

JUN - 4 2003

Joseph A. Conti
Director, Regulatory Affairs
Bayer Environmental Science
95 Chestnut Ridge Road
Montvale, NJ 07645

Subject: Amendment - Label Revisions/Fenthion Cancellation
Baytex Liquid Concentrate Insecticide
EPA Registration No. 432-1285
Your submission dated March 31, 2003

Dear Mr. Conti:

The Agency has received your request for amended registration and accepts the following terms and conditions for conditional registration under Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

1. You requested a voluntary cancellation for this registration on March 31, 2003. A notice will issue in the Federal Register shortly announcing the receipt of your request. The notice provides for a 60-day comment period. Following the comment period, the Agency will determine whether to grant or deny your request. If the Agency grants the voluntary cancellation request, EPA intends to issue the cancellation order with an effective date of June 30, 2004.
2. If a cancellation order issues, the order will contain a provision to allow Bayer to accept returns of all unopened material until December 31, 2004.
3. As of the effective date of this amended registration, all pesticide product released for shipment must be labeled in accordance with the terms and conditions set forth in this amended registration.
4. No later than 30 days from the effective date of the approval of the amended label, all pesticide product in the possession of distributors or users must be relabeled in accordance with the terms and conditions set forth in this amended registration.
5. All relabeling must occur within a registered establishment or the registrant must receive approval from EPA's Office of Enforcement and Compliance Assurance to deviate from this requirement.

6. Bayer Environmental Science will have the right as the exclusive data submitter to grant access to their existing data package, in the event a follow-on registrant is willing to perform required data.
7. The amended labeling for Fenthion must contain the following language: "Use of this product is prohibited after November 30, 2004."
8. In addition to the above agreed upon conditions the Agency is requesting the following label changes (**Bold indicates new language**)
 - a. As communicated to Bayer Environmental Science, because of our concerns with potential exposure to non-target organisms, the amended labeling for Fenthion must contain the following language "Do not apply Baytex over the same area more than once every seven(7) days."
 - b. Under the Protective Clothing statements, revise the last two sentences of the first paragraph to read "... approval number 14 **G** or a **NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE prefilter.** For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a **NIOSH approved respirator with any R, P, or HE filter.**" This will be consistent with PR Notice 98-9.
 - c. In the Environmental Hazards statement, revise the third sentence to read "...if permits are required or regulatory mandates exist." Also, move this statement to the Directions for Use section beneath the misuse statement.
 - d. Under the MIXING FOR ULV APPLICATIONS section, delete the redundant statements "Correct droplet size includes.....verified annually." These statements already appear under the AIRCRAFT APPLICATION section. In this same section, move the GPS requirement to the AIRCRAFT APPLICATION section, since it doesn't apply to ground application.
 - e. Under the RESTRICTIONS section, replace Use Restriction 11 with: "This product may only be applied at rates between 0.05 lb ai/A and 0.1 lb ai/A when a threat to public or animal health has been declared by State officials or if specifically approved by the State for mosquito control during a natural disaster recovery effort."
 - f. Under the ULTRA LOW VOLUME SPRAY directions replace the parenthetical (0.05 to 0.1 lb. active ingredient) with (See Use Restrictions II).
 - g. Under AIRCRAFT APPLICATION, Thermal Fog, specify the unit dose of application, i.e., "Baytex L.C. (fl oz) 0.4".

- h. Under the heading DIRECTIONS FOR USE, add the phrase "Restricted Use Pesticide."
- i. Under "Caution - Special Instructions," the statement beginning "Vehicles used to apply Baytex ..." should be listed as item 3.
- j. Change "Caution" to "Warning" or "Note" on page 5.
- k. Under Aircraft Application change 80MMD to 80 microns on pg 4 and revise the beginning of the second sentence on pg 5 to read "No more than 5 % of the droplets may be larger than 80 microns, as determined xxxx etc".
- l. Under "Thermal Fog" delete "Repeat applications as necessary".
- m. Under Environmental Hazards revise critical habitat to "Federally Designated Critical Habitat".

If you fail to satisfy any of the terms or conditions imposed by this registration EPA may issue a notice of intent to cancel the registration under FIFRA Sect 6(e). Your release for shipment of the product constitutes acceptance of these conditions. Submit three copies of the revised final printed label for the record. A stamped copy of the label is enclosed for your records. If you have any questions in regard to this letter please feel free to call me at 703/305-6100.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

RESTRICTED USE PESTICIDE

Due to High Toxicity to Fish and Very High Toxicity to Birds and Aquatic Invertebrates For application by, or under the supervision of, personnel certified in public health pest control or mosquito control. Certified applicators must also insure that all persons involved in these activities are informed of the Precautionary Statements and limitations of the product as described in the label text. For each application, a record must be kept of: date, time and areas where applications occurred; type and size of spray nozzle used; dilution and application rate; speed of application vehicle (whether air or ground); insecticide delivery system (i.e., line size, filters, pumps); climate factors (e.g., ambient temperature, wind speed/direction) at or close to ground level (6 feet) as determined using the most reliable means possible; and employees involved in mixing, loading and applying fenthion. These records must be kept by the mosquito control district for a minimum of two years using storage methods that allow the records to be easily retrieved.

**BAYTEX®
Liquid Concentrate Insecticide**

For adult mosquito control in Florida only. Consult with the Florida Department of Agriculture and Consumer Services before applying this product. For effective control of adult mosquitoes.

Use of this product is prohibited after November 30, 2004.

ACTIVE INGREDIENT:

Fenthion, O,O-Dimethyl O-(3-methyl-4-(methylthio)phenyl)phosphorothioate... 95%

INERT INGREDIENTS: 5%

..... 100%

Do not store below 45°F. Keep in a cool, dry place.

One gallon contains 9.67 pounds O,O-Dimethyl O-[3-methyl-4-(methylthio)phenyl] phosphorothioate.

EPA Reg. No. 432-1285

NET CONTENTS: ____ Gallons

STOP – Read the label before use

Keep out of reach of children.

WARNING AVISO

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

- If Swallowed
 - Call a poison control center or doctor immediately for treatment advice.
 - Have person sip a glass of water if able to swallow.
 - Do not induce vomiting unless told to by a poison control center or doctor.
 - Do not give anything to an unconscious person.
- If on Skin or Clothing
 - Take off contaminated clothing.
 - Rinse skin immediately with plenty of water for 15 to 20 minutes.
 - Call a poison control center or doctor for treatment advice.

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUN - 4 2003

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

432-1285

- If Inhaled
 - Move person to fresh air.
 - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice.
- If in Eyes:
 - Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 - Call a poison control center for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. The Emergency Response Telephone No. is 800-228-5635. Note to Physician: Fenthion is an organophosphate insecticide. If symptoms of cholinesterase inhibition are present, atropine sulfate by injection is antidotal. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: May be fatal if swallowed, inhaled, or absorbed through skin. Rapidly absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear protective clothing and waterproof gloves. Wear mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and National Institute for Occupational Safety and Health. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.

Any worker displaying clinical signs of cholinesterase-inhibition, such as headaches, nausea, and dizziness must have an immediate physical examination and appropriate cholinesterase measurements be taken within two hours of complaint. If initial examination was not conducted by a board-certified person who is certified in occupational health, then a separate examination must be conducted within 24 hours by a person so certified.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish and very highly toxic to birds and aquatic invertebrates.

Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Before making the first application in a season, consult with the primary State agency responsible for regulating the use of pesticides to determine permits are required or regulatory mandates exist. Do not apply directly to water (e.g., lakes, swamps, rivers, permanent streams, natural ponds, marches or estuaries), except to target areas where mosquitoes may rest. Do not contaminate untreated water when cleaning or disposing of equipment washwaters or rinsate.

Do not apply BAYTEX directly over or upwind from critical habitat for threatened and endangered avian species.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product over or allow it to drift to blooming crops or weeds while bees are visiting the treatment area.

PROTECTIVE CLOTHING STATEMENTS

WEAR THE FOLLOWING PERSONAL PROTECTIVE EQUIPMENT DURING MIXING/LOADING AND CLEANING OF APPLICATION EQUIPMENT:

Protective suit of one or two pieces that covers all parts of the body except head, hands, and feet; chemical-resistant gloves; chemical resistant shoes (or chemical-resistant shoe coverings or chemical-resistant boots); and a NIOSH or MSHA approved respiratory protection device. In addition, mixers/loaders must wear a chemical resistant apron.

During equipment cleaning, the respirator need not be worn.

For handling activities during aircraft or ground application, wear either a respirator with an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH) approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C).

IF MIXING/LOADING IS PERFORMED USING A CLOSED SYSTEM, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: Long-sleeve shirt, long-legged pants; chemical resistant gloves; chemical-resistant apron, shoes and socks. Goggles or face shield must be worn when the system is under pressure. All other protective clothing and equipment required for use with open systems must be available nearby.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, PROTECTIVE CLOTHING AND EQUIPMENT IS OPTIONAL WHEN IN THE CAB. Protective clothing (as described in the first paragraph of this section dealing with PROTECTIVE CLOTHING AND WORK SAFETY STATEMENTS") is required for the spray operator if leaving the cab or cockpit to repair or clean the equipment. Contaminated clothing must not be returned to the cab or cockpit unless an air tight container is used.

IMPORTANT! If BAYTEX LC comes in contact with skin, wash off with soap and water and get medical attention.

Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or using the toilet.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes.

Shower using soap and water. Wear clean clothes. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Clothing that becomes heavily contaminated or drenched with BAYTEX LC must be destroyed according to State and local regulations. **HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.**

DIRECTIONS FOR USE

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

Precise application of BAYTEX is critical to avoid harming humans and wildlife. Avoid contamination of feed or food. Any system used to apply this product must be capable of

providing the correct droplet size as specified below. Likewise, all applications must use the correct droplet size as specified below. Careful attention to directions concerning nozzles, nozzle positioning, air speed and droplet size is essential to avoid unwanted effects. Under-atomization produces large particles that will quickly fall to the ground and create a hazard to non-target organisms, while over atomization produces finer particles which either evaporate or dissipate.

Correct particle size is critical to ensure effective mosquito control.

The entire spray system must be inspected before each operation to correct any leaks or obstructions, to detect whether the nozzle, hoses, or other parts are worn and need replacement, to ensure that the flow is properly calibrated and to determine that adequate pressure is being maintained. Adequate cleaning and maintenance of unit must be performed to ensure that the entire system is operating properly. When using rotary atomizers, sleeves and filters must be changed with each application. Other spray system components essential for correct droplet size must be cleaned or replaced as needed to ensure correct droplet size. Detailed maintenance records must be kept for all equipment. Spray only when wind speed is between 3 and 15 mph at or within 12 feet of ground level. Under calm conditions significant amounts of applied material may fall to the ground, becoming unavailable for mosquito contact and increasing the exposure to non-target organisms.

MIXING FOR ULV APPLICATIONS: BAYTEX Liquid Concentrate contains no emulsifying agent and should be applied with Ultra Low Volume equipment capable of accurately and uniformly applying the designated amount of BAYTEX Liquid Concentrate per acre. (See NOTE).

Correct droplet size includes a range between 10 microns to 30 microns as determined by volume median diameter (VMD). No more than 5% of the droplets should be larger than 50 microns, as determined by readings from microscopic slides or other scientifically verified technique. The size of at least 200 droplets must be measured. The readings must be verified annually.

After June 30, 2004, aircraft applying fenthion must be equipped with global positioning guidance systems that monitor/record precise location of applications.

**APPLICATION RATES - Mosquitoes (Adults Only)
(Florida Only)**

	BAYTEX L.C.
	(fl oz)
AIRCRAFT APPLICATION	0.66 to 1.4

ULTRA LOW VOLUME SPRAY: For control of mosquito adults, BAYTEX Liquid Concentrate may be applied undiluted in any aircraft equipment that has been adapted and calibrated for applying ultra low volumes of spray material. Apply specified dosage (0.05 to 0.1 lb active ingredient) per acre using the liquid concentrate in undiluted form with aircraft equipment capable of applying the proper volume per acre.

Use lower rate when applying to open non-canopied areas; use higher rate when applications are made in areas having a vegetation canopy.

No more than 5% of the droplets should exceed 80 MMD.

8/10

Correct droplet size includes a range between 10 microns to 30 microns as determined by volume median diameter (VMD). No more than 5% of the volume may be larger than 50 microns, as determined by readings from microscopic slides or other scientifically verified technique. The size of at least 200 droplets must be measured. The readings must be verified annually.

AIRCRAFT APPLICATION

0.4

THERMAL FOG: For control of mosquito adults apply specified dosage (0.03 lb active ingredient) per acre using the product mixed in 0.2 to 0.8 quarts of oil per acre. Apply as a thermal fog by injecting solution into FAA approved engine exhaust system. Repeat applications as necessary.

**APPLICATION RATES - Mosquitoes (Adults Only)
(Florida Only)**

GROUND APPLICATION

Ground ULV Concentrate Application: Applications may be made in residential areas, municipalities, tidal marshes, swamps and woodlands. Do not apply to any agricultural crops. Apply undiluted BAYTEX Liquid Concentrate at the rate of 1.2 fluid ounce/minute at 5 mph; 2.4 fluid ounce/minute at 10 mph and 3.6 fluid ounce/minute at 15 mph; applying a 300-foot swath. These flow rates are equivalent to 0.03 pounds active ingredient per acre.

CAUTION - SPECIAL INSTRUCTIONS: This application can be made only under the following conditions:

(1) Application in calm air conditions is to be avoided. (2) Application is not to be made in the immediate vicinity of pedestrians. See NOTE.

NOTE: Maximum effect is produced by particles 10-20 microns in size. Volume Median Diameter (VMD) of the droplets produced may not exceed 17 microns and no droplet may be larger than 40 microns, as determined by readings from microscopic slides or other scientifically verifiable technique. Regardless of the method used to collect drops, the size of at least 200 droplets must be measured. These readings must be verified annually. Droplets 45 microns or larger may cause permanent damage to automobile paint finishes.

Vehicles used to apply BAYTEX must be air-conditioned and equipped with an automatic flow control device.

RESTRICTIONS

1. Do not apply over food crops, forage crops or rice.
2. Do not use inside homes or in buildings where food is processed or stored.
3. Do not apply directly to animals.
4. Do not apply when it is raining in the treatment area.
5. Do not use on or allow spray treatment to drift onto potable water supplies. Do not contaminate feed, drinking water, milk or milk-handling equipment.
6. Do not apply this product through any type of irrigation system.
7. Do not apply above a temperature inversion.
8. Apply during early morning or late evening.

- 9/10
9. Do not apply Baytex over the same area more than once every 4 days.
 10. Human flagging is prohibited.
 11. This product may only be applied at a rate below 0.05 lbs/acre under normal conditions. Rates up to 0.1 lbs/acre may be used during periods when there are threats to public and animal health or State declared emergency or disaster recovery.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

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: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material is spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides above. In spill or leak incidents keep unauthorized people away. You may contact the Bayer Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Emergency Response Telephone Number is 800-334-7577, or contact Chemtrec at 800-424-9300.

IMPORTANT: Read these entire Directions and Conditions of Sale before using BAYTEX Liquid Concentrate.

CONDITIONS OF SALE: THE DIRECTIONS ON THIS LABEL WERE DETERMINED THROUGH RESEARCH TO BE THE DIRECTIONS FOR CORRECT USE OF THIS PRODUCT. THIS PRODUCT HAS BEEN TESTED FOR A RANGE OF WEATHER CONDITIONS SIMILAR TO THOSE WEATHER CONDITIONS THAT ARE ORDINARY AND CUSTOMARY IN THE GEOGRAPHIC AREA WHERE THE PRODUCT IS USED. INSUFFICIENT CONTROL OF PESTS AND/OR INJURY TO THE CROP TO WHICH THE PRODUCT IS APPLIED MAY RESULT FROM THE OCCURRENCE OF EXTRAORDINARY OR UNUSUAL WEATHER, OR FROM FAILURE TO FOLLOW LABEL DIRECTIONS.

IN ADDITION, FAILURE TO FOLLOW LABEL DIRECTIONS MAY CAUSE INJURY TO OTHER CROPS, ANIMALS, MAN, OR THE ENVIRONMENT. BAYER OFFERS, AND THE BUYER ACCEPTS AND USES, THIS PRODUCT SUBJECT TO THE CONDITIONS THAT EXTRAORDINARY OR UNUSUAL WEATHER, OR

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**FAILURE TO FOLLOW LABEL DIRECTIONS ARE BEYOND THE CONTROL OF
BAYER AND ARE THEREFORE, THE RESPONSIBILITY OF THE BUYER.**

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