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PRODUCT MANAGER NO. Linda Hollis/P. Hutton (PM-18)

PRODUCT NAME(S) CYD-X

COMPANY NAME Espro, Inc.

SUBMISSION PURPOSE Section 3 Registration

SHAUGH. NO.	CHEMICAL	% FORMULATION
<u>128885</u>	<u>Cydia pomonella NPV</u>	<u>3.5</u>
_____	_____	_____
_____	_____	_____

EEB REVIEW

Pesticide Name: CYD-X: *Cydia pomonella* Nuclear Polyhedrosis Virus

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

Espro, Inc. has requested a Section 3 Registration for CYD-X which contains *Cydia pomonella* a multi-capsid nuclear polyhedrosis virus. The product is active against caterpillars of the codling moth on the following crops: apples, pears, and walnuts.

100.2.0 Formulation Information

An Aqueous Suspension Biological Insecticide

ACTIVE INGREDIENT*

Granular inclusion bodies (GIBs) of the codling moth granulosis virus.....	0.2%
Inert Ingredients.....	99.8%
TOTAL	100.0%

*This lot contains at least 100 billion GIBs and 5 million activity units (AUs) per milliliter.

100.3.0 Application Methods, Directions, Rates

CYD-X is a highly selective insecticide for use against codling moth caterpillars on the following crops using the listed rates:

	Billion AUs/acre	Fl. ozs. /acre
Apples, pears, walnuts	50-75	1/3-1/2

CYD-X should be mixed with non-chlorinated water (near pH 7.0) at the labeled rates and agitation should be used during mixing. The final formulation should be mixed for 10-30 minutes before use. Treatment should be made when the insect larvae are young (early instars) and are actively feeding on foliage. If insect infestations are heavy, the higher label rates should be used. A spreader/sticker and ultraviolet screening agent may be needed to enhance the performance of this product.

100.4.0 Target Organisms

codling moth caterpillar

100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION: See additional precautionary statements and statements of practical treatment on the side panel

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

ENVIRONMENTAL HAZARD STATEMENT: Do not contaminate water by cleaning of equipment or disposing of wastes..

(Pesticide and container disposal directions are adequate)

101.0.0 Hazard Assessment

101.1.0 Discussion

The nuclear polyhedrosis virus used as the a.i. in this product is *Cydia pomonella* isolated from the codling moth. The registrant has addressed each of the requirements for this type of product by supplying data from studies found in the open literature. This data will be used to justify waivers for each of these requirements.

A review of the studies submitted for this product demonstrated that no significant risk to nontarget wildlife should be expected from exposure of this product at the proposed use rates.

101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

Avian Studies

No avian studies using this particular virus have been cited in the literature, however, studies using other NPVs have been reported. *Spodoptera litura* was fed to chicks (1.5×10^{10} PIBs dosage) with no effect on behavior, temperature, weight gain, or feed conversion ratio. The gypsy moth NPV has been shown to have no effect on caged quail and several species of free-living birds tested in the wild. Twelve different NPVs have been tested on a number of bird species with no adverse effects being reported. Therefore no adverse effects to birds are expected from the use of CYD-X.

Fish Studies

Several tests have been conducted testing the effect of NPVs on fish. Rainbow trout and sunfish were exposed to 10^7 and 10^8 polyhedra/gal of *Autographa californica* NPV and no mortality was observed. White suckers and trout were fed spruce budworm NPV at 10^7 polyhedra/gm body weight and no mortality or virus replication in the fish tissues was observed. Salmon and trout were exposed to Douglas-fir tussock moth NPV by injection, by adding the virus to their water, and by inoculating cell cultures (10^6 units/ml) with no evidence of toxicity or infection. The gypsy moth NPV did not adversely effect bluegill or brown trout, challenge by *Neodiprion lecontei* NPV (10^6 PIBs/g body weight per os) did not produce a response in rainbow trout, *Mamestra brassicae* NPV was shown to pass harmlessly through the alimentary tract of trout after feeding, and spruce budworm NPV was shown not to interfere with a cytopathogenic virus or infect a minnow cell line. Reports in the literature which tested other NPVs indicate that NPVs do not cause adverse effects to fish.

Mammalian Wildlife

These studies are required only when toxicology data are inadequate for assessment of hazard to wild mammals. The available toxicology data indicates that risk to wild mammals from the proposed uses of CYD-X insecticide is minimal.

Aquatic Invertebrate Studies

A literature search was conducted and no studies were found testing the effect of *Cydia pomonella* NPV on aquatic invertebrates. However, there were studies testing the effect of other NPVs on aquatic invertebrates. *N. lecontei* NPV did not produce any Daphnid mortality or brood size changes after 14 days with a dose of 2.4×10^4 PIBs/ml. The virus was not found in any of the fish tissue sectioned at the end of the study. Gypsy moth NPV had no effect on *Daphnia*, *Chironomus*, or *Notonecta*, and *H. zea* NPV had no effect on *Daphnia*. Based on these studies and the fact that aquatic invertebrates have frequent exposure to NPVs in nature with no documented adverse effects, *Cydia pomonella* NPV should not have any adverse on aquatic invertebrates.

Estuarine and Marine Animal Studies

A search of the literature uncovered two studies using *Autographa californica* NPV and shrimp. White and brown shrimp injected with 10^{11} virus rods or fed a diet containing up to 8000 polyhedra/ul of food produced no indication of virus toxicity or pathogenicity upon gross observations or examination of various shrimp tissue. The estuarine grass shrimp, *Palaemonetes* after being feed food pellets containing 10^7 polyhedra/pellet showed no differences in mortality or behavior between the treated and control shrimp after 30 days. The shrimp showed no evidence of virus infection, viral replication or cytopathogenic activity. From the results of these studies, NPVs such as *Cydia pomonella* should not cause adverse effects on estuarine and marine animals.

Nontarget Plant Studies

The NPVs are unique among the described viruses and are not biochemically or morphologically similar to plant viruses. To our knowledge, there are no reports in the literature of Baculoviruses (which includes this virus) as being toxic or pathogenic to plants or plants being affected in any way by these viruses. In view of this information, no nontarget plant hazard is expected from the proposed uses of CYD-X insecticide.

Honey Bee Studies

A review of the literature demonstrated that several NPVs had been tested on honey bee. A review of 6 publications contained in a literature review of the baculoviruses showed that NPVs from 6 lepidoptera larvae (*Autographa californica*, *Choristomeura fuiferana*, *Heliothis zea*, *Mamestra brassicae*, *Thymelicus lineola*, and *Neodiprion lecontei*) were tested on honeybees and did not show any abnormalities or deleterious effects in egg production, brood rearing, worker and queen mortality, and general colony behavior. In addition, the NPVs *S. frugipeda*, *Heliothis zea*, *Trichoplusia ni*, *Lymantria dispar*, *Hemerocampa (Orygia) pseudotsugata*, and *Neodiprion sertifer* had been fed to honey bees (*Aphis mellifera*) in observation hives at a dose of 1×10^{10} polyhedra/200 ml of 50% sucrose solution. No differences were observed between treated and control colonies. From these results, it appears to the best of our knowledge that NPVs such as *Cydia pomonella* should not cause adverse effects to honey bees.

Nontarget Beneficial Insect Studies

There are a number of literature citations concerning NPV testing on predators and parasites. The reports indicate that there does not seem to be an effect on predators (pentatomids, lacewings, ladybirds and scavenger beetles) that consume NPV infected larvae. Parasites also do not seem to be directly affected by NPVs. NPV infected *Spodoptera litura* larvae did not alter the development of the parasite *Parasarchopaga misera* and NPV infection in the lawn armyworm, *Spodoptera maruitia*, did not seem to affect parasitization by the solitary internal larval parasite, *Apanteles marginiventris*. However, the parasites host may die prematurely which would cause the larvae not to develop. This should only occur when the larvae are infected at an early stage (later infection would allow the parasites to develop) and generally the parasites tend to avoid parasitizing diseased larvae. From these results, it does not appear to the best of our knowledge that NPVs will cause adverse effects to predatory or beneficial insects

101.3.0 Endangered Species Considerations

This product may be expected to be used throughout the United States with possible exposure to all endangered/threatened species that are susceptible to this virus. Based on the toxicity and exposure data, EEB feels that there will not be a "may affect" situation for endangered mammals, birds, non-lepidopteran invertebrates, plants and aquatic species.

The use of CYD-X insecticide in Washington, Oregon, California and Florida, however, may affect endangered lepidopteran insect species. Based on information available to EEB, the following are counties in which the use of this product may result in hazard to endangered/threatened species of lepidopterans:

<u>County, State</u>	<u>Species of Concern</u>
Los Angeles, CA	El Segundo blue butterfly Palos Verdes blue butterfly
Contra Costa, CA	Lange's metalmark butterfly
Mendocino, CA	Lotis blue butterfly
San Francisco, CA	Mission blue butterfly
San Mateo, CA	Mission blue butterfly San Bruno elfin butterfly
Monterey, CA	Smith's blue butterfly
Kern, CA	Kern primrose sphinx moth
Dade, FL	Schaus swallowtail butterfly

Monore, FL
Lane, OR
Pacific, WA
Tillamook, WA

Schaus swallowtail butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly
Oregon silverspot butterfly

1. In California the species and specific areas to be avoided are as follows:

Lotis blue butterfly - Mendocino County - 3 miles south of Mendocino City to Fort Bragg along a 2 mile corridor along Highway 1.

Lange's metalmark butterfly - Contra Costa County - Antioch Sand Dunes Wildlife Refuge.

Mission blue butterfly and San Bruno elfin butterfly - San Mateo County - San Bruno Mountain, Milgara Ridge, Skyline College (Guadalupe Canyon Parkway), Sweeney Ridge, and Montana Mountain.

Smith's blue butterfly - Monterey County - Seaside Marina coastal dune complex from the City of Monterey to Point Gorda, Fort Ord Military Reservation, Seaside Dunes, California Department of Fish and Game preserve near the mouth of the Salinas River, Monterey Sand Hills, Lobos State Preserve, Partington Canyon between Highway 1 and Partington Cove, Burns Creek, several west-facing canyons adjacent to Highway 1 between Malpaso and Garrapatacreeks, north-facing slopes adjacent to Carmel River between Boronda and Paso Hondo roads near Carmel Valley, Vasquez Knob, and Paraiso springs.

El Segundo blue butterfly - Los Angeles County - International Airport and Chevron Refinery.

Kern primrose sphinx moth - Kern County - Walker Basin.

2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/threatened species. CYD-X should not be applied near any

2. In Florida, the insect virus, or any formulations thereof, should not be used in the Dade County Keys in Key Biscayne national Park, thence southward to Lower Metacumbe Key in Monroe County
3. The insect virus, or any formulations thereof, should not be near the Pacific Ocean in Tillamook County, Oregon and Pacific County, Washington, where the Oregon silverspot butterfly is known to occur.

The registrant will need to ensure that the use of this product does not cause a hazard to these endangered/threatened species. Guano should not be applied near any of the habitats of these insects. If the product is to be used in any of the listed counties, the applicator should avoid the specific areas containing these insect habitats.

101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

Generic Data Requirements For Gusano

Data Requirements	Test ¹ Substance	Use ² Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?
<u>§158.740 Microbial Pesticide Nontarget Organism - Tier I</u>					
<u>Avian Testing</u>					
154-16 Avian Acute Oral					
- bobwhite quail	TGAI	A,B,G	No	---	No ⁴
- mallard duck	TGAI	A,B,G	No	---	No ⁴
<u>Aquatic Organism Testing</u>					
154-19 Freshwater Fish LC50					
- rainbow trout	TGAI	A,B,G	No	---	No ⁴
154-20 Freshwater Invertebrate					
- <u>Daphnia magna</u>	TGAI	A,B,G	No	---	No ⁴
154-21 Estuarine and Marine					
- animals	TGAI	A,B,G	No	---	No ³

101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate and no additions/modifications need to be made.

Endangered Species Labeling: Endangered species labeling is deferred until the Technical Bulletin information is made available by OPP.

102.0.0 Classification: N/A

103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of CYD-X by Espro, Inc. for control of codling moth on apples, pears, and walnuts. The studies submitted by the registrant do not specifically address the testing requirements but can be used to grant waivers for each of the requirements. EEB concludes that risk to nontarget wildlife from the proposed uses of CYD-X will be minimal to nonexistent.

Endangered species considerations

The use of CYD-X insecticide in Washington, Oregon, California and Florida may affect endangered Lepidopteran insect species. The specific locations of the endangered species in these areas are listed in section 101.3.0. This product should not be used in close proximity to these areas to ensure that no exposure to the endangered species occurs.

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