

Reg # 53871-5

PM-18

File
199



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

FEB 23 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Adrian Krygsman
FERMONE CORPORATION
2620 N. 37th Drive
Phoenix, AZ 85009

Subject: Label Amendment Submission of 10/25/93 in Response to PR Notice 93-7
EPA Reg. No. 53871-5
FERMONE BT FLOWABLE CONCENTRATE

IMPORTANT NOTICE: This Letter Requires You to Submit a Notification to the Office of Compliance Monitoring within 20 Days.

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted subject to the comments listed on the enclosed sheet. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

SERIOUS ERROR(S) ON SUBMITTED LABELING:

EPA has determined that one or more of the errors on the labeling you submitted to the Agency is categorized as "serious" as defined in PR Notice 93-11. In general, serious errors are those that may create a potential for harm to workers, handlers, other persons, or the environment; or those that prevent the achievement of the basic goals of the Worker Protection Standard (WPS) or FIFRA.

YOU MUST NOT SELL OR DISTRIBUTE (INCLUDING RELEASE FOR SHIPMENT) ANY PRODUCT BEARING THE SUBMITTED LABELING. Sale or distribution of any product with the incorrect labeling is a violation of FIFRA that could result in initiation of an action for civil penalties and/or cancellation of your product. This matter has been referred to the Office of Compliance Monitoring (OCM) for further action.

YOU MUST SUBMIT A NOTIFICATION TO THE OFFICE OF COMPLIANCE MONITORING WITHIN 20 DAYS OF THE DATE OF THIS LETTER.



Recycled/Recyclable
Printed with Soy/Candore ink on paper that
contains at least 50% recycled fiber

Each notification must include the following information:

1. Registrant's name and address.
2. EPA Registration number of the product for which the labeling was submitted.
3. Whether any product already has been sold or distributed (this includes released for shipment) bearing the submitted labeling.

In addition, the notification must include the following information, IF you have already sold or distributed any product bearing the submitted labeling:

1. Quantity of the product that has been sold or distributed.
2. EPA Producing Establishment number.
3. Location of the product, if known.
4. Proposed plan for assuring that product with the incorrect labeling in your control, as well as that in the hands of dealers/distributors/users, will be corrected. The plan must include your proposal for assuring that the labeling is corrected as soon as possible.

Submit the notification to:

Michael Wood, Director
Compliance Division, (7203)
Worker Protection Notification
Office of Compliance Monitoring
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

~~Failure to~~ submit a notification also may result in initiation of an action under FIFRA for ~~civil penalties~~, if you sold or distributed (this includes released for shipment) product bearing the incorrect labeling.

IN ADDITION, YOU SHOULD CONTACT IMMEDIATELY THE PERSONS TO WHOM YOU SOLD OR DISTRIBUTED YOUR PRODUCT AND INFORM THEM NOT TO SELL OR DISTRIBUTE ANY PRODUCT WITH THE INCORRECT LABELING.

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the WPS labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have neither been reviewed nor accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

Submit the required notification. Then by the next label printing make all the specified changes to your labeling. Send to EPA one (1) copy of the final printed labeling:

- BEFORE selling or distributing any product bearing the final printed labeling as amended

AND

- WITHIN one year from date of this acceptance.

Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL)
 Office of Pesticide Programs (7505C)
 U.S. Environmental Protection Agency
 401 M Street, SW
 Washington, D.C. 20460-0001

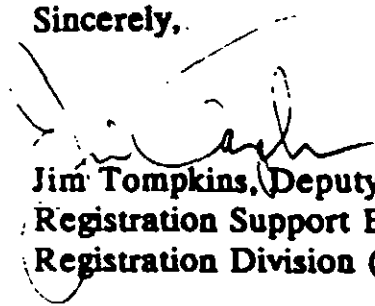
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Hand or courier deliveries of final labeling may be made to:

Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Sincerely,



Jim Tompkins, Deputy Chief
Registration Support Branch
Registration Division (7505W)

Attachment

cc: Office of Compliance Monitoring

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division

Adrian Krygsman
FERMONE CORPORATION
2620 N 37TH DR
PHOENIX AZ 85009

Comment for: EPA Reg Nr.53871-5
FERMONE BT FLOWABLE CONCENTRATE

The following specific comments pertain to your WPS labeling submission concerning the product cited above:

The requirement under the heading "Personal Protective Equipment" must state: "Applicators and other handlers must wear:". Cross out your lead-in statement and replace it with correct one. EXCEPTIO~~n~~: If you have an entirely separate PPE section specifying what "Mixers and loaders must wear", the requirement under the heading "Personal Protective Equipment" must state: "Applicators and other handlers (other than mixers and loaders) must wear:". Cross out your lead-in statement and replace it with the correct one.

You have incorrectly placed inside the Agricultural Use Requirements box on your proposed labeling the prohibition against applying the product so it contacts any person (and related statements). Remove the following statements from the Agricultural Use Requirements box and place them in the Directions For Use section on your labeling immediately following (or below) the sentence "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." The exact location is shown in Section F on Part 2 of the Product Worksheet in Supplement Three-A to PR Notice 93-7.

You have incorrect wording in the second-to-last sentence in the first paragraph in the Agricultural Use Requirements box on your proposed label. The sentence must be as follows: "It also contains specific instructions and exceptions pertaining to the statements on this label about personal

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FERMONE CORPORATION
EPA Reg. Number: 53871-5
FERMONE BT FLOWABLE CONCENTRATE
Application date: 10/25/93
Original Submission

protective equipment (PPE), and restricted-entry interval."

Correct the typographical errors circled on your proposed label.

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (& DOMESTIC ANIMALS)**

May cause eye irritation. Avoid contact with human skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers (other than mixtures and loaders) must wear:

- A. Long-sleeved shirt and long pants,
- B. Chemical resistant gloves, such as neoprene rubber or PVC or Viton or nitrile rubber or butyl rubber or barrier laminate.
- C. Shoes plus socks must be worn.

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

USER SAFETY RECOMMENDATIONS:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing 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 contaminate water by cleaning equipment or disposal of waste.

FERMONE Bt FLOWABLE CONCENTRATE

For the Control of Lepidopterous Larvae

Active Ingredients:

Bacillus thuringiensis Berliner var.

kurstaki.....15.0%

(Primary Powder Fermentation Product, Potency of 7,500 International Units per mg. of product (equivalent to 32 billion IU/gal.)

Inert Ingredients..... 85.0%

Total.....100.0%

ACCEPTED with COMMENTS in EPA Letter Dated

FEB 23 1994

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

53871-5

CAUTION

KEEP OUT REACH OF CHILDREN

E.P.A. REG. NO. 53871-5

E.P.A. ESTAB. NO. 53871-AZ-1

NET CONTENTS:

LOT #

MFG. BY:

FERMONE CORPORATION INC.
2620 N. 37TH DRIVE
PHOENIX, AZ. 85009
602-233-9047

DIRECTIONS FOR USE

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

Fermone Bt flowable concentrate contains the spores and toxic crystals of *Bacillus thuringiensis kurstaki*. Fermone Bt flowable concentrate is a stomach poison and has high specific activity against lepidopterous caterpillars. Individuals eating Fermone Bt fc stop feeding within hours and die 2-5 days later. Apply as soon as caterpillars are seen.

The use of spreader-stickers is recommended on cole crops. Good coverage is essential and spraying to run-off is recommended. The tank contents should be agitated to prevent settling. Half-fill the spray tank with water, add the correct quantity of Fermone Bt fc and continue filling to obtain the proper mix ratio. Use the higher rates against heavy worm infestations or on advanced larval stages.

Spray Volumes:

Aerial Applications: Use recommended amount of Fermone Bt fc in 3 to 20 gallons of water. Apply early morning or evening when air is calm.

Ground Application: Use recommended amount in a minimum of 5 to 80 gallons of water depending on the type of crop.

Ground Application to Trees and Vines: Use recommended amount of Fermone Bt fc (per acre rate) in 100 gallons of water in high pressure, high gallonage sprayers. Wet foliage thoroughly with spray, but not to the point of excessive run-off. For mist blowers, use recommended amount (per acre rate) in 10-50 gallons of water.

Re-Entry

Fermone Bt fc may be applied up to and including the day of harvest and in storage

BEST AVAILABLE COPY

STORAGE AND DISPOSAL:

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

Storage: Store in a cool, dry place. Keep containers tightly closed when not in use. Store in temperatures above freezing and below 32 deg. C (90 deg. F).

Pesticide Disposal: Pesticide waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility in accordance with federal and local regulations.

Container Disposal: Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by incineration or if allowed by State and Local authorities, by burning. If burned stay out of smoke.

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). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

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

- Coveralls
- Chemical resistant gloves such as neoprene rubber or PVC or Viton or nitrile rubber or butyl rubber or barrier laminate.
- Shoes plus socks

APPLICATION RATES	PESTS	RATES (LBS./ACRE*)
CROP		
COTTON	Loopers, bollworm, budworm, armyworm	1.0-2.0
NUT TREE	Redhumped caterpillars, fall webworm, tent caterpillars, omnivorous leafroller, filbert leafroller	0.5-1.0
TREE FRUITS	Redhumped caterpillars, tent caterpillars, omnivorous leafroller, tortrix moth, cankerworms, leafrollers, fruit tree leafroller, gypsy moth.	0.5-1.0
CITRUS	Orange dog, fruit tree leafroller, citrus cutworm	0.5-1.0

SOYBEANS	Loopers, budworm, hornworm, velvetbean caterpillar, cloverworm	0.5-2.0
ALFALFA, PASTURE HAY, SMALL GRAINS, FORAGE CROPS	Alfalfa caterpillar Armyworm, looper	0.125-0.25 1.0-2.0
SUGAR BEETS	Cabbage looper, omnivorous leafroller, armyworm	1.0-2.0
VEGETABLES OF THE FOLLOWING GROUPS: ROOT & TUBER LEAVES OF ROOT AND TUBER	Imported cabbage worm, cloverworm, hornworm, alfalfa caterpillar Webworms, loopers, cutworm, Saltmarsh caterpillar, Melonworm, pickleworm	0.25-0.5 0.5-1.0
BULB, LEAFY BRASSICA	Armyworm, budworm, tomato fruitworm, corn earworm, diamondback moth	1.0-2.0
COLE, LEAFY LEGUMES FOLIAGE OF LEGUMES FRUITING, CUCURBIT, VINES	leafrollers, leaffolders, berry moths, tortirix moths, grapeleaf skeletonizer	0.5-1.0
TOBACCO	Budworm, hornworm, looper	0.5-2.0
TURF	Sod Webworm	1.0-2.0
FORESTS SHADE TREES ORNAMENTALS SHRUBS, SUGAR, MAPLE TREES	Gypsy Moth, Spruce Budworm, Browntail Moth Tussock Moths, Pine butterfly, bagworm, leafrollers, tortrix, mimosa webworms, tent caterpillars, jackpine budworm, black-headed budworm, elm spanworm, saddled prominent and saddleback caterpillars Red humped caterpillar, Spring and Fall cankerworm, California Oakworm, Fall webworm	1.0-2.5 0.75-2.0 0.5-1.0
GREENHOUSE (E.G. TOMATO, CUCUMBER, FLOWERS, LETTUCE ETC.)	Loopers, bollworm, diamondback moth fruitworm, hornworm, armyworm	0.5-2.0
STORED PRODUCTS	Tobacco moth Almond moth, Indian meal moth, flour moth	0.5/lb. in 6 gal. 2.0/lb. in 3 gal.

*Use the higher recommended rates on advanced larval stages or under high density larval population
Warranty: Limitation of damages: Fermone Corporation Inc. warrants that this material conforms to the chemical description and guaranteed limits of active ingredients as stated on this label. Fermone Corporation Inc. makes no other express or implied warranty of fitness or merchantability of any kind. Fermone Corporation Inc. maximum liability for breach of this warranty shall not exceed the purchase price of this product. In no event shall Fermone Corporation Inc. be liable for indirect or consequential damages. This warranty shall not be changed by oral or written agreement unless signed by a duly authorized officer of Fermone Corporation Inc. . Buyer assumes all risk of use or handling whether in accordance with directions or not.

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