

70051-44

4/6/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/12

Ms. Christine A. Dively
Director of Regulatory Affairs
Certis USA, LLC
9145 Guilford Road, Suite 175
Columbia, MD 21046

APR 06 2010

Re: Certis USA, LLC; CYD-X®
EPA Registration No. 70051-44
Minor Label ("Fast Track") Amendment
Resubmission dated 09/22/2009
Decision #406678

Dear Ms. Dively:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Separation of the label into two distinct, stand-alone sublabels (i.e., sublabel A for agricultural uses and sublabel B for residential uses) to accommodate the addition of residential uses and the associated labeling language unique to these particular uses (e.g., Net Contents, Environmental Hazards, Directions for Use, Storage and Disposal, and National Organic Program labeling).
- 2) Correction of minor formatting and typographical errors found on sublabel A.
- 3) Addition of a hot line number in the First Aid Box of sublabel A.
- 4) Addition of the requirements for waterproof gloves and a dust/mist filtering respirator, meeting certain National Institute for Occupational Safety and Health (NIOSH) standards, to the Personal Protective Equipment section of sublabel A.
- 5) Modification of the User Safety Recommendations of sublabel A.
- 6) Addition of a chemigation prohibition statement ("Do not apply this product through any type of irrigation system") to sublabel A per Pesticide Registration (PR) Notice 87-1.
- 7) Modification of the Directions for Use on sublabel A for purposes of enhanced clarity.
- 8) Adjustment of the Storage and Disposal instructions on sublabel A per PR Notice 2007-4.

CONCURRENCES							
SYMBOL	7511P	7511P					
SURNAME	KAUSCH	Reynolds					
DATE	04/06/2010	4/6/10					

Ms. Christine A. Dively
EPA Registration Number 70051-44

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The changes referred to on the previous page, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you:

- 1) Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of this condition. If you have any questions, contact Ms. Jeannine Kausch at 703-347-8920 or by email at kausch.jeannine@epa.gov.

A stamped copy of the label is enclosed for your records.

Sincerely,

Handwritten signature of Sheryl K. Reilly, with the word "for" written at the end of the signature.

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):
- A-79 Enclosure
- Acceptable Label

MASTER LABEL

This master label bears directions for agricultural and homeowner use with various application rates specific to the container size.

CYD-X
Insecticidal Virus

Sublabel A: Agricultural Use
Sublabel B: Homeowner Use

Active Ingredient:	
<i>Cydia pomonella</i> granulovirus.....	0.06%
Other Ingredients:.....	99.94%
Total.....	100.00%

KEEP OUT REACH OF CHILDREN

CAUTION

EPA Registration Number: 70051-44
EPA Establishment Number: 70051-CA-001

Manufactured by:
Certis U.S.A., L.L.C.
9145 Guilford Road, Suite 175
Columbia, Maryland 21046

ACCEPTED

APR 06 2010

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 70051-44

1/12

SUBLABEL A: Agricultural Use

CYD-X®

INSECTICIDAL VIRUS

An Aqueous Suspension
Biological Insecticide for Control of the Codling Moth

FOR ORGANIC PRODUCTION



Active Ingredient*:
Cydia pomonella granulovirus.....0.06%
Other Ingredients:..... 99.94%
Total.....100.00%

*Contains at least 3×10^{13} viral occlusion bodies (OBs) per Liter.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Net Contents: 1 Quart
Lot No.:
EPA Reg. No. 70051-44
EPA Est. No. 70051-CA-001

Manufactured by:
Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046
CERTIS

CYD-X® is an insecticidal virus product for control of larvae of the codling moth. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): CAUTION:

Harmful if inhaled. Avoid breathing spray mist. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements:

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

USER SAFETY RECOMMENDATIONS:

Users Should:

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS:

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Do not apply this product through any type of irrigation system.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water) is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

CYD-X® BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

CYD-X® contains an insecticidal baculovirus (scientific name: *Cydia pomonella* granulovirus or CpGV) that is specific to larvae of the codling moth (*Cydia pomonella*). Because of this specificity to the codling moth, CYD-X® provides a unique opportunity for biological control of codling moth without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

BIOLOGICAL PROPERTIES and MODE OF ACTION

CYD-X® is a biological insecticide, which must be ingested by larvae in order to be effective. Upon ingestion, the viral occlusion bodies (OBs) dissolve in the larval midgut and release infectious virions. These enter the cells lining the digestive tract and replicate in the nuclei of those cells. The resulting progeny virus infects other tissues within the larva, which stops feeding and eventually dies from massive viral infection. After death, the larva disintegrates, releasing billions of new OBs, which may infect other codling moth larvae upon ingestion. Death occurs 3 to 7 days after ingestion of CYD-X®, depending on dosage and ambient temperature. Death may occur more quickly at higher temperatures and higher dosage.

Baculoviruses have been found only in invertebrates; currently, there are no reports of members of this family infecting vertebrates or plants. CYD-X® virions do not reproduce in mammalian cells. This product can be inactivated by continuous exposure to temperatures above 86°F. For best results, keep the product refrigerated or frozen when not in use.

MIXING INSTRUCTIONS

CYD-X® must be mixed with water and applied as a spray to fruit and foliage. Use non-chlorinated water at a pH near 7.0 in the spray-tank mix.

APPLICATION RATES

CROP	Application rate	Comments
Apple, pear, plum, prune, and walnut	1 to 6 fluid ounces per acre of trees	<p>Apply in sufficient water to thoroughly wet the tree canopy without excessive runoff. Select a spray volume appropriate to tree size and density of foliage. For small trees, use 50 -100 gallons of spray per acre. Larger trees with denser canopy may require 100-200 gallons of spray per acre. Consult your local Cooperative Extension Service if you need advice about how to attain good spray coverage in your orchard.</p> <p>Make at least two (2) applications of CYD-X® per codling moth larval generation. Target small larvae early in their life cycle. Repeat as necessary to maintain control. CYD-X® breaks down under direct exposure to sunlight. If codling moths are still flying and laying eggs, reapply after 7 - 8 sunny days.</p> <p>If using temperature models (heat unit accumulation measured in degree days) and pheromone trap catch to predict codling moth development, make the first spray against the first larval generation around 250 degree days after codling moth Biofix (first moth flight). If targeting the second generation, start at approx. 1100-1200 degree days after biofix. "No Biofix" models (using heat units only, with no trap catch information) are now used in some growing regions. Consult your local Cooperative Extension Service for information about using degree day models to guide spray timing.</p> <p>If not using heat units to time sprays, apply CYD-X® in the 1st and 2nd cover sprays against first generation larvae. For second generation, apply in the 4th and 5th cover sprays.</p> <p>Frequent applications at low rates may be more effective than one or two applications at high rate.</p>

CYD-X ® can be applied up to and including the day of harvest and storage.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 86°F. Bioactivity may be impaired by storage above 86°F. Storing the product in a freezer or refrigerator will extend its shelf life.

PESTICIDE DISPOSAL:

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by State and local ordinances.

WARRANTY

Certis USA L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SUBLABEL B: Homeowner Use

CYD-X®

INSECTICIDAL VIRUS

An Aqueous Suspension
Biological Insecticide for Control of the Codling Moth
In Home Garden settings

 FOR ORGANIC GARDENING



Active Ingredient*:

<i>Cydia pomonella granulovirus</i>	0.06%
Other Ingredients:	99.94%
Total	100.00%

*Contains at least 3×10^{13} viral occlusion bodies (OBs) per Liter.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Net Contents: 1.5 fl. oz. and 2.0 fl. oz.

Lot No.:
EPA Reg. No. 70051-44
EPA Est. No. 70051-CA-001

Manufactured by:
Certis USA
9145 Guilford Road
Suite 175
Columbia, MD 21046
CERTIS

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FIRST AID

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924

ENVIRONMENTAL HAZARDS:

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

CYD-X® BIOLOGICAL INSECTICIDE

PRODUCT DESCRIPTION

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Baculoviruses have been found only in invertebrates; currently, there are no reports of members of this

family infecting vertebrates or plants. CYD-X® virions do not reproduce in mammalian cells. This product can be inactivated by continuous exposure to temperatures above 86°F. For best results, keep the product refrigerated or frozen when not in use.

MIXING INSTRUCTIONS

CYD-X® must be mixed with water and applied as a spray to fruit and foliage. Use non-chlorinated water at a pH near 7.0 in the spray-tank mix.

Application rate:

Mix 1 teaspoon of CYD-X® per 5 gallons of water and apply directly to each tree using a hand pump sprayer or other suitable spray equipment. Spray just enough to wet all leaves and fruit with minimal run-off or dripping. Total coverage depends on the size of trees to be sprayed and the type of sprayer used.

When to spray:

Apply CYD-X® first in late spring or early summer, when eggs of the first generation of codling moth begin to hatch. For maximum effectiveness, apply CYD-X® at least twice during each larval generation. When pest pressure persists, additional applications of CYD-X® may be necessary in mid- to late summer. Consult your local Cooperative Extension Service for more information about the best timing of codling moth sprays.

CYD-X® breaks down under direct exposure to sunlight. If codling moths are still flying and laying eggs, reapply after 7 to 8 sunny days.

CYD-X® can be applied up to and including the day of harvest and storage.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE:

Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill container.

If empty:

Place in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency or 1-800-CLEAN-UP for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

Certis USA L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.