



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Biopesticides and Pollution Prevention Division (7511P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

69553-12

Date of Issuance:

6/20/2023

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

MADEX XLV

Name and Address of Registrant (include ZIP Code):

Andermatt Group AG
 Stahlermatten 6
 CH-6146 Grossdietwil
 Switzerland

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when EPA requires all registrants of similar products to submit such data.

Signature of Approving Official:

Alexandra Boukedes
 Digitally signed by
 Alexandra Boukedes
 Date: 2023.06.20 16:55:02
 -04'00'

Alexandra Boukedes, Product Manager 92
 Microbial Pesticides Branch
 Biopesticides and Pollution Prevention Division (7511M)
 Office of Pesticide Programs

Date:

6/20/2023

2. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 69553-12."
3. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.


Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 06/12/2023

If you have any questions, please contact Andrew Queen by phone at 202-566-1539 or via email at queen.andrew@epa.gov.

Sincerely,

 Digitally signed by
Alexandra Boukedes
Date: 2023.06.20
16:54:29 -04'00'

Alexandra Boukedes, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure:

optional/alternate text is shown in [brackets]

<i>CYDIA POMONELLA</i> GRANULOVIRUS ISOLATE GV-0017	GROUP	31	INSECTICIDE
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MADEX XLV

Insecticidal Virus

Sublabel A: Agricultural Use

Sublabel B: Residential Use

Active Ingredient*:

Cydia pomonella granulovirus isolate GV-0017 0.06%

Other Ingredients:

99.94%

Total:

100.00%

*Contains a minimum of 3×10^{13} viral occlusion bodies per liter of product.

Store below 41°F

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No.: 69553-RE

EPA Est. No.:

Origin of Product: Switzerland

Manufactured by: Andermatt Biocontrol Suisse AG

Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

Manufactured for: Andermatt Group AG

Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

ACCEPTED

Jun 20, 2023

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 69553-12

<i>CYDIA POMONELLA</i> GRANULOVIRUS ISOLATE GV-0017	GROUP	31	INSECTICIDE
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SUBLABEL A: Agricultural Use

MADEX XLV

Insecticidal Virus



FOR ORGANIC PRODUCTION



Active Ingredient*:

Cydia pomonella granulovirus isolate GV-0017

0.06%

Other Ingredients:

99.94%

Total:

100.00%

*Contains a minimum of 3×10^{13} viral occlusion bodies per liter of product.

Store
below
41°F

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSIDE/SIDE/BACK/OTHER PANEL FOR FIRST AID, PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE.

Net Contents:

Lot No.:

EPA Reg. No.: 69553-RE

EPA Est. No.:

Origin of Product: Switzerland

[Manufactured by: Andermatt Biocontrol Suisse AG

Stahlermatten 6

CH-6146 Grossdietwil

Switzerland]

[Manufactured for: Andermatt Group AG
 Stahlermatten 6
 CH-6146 Grossdietwil
 Switzerland]

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • 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 eyes. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information. For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center (NPIC) at 1-800-858-7378.</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- waterproof gloves
- shoes plus socks
- protective eyewear

Mixers/loaders and applicators must wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

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

Engineering Controls

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR §170.607(d) and (e)], 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 breakdown.

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 the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For terrestrial uses: 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 washwater 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.

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 intervals (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
- Protective eyewear

PRODUCT INFORMATION

MADEX XLV acts very specifically against larvae of the Codling Moth, *Cydia pomonella*, and the Oriental Fruit Moth, *Grapholita molesta*, as a pre-harvest biological insecticide on pome fruit trees, stone fruit trees and tree nuts. MADEX XLV contains a baculovirus that is infective to Codling Moth and Oriental Fruit Moth larvae. To be effective, deposits of MADEX XLV must be ingested by the larvae. Thus, thorough coverage of target foliage and/or fruits where the larvae are feeding is essential. Upon ingestion, the viral occlusion bodies (OBs) dissolve in the larval midgut and release infectious virions. These infect and replicate within insect cells to infect other tissues within the larva, which stops feeding and eventually dies from massive viral infection. After death, the larva disintegrates, releasing large numbers of new OBs which may infect other Codling Moth and Oriental Fruit Moth larvae upon ingestion. Larvae mortality occurs a few days after ingestion of MADEX XLV, depending on dosage and ambient temperature.

USE INFORMATION

SHAKE WELL BEFORE USING

Start spraying shortly before larvae hatch from the eggs or before the larvae feed their way into the fruit. Due to unfavorable weather conditions, flight, egg laying, and hatching may extend over a longer period and up to 6 applications may be needed. Frequent applications at low rates may be more effective than one or two applications at high rates.

Use sufficient water to obtain thorough, uniform coverage. Because MADEX XLV acts through ingestion of treated plant material, thorough spray coverage is essential for optimum control of targeted pest insects. Using increased water volumes will typically result in better spray coverage, especially under adverse conditions such as dry hot weather or dense plant foliage. Avoid run-off. MADEX XLV is rainfast as soon as it has dried.

Use Restriction

Do not apply this product through any type of irrigation.

MIXING AND APPLICATION INSTRUCTIONS

Mix MADEX XLV with water and apply as a spray to fruit and foliage of trees in orchards and nurseries. Use water for mixing the spray at or near neutral pH (7) before adding MADEX XLV.

CROP	RATE	COMMENTS
Pome and Stone fruit trees, and tree nuts including: apple, pear, quince, apricot, aprium, cherry, nectarine, peach, plum, pluot, prune, almond, walnut, and hybrids of these	0.5 - 3.0 fluid ounces of MADEX XLV per acre, depending on pest pressure and application frequency.	Select a spray volume appropriate to tree size and density of foliage. For small trees, use 50-100 gallons of water per acre. Larger trees with denser canopies require 100-200 gallons of water per acre. Consult your local Cooperative Extension Service if you need advice about how to attain good spray coverage in your orchard. Make at least two (2) and up to six (6) applications of MADEX XLV per Codling Moth or Oriental Fruit Moth larval generation. Target small larvae early in their life cycle. Repeat as necessary to maintain control, making no more than six (6) applications per larval generation. MADEX XLV breaks down under direct exposure to sunlight. If moths are still flying and laying eggs, reapply after 6-8 sunny days (counting 2 partially sunny days as 1 sunny day).

MADEX XLV may be applied up to and including the day of harvest.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 41°F (5°C).

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:

[For nonrefillable rigid containers 5 gal or less: Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse** as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 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. **Pressure rinse** as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. [For non-plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.] [For plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.]

[For nonrefillable non-rigid containers any size: Nonrefillable container. Do not reuse or refill this container. Completely empty [container] [bag] into application equipment. [For bags: Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration.] [For non-bag containers: Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.]

[For refillable rigid containers larger than 5 gal: Refillable container. Contact your [company name] representative to have this container refilled. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10% full with water and, if possible, spray all sides while adding water. Agitate vigorously or recirculate water with the pump for two minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. [For non-plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.] [For plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration or by other procedures approved by state and local authorities.]

[For nonrefillable rigid containers larger than 5 gal: Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. **Triple rinse** as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. **Pressure rinse** as follows: Empty the remaining contents into application equipment or a mix tank and

continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 psi for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. [For non-plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.] [For plastic containers: Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.]

WARRANTY

Andermatt Group AG 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. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SUBLABEL B: Residential Use

MADEX XLV

Insecticidal Virus



FOR ORGANIC GARDENING



Active Ingredient*:

Cydia pomonella granulovirus isolate GV-0017

0.06%

Other Ingredients:

99.94%

Total:

100.00%

*Contains a minimum of 3×10^{13} viral occlusion bodies per liter of product.

Store below 41°F

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSIDE/SIDE PANEL FOR FIRST AID, PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE.

Net Contents:

Lot No.:

EPA Reg. No.: 69553-RE

EPA Est. No.:

Origin of Product: Switzerland

[Manufactured by: Andermatt Biocontrol Suisse AG

Stahlermatten 6

CH-6146 Grossdietwil

Switzerland]

[Manufactured for: Andermatt Group AG

Stahlermatten 6

CH-6146 Grossdietwil

Switzerland]

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • 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 eyes. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information. For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center (NPIC) at 1-800-858-7378.</p>	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

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.

PRODUCT INFORMATION

MADEX XLV acts very specifically against larvae of the Codling Moth, *Cydia pomonella*, and the Oriental Fruit Moth, *Grapholita molesta*, as a pre-harvest biological insecticide on pome fruit trees, stone fruit trees and tree nuts. MADEX XLV contains a baculovirus that is infective to Codling Moth and Oriental Fruit Moth. To be effective, deposits of MADEX XLV must be ingested by the larvae. Thus, thorough coverage of target foliage and/or fruits where the larvae are feeding is essential. Upon ingestion, the viral occlusion bodies (OBs) dissolve in the larval midgut and release infectious virions. These infect and replicate within insect cells to infect 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 and Oriental Fruit Moth larvae upon ingestion. Larvae mortality occurs between 3 to 7 days after ingestion of MADEX XLV, depending on dosage and ambient temperature.

Use Restrictions

For use only on pome and stone fruit trees, and tree nuts, including apple, quince, pear, peach, nectarine, apricot, plum, prune, cherry, walnut, almond, pluot, aprium, and hybrids of these, in residential settings. Not for use on trees or fruit grown for sale or other commercial use.

MIXING AND APPLICATION INSTRUCTIONS

SHAKE WELL BEFORE USING

Mix MADEX XLV with water and apply as a spray to the fruits and foliage of plants. Use water at or near neutral pH (7).

Mix 1/2 teaspoon of MADEX XLV per 5 gallons of water and apply directly to each tree using a hand pump sprayer or other suitable spray equipment. Spray a sufficient volume to thoroughly wet all leaves and fruit with minimal run-off or dripping.

Apply MADEX XLV first in late spring or early summer, when eggs of the first generation of Codling Moth or Oriental Fruit Moth begin to hatch. Due to weather conditions (e.g., cooler temperatures), the flight, egg-laying, and hatching may extend over a longer period of time and more applications may be needed to cover the entire hatching period. Apply MADEX XLV at least twice (2) during each larval generation. When pest pressure persists, make additional applications of MADEX XLV in mid- to late summer. Consult your local Cooperative Extension Service for more information about the best timing of Codling Moth and Oriental Fruit Moth sprays.

MADEX XLV breaks down under direct exposure to-sunlight. If moths are still flying and laying eggs, reapply after 6-8 sunny days (counting 2 partially sunny days as 1 sunny day).

MADEX XLV may be applied up to and including the day of harvest.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 41°F (5°C).

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

Andermatt Group AG 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. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.