UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 55947-59

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APR 1 3 1994

D.D. Hardee Laboratory Director USDA, ARS, JWDSRC, SIML P.O. Box 346 Stoneville, MS- 38776

Subject: Alternate Formulation for ELCAR Biological Insecticide

Sandoz Agro, Inc., EPA Reg. No. 55947-59

Application dated 2/15/94

Dear Mr. Hardee:

The application for an alternate formulation (liquid formulation of the Sandoz Agro, Inc. wettable powder formulation) for the product referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable with comments as stated below.

- I. Please modify your label to include the following:
- a. Revise the active ingredient statement to read.. "Polyhedral Inclusion Bodies of the Nuclear Polyhedrosis Virus of Heliothis zea"
- b. Under the signal word Caution, add the heading Statement of Practical Treatment and the following phrase. "In case of contact with eyes flush with plenty of water for atleast 15 minutes. If on skin, was thoroughly with soap and water".
- c. Delete the heading "Hazards to Humans" from the label.
- d. Add the heading "Precautionary Statements:" Hazards to Humans and Domestic Animals" to the label placing it in front of the statement 'causes moderate eye irritation'.
- e. Add the word "skin" to the statement 'Avoid contact with eyes or clothing'.
- f. Add the heading "Environmental Hazards" to the label and the following statement "Do not contaminate water when disposing of equipment washwaters".

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ELCAR page 2

- Add the following to the end of your Storage statement. "Use g. this product within a 24 hr period after storage removal. Discard any unused material after the initial 24 hr storage removal. (Product may be re-refrigerated if not used within the initial 24 hr period)".
- Submit five copies of your labeling incorporating these modifications, and a hard copy of your confidential statement of formula.

If you have any questions regarding this matter, feel free to contact Linda Hollis of my team at (703) 305-6397.

Sincerely,

Phil Hutton, PM 18

Phil Kather

Insecticide/Rodenticide Branch Registration Division 7505C

cc: F. Piszkiewicz Sandoz Agro, Inc.

M. Randy Bell

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EPA Form 1320-1A (1/90)

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ELCAR® BIOLOGICAL INSECTICIDE

FOR USE AGAINST:

Heliothis zea:

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Cotton Bollworm, Tomato Fruitworm, Soybean Podworm,

Sorghum Headworm, Corn Earworm

Heliothis virescens:

Tobacco Budworm

ACTIVE INGREDIENT:

Nuclear Polyhedrosis Virus of Heliothis zea* 0.25%

INERT INGREDIENTS: 99.75%

TOTAL

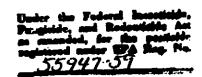
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KEEP OUT OF REACH OF CHILDREN

CAUTION

HAZARDS TO HUMANS

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

EPA Reg. No. 55947-59 EPA Est. No. 55947-CA-2

Net Contents: 5.0 Gallons

20 lb.

SANDOZ AGRO, INC. DES PLAINES, IL 60018

^{*}Contains at least 75 billion Polyhedral Inclusion Bodies per fluid ounce of product.

DIRECTIONS FOR USE

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

GENERAL:

Apply at first sign of newly hatched worms and repeat as long as egg disposition continues at 3-7 day intervals to suppress the <u>Heliothis zea</u> and <u>Heliothis virescens</u> populations. Thorough even coverage is essential.

Do not apply this product through any type of irrigation system.

MIXING:

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ELCAR® Microbial Insecticide is an aqueous suspension which needs to be mixed with water. It is applied as a foliar spray. Place recommended quantity in spray tank for dilution. Maintain agitation while mixing and spraying. Do not allow diluted sprays to stand in the tank for more than 12 hours.

APPLICATION

Use recommended amounts in 1 quart to 20 gallons of water or water-spray adjuvant mixture per acre in a properly calibrated air or ground sprayer. Stickers may be added when anticipating heavy dews or rains. Spray tank mixture should be approximately between pH 6-9.

RECOMMENDATIONS

CROPS	PESTS	RATE PER ACRE
Cotton, Sorghum, Soybeans Tomatoes, Corn, Tobacco, Peanuts, Lettuce, Strawberries, Beans, Wild Geraniums, Wild Clover	<u>Heliothis</u> zea <u>Heliothis</u> <u>virescens</u>	3-6 fl. oz.
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TANK MIX COMBINATIONS

CROP	PESTS	INSECTICIDE	RATE PER ACRE
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All crops listed above	Heliothis zea Heliothis virescens	ELCAR® + THURICIDE® HPC or THURICIDE® HPWP or JAVELIN® WG	3-6 fl. oz. + 1 pt 1 qt. or 1/4 - 1/2 lb. or 1/4 - 1 lb.

Use ELCAR® in combination with THURICIDE® and JAVELIN® WG for an increased larvicidal effect. Use the low rate combination for suppression of light infestations and use the high rate combination for suppression of moderate infestations. Apply

at first sign of newly hatched worms and repeat as long as egg deposition continues at 3-7 day intervals.

STORAGE AND DISPOSAL

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

STORAGE:

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Store under refrigeration of in freezer. Activity may be impaired by storage at temperatures above 40° F.

PESTICIDE DISPOSAL:

Pesticide, spray mixture or rinse water than cannot be used according to label instructions must be disposed of according to federal, state, or local procedures.

CONTAINER DISPOSAL:

Completely empty container and rinse water into application equipment then dispose of empty container in a sanitary landfill or as directed by state and local authorities.

AGRICULTURAL PESTICIDE GENERIC SUPPLEMENTAL LABELING For compliance with the Worker Protection Standard (40 CFR part 170)

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When this product is used on an agricultural establishment (farm, forest, nursery, or greenhouse) for the commercial or research production of agricultural plants, users must comply with the instructions in this supplemental labeling. Users who must comply with these instructions include owners/operators of the agricultural establishment and owners/operators of commercial businesses that are hired to apply penticides on the agricultural establishment or to perform erop-advising tanks on such establishments. Failure to comply with the requirements on this supplemental labeling and with the Worker Protection Standard (40 CFR part 170) is a violation of Federal law, since it is illegal to use a pesticide product in a manner inconsistant with its labeling.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR 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 in this labeling about personal protective acuirement, restricted-entry intervals, and notification to workers. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard (WPS).

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.

Entry-Restrictions: Do not enter or allow worker entry during the restricted-entry interval (REI). The restricted-entry interval for this product is:

- the specific number of hours or days (if any) listed elsewhere on the product labeling as the reentry interval or entry restriction for the crop or site, if 12 hours or more;
- 12 hours, if no specific number of hours or days is listed elsewhere on the product labeling as the reentry interval or entry restriction for the crop or site;

The restricted-entry interval for this product must be at least 12 hours.

Notification Instructions: Follow the rules in the WPS for notifying workers of the application. Exception: If the manufaction about notification (if any) listed elsewhere on the product labeling require posting of treated areas (rather than offering a choice), you must notify workers of the application by warning them orally AND by posting signs at entrances to the contract areas, following the rules in the WPS.

Port and Prefective Equipment (PPE) Requirements:

- Handler PPE: Pesticide handlers must wear the PPE listed elsewhere in the product labeling for applicators. If specific PPE is required elsewhere on the product label for specific handling tasks (such as mixing or loading), it must be worn while performing such tasks. In any case, any handler using this product must wear no less than: long-sleeved shirt, long pants, shoes, socks, and chemical-resistant or waterproof gloves.
- Early Entry PPE: PPE required for early entry to treated areas that is permitted under the Worker Projection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is the same PPE as required alsowhere on this product label for applicators, except that any respirator requirement is waived. In any case, the minimum PPE required for any early entry worker exposed to this product is no less than: coveralls, shoes, socks, and chemical-resistant or waterproof gloves.

Conflicting Instructions: If the requirements of the WPS conflict with instructions listed elsewhere on this product label, users must obey the more protective requirements.

U.S. ENVIRONMENTAL PROTECTION AGENCY

AUGUST, 1993