

NITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 2 4 2009

Mr. Nasser Assaf, Ph.D. Valent BioSciences 870 Technology Way, Suite 100 Libertyville, Il 60048

Dear Dr. Assaf:

Subject:

Amendment- efficacy data MRID 47572501

Cyper-Active 2.14 EC

EPA Registration Number 73049-154

Your submission dated October 8, 2008

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments:

- 1. Change "Kills Mosquitoes that may carry West Nile Virus, Encephalitis, yellow fever and malaria" to Kills Mosquitoes that may carry West Nile Virus".
- 2. The submitted data do not support the addition of kill claims for the public health pests for the following reasons:
 - a. The directions for use are for residual control. The submitted data only demonstrated intrinsic toxicity of the product. The product cannot claim both "kills" and "controls" claims on the label, since they are both contradictory and confusing to the consumer.
 - b. The directions for use for some of these pests state to spray into hiding places such as cracks and crevices, along baseboards and floors, etc. The design of this study was a direct spray to the arthropod from close range.
 - c. It cannot be determined from the design of this study if the dose rates and amounts of product applied reflect the product application rates. The study design involved 1 to 6 pump sprays directly to the arthropod. It is evident that "kill" is a function of how many "pumps" are administered to the arthropods. In addition, the label does not state that the product must spray directly on the arthropod. It is also unclear what is meant by run-off (since material cannot run-off from enclosed petri dish!).

- d. Control mortality was too high for some of the arthropods tested (pavement ant; Culex.; stable flies; house fly; fire ant; and black fly (26.2%).
- e. Not only the number of "pumps" administered, but also it was shown that the concentration tested (range from 0.01% to 0.05%) effects the efficacy. The label states to use 0.1% ai per 1 gallon of water for certain arthropod species, and 0.2% ai for other arthropod species. The directions for use are unclear on the label. Does the user put ½ fluid ounce of product n one gallon of water to make a 0.1% dilution? The label states to use 0.1% ai per 1 gallon of water for certain arthropod species, and 0.2% for other arthropod species; I do not know how this compares to the rates tested of 100 ppm, 300 ppm and 500 ppm)
- f. In the results it was reported that for house flies, they should be evaluated at time intervals between 5 and 15 minutes and concentrations between 100 and 500 ppm, whereas for smoky brown cockroaches, they should be evaluated at time intervals between 30 and 60 minutes at concentrations between 100 and 500 ppm. How this method of observation relates to actual use of product is unclear.
- g. Too few arthopods were tested for the spiders, scorpions and centipedes.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,

Richard Gebken

Product Manager (13)

Insecticide Branch

Registration Division (7505P)

Enclosure

CYPER-ACTIVE® 2.14 EC

- · For Industrial/Institutional/Commercial Use Only
- [Kills On Contact & Keeps On Protecting
- · Crack And Crevice, Spot Spray For Residual Cockroach Control
- For Residual And Contact Control Of Cockroache (Waterbugs), Crickets, Silverfish (Firebrats), Centipedes, Millipedes, Earwigs, Sowbugs (Pil&lbugs), Spiders, Ants, Flies, Mosquitoes, Gnats, Small Flying Moths, Wasps, Hornets, Yellow Jackets And Bees.
- Kills Cockroaches [(Including American cockroach, Oriental cockroach, German cockroach and smokybrown cockroaches)]
 (Waterbugs), Crickets, Silverfish (Firebrats), Centipedes, Millipedes, Earwigs, fleas, scorpions, termites, ticks, bedbugs, Sowbugs (Pillbugs), Spiders (Including black widow, brown (recluse or violin), hobo and funnel web), Ants (Including Pharaoh, carpenter, fire ant), Flies, Mosquitoes), Gnats, Small Flying Moths, Wasps Hornets, Yellow Jackets, And Bees.
- Kills Bedbugs
- · Kills Mosquitoes that may carry West Nile Virus, Encephalitis, yellow fever and malaria
- · Cyper-Active Contains 2.14 Pounds Active Ingredient Per Gallon
- · Contains Cypermethrin
- · Makes up to 2 Gallons (1 oz. bottle)
- · Concentrate Strength]

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ACTIVE INGREDIENT:

 Cypermethrin*
 26.0%

 OTHER INGREDIENTS**:
 74.0%

 100.0%

*Cis/trans ratio: 45/55 (+/-) 10.

**Contains Xylene Range Aromatic Solvent.

FEB 2 4 2009

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PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN WARNING

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 73049-154 Item No. 15269

EPA Est. No.

FIRST AID				
 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. 				
 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes, Call a poison control center or doctor for treatment advice. 				
 Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person. 				
 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 further treatment advice. 				

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. 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.

NOTE TO PHYSICIAN

Inducing vomiting as first aid for this substance may result in increased risk of pneumonia or pulmonary edema caused by aspiration of the hydrocarbon solvent. Vomiting should be induced only under professional supervision.

NET CONTENTS:

PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

WARNING

Causes substantial but temporary eye injury. Causes skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses. Harmful if swallowed, inhaled, or absorbed through skin. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Environmental Hazards

This product is extremely toxic to fish. Do not contaminate water when disposing of equipment washwaters. Do not apply directly to any body of water, or to any areas where surface water is present or to intertidal areas below the mean high water mark. Apply this product only as specified on this label. Care should be used when spraying to avoid fish and reptile pets by removing pets and covering fish tanks before spraying.

Physical Or Chemical Hazards

Combustible. Do not use or store near heat or open flame. Flashpoint 140°F Min. Do not apply this diluted product in conduits, motor housings, junction and switch boxes or other electrical equipment because of possible shock hazard. Do not use on surfaces that can be harmed or stained by water.

DIRECTIONS FOR USE

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

Please read entire label before using this product.

NOT FOR USE IN USDA MEAT AND POULTRY PLANTS.

Do not use in food/feed areas of food/feed handling establishments, restaurants, or other areas where food/feed is commercially prepared or processed. Do not use in serving areas while food/feed is exposed or facility is in operation. Serving areas are areas where prepared foods/feeds are served such as dining rooms but excluding areas where foods/feeds may be prepared or held. In the home, all food/feed processing surfaces and utensils should be covered during treatment or thoroughly washed before reuse. Exposed food/feed should be covered or removed. Nonfood areas are areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, basements, boiler rooms, garages, mop closets and storage rooms (after canning and bottling).

FOR RESIDUAL PEST CONTROL IN AND ON buildings and structures and their immediate surroundings and on modes of transport. PERMITTED AREAS OF USE INCLUDE industrial buildings, houses, apartment buildings, laboratories, greenhouses, and the nonfood/feed areas of stores, warehouses, vessels, railcars, trucks, trailers, schools, nurseries, day camps, lath houses, seed houses, food handling establishments, packaging and processing plants, commercial, industrial, office, institutional and storage rooms, egg processing plants, supermarkets, restaurants, bottling plants, canneries, flour and feed mills, bakeries, laboratories and hospitals. IN HOSPITALS: patients should be removed prior to treatment. Also for use in campers, mobile homes, buses, automobiles, and boxcars. Also for use in dog kennels and horse stables. IN HORSE STABLES: not for application if horses will be used for food.

Cyper-Active insecticide is intended for dilution with water for spray application.

Fill sprayer with the desired volume of water and add Cyper-Active insecticide. Close and shake before use in order to insure proper mixing. Shake or reagitate sprayer before use if spraying is interrupted. Make up only as required.

Pests		Concentration of Active Ingredient	Dilution Rate
Ants Carpenter Ants Centipedes Cockroaches (Maintenance) Crickets Firebrats Earwigs Scorpions Bedbugs	Flies Millipedes Pillbugs Silverfish Sowbugs Gnats Mosquitoes Ticks Termites	0.1% per 1 gal. water	1/2 fl. oz.

Bees

Hornets

0.2%

water

per 1 gal.

1 fl. oz.

Cockroaches (Clean-out)

Yellow Jackets

Wasps

Fleas

Small Flying

Spiders

Moths

INDOORS

Cockroaches, Spiders, Crickets, Silverfish and Firebrats: Apply as a coarse, low pressure spray to areas where these pests hide, such as baseboards, corners, storage areas, closets, around water pipes, doors and windows, attics and eaves, behind and under refrigerators, cabinets, sinks, furnaces, and stoves, the underside of shelves, drawers and similar areas. Pay particular attention to cracks and crevices.

Ants: To kill ants within buildings and homes, spray trails, nests and points of entry. Spray directly on ants where possible.

Carpenter Ants: Make spot applications as a spray to any trails, around doors and windows, wall voids, crawl spaces, and other places where ants enter premises. Where possible, treat ant nest or infested wood directly.

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

Wasps, Hornets, Yellow Jackets, Bees: Application should be made in the late evening when insects are at rest. Spray liberally into hiding and breeding places, especially under attic rafters, contacting as many insects as possible.

Sowbugs, Pillbugs, Millipedes, Earwigs, Scorpions and Centipedes: Apply around doors and windows and other places where these pests may be found or where they may enter premises. Spray baseboards, storage areas and other locations. Refer to barrier treatment directions to prevent infestation.

Flies, Mosquitoes, Gnats, Small Flying Moths: Apply directly to walls, ceilings, window screens, and other flying insect resting areas as a residual surface treatment. May be used inside residential buildings as well as in and around carports, garages, and storage sheds.

Bedbugs: 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.

TO CONTROL Fleas and Ticks: Apply as a spot treatment to infested areas such as pet beds and resting quarters, nearby cracks and crevices, along and behind baseboards, window and door frames and localized areas of floor and floor coverings where these pests may be present. Old bedding of pets should be removed and replaced with clean, fresh bedding after treatment. Do not treat pets with this product.

OUTDOORS

Do not apply this product to edible crops.

Ants, Bees, Centipedes, Cockroaches, Crickets, Firebrats, Millipedes, Silverfish, Sowbugs, Spiders, Flies, Mosquitoes, Gnats, Small Flying Moths, Wasps, Hornets, Yellow Jackets. Apply as a residual spray to surfaces of buildings, porches, screens, window frames, eaves, patios, lawns, refuse dumps, garages in either hand or power sprayer. Treat other areas where these pests are found.

TO CONTROL Fleas and Ticks: Apply Cyper-Active to areas where fleas and ticks are most likely to be found, such as, but not limited to, dog houses, kennels runways, cracks and crevices in sidewalks, paths or patios where pests may rest.

BARRIER TREATMENT: To help prevent infestation of buildings, apply to a band of soil and vegetation 6 to 10 feet wide around and adjacent to the building. Also, treat the building foundation to a height of 2 to 3 feet where pests are active and may find entrance. Apply as a coarse spray to thoroughly and uniformly wet the band area, using 1 gallon of spray mix per 400 square feet.

Termites and Carpenter Ants: (localized only). Apply Cyper-Active 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. Retreat if needed but not more than once per week.

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 active termite infestation, contact a professional pest control operator in your area.

STORAGE AND DISPOSAL

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

Storage: Store product in original container and keep container closed when not in use. Do not store near food or feed. Protect from freezing. In case of spill or leak on floor or paved surfaces, soak up with sand, earth or synthetic absorbent. Remove to chemical waste area.

Pesticide Disposal:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative of the nearest EPA Regional Office for Guidance.

Container Disposal:

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying.

[5 gallons or less:]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Greater than 5 gallons/50 lbs.:]

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least on complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedures two more times.

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 must 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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