

PM 12

53871-6

10/88 File



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. 53871-6
LARVO-BT

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/Candela ink on paper that
contains at least 50% recycled fiber



2 of 8

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.

3 of 4

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:

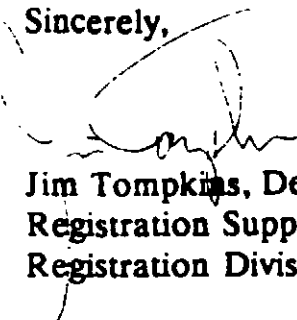
Document Processing Desk (FIN-LABEL)
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001



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

78

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.53871-6
LARVO-BT

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. EXCEPTION: 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 of 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

✓

10/25/93

PERMONE CORPORATION
EPA Reg. Number: 53871-6
LARVO-BT
Application date: 10/25/93
Original Submission

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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS (4
DOMESTIC ANIMALS)**

Avoid inhalation or contact with eyes, skin, or open wounds. Do not inhale spray mist. In case of contact, immediately flush eyes or skin with plenty of water.

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 mixers 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.

Follow 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 discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Do not contaminate water when disposing of equipment washwaters.

Forestry Use: Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Aerial application over such sites is permissible only when they are not visible from above the tree canopy. Do not contaminate water when disposing of equipment washwaters.

Direct Water Application: Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles.

**LARVO-BT®
FLOWABLE CONCENTRATE**

BIOLOGICAL INSECTICIDE

Active Ingredients

Bacillus thuringiensis, Berliner Strain.....26.4%

Potency:

At least 200 million viable spores per mg.
(equivalent to 125 billion IU per qt.)

Inert ingredients.....73.6%
100.0%

ACCEPTED
with COMMENTS
In EPA Letter Dated

MAY 28 1984

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

53871-6

**CAUTION
KEEP OUT OF REACH OF
CHILDREN**

EPA REGISTRATION NO. 53871-6
EPA ESTABLISHMENT NO. 53871-AZ-1

NET CONTENTS: 1 QUART

LOT#
USE BEFORE:

MFG. BY:

FERMONE CORPORATION, INC.
2620 N. 37TH DRIVE
PHOENIX, AZ 85009

(602)-233-9047

LARVO-BT is a registered trademark
of Fermone Corporation, Inc.

BEST AVAILABLE COPY

Fermone Corporation, Inc. warrants that this product (1) conforms to the ingredient statement on the label and (2) is reasonably fit for the purposes set forth in the Directions for Use. Except as so warranted the product is sold as is. Fermone Corporation, Inc. makes no warranty express or implied.

DIRECTIONS FOR USE

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

Larvo-Bt is a biological insecticide for the control of certain lepidopterous larvae (caterpillars or worms). Treated larvae usually stop eating within hours of ingestion and die within 1-5 days. Best control is obtained when larvae are small and actively feeding. Thorough and uniform spray coverage will improve control. For aerial applications, apply in 2-10 gallons of water per acre.

Repeat applications every 3-10 days, depending on the insect population and severity of infestation. Use the higher label rates and shorter spray intervals under heavy pest population pressure.

Larvo-Bt may be used with approved spreader-stickers or in combination with certain chemical insecticides at reduced rates. Consult State Agricultural Extension or Experiment Station Specialists for specific local recommendations for mixtures with other pesticides.

Do not use mixtures unless officially recommended and endorsed by State Agricultural Specialists or Extension Specialists.

Larvo-Bt is exempt from tolerance requirements and may be applied up to the day of harvest. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

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

DIRECTIONS FOR USE (CONTINUED)

BEST AVAILABLE COPY

CROPS	INSECTS	RATE	
		l. oz. per acre	l. oz. per 100 gals
VEGETABLES, including leafy, root, stalk, seed, and pod type, such as: beans, beets, broccoli, brussels sprouts, cabbage, carrots, cauliflower, celery, chard, chinese cabbage, cole crops, cucurbits, endives, escarole, eggplant, kale, kohlrabi, lentils, lettuce, mint, mustard greens, onions, parsley, peas, peppers, tomatoes, turnips, turnip greens, melons, watermelons.	armyworm,	2-4½	
	bollworm,	2	
	corn earworm,	2	
	diamondback moth,	2	
	green cloverworm,	2	
	hornworm,	2	
	imported cabbageworm,	2	
	looper,	2	
	melonworm,	2	
	rindworm,	2	
	pickleworm,	2	
	saltmarsh caterpillar,	2	
	tobacco budworm,	2	
	tomato fruitworm,	2	
	variegated cutworm, webworm.	2	
SMALL FRUITS, GRAPES, BERRIES, STRAWBERRIES, POME & STONE FRUIT, NUTTREES, CITRUS, TROPICAL FRUITS.	gypsy moth,	2-4½	
	cankerworm,	2	
	fall webworm,	2	
	fruitworm,	2	
	hornworm,	2	
	leafroller,	2	
	leafroller,	2	
	looper,	2	
	orangedog,	2	
	redhumped caterpillar,	2	
	saltmarsh caterpillar,	2	
	skeletonizer,	2	
	tent caterpillar,	2	
	tufted apple budmoth,	2	
	walnut caterpillar.	2	

CROPS	INSECTS
ROW CROPS such as: cotton, peanuts, soybeans, safflower, sunflower, sugarbeets, tobacco.	armyworm, cotton bollworm, green cloverworm, hornworm, looper, saltmarsh caterpillar, tobacco budworm, velvetbean caterpillar.
SMALL GRAINS, FORAGE CROPS, ALFALFA, HAY, PASTURE, RANGELAND, TURF.	sod webworm, alfalfa caterpillar, looper, rangeland caterpillar, skipper.
ORNAMENTALS, GREENHOUSE PLANTS, SHADE TREES, FOREST.	armyworm, gypsy moth, spruce budworm bagworm, budworm, cankerworm, diamondback moth, hornworm, leafroller, looper, oakworm, oleanderworm, spanworm, redhumped caterpillar, saddleback caterpillar, tent caterpillar, tussock moth.
STORED PRODUCTS grains, legumes, peanuts, oilseeds, other seeds.	indian meal moth, almond moth, mediterranean flour moth.
Apply at a rate of 1 gallon of spray per 15 bushels of grain 1 gallon of spray per 50 sq. ft. if treating 4-6 inches of surface	