UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Delta Biological Products, Inc. c/o Dr. Gene Bellet 7270 West 98th Terrace, Suite 100 Overland Park, Kansas 66212

> Subject: Alternate Formulation Request Dated 5/12/92, Revised Alternate Formulation Request Dated 1/7/93, and Labeling Date Punched 5/28/92 EPA File Number: 43:67-1

Dear Dr. Bellet:

The alternate formulation amendment (Confidential Statement of Formula (CSF) dated 5/22/92) submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is not acceptable because one of the inert ingredients in the formulation, p-Aminobenzoic Acid, is not cleared for food use. The revised alternate formulation (CSF dated 1/7/93) removing p-Amincbenzoic Acid and replacing it with Polyfon O is acceptable provided that you:

- Submit/cite all data required for 1. registration/reregistration of your product under FIFRA 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - The front page of the 8.5" by 11" label page a. represents the front panel. On the front panel of your pesticide, the EPA Registration and Establishment Numbers should appear between the Name and Address of the Manufacturer and the Net Contents Statement (#4 and #5 on the enclosed sample format for an Unrestricted Use Product Label).

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EPA Form 1320-14 (1/90)			Printed on Remain			OFFICI	AL FILE COPY

- c. The third page of the 8.5" by 11" label page represents the right panel. On your third page, the following statement must be removed, "Delta Bt does not harm Honeybees or other beneficial or predaceous insects."
- d. Remove all stored product uses from your label; the revised alternate formulation dated 1/7/93 contains Morwet D-425 which is exempt from the requirement of a tolerance when used in accordance with good agricultural practice as an inert ingredient in a pesticide formulation applied to growing crops only (40 CFR 180.1001(d)).

 Morwet D-425 is not cleared for after harvest use (40 CFR 180.1001(c)).
- With regard to tank mixing your product with e. another pesticide, bring your label into compliance with Pesticide Registration Notice 82-1 (copy enclosed). Replace your statement "Delta Bt may be tank mixed with other labelled insecticides to enhance control when mixed or overlapping generations of larvae are present. Check tank mix compatibility of Delta Bt and other insecticide before tank mixing." with "This product can be mixed with

including percentage of active ingredient and type of formulation, or specific product name, or both) for use on ________(crops/sites) in accordance with the wore (most) 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."

Delete "For additional control, tank mix Delta BT with a labelled ovicide or other labelled products such as pyrethroids, carbamates, organophosphates in accordance with labelling recommendations."

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3. Because your present EPA accepted label dated June 4, 1992 has after harvest crop uses, the alternate formulation dated 1/7/93 cannot be used in conjunction with this label. Delta Biologicals may use its supply of printed labeling with its original formulation (CSF dated 1/21/93) for a period of one year, not to exceed January 25, 1994.

After January 25, 1994, all labeling must represent the enclosed stamped EPA accepted labeling with all comments incorporated (dated 1/25/93). If Delta Biological wishes to market the alternate formulation (CSF dated 1/7/93), only the enclosed stamped EPA accepted labeling incorporating all of the above comments can accompany it. Submit five (5) copies of this final printed labeling before releasing the alternate formulation 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.

Stamped copies of the labers (1 Gallon and 1 Quart) are enclosed for your records.

Sincerely,

Phil Hutton

Product Manager (18)

Insecticide-Rodenticide Branch

Registration Division

Office of Pesticide Programs

Enclosures:

- * Labels (2)
- * A-79
- * Sample Label Format
- * PR Notice 82-1

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DELTA BT

DELTA BT-BIOLOGICAL INSECTICIDE

ACTIVE INGREDIENTS:

Bacillus thuringiensis, subspecies <u>kurstaki</u>
Lepidopteran active toxin 26.4%

INERT INGREDIENTS:

73.63

EPA REGISTRATION NO. 43567-1 EPA ESTABLISHMENT NO. 43567-LA-01

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT:

If swallowed: Induce vomiting and call a physician.

If on skin: Wash thoroughly with soap and water.

If in eyes: Hold eyelids open and flush with copius amounts of clean water for 10-15 minutes.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS: Avoid inhalation or contact with eyes. Avoid breathing spray mist.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters. :...

SHAKE WELL BEFORE USEG

MANUFACTURED BY:
Delta Biological Products, Inc.
Rt. 1, Box 639, Airport Road
Bascop, La. 71220
NET CONTENTS:

NET CONTENTS

1 Quart

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BEST AVAILABLE COPT

ACCEPTED
with COMMENTS
in EPA Letter Dated

JAN 25 1993

Under the Pederal Insentition Funglation and Rederateds And to assessed, for the postable registered under EPA Reg. No. 43567-1

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool place. Do not allow spray solution to stand more than 12 hours before use. Do not use or store near heat and/or open flame.

PESTICIDE DISPOSAL: Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent), adding rinsate to spray tank. Offer rinsed containers 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. Do not reuse container.

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Delta BT is a highly selective, highly concentrated biological insecticide for use against larvae (caterpillars or worms) of lepidopterous insects. Delta BT must be eaten by the targeted larvae to be effective. Once a lethal dose is ingested, Delta BT paralyses the midgut of the larvae. Usually within 1 hour the larvae stop feeding, thus crop damage is halted. Affected larvae move slowly, discolor, shrivel, darken and die from starvation within several days.

Larvae must be actively feeding on treated, exposed plant parts. Complete coverage of plant foliage where larvae are feeding is essential for effective pest control. A suitable spreader sticker, cleared for use on growing and harvested crops, may be added to increase spray coverage, uniform deposition, and adherance. Treat when larvae are young (1st and 2nd instars) before crop is Monitoring insect infestation by close. extensively damaged. scouting and 'early attention to infestation is highly recommended. . For heavy infestation and mature worms, use the higher label rates. Re-treat at intervals necessary to maintain control, usually 3-14 ·· days depending on factors such as plant growth rate, rainfall after treatment, and moth activity. Delta BT may be tank mixed: with " other labelled insecticides to enhance control when mixed or Check tank mix overlapping generations of larvae are present. compatibility of Delta BT and other insecticide before tank mixing.

Delta BT does not harm Honeybees or other beneficial or predaceous insects.

DIRECTIONS FOR USE:

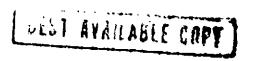
It is a violation of federal law to apply this product in a manner inconsistent with its labelling.

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

Delta Bt may be applied up to the day of harvest.

Delta BT may be applied by aerial equipment or conventional ground equipment with quantities of water necessary to ensure complete, uniform coverage of infested plant foliage. Apply Delta BT, in, at least 1 to 10 gallons of total spray volume per acre by air and in at least 10 to 20 gallons of total spray volume per acre by ground. Higher spray volumes increase coverage. Ground application on trees should be made with 100 to 400 gallons of spray volume. Add Delta BT to agitated spray solution. Agitate tank mixes thoroughly and continuously.

Do not mix more Delta BT than can be used in a 12 hour period.



The following pests may be treated with Delta BT. Complete coverage of plants and trees is essential for effective control of the following pest:

CROP

PEST

RATE (fl.os. per acre)

2.5-4

Cotton, tobacco, peanuts, safflower, soybeans, sunflower, sugarbeets, rice Cotton bollworm, tobacco budworm, cabbage looper, armyworm, green cloverworm, hornworm, saltmarsh caterpillar, velvetbean caterpillar, soybean looper

- NOTE: For heavy infestations and mature worms use up to 4.0 fl. oz. per acre (1 gal. per 32 acres).
 - For additional control, tank mix Delta BT with a labelled ovicide or other labelled products such as pyrethroids, carbamates, organophosphates in accordance with labelling recommendations.

Vegetables:

beans, broccoli, ca

brussel sprouts, mo

cabbage, cauliflower, c¹

celery, cucumbers, ri

lettuce, mustard sa

greens, melons, va

potatoes, spinach, we

tomatoes, turnip

greens, beets, carrots,

chard, chinese cabbage,

cole crops, cucurbits,

endives, escarole,

eggplant, kale, kohlrabi,

lentils, mint, onions,

parsley, peas, peppers, turnips, watermelons

Carbage looper, imported cabbage worm, diamondback moth, corn earworm, green cloverworm, melonworm, rindworm, pickleworm, saltmarsh caterpillar, variegated cutworm, webworm.

NOTE: - For heavy infestations and mature worms use up to 4 fl. oz. per acre (1 gallon per 32 acres).

- For additional control, tank mix Delta BT with a labelled ovicide or other labelled products such as pyrethroids, carbamates, organophosphates in accordance with labelling recommendations.

2.5-4

For hand held sprayers used to treat vegetables use: ½ fl. oz. or approximately 15 milliliters of Delta BT in a gallon of water.

Greenhouse flowers, ornamentals, plants, shade trees, forests Cabbage loopers, omniverous looper, bagworm, cankerworm, oakworm, oleanderworm, spanworm, saddleback caterpillar, tussock moth, armyworm, gypsy moth, spruce budworm, bedworm, diamondback moth, hornworm, leafroller, red-humped caterpillar, tent caterpillar

- NOTE: For heavy infestations and mature worms use up to 4 fl. oz. per acre (1 gallon per 32 acres).
 - For hand held sprayers used to treat vegetables use: ½ fl. oz. or approximately 15 milliliters of Delta BT in a gallon of water:

Rangeland,
Pastureland
pasture, hay, small
grains, forage crops,
rangeland, alfalfa,
turf

European skipper, rangeland caterpillar, fall armyworm, sod webworm alfalfa caterpillar, looper

2.5-4

2.5 - 4

NOTE: - For heavy infestations and mature worms use up to 4 : fl. oz. per acre (1 gallon per 32 acres).

Orchards, fruit trees, forestland timber, pecan, walnut, almond, apple, orange, shade trees, spruce, grapes, berries, strawberries, pome, stone fruit, tropical fruits

Fall webworm, rechumped caterpillar, tent caterpillar, leaf roller, orangedog, fruit-tree leafroller, eastern spruce budworm, gypsy moth, bagworm, cankerworm, fruitworm, hornworm, leaffolder, saltmarsh caterpillar, skeletonizer, tuffed apple bedmoth, walnut caterpillar

- **MOTE:** For heavy infestations and mature worms use up to 4 fl. oz. per acre (1 gallon per 32 acres).
 - For hand held sprayers used to treat vegetables use: 1/2 fl. oz. or approximately 15 milliliters of Delta BT in a gallon of water.
 - Trees should be sprayed using high volumes of water to provide uniform coverage.

Stored products grains, legumes, peanuts, oilseeds, other seeds

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Indian mealmoth, almond moth, mediterranean flour moth

21 fl. oz. per 100 gallon

NOTE: - For heavy infestations and mature worms use up to 4 fl. oz. per acre (1 gallon per 32 acres).

WARRANTY

Delta Biological Products, Inc. makes no warranty, expressed or implied, concerning this material except those which are contained on this label.