

73049-349

02/24/2009

1/5

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 24 2009

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

Dear Dr. Assaf:

Subject: Amendment- efficacy data MRID 47572701
PyraPerm Household Insect Killer WBA P59
EPA Registration Number 73049-349
Your submission dated October 6, 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 black widow, brown recluse, hobo spider, centipedes, or carpenter ants for the following reasons:

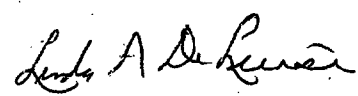
- a. The label directions state to spray from a distance of 12 to 15 inches, whereas in the study, the arthropods were sprayed from a distance of 6 to 8 inches.
- b. The directions for use state the product is both "residual control" and "contact kill". The product cannot claim both on the label, since they are both contradictory and confusing to the consumer.
- c. The directions for use for some of these pests e.g., centipedes and spiders, 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.
- d. The study design involved a "one second" blast. The directions for use on the label do not state to "spray for a period of one second." The directions for use are too vague in regard to how long to spray the product.
- e. There were no directions for carpenter ants on the label.

3. Revise the term spider to read "spider (except black widow, brown recluse and hobo).
4. Delete the term "centipede".
5. Delete the term "carpenter ants".

Please note you can also revise the entire label to reflect a contact kill product only, and to revise the directions for use to state that the product is contact kill only (removing all reference to "control") and to include directions such as "Arthropod must be directly contacted (from a distance of about 6 to 8 inches) in order to be effective. Contact as many pests as possible."

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

3/5

PYRAPERM®

HOUSEHOLD INSECT KILLER WBA P59

- [Contains Pyrenone® And Permanone®
- Controls Residential And Garden Insects
- Seeks Out Bugs Where They Hide
- Kills On Contact
- For Household Use
- Non-Staining
- A Broad Spectrum Insecticide Highly Effective Against Ants, Bedbugs, Beetles (Including Carpet, Flour, Grain, And Ground Beetles), Clover Mites, Cockroaches, Crickets (Including Mole Crickets), Earwigs, Firebrats, Fleas, Millipedes, Moths, Pillbugs, Scorpions, Silverfish, Sowbugs, Ticks And Other Pests Listed On The Label
- Kills Cockroaches [(Including American cockroach, Oriental cockroach, German cockroach and smokybrown cockroaches)] (Waterbugs), Crickets, Silverfish (Firebrats), Centipedes, Millipedes, Earwigs, fleas, scorpions, 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 and Small Flying Moths.
- Kills Mosquitoes that may carry West Nile Virus, Encephalitis, yellow fever and malaria
- Kills Lice And Their Eggs
- For Use On Bedding, Furniture And Other Inanimate Objects Infested With Lice
- No Unpleasant Odor
- Water-Based Formula
- For Use On Premises To Control Fleas And Ticks
- Protects For Up To 4 Weeks [1 Months] Against Fire Ants
- Protects For Up To 12 Weeks [3 Months] Against German Cockroaches]

ACTIVE INGREDIENTS:

Pyrethrins.....	0.1 %
Piperonyl Butoxide*	0.5 %
Permethrin**	0.2 %

OTHER INGREDIENTS†:	99.2 %
	100.0 %

*Equivalent to 0.4% (butylcarbityl)(6-propylpiperonyl) ether and 0.1% related compounds.

**Cis/trans ratio: Max. 55% (+/-) cis and min. 45% (+/-) trans.

†Contains petroleum distillate.

REGISTERED
with EPHS
in EPA Label Board

FEB 24 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
it is unlawful for the pesticide
to be used under EPA Reg. No.

73049-349

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

(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. 73049-349

EPA EST. NO.

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
If Inhaled:	<ul style="list-style-type: none"> • 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	
Contains petroleum distillate - vomiting may cause aspiration pneumonia.	

See Back Panel For Additional Precautions

NET CONTENTS:

PRECAUTIONARY STATEMENTS

Hazards To Humans & Domestic Animals

CAUTION

Harmful if swallowed or inhaled. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

Environmental Hazards

This product is toxic to fish. Do not apply directly to any body of water.

Physical and Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not use this product in or on electrical equipment due to the 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.

Avoid contamination of feed and foodstuffs. Remove pets and birds and cover fish aquaria before spraying. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry.

Do not use in food/feed handling establishments, restaurants or similar sites where food is commercially prepared, processed or served. In the home, cover all food processing surfaces and utensils during treatment or thoroughly washed before use. Cover or remove exposed food.

Test product on an inconspicuous area before applying. Spray until surface is slightly wet but not to the point of run-off. Over application may cause damage. Will not stain surfaces or fabrics where water alone causes no damage.

SHAKE WELL BEFORE USING

Remove protective cap, hold container upright and spray from a distance of 12 to 15 inches.

INDOORS:

Cluster Flies, Houseflies, Fruit Flies, Mosquitoes, Gnats, Black Flies, Skipper Flies, Blow Flies and Small Flying Moths: Close all doors and windows and direct spray upward into center of room with a slow sweeping motion. Spray 5-10 seconds for average room, moving toward the door. Direct spray to all parts of the room, especially windows and other light sources which attract these insects.

Keep nozzle in constant motion. Leave room and keep area closed for 15 minutes after spraying. Ventilate room thoroughly before re-entry. Sweep up and discard fallen insects.

Cockroaches, Waterbugs, Palmetto Bugs, Silverfish, Firebrats, Crickets, Scorpions, Spiders, Centipedes, Millipedes, Sowbugs and Pillbugs: Spray into hiding places such as cracks and crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray whenever possible.

Ants: Spray trails, nests and points of entry. Spray on ants where possible.

Carpet Beetles: Spray directly on beetles, floors, baseboards, shelves and carpets.

Bedbugs: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and floors. Allow all sprayed articles to dry thoroughly before use.

TO CONTROL Clothes Moths and Carpet Beetles on wool and other proteinaceous fibers: Remove infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. After airing, infested articles may be treated by spraying lightly, keeping nozzle at least three feet from fabric to avoid staining.

Fleas IN BUILDINGS - SPACE SPRAY: Hold can 36 inches above floor and direct spray toward floor and lower walls at a rate of 10 seconds per 100 sq. ft. making sure that all floor, sofa and chair surfaces are contacted. Leave room and keep area closed for 15 minutes. Open and ventilate before reoccupying. Repeat treatment after 7 days if needed.

Fleas & Ticks (Adults and Larvae): Remove and thoroughly clean or destroy dog bedding. Spray dog sleeping quarters, bed, entire floor and floor covering, with special attention to cracks and crevices around baseboards, and window and door frames. Infested upholstered furniture and mattresses may also be treated with this product.

TO Kill Lice and Louse Eggs: Spray on an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray only those garments and parts of bedding, including mattresses and furniture that cannot be either laundered or dry cleaned. Allow all sprayed articles to dry thoroughly before use.

OUTDOORS:

Remove all exposed food and cooking utensils. Cover all food handling surfaces and/or wash thoroughly after treatment and before use. Do not use on edible crops.

Point spray nozzle away from face. Hold can on slight downward angle. For best results, spray when air is calm. Allow a few minutes for

product to take effect. Spray with wind if breeze is blowing.

FLYING INSECTS: *Flies, Mosquitoes, Gnats and Small Flying Moths.* Allow fog to drift over area. Direct spray toward bushes, or grass from at least 4 to 6 feet away. Give special attention to breeding areas such as garbage cans and compost piles.

CRAWLING INSECTS: *Ants, Cockroaches, including Asian Cockroaches, Crickets, Earwigs, Spiders, Mole Crickets, and Silverfish.* Hold can 12 to 18 inches from surface to be treated and spray in infested surface of patio or picnic area, hitting as many insects as possible. Spray to slightly moisten the surface. Also spray legs of tables and chairs to repel ants. Spray ant hills for best control.

FOR THE CONTROL OF GARDEN INSECTS: For use on roses, dahlias, asters and other ornamentals to kill *Japanese Beetles* hit by spray, as well as *Whiteflies, Aphids, exposed Thrips, Spiders, Red Mites* and *Leafminers*.

Not for use on plants being grown for sale or other commercial use.

May be used on plants, as well as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

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

Effective when used as directed against *Whiteflies, Aphids, Spider and Red Mites, Exposed Thrips, Lace Bugs, Japanese Beetles, Pavement Ants, Clover Mites* and *Armyworms*. When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Spray in one second bursts. 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. Contact insects directly whenever possible. Repeat treatment as infestations occur.

STORAGE AND DISPOSAL

Storage: [Do not store near heat or open flame.] [Store in a cool, dry area away from children.] [Store in a cool, dry area away from [inaccessible to] children and pets and away from heat, sparks and open flame.] [Do not transport or store below 32°F.] [Protect from freezing.] [Do not freeze.]

Disposal: Do Not Puncture or Incinerate! Non-refillable container. Do not reuse or refill this container. *If empty:* Place in trash or offer for recycling if available. [This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label.]

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

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.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, VALENT BIOSCIENCES CORPORATION MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Valent BioSciences Corporation is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Valent BioSciences Corporation disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT VALENT BIOSCIENCES CORPORATION'S ELECTION, THE REPLACEMENT OF PRODUCT.

©Valent BioSciences Corporation, 2008

PyraPerm is a registered trademark of the Valent BioSciences Corporation.

Pyrenone and Permanone are registered trademarks of the Bayer AG.

Valent BioSciences Corporation
Environmental Science Division
 870 Technology Way
 Libertyville, IL 60048
 List No. 73049349 02-0638/R2