

55638-34

10/21/1998

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 21 1998

Mr. Dirk Ave
Director, Regulatory Affairs
Ecogen, Inc.
2005 Cabot Blvd West
Langhorne, PA 19047-3023

Dear Mr. Ave:

Subject: CryMax® Formulation and Labeling Amendments to Use Construct 11831 for
Commercial Production // Your Confidential Statement of Formula Dated 7/15/97
EPA Registration No. 55638-34

The amendments referred to above, submitted in connection with registration under
FIFRA section 3(c)(7)(A), are acceptable provided that:

- 1) You submit and/or cite all data required for registration/re-registration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data. You are required to comply with the *Bacillus thuringiensis* RED.
- 2) Your CSF dated 7/15/97 is now the basic and only CSF for this product.
- 3) You submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

| CONCURRENCES | | | | | | | |
|--------------|----------|--------|--|--|--|--|--|
| SYMBOL | 7511c | 7511c | | | | | |
| SURNAME | Muller | Horton | | | | | |
| DATE | 10/20/98 | 10/20 | | | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Sincerely,

Janet L. Andersen

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division (7511C)

CONCURRENCES

| | | | | | | |
|---------|--|--|---|--|--|--|
| SYMBOL | | | 2 | | | |
| SURNAME | | | | | | |
| DATE | | | | | | |

CRYMAX®

BIOINSECTICIDE

CRYMAX® water dispersible granule bioinsecticide is a biological insecticide for the control of lepidopteran pests.

Active Ingredient:

| | |
|---|----------------|
| <i>Bacillus thuringiensis</i> subspecies <i>kurstaki</i> EG7841 | |
| Lepidopteran active toxin | 15.00% |
| Inert Ingredients | 85.00% |
| TOTAL | 100.00% |

2.4 oz. active ingredient per pound
Potency: 64,000 International Units per milligram of product or 29 billion International Units per pound of product. Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section.

STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place inaccessible to children.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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 agency responsible for pesticide regulation.

KEEP OUT OF REACH OF CHILDREN
CAUTION

ACCEPTED
with COMMENTS
In EPA Letter Dated
OCT 21 1998
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 55638-34

STATEMENT OF PRACTICAL TREATMENT

If In Eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment (PPE):

- Applicators and other handlers must wear:
- Long sleeved shirt and long pants
- Shoes plus socks

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

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 by cleaning of equipment or disposal of equipment wash water.

EPA REG. No. 55638-34
EPA Est. Nos. 39578-TX-107, 42761-MS-104, 67250-IL-209
(Subscript refers to last 2 digits of lot number on container.)
Net Contents: 5 U.S. Pound Bag

AGRICULTURAL USE REQUIREMENTS

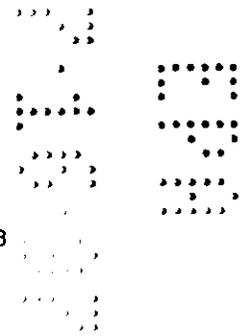
Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements 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. The requirements in this section 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.



Ecogen Inc.
2005 Cabot Blvd. West, P.O. Box 3023
Langhorne, PA 19047-3023
215/757-1590 or 800/220-2135



NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to the uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Do not enter treated areas without protective clothing until sprays have dried.

Preharvest Interval: CRYMAX may be applied to the crops listed in the APPLICATION RATE TABLE at any time, up to and on the day of harvest.

Mode of Action: After consuming a lethal dose of CRYMAX, larvae will cease to feed, but may remain alive on foliage for several days before disappearing. Larvae begin to move slowly, become discolored, shrivel and blacken prior to death.

MIXING INSTRUCTIONS

CRYMAX may be applied with conventional ground, aerial or hand held application equipment with quantities of water sufficient to provide thorough coverage of infested plants. To obtain a suitable mixture with water, add enough water to allow maximum agitation. With agitator running, slowly add in the CRYMAX. Continue agitation. Add remainder of water and other spray materials and agitate until mixed. Maintain suspension while loading and spraying. Do not mix more CRYMAX than can be used in a 24-hour period. Rinse and flush spray equipment thoroughly following each use. Do not contaminate water when disposing of equipment washwaters.

In order to make proper decisions on application rates to be used, follow the recommendations in the **APPLICATION RATE TABLE**.

APPLICATION INSTRUCTIONS

CRYMAX is a bioinsecticide for use against the lepidopteran larvae listed in the APPLICATION RATE TABLE. Larvae must consume deposits of CRYMAX to be affected. Always follow these directions:

- Make applications when larvae are still small (early instars) and actively feeding on foliage or other plant parts.
- Make applications before noticeable foliar damage occurs.
- Thorough spray coverage is essential for good insect control. For ground applications, directed drop nozzles should be used for certain vegetable crops.
- When insect infestations are heavy, use the higher label rates, shorten the spray interval, and/or use larger total spray volume to improve spray coverage.
- Applications should be repeated at an interval sufficient to maintain control, depending upon plant growth, insect pressure and weather conditions after spraying.
- For crops such as Fruits, Nuts and Vines, applications are often timed to stage of development and recommendations from local Extension personnel should always be followed.

- Local conditions may affect the use of CRYMAX. Consult your State Agricultural Extension Specialist for specific recommendations related to local crop protection problems.
- Spray water/spray tank solutions should not exceed pH 8.0. If necessary, buffer water to near neutral pH.

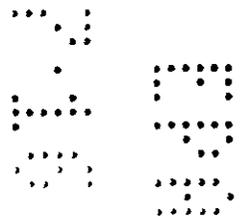
HAND HELD EQUIPMENT

When using hand held equipment, mix 2 teaspoons per gallon of water or 1 1/2 pounds per 100 gallons of spray solution. Spray to wet, but not to runoff.

TANK MIX

Combinations of CRYMAX with commonly used insecticides, fungicides, or other spray tank adjuvants are generally not deleterious to performance. It is advisable to test physical compatibility by mixing all components in a small container in proportionate quantities prior to mixing in spray tank. This product cannot be mixed with any product containing a label prohibition against such mixing. No label dosage rate should be exceeded. Application must be made in accordance with the more restrictive of label limitation and precautions.

- For improved durability of spray deposits, a spreader/sticker approved for use on growing crops may be used for hard-to-wet crops such as cole crops.



CHEMIGATION

Apply this product only through center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set or hand move sprinkler systems. **Do not apply this product through any other type of irrigation system.** Crop injury or lack of effectiveness can result from nonuniform distribution of treated water.

If you have questions about calibration, contact your State Extension Service Specialist, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS:

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure Zone (RPZ), backflow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

SPRINKLER CHEMIGATION:

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The pesticide injection pipeline must contain a functional automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

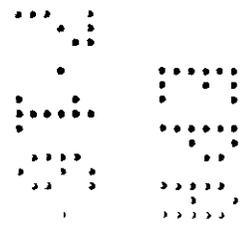
The active ingredient in CRYMAX will settle in the tank and injection lines; adequate agitation must be provided before and during the injection period. Use only in systems that apply uniformly and have appropriate check valves. When application is complete, thoroughly flush the injection system and sprinkler lines.

MIXING RECOMMENDATIONS FOR CHEMIGATION:

Follow general **MIXING INSTRUCTIONS** and keep the ratio at three parts water to one part CRYMAX. Also, provide mild uniform agitation throughout the suspension but do not agitate excessively.

SPRAY VOLUME:

For chemigation use irrigation levels of 0.15 to 0.5 inches of water per acre. Up to 1 inch of irrigation water may be used, but efficacy may be reduced. The product should be applied continuously for the duration of the water application.



APPLICATION RATE TABLE

I. VEGETABLE & COLE CROPS

| Crop such as: | Insect Pest |
|--|-----------------|
| Artichokes | Napa |
| Arugala | Okra |
| Asparagus | Onions |
| Beans | Parsley |
| Beets | Parsnips |
| Bok Choy | Peas |
| Broccoli | Peppers |
| Brussels sprouts | Potatoes |
| Cabbage | Pumpkins |
| Cardoni | Radishes |
| Carrots | Rutabaga |
| Cauliflower | Salsify |
| Celeriac | Shallots |
| Celery | Soybean foliage |
| Chick peas | Spinach |
| Chicory | Squash |
| Chinese cabbage | Sugar beets |
| Collards | Sweet potatoes |
| Cucumber | Swiss chard |
| Cucurbits | Tomatoes |
| Dry bulb onions | Turnips |
| Eggplants | Watercress |
| Escarole | |
| Endive | |
| Garlic | |
| Green onions | |
| Greens (Beets, China, Dandelion, Mustard, Turnip) | |
| Horseradish | |
| Kale | |
| Kohlrabi | |
| Leeks | |
| Lentils | |
| Lettuce (Head, Leaf, Romaine) | |
| Malanga | |
| Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.) | |

Rate/Acre: 0.5 - 1.5 pounds

II. HERBS & SPICES

| Crop such as: | Insect Pest |
|---------------|-----------------------|
| Basil | Alfalfa looper |
| Chives | Armyworm |
| Cilantro | Diamondback moth |
| Dill | European corn borer |
| Oregano | Green cloverworm |
| Peppermint | Imported cabbageworm |
| Thyme | Loopers |
| | Saltmarsh caterpillar |

Rate/Acre: 0.5 - 1.5 pounds

III. PASTURE & HAY CROPS

| Crop such as: | Insect Pest |
|-------------------------|------------------------|
| Alfalfa (hay & seed) | Alfalfa caterpillar |
| Pasture (grasses & hay) | Armyworm |
| Silage | Beet armyworm |
| | European skipper |
| | Loopers |
| | Webworm |
| | Yellowstriped armyworm |

Rate/Acre: 0.5 - 1.5 pounds

IV. FRUIT, NUT & VINE CROPS

| Crop such as: | Insect Pest |
|---|---|
| Pome and Stone Fruit Trees: Apples Apricots Cherries Nectarines Peaches Pears Plums Prunes Quince | Cankerworm (Spring & Fall) Cherry fruitworm Eastern tent caterpillar Fall webworm Fruitree leafroller Green fruitworm Gypsy moth Navel orangeworm Obliquebanded leafroller Omnivorous leafroller Oriental fruit moth Pandemis leafroller Peach twig borer Redbanded leafroller Redhumped caterpillar Tortrix moth (Orange and Garden) Tufted apple budmoth Variegated leafroller Walnut caterpillar Western tent caterpillar |
| Nut Trees: Almonds Chestnuts Filberts Pecans Pistachios Walnuts | Citrus cutworm Filbert leafroller Filbert webworm Fruitree leafroller Hickory shuckworm Navel orangeworm Obliquebanded leafroller Omnivorous leafroller Pecan nut casebearer Peach twig borer Redhumped caterpillar Roughskinned cutworm Western tent caterpillar |
| Citrus | Amorbia Citrus cutworm Fruitree leafroller Omnivorous leafroller Orangedog |
| Small Fruit and Berries: Blackberries Blueberries Boysenberries Cranberries Currants Loganberries Raspberries Strawberries | Achema sphinx moth Armyworm Blackheaded fireworm Blueberry leafroller Cranberry girdler Fruitree leafroller Grape berry moth Gypsy moth Loopers Obliquebanded leafroller Omnivorous looper Tobacco budworm |
| Grapes | Grape berry moth Cherry fruitworm Grape leafroller Grapeleaf skeletonizer Green fruitworm Omnivorous leafroller Orange tortrix Saltmarsh caterpillar Yellowstriped armyworm |
| Tropical and Other Fruit: Avocados | Amorbia Loopers Orange tortrix Omnivorous leafroller Omnivorous looper Spanworm |
| Bananas | Banana skipper |
| Kiwi | Omnivorous leafroller |
| Persimmons Pomegranate | Citrus cutworm Fall webworm Filbert webworm Omnivorous leafroller Redhumped caterpillar Tent caterpillar |
| Pineapple | Gummosa-Betrachetia commosae Thecla-Thecla basitides |
| Tropical fruits | Hornworms Leafrollers Loopers Omnivorous leafroller |

V. FIELD CROPS

| Crop such as: | Insect Pest |
|---|---|
| Canola/Rape Seed Evening Primrose Meadow foam | Amyworm Diamondback moth Imported cabbageworm Loopers |
| Corn (Field, Sweet, Popcorn) | Amyworm European corn borer Southwestern corn borer |
| Cotton* | Beet armyworm Bollworm Cabbage looper Cotton leaf perforator Saltmarsh caterpillar Soybean looper Tobacco budworm Yellowstriped armyworm |
| Hops | Amyworm Loopers Obliquebanded leafroller Omnivorous leaflier Spotted cutworm |
| Jujuba | Looper (<i>Anacamptodes spp.</i>) |
| Peanuts | Green cloverworm Loopers Podworm Velvetbean caterpillar |
| Rice | Amyworm Green cloverworm Loopers Saltmarsh caterpillar Velvetbean caterpillar |
| Safflower | Amyworm Loopers Saltmarsh caterpillar |
| Small Grains (Barley, Oats, Rye, Wheat, etc.) | Amyworm Loopers |
| Sorghum | European corn borer Headworm Saltmarsh caterpillar Velvetbean caterpillar |
| Soybeans | Green cloverworm Podworm Soybean looper Velvetbean caterpillar |
| Sunflowers | Banded sunflower moth Beet armyworm Headmoth Loopers Sunflower moth |
| Tobacco | Tobacco budworm Tobacco hornworm Loopers |

Rate/acre: 0.5-1.5 pounds

*Use CRYMAX at 0.25 lb/acre to control light to moderate populations of newly hatched tobacco budworm and bollworm in integrated pest management programs. Repeat treatments at four to five day intervals or as long as necessary until results are acceptable. Ovicides or synthetic pyrethroids can be combined with CRYMAX in accordance with the more restrictive of label limitations and precautions. No label dosage rates should be exceeded. This product cannot be mixed with any product containing a label prohibition against such mixing.

VI. COMMERCIAL FLOWER & ORNAMENTAL PLANTS

| Crop such as: | Insect Pest |
|---|---|
| Bedding plants Flowers (Greenhouse and field) Greenhouse Ornamentals Vegetables Container stock | Amyworm Azalea moth Beet armyworm Diamondback moth Ello moth (hornworm) Florida fern caterpillar lo moth Loopers Oleander moth Omnivorous leafroller Omnivorous looper Tobacco budworm |

Rate/Acre: 0.5 - 1.5 pounds

VII. FOREST, SHADE TREE & NURSERY STOCK

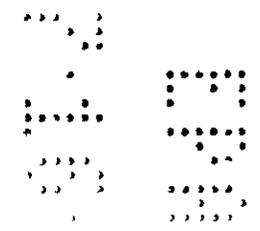
| Crop such as: | Insect Pest |
|--|--|
| Forest Shade trees Nursery trees | Bagworm Blackheaded budworm Browntail moth California oakworm Douglas fir tussock moth Elm spanworm Fall webworm Fruitree leafroller Greenstriped mapleworm Gypsy moth Jack pine budworm Mimosa webworm Pine butterfly Redhumped caterpillar Saddleback caterpillar Saddle prominent caterpillar Spring and Fall cankerworm Spruce budworm Tent caterpillar Tortrix Western tussock moth |

Rate/Acre: 0.5 - 1.5 pounds

VIII. TURF

| Crop such as: | Insect Pest |
|---------------|--|
| Turf | Amyworm Sod webworm Tropical sod webworm |

Rate/Acre: 0.5 - 1.5 pounds



WARRANTY AND CONDITIONS OF SALE

Ecogen warrants that this product conforms to the description on this label and is reasonably fit for the purposes stated on this label when used in accordance with the directions on this label under normal conditions of use.

ECOGEN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

If this product is defective, Buyer's exclusive remedy shall be the replacement of the product, or if replacement is impracticable, refund of the purchase price. In no case will Ecogen be liable for incidental, consequential, or special damages resulting from the handling, storage or use of this product.