a Protocol of Toxicological and Pathogenicity Tests Using Insect Viruses. (Unpublished study received Mar 3, 1968 under 8G0722; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:091244-S)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00081456	Marking, L.L. (1966) Letter sent to Howard T. Dulmage dated Sep 14, 1966 [Preliminary testing of Biotrol against three species of fish]. (U.S. Fish and Wildlife Service, Fish Control Laboratory; unpublished study; CDL:091244-X)
00081457	Butler, P.A. (1966) Letter sent to Howard T. Dulmage dated Oct 28, 1966 [Effect of the polyhedrosis and carrier when injected intraperitoneally in the sheepshead minnow]. (U.S. Fish and Wildlife Service, Bureau of Commercial Fisheries, Biological Laboratory; unpublished study; CDL:091244-Y)
00081459	Marking, L.L. (1966) Letter sent to Howard T. Dulmage dated Oct 14, 1966 [Toxicity of the virus material and virus-free carrier to rainbow trout]. (U.S. Fish and Wildlife Service, Fish Control Laboratory; unpublished study; CDL:091244-AA)
00081461	Chauthani, A.R.; Murphy, D.; Claussen, D.; et al. (1968) The Effect of Human Gastric Juice on the Pathogenicity of Heliothis zea (Boddie) Nuclear Polyhedrosis Virus. (Unpublished study received Mar 3, 1968 under 8G0722; prepared in cooperation with Univ. of California--Riverside, Dept. of Biological Control, submitted by Nitrilite Products, Inc., Buena Park, Calif.; CDL: 091244-AC)
00082090	Nutrilite Products, Incorporated (1965) Toxicity and Pathogenicity Studies Completed. (Unpublished study received Jul 5, 1966 under 6G0481; CDL:090539-C)
00082091	Dulmage, H.T.; Halverson, G.R. (1965) Report on Clinical and Physical Examinations of Laboratory Personnel Heavily Exposed to the Nuclear Polyhedrosis Virus of Heliothis zea. (Unpublished study received Jul 5, 1966 under 6G0481; submitted by Nutrilite Products, Inc., Buena Park, Calif.; CDL:090539-D)
00082092	Nutrilite Products, Incorporated (19??) Name, Chemical Identity, and Composition of the Pesticide Chemical: [Biotrol VHZ]. (Unpublished study received Jul 5, 1966 under 6G0481; CDL:090539-F)
00082094	Nutrilite Products, Incorporated (1965?) Production Methods of Manufacture of Biotrol VHZ. (Unpublished study received Jul 5, 1966 under 6G0481; CDL:090539-H)
00082218	Nutrilite Products, Incorporated (19??) Name, Chemical Identity, and Composition of the Pesticide Chemical: [Biotrol VHZ]. (Unpublished study received May 6, 1968 under 6G0481; CDL:090540-A)

Heliothis zea NPV Bibliogra
Reregistration Eligibility Do
December, 1990

MRID	Citation
00082220	Nutrilite Products, Incorporated (1967) [T VHZ in Rats and Mice]. (Compilation; u May 6, 1968 under 6G0481; CDL:090540-E)
00082221	Nutrilite Products, Incorporated (1967) De Guinea Pigs to Test for Possible Allerg (Unpublished study received May 6, 1968 090540-G)
00082222	Nutrilite Products, Incorporated (1967) To Safety of Animals (U.S.D.A. Requirement lished study received May 6, 1968 under
00082223	Nutrilite Products, Incorporated (1968) To (Compilation; unpublished study receive 6G0481; CDL:090540-I)
00089265	Dulmage, H.T.; Heimpel, A.; Ignoffo, C.M. Planned Animal Tests: Safety Testing P Procedures for Biotrol VHZ: Nutrilite the Polyhedrosis Virus of Heliothis ze study received Aug 6, 1965 under PP041 with Nutrilite Products, Inc., submitt tural Research Service; CDL:090452-A)
00089268	Heimpel, A.M.; Ignoffo, C.M. (1964) Repor with Heliothis zea (Boddie) to Apprais Insect Virus on Laboratory Animals. (Service, Entomology Research Div.; unp 090452-F)
00090423	Woodard, M.W.; Banerjee, B.N.; Woodard, G 7083: Safety Evaluation in Rhesus Monk Subcutaneous Injection; Single and Rep Single and Repeated Oral Administrati including letter dated Mar 11, 1971 f erjee, received Jun 4, 1971 under 8G0 Research Corp., submitted by Internat Corp., Libertyville, Ill.; CDL:091213
00091306	Ignoffo, C.M.; Batzer, O.F.; Barker, W.M Heliothis Nucleopolyhedrosis Virus fo tion to Rats. (Unpublished study rec 4456-EX-11; submitted by Internationa Corp., Libertyville, Ill.; CDL:127260

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00100998	Booth, T.; Miller, J. (1971) Survey of Wildlife within and Adjacent to Test Cotton Fields on Worth Matteson, Jr. Farm near ..., Little River County, Arkansas. (Unpublished study received Oct 21, 1971 under 8G0722; prepared by Univ. of Arkansas, Div. of Agriculture, Agricultural Extension Service, submitted by Nutrilite Products, Inc., Buena Park, CA; CDL:091247-D)
00100999	Nutrilite Products, Inc. (19??) [Biotrol VHZ: Toxicity to Wildlife]. (Compilation; unpublished study received Oct 21, 1971 under 8G0722; CDL:091247-E)
00101002	Nutrilite Products, Inc. (19??) Name, Chemical Identity, and Composition of the Pesticide Chemical: [Biotrol VHZ]. (Compilation; unpublished study received Jun 1, 1965 under 6G0481; CDL: 092770-B)
00101003	Nutrilite Products, Inc. (1959?) Present and Planned Animal Tests: Safety Testing Procedures, Standardization Procedures for Biotrol VHZ: Nutrilite Products Preparation of the Polyhedrosis Virus of Heliothis zea. (Protocol; unpublished study received Jun 1, 1965 under 6G0481; CDL:092770-C)
00101005	U.S. Agricultural Research Service (19??) Testing for Safety of Bacterial and Viral Pesticides. (Unpublished study; CDL: 092705-A)
00101017	International Minerals & Chemical Corp. (1969) [Chemistry of Heliothis Virus as an Insecticide]. (Compilation; unpublished study received Jun 4, 1971 under 8F0697; CDL:093002-A)
00101018	Totman, L.; Bleiberg, M. (1968) Polyhedral Virus: Evaluation of the Carcinogenic Potential in Mice: Addendum to the Final Report. (Unpublished study received Jun 4, 1971 under 8F0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, IL; CDL:093002-B)
00101019	International Minerals & Chemical Corp. (1967) Bioassay of Cotton Bollworm (Heliothis) Virus: No. 67185 AM. (Unpublished study received on unknown date under 8G0697; CDL:093003-A)
00101020	Shapiro, M. (1971) Serological Studies on Heliothis Nucleopolyhedrosis Virus. (Unpublished study received on unknown date under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, IL; CDL:093003-B)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00101021	Woodard Research Corp. (1969) Proposed Protocol: NPV-virus-technical: Polyhedrosis Virus: Safety Evaluation by a Single and Repeated Subcutaneous Injection, by a Single and Repeated Oral Administration and by Single and Repeated Inhalation Exposure in Rhesus Monkeys. (Unpublished study received on unknown date under 8G0697; submitted by International Minerals & Chemical Corp., Libertyville, IL; CDL:093003-D)
00101024	International Minerals & Chemical Corp. (19??) Confidential Disclosure of Ingredients: [Viron H]. (Unpublished study received Aug 17, 1972 under 3F1304; CDL:094118-A)
00101026	International Minerals & Chemical Corp. (1973) Serological Tests on Employees Involved in Viron/H Production in 1972. (Unpublished study received on unknown date under 3F1304; CDL: 094118-C)
00101028	Woodard, G. (1967) Safety Evaluation Tests with the Nuclear Polyhedrosis Virus of Heliothis. (Unpublished study received Oct 2, 1968 under 8F0697; prepared by Woodard Research Corp., submitted by International Minerals & Chemical Corp., Libertyville, IL; CDL:096410-A)
00101029	Rafajko, R. (1967) In Vitro Tissue Culture Studies with Nuclear Polyhedrosis Virus of Heliothis. Final rept. (Unpublished study received Oct 2, 1968 under 8F0697; prepared by Medical Research Consultants, Inc., submitted by International Minerals & Chemical Corp., Libertyville, IL; CDL:096410-D)
00101034	Summers, M. (1978?) Development and Standardization of Identification and Monitoring Techniques for Baculovirus Pesticides: EPA Grant 805232. (Texas A & M Univ. for U.S. Environmental Protection Agency, Health Effects Research Laboratory; unpublished study; CDL:099124-B)
00101036	Meinecke, C.; McLane, W.; Rehnborg, C. (1970) Toxicity-pathogenicity studies of a nuclear-polyhedrosis virus of Heliothis Zea in white mice. Journal of Invertebrate Pathology 15(1):10-14. (Also in unpublished submission received Feb 28, 1971 under 6296-EX-2; submitted by Nutrilite Products, Inc., Buena Park, CA; CDL:127372-A)
00101040	Nutrilite Products, Inc. (1971) Safety Evaluation: [Biotrol VHZ]. (Compilation; unpublished study received Sep 16, 1971 under 6296-EX-2; CDL:127383-B)

Heliothis zea NPV Bibliography
Reregistration Eligibility Document
December, 1990

MRID	Citation
00101041	Nutrilite Products, Inc. (1972) Safety Evaluation: [Biotrol VHZ]. (Compilation; unpublished study received on unknown date under 6296-EX-2; CDL:127384-B)
00101044	Sandoz, Inc. (1974) [Elcar Insecticide: Chemical Study]. (Compilation; unpublished study received Jun 6, 1975 under 11273-17; CDL:220964-A)
00101045	Shieh, T. (1975) Studies on Stability, Persistence and Field Efficacy of Elcar (SAN 240 WP). (Unpublished study received Jun 6, 1975 under 11273-17; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:220964-B)
41556401	Van Beek, N. (1990) Characterization of the Helithios zea Singly-Imbedded Nucleur Polyhedrosis Virus (NPV) Preparation (Trade name Elcar) by Restriction Endonuclease Digestion. Unpublished study prepared by Sandoz Crop Protection Corp. 10 p.