

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Janice K. Sharp, Ph.D. Valent BioSciences Corp. 870 Technology Way, Suite 100 Libertyville, IL 60048

APR 1 4 2005

Dear Dr. Sharp:

Subject: Amendments - Add efficacy claims: and

Revise Basic and Alternate Confidential Statements of Formula

UltraTec 300RTU Insecticide

Additional Brand Name: UltraTec HPC 3 EPA Registration Number 73049-187 Your submission dated October 22, 2004

The amendments referred to above, submitted in connection with registration under with registration under FIFRA section 3(c)(7)(a), are acceptable provided that you:

- 1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)5 or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
- 2. Make the label changes listed below before you release the product for shipment bearing the amended labeling:
- a Regarding the proposed 4 month residual claim against Carpenter Ants, the data cited are not adequate for the support of a 4 month residual claim because the product proved efficacious up to only 1 month when applied to non-porous surfaces (eg., vinyl tile), and there was no residual activity when applied to porous surfaces (eg., concrete block). Therefore, either delete the claim or decrease it to 1 month and the label specifies when applied to non-porous surfaces. To support a 1 month claim when applied to porous surfaces, you must submit or cite corroborative efficacy data showing 30 day residual activity of the subject formulation when applied to unfinished plywood sheeting.
- b. Regarding the proposed 5 month residual claim against house flies, re-evaluation of the referenced data does support this claim and it is acceptable.
- c. Regarding the proposed 4 month residual claim against stable flies, re-evaluation of the referenced data does support this claim and it is acceptable.

- d. Regarding the proposed 3 month residual claim against Pharaoh ants, crazy ants, and fire ants, the claim is not supported by the cited data and is not acceptable. The cited data support only a one week residual claim for these pests. Therefore, either delete the claim or change it to one week. The Agency notes that these pests were not included in the directions for use on the submitted labeling.
- e. Regarding the proposed 4 week residual claim and the controls claim against cat fleas, Ctenocephalides felis, these claims are not acceptable since they are not supported by the cited data, as reflected in the original review and letter to the previous registrant Aventis Environmental Science dated July 17, 2000 [the product then bearing EPA Reg. No. 73049-187]. The Kills claim against fleas without any residual claims may remain on the label. Pursuing the Controls claim against cat fleas or the residual claim will require submitting or citing other data to support these claims.
- f. Regarding the proposed 4 month residual claim against mosquitoes and the claim against mosquitoes that may carry West Nile Virus and Equine Encephalitis, these claims are not acceptable since they are not supported by the cited data. Please note that the referenced study provided data on only one species of mosquito, Anopheles atroparvus (the other "mosquito" species tested, C. lectularius, is in fact the bed bug). The claim for mosquitoes that may carry West Nile Virus and Equine Encephalitis will require citation of supporting data for at least two species of mosquito known to vector the diseases.
- g. Regarding the proposed claim of "Controls ticks that may carry Lyme disease, the submitted data do not support a Controls claim. The claim "Kills Ticks" or "Kills ticks that may transmit Lyme disease".may appear on the label.
- h. In the Directions For Use for Ticks, revise "Ticks (including deer ticks which may carry Lyme Disease)" to read "Ticks (including deer ticks which may transmit Lyme Disease)".
- i. Add the following precaution to the paragraph under the heading Outdoors: "Remove all exposed food and cooking utensils. Cover all food handling surfaces or wash thoroughly after treatment and before use. Do not use on edible crops.".
- j. Revise the first sentence under the heading Crawling Insects to read: "Hold can two (2) to three (3) feet from surface to be treated and spray in infested surface of patio or picnic areas, hitting as many insects as possible. Spray to slightly moisten the surface.".

Please submit four (4) copies of the revised amended label prior to release for shipment. Please note that labeling submitted to the Agency for amendment should bear the master name of record, not an additional brand name. If you wish to change the master name of record for this product to UltraTec HPC 3 please so indicate on your next label submission.

The revised Basic and Alternate Confidential Statements of Formula (CSFs) dated October 22, 2004 are acceptable and have been added to this product's registration file. The new Basic CSF supersedes all previous Basic CSFs for this product.

Sincerely,

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

ACCEPTED with COMMENTS

In EPA Letter Dated:

APR 1 4 2005

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

UltraTec® HPC 3

- | For Indoor And Outdoor Use
- Ready-To-Use
- Easy-To-Use
- Water-Based
- Kills On Contact
- Kills Fast
- · Long-Lasting
- Keeps Killing Ants For Up To 3 Months [12 weeks]
- Keeps Killing Carpenter Ants for ups to 4 Months [16 weeks]
- Keeps Killing Pharaoh ants, crazy ants and fire ants for up to 3 months (12 weeks, 90 days)
- Keeps Killing German cockroaches and fleas for up to 12 months [1 year, 52 weeks]
- Keeps Killing Fleas For Up To 4 12 Months [1 year, 52 weeks]
- Kills Cat Fleas
- Keeps Killing Mosquitoes for up to 4 months [16 weeks, 120 days]
- Keeps Killing Flies For Up To 5 Months [20 weeks]
- Keeps Killing German Cockroaches For Up To 12 Months [1 Year, 52 weeks]
- Odorless
- Non-Staining
- No Oily [Greasy] Residue
- Contains Deltamethrin The Third Generation Pyrethroid
- For Use In And Around Horse Stables
- Keeps Killing Stable Flies for up to 18 weeks [4.5 months, 135 days]
- · For Use On House Plants
- For Use On Ornamental Plants
- Kills Fleas & Ticks
- Kills Home Invading Pests
- Kills Spiders, Centipedes And Scorpions
- Kills Roaches, Ants And Fleas On Contact
- Kills Pantry Pests
- Kills Plant Pests
- Kills Aphids, Mealy Bugs, Lace Bugs, Thrips, Leafminers And Mites
- Kills Spider Mites
- Kills Japanese Beetles
- Also Controls Termites, Carpenter Ants & Carpenter Bees
- Controls ticks that may carry Lyme disease
- Controls Mosquitoes that may carry West Nile Virus and Equine encephalitis]

* Not For Use On Plants Grown For Sale Or Other Commercial Use

ACTIVE INGREDIENT:

PRECAUCION AL USARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicado ampliamente. (TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

EPA REG. NO.: 73049-187

EPA EST. NO.:

KEEP OUT OF REACH OF CHILDREN CAUTION

See Side Panel for Additional Precautions

NET CONTENTS:

In case of Medical emergencies or health and safety inquiries or in case of fire, leaking or damaged containers, information may be obtained by calling 1-877-315-9819.

PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals CAUTION

Contact with product may result in transient tingling and reddening of the skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards

This product is extremely toxic to fish and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when disposing of washwater or rinsate. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Physical or Chemical Hazards

Do not apply this product in or on electrical equipment due to possibility of shock hazard.

DIRECTIONS FOR USE

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

General Information: Hold container upright. Do not spray up into air. Apply to surfaces only as a spot and crack & crevice treatment. [Turn sprayer nozzle to "on" position.] Hold approximately 12 inches from surface to be sprayed. Squeeze trigger to spray until surface is slightly moist but not to the point of runoff. Over application may cause damage. Test in an inconspicuous area before applying.

Do not allow children or pets to contact treated surfaces until spray has dried.

UltraTec HPC's long-lasting action keeps on killing *Fleas* for up to 12 months [1 year] 120 days [16 weeks; 4 months] and *German Cockroaches* for up to 12 months [1 year], *Ants* for up to 90 days [12 weeks; 3 months], *Flies* for up to 150 days [20 weeks; 5 months] after you spray. More frequent applications may be necessary on concrete surfaces. Check these areas in 4 weeks and retreat if insect activity continues. Contact kill gives you immediate results when spraying insects directly, while residual activity kills insects when they return to treated areas. This formulation is non-staining on surfaces where water alone does not stain. However, when treating delicate fabrics or high value items, first test an inconspicuous area and allow to dry.

UltraTec HPC is intended to be used in and around residences and their immediate surroundings such as (but not limited to): apartments, atriums, attics, automobiles, basements, bathrooms, boats, cabins, campers, carports, cat sleeping quarters, clothes storage, condominiums, decks, dens, driveways, garages, gazebos, homes, kitchens, lanais, living rooms, parlors, patios, pet sleeping areas, play rooms, porches, recreational vehicles, rooms, solariums, storage areas, sun rooms, utility rooms and verandahs. Do not use in commercial food handling establishments, restaurants or other places where food is commercially prepared or processed.

INDOORS:

Cockroaches (including adult and immature stages of both non-resistant and organophosphate and carbamate resistant strains), Ants, Boxelder Bugs, Centipedes, Crickets, Dermestids, Firebrats, Fleas, Palmetto Bugs, Silverfish, Sowbugs, Ticks and Waterbugs: Apply as a spot and crack & crevice treatment to areas where these pests crawl and hide, especially in hidden areas around sinks and storage areas, behind baseboards, around doors and windows, behind and under refrigerators, cabinets, sinks and stoves, the underside of shelves, drawers, bookcases, and similar areas. Cover all food handling surfaces and cover or remove all food and cooking utensils or wash thoroughly after treatment. Exposed food should be covered or removed. Repeat as necessary but not more than once per week.

[Roaches: Spray in cracks and crevices, around baseboards and other hiding places.]

Ants: Spray ant trails and around doors and windows and other places where ants enter the house. Repeat as necessary but not more than once per week.

Carpenter Ants: For effective control, locate and treat nests and surrounding areas. Apply around doors and windows and other places where ants enter premises and where they crawl and hide. Spray into infested wood through existing openings.

Ticks [(including deer ticks which may carry Lyme disease)] and Fleas on Surfaces: Remove pet bedding and destroy or clean thoroughly. Spray pet resting quarters. Adult fleas and larvae contacted by spray will be killed. Put fresh bedding down once spray has dried. Do not spray animals directly. For best results, pets should be treated with an appropriate flea and/or tick control product registered for use on pets before allowing them to return to the treated area. Spray rugs and carpets where infestations are bad. Delicate fabrics should be tested for staining in an inconspicuous area prior to use.

Spiders: Apply along and behind baseboards, to window and door frames, corners, pipes, storage localities, attics, crawl spaces and other areas over which these pests may crawl.

Centipedes, Ground Beetles, Pillbugs, Sowbugs, Scorpions and Ticks: Apply around doors and windows and other places where these pests

may enter premises. Treat baseboards, storage areas and other locations where these pests are found.

[Silverfish, Crickets, Spiders: Apply to areas infested by these pests.]

FLYING INSECTS: Houseflies, Gnats, Mosquitoes and Small Flying Moths: Spray localized resting areas, such as under eaves, porches, inside surfaces of window and door frames, surfaces around light fixtures and cords, railings, etc. and anywhere these insects may rest. Insects coming to rest on treated surfaces will be killed.

[FLYING INSECTS: Spray resting areas. Insects coming to rest on treated surfaces will be killed.] HORSE STABLES: To Control Stable Flies, Horn Flies, Houseflies, Face Flies, Horse Flies, Deer Flies, Mosquitoes and Gnats. Apply thoroughly to surfaces until wet. Insects coming to rest on treated surfaces will be killed or repelled. Repeat treatment as necessary but not more than once per week. Do not spray animals or humans, or apply to animal feed or watering equipment.

PANTRY PESTS - Grain Beetles (Rusty, Merchant and Saw-Toothed), Flour Beetles (Red and Confused), Chocolate Moths, Cigarette Beetles, Clover Mites, Cluster Flies, Drugstore Beetles, Elmleaf Beetles, Rice Weevils, Lesser Grain Borers, Spider Beetles and Tobacco Moths: Treat exposed stages. Remove all food-stuffs, utensils and shelf paper from area to be treated. Discard used shelf paper and any infested foodstuffs. Apply spray to shelves and in cracks and crevices behind and under cupboards and cabinets. Allow to dry prior to replacement of shelf paper, food and utensils. Wash any exposed food handling surfaces and utensils before use.

Carpet Beetles (Black, Furniture and Varied): Spray on and under edges of floor coverings, under rugs and furniture and in closets or other localities where these insects are found.

Webbing Clothes Moths: Use this product as a crack and crevice treatment in closets and other storage areas where these pests are found. This is an adjunct treatment and will not control moth larvae already on clothes. Do not apply to clothing.

Bedbugs and Lice: Remove linens and wash before reuse. Lightly spray mattresses, especially tufts, folds and edges. Apply to the interior of the frame. Allow to dry before remaking bed.

Also, treat your yard with a product registered for yard application.

OUTDOORS:

For outdoor use only as an aid in controlling these insects. Point sprayer away from face. Hold sprayer on a slight downward angle, approximately 12 inches from surface to be sprayed. Spray with wind if breeze is blowing. Do not contaminate fish ponds or apply directly to water.

PESTS ON OUTSIDE SURFACES OF BUILDINGS: For control of building infestation to Ants, Clover Mites, Crickets and Sowbugs (Pillbugs). Spray foundation of building where insects are active and may find entrance up to a height of 2 to 3 feet. Apply to outside surfaces of buildings where insects tend to congregate. Spray areas include (but are not limited to) screens, window frames, eaves, porches, patios, garages and refuse dumps. Repeat treatment as necessary but not more than once per week.

CRAWLING INSECTS: Ants, Cockroaches (including Asian Cockroaches), Centipedes, Crickets, Mole Crickets, Water Bugs and Silverfish. Spray infested surface of patio or picnic area. Also spray legs of tables and chairs.

Ants: Spray freely around ant trails and hills. Spray around nests hidden under steps, brickwork, concrete, etc. Break apart accessible nests and spray freely on and around debris. Repeat as necessary but not more than once per week.

[Ants: Spray ant trails and hills. If nest can be located, spray surface of nest until wet.]

Lone Star Ticks, Dog Ticks, Crickets and Fleas: Apply thoroughly to infestation in bushes, grass or weeds.

Wasps, Hornets, Yellow Jackets and Bees: Spray nests and other surfaces where bees may rest. Aim spray at nest openings. Applications should be made late in the evening when insects are at rest.

FLYING INSECTS: Houseflies, Gnats, Mosquitoes and Small Flying Moths: Spray outside surfaces of window and door frames and other areas where these pests may enter the home. Also spray localized resting areas, such as under eaves, porches, surfaces around light fixtures and cords, railings, etc. where these insects may rest. Insects coming to rest on treated surfaces will be killed.

Termites, Carpenter Ants and Carpenter Bees: (for localized control only.) Apply UltraTec HPC to voids or channels in damaged wood of a structure, or to cracks, crevices and spaces in and between wooden portions of a structure or between wood and the foundation, in locations vulnerable to attack such as crawl spaces.

For *Termites*, the purpose of such applications is to kill workers or winged forms which may be present in the treated areas at the time of application. Not recommended as sole protection against termites. For active infestations, get a professional inspection. Such applications are not a substitute for mechanical alteration, soil treatment or foundation treatment but are merely a supplement. For severe termite infestation, contact a professional pest control operator in your area.

HOUSE PLANTS: To control Aphids, Japanese Beetles, Lace Bugs, Leafminers, Mealy Bugs, Mites and Spider Mites on house plants. Prior to spraying, remove plants from living and eating areas. Put in an area not likely to come in contact with pets, children or food. Plants can be returned to original location when leaves dry. If plants cannot be moved, cover or remove exposed food and food handling surfaces.

Apply spray to upper and lower surfaces of foliage. Avoid wetting blossoms if possible. Repeat applications as necessary but not more than once per week.

FOR CONTROL OF ORNAMENTAL GARDEN INSECTS: For use on roses, dahlias, asters and other ornamentals to kill Japanese Beetles hit by spray, as well as Whiteslies, Aphids, Armyworms, Lace Bugs, Mealy Bugs, Exposed Thrips, Pavement Ants, Spiders, Spider and Red Mites, Clover Mites and Leasminers.

Not For Use On Plants Grown For Sale Or Other Commercial Use

May be used on plants, as well as a multi-purpose spray in small ornamental gardens and for spot treatments to prevent insects from spreading into large garden areas.

May also be used on other plants such as African violets, asters, azaleas, begonias, camellias, carnations, chrysanthemums, delphiniums, dogwood, English ivy, euonymus, fuschia, geraniums, crassula, grape vine, Kentia palm, laurel, marigolds, rhododendrons, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90°F. Over application may cause damage. DO NOT apply to vegetable plants or other plants used for food. Spray insects directly whenever possible. Repeat treatment as necessary but not more than once per week.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area away from <u>[inaccessible to]</u> children <u>and pets and away from heat, sparks and open flame</u>. [Protect from freezing.] [Store above 32°F.] [Do not <u>transport or</u> store below 32°F. (0°C)] If freezing occurs, allow product to thaw and shake well before using [use]. [Some product separation may occur on freezing which is reversible on shaking]. Freezing does not adversely affect [this product] [performance].

Container Disposal: If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability. CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Valent BioSciences Corporation. All such risks shall be assumed by the user or buyer.

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Valent BioSciences Corporation Environmental Science Division 870 Technology Way Libertyville, IL 60048 List No. 73049187 02-0582/R4

Additional Alternate Front Panel Bullets:

[Keeps Killing For Up To 4 [8, 12, 16] Weeks

- Keeps Killing For Up To I [2, 3, 4] Months
- Keeps Killing For Up To 30 [60, 90, 120] Days
- No Drips No Runs
- Stays Where You Put It
- Does Not Stain Surfaces
- Does Not Stain Fabrics

- No Shaking Required
- No Shake Formula
- No Drip Formula]

[] Indicates alternate text in addition to any subset of the directions for use.