PM90) 55638-34) 1/8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR - 7 1997

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

David L. Olson
Director, Regulatory Affairs
Ecogen, Inc.
2005 Cabot Boulevard West
P.O. Box 3023
Langhorne, PA 19047-3023

SUBJECT: **CRYMAX Bioinsecticide (EPA Reg. No. 55638-34)**
Bacillus thuringiensis subspecies kurstaki strain EG7841
Ecogen Response to EPA February 13, 1996 Aquatic Risk Assessment
Label Amendments: Addition of Watercress
Modified Environmental Hazard Statement
Your Submission dated May 20, 1996 and March 3, 1997

Dear Mr. Olson:

The Agency is responding to your request for the above. Specifically, you have responded to the Agency's concerns detailed in an Ecological Effects Risk Assessment dated 2/13/96 regarding the potential for chronic risk to aquatic invertebrates resulting from the application of CryMax to water grown crops such as watercress. Your March 3, 1997 transmission contained a label containing watercress and a modified Environmental Hazard Statement. The Agency's conclusions follow and are based on the attached February 5, 1997 BPPD review:

(1) The Agency concurs with Ecogen that CRYMAX's chronic risk to aquatic invertebrates is minimal to nonexistent. The aquatic chronic risk quotient is 0.163 for freshwater aquatic invertebrates and the aquatic acute risk quotient is 0.0056 for freshwater aquatic invertebrates is 0.0056. None of these risk quotients trigger a level of concern.

Note that the calculated EEC is now 0.390 mg/L and not 0.165 mg/L based on a maximum use rate of 1.5 lbs product per acre. BPPD previously calculated the EEC based on percent of lepidopteran toxin (15%) rather than on the percent of *Bt* fermentation solids and solubles, including lepdopteran toxin that make up 35.4% of the CRYMAX formulation.

The amendments referred to above, submitted in connection with registration under the Federal Insecticide, fungicide, and Rodenticide Act, as amended, are acceptable.

(2) However, you should note that the Agency considers endangered lepidopterans that may be exposed to be at risk. Therefore the following generic language is brought to your attention:

"The Agency has concerns about the exposure of threatened and endangered species. Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and to

implement mitigation measures that will eliminate the adverse impacts.
The program will require users to consult count-specific bulletins. These bulletins will provide information about specific use restrictions to protect endangered and threatened species in the county of specific pesticide use. Consultations with Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Protection Program in the Federal Register and have enforceable county-specific bulletins. Because the Agency is taking this approach for protection of endangered and threatened species, it is not imposing label modifications at this time. Rather, any requirement for product use modifications will occur in the future under the Endangered Species Protection Program."

For section 18s, it is the responsibility of the state to determine whether or not the pesticide will be used in areas where possible threatened or endangered species exist; therefore, the state should provide specific labeling language.

A copy of the stamped label is enclosed for your records. If you have any questions regarding this letter, please contact Teung F. Chin, Regulatory Action Leader, at (703) 308-1259.

Sincerely,

Janet L. Andersen, Ph.D.
Division Director
Biopesticides and Pollution
Prevention Division (7501W)

Enclosure

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CRYMAX™

BIOINSECTICIDE

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

Active Ingredient:

Bacillus thuringiensis subspecies *kurstaki* strain 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.

KEEP OUT OF REACH OF CHILDREN

CAUTION

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-1[07], 42761-MS-1[04], 67250-IL-2[08]
(Subscript refers to last 2 digits of lot number on container.)
Net Contents: 5 U.S. Pound Bag

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.

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.

ACCEPTED
MAR 7 1997
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 55638-34

ECOGEN

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

SPECIMEN LABEL

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.

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APPLICATION RATE TABLE

I. VEGETABLE & COLE CROPS

Crop such as:		Insect Pest
Artichokes	Napa	Alfalfa looper
Arugala	Okra	Armyworm
Asparagus	Onions	Artichoke plume moth
Beans	Parsley	Beet armyworm
Beets	Parsnips	Cabbage budworm
Bok Choy	Peas	Cabbage looper
Broccoli	Peppers	Cabbage webworm
Brussels sprouts	Potatoes	Celery leaftier
Cabbage	Pumpkins	Corn earworm
Cardoni	Radishes	Cross-striped cabbageworm
Carrots	Rutabaga	Diamondback moth
Cauliflower	Salsify	European corn borer
Celeriac	Shallots	Green cloverworm
Celery	Soybean foliage	Imported cabbageworm
Chick peas	Spinach	Melonworm
Chicory	Squash	Omnivorous leafroller
Chinese cabbage	Sugar beets	Pickleworm
Collards	Sweet potatoes	Rindworm complex
Cucumber	Swiss chard	Saltmarsh caterpillar
Cucurbits	Tomatoes	Southern armyworm
Dry bulb onions	Turnips	Soybean looper
Eggplants	Watercress	Tobacco budworm
Escarole		Tomato fruitworm
Endive		Tomato hornworm
Garlic		Tomato pinworm
Green onions		Velvetbean caterpillar
Greens (Beets, China, Dandelion, Mustard, Turnip)		Yellowstriped armyworm
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:	Cankerworm (Spring & Fall)
Apples	Cherry fruitworm
Apricots	Eastern tent caterpillar
Cherries	Fall webworm
Nectarines	Fruittree leafroller
Peaches	Green fruitworm
Pears	Gypsy moth
Plums	Navel orangeworm
Prunes	Obliquebanded leafroller
Quince	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:	Citrus cutworm
Almonds	Filbert leafroller
Chestnuts	Filbert webworm
Filberts	Fruittree leafroller
Pecans	Hickory shuckworm
Pistachios	Navel orangeworm
Walnuts	Obliquebanded leafroller
	Omnivorous leafroller
	Pecan nut casebearer
	Peach twig borer
	Redhumped caterpillar
	Roughskinned cutworm
	Western tent caterpillar
Citrus	Amorbia
	Citrus cutworm
	Fruittree leafroller
	Omnivorous leafroller
	Orangedog
Small Fruit and Berries:	Achema sphinx moth
Blackberries	Armyworm
Blueberries	Blackheaded fireworm
Boysenberries	Blueberry leafroller
Cranberries	Cranberry girdler
Currants	Fruittree leafroller
Loganberries	Grape berry moth
Raspberries	Gypsy moth
Strawberries	Loopers
	Obliquebanded leafroller
	Omnivorous looper
	Tobacco budworm
Grapes	Grape berry moth
	Cherry fruitworm
	Grape leaffolder
	Grapeleaf skeletonizer
	Green fruitworm
	Omnivorous leafroller
	Orange tortrix
	Saltmarsh caterpillar
	Yellowstriped armyworm
Tropical and Other Fruit:	Amorbia
Avocados	Loopers
	Orange tortrix
	Omnivorous leafroller
	Omnivorous looper
	Spanworm
Bananas	Banana skipper
Kiwi	Omnivorous leafroller
Persimmons	Citrus cutworm
Pomegranate	Fall webworm
	Filbert webworm
	Omnivorous leafroller
	Redhumped caterpillar
	Tent caterpillar
Pineapple	Gummosos-Batrachedra commosae
	Thecla-Thecla basilides
Tropical fruits	Hornworms
	Leafrollers
	Loopers
	Omnivorous leafroller

Rate/Acre: 0.5-1.5 pounds

V. FIELD CROPS

Crop such as:	Insect Pest
Canola/Rape Seed Evening Primrose Meadow foam	Armyworm Diamondback moth Imported cabbageworm Loopers
Corn (Field, Sweet, Popcorn)	Armyworm European corn borer Southwestern corn borer
Cotton*	Beet armyworm Bollworm Cabbage looper Cotton leaf perforator Saltmarsh caterpillar Soybean looper Tobacco budworm Yellowstriped armyworm
Hops	Armyworm Loopers Obliquebanded leafroller Omnivorous leaftier Spotted cutworm
Jojoba	Looper *(Anacamptodes spp.)*
Peanuts	Green cloverworm Loopers Podworm Velvetbean caterpillar
Rice	Armyworm Green cloverworm Loopers Saltmarsh caterpillar Velvetbean caterpillar
Safflower	Armyworm Loopers Saltmarsh caterpillar
Small Grains (Barley, Oats, Rye, Wheat, etc.)	Armyworm 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	Armyworm Azalea moth Beet armyworm Diamondback moth Ello moth (hornworm) Florida fern caterpillar Io 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 Fruittree 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	Armyworm Sod webworm Tropical sod webworm

Rate/Acre: 0.5 - 1.5 pounds

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.

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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.