

48665-2

8/4/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 4, 2009

Ms. Peggy M. Galloway,
Regulatory Agent for Shoo-fly
c/o Landis International, Inc.
P.O. Box 5126
Valdosta, GA 31603-5126

**Subject: Amended Labeling, Response to EPA Letter of August 12, 2008 & PR Notice 2007-4
Shoo-fly CONCENTRATE I, EPA Reg. No. 48665-2
Your Submission Dated May 13, 2009**

Dear Ms. Galloway:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following provision(s):

General Statement:

1. Delete all text throughout the label marked with "strikethrough."
2. Change the Signal Word from "**CAUTION**" back to "**DANGER**" in the first aid statements and in the precautionary statements sections of this label. In order to change the Signal Word from "**DANGER**" to "**CAUTION**," you must submit product-specific acute toxicity data for review by the Agency.

Optional Marketing Claims section comment(s):

3. Delete the 1st optional marketing claim. USDA no longer maintains a list of non-proprietary substances.

Ingredient Statement comment(s):

4. Revise the ingredient listed as "Piperonyl butoxide, technical" to read: "Piperonyl butoxide, technical*"
5. Add the following text as a 1st footnote in this section specifically for piperonyl butoxide, technical:
"*Equivalent to 24.00% of (butylcarbityl)(6-propylpiperonyl) ether and 6.00% of related compounds."
6. Revise "**INERT INGREDIENTS**" to read "**OTHER INGREDIENTS**"

First Aid Statement section comment(s):

7. Revise the Signal Word to read "**DANGER!**" as explained in Review Point #2 above.
8. Revise the statement "**See Inside for Additional Precautionary Statements**" to read "**See Side Panel for Additional Precautionary Statements**"
9. Replace the 7th and 8th rows in this section (table) with: "**HOT LINE NUMBER:** Have the product container or product label with when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call CHEMTREC at 1-800-424-9300 (24-hours per day. 7 days per week)."

2008

Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s):

10. Revise the Signal Word to read "**Danger**" as explained in Review Point #2.
11. Insert the following text immediately preceding the existing 1st sentence: "Causes irreversible eye damage."
12. Insert the following text immediately preceding the existing 2nd sentence: "Avoid breathing vapors or spray mist."

Environmental Hazards Statement section comment(s):

13. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, replace this section with: "This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This product has a potential for run-off for several weeks after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product.

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

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions for Use for additional precautions and restrictions."

Directions for Use section comment(s):

14. To facilitate inclusion of language from the REDs for pyrethrins and piperonyl butoxide, add the following new subsection in its own text box immediately following the statement "It is a violation of Federal law ..." as follows:

GENERAL PRECAUTIONS & USE RESTRICTIONS
<ul style="list-style-type: none">• Apply this product only as specified on this label.• Do not contaminate of food or feedstuffs.• Do not use on or around horses intended for human consumption.• Do not use in aircraft cabins.• Do not enter or allow others to enter until sprays have dispersed, and the treated area has been thoroughly ventilated. Do not remain in treated area. Exit area immediately and remain outside the treated area until sprays have dispersed.• Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the treated area during application.• Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment and food preparation surfaces, or wash them before use.• For indoor food handling/processing facilities: Do not make space spray applications when facility is in operation. During space spray applications, cover or remove exposed food. Do not apply more than 1 time per day.• During space spray applications, cover food processing surfaces or clean after treatment with a suitable detergent, rinse with potable water before use. Do not apply more than 1 time per day.• Do not use in nurseries or rooms where infants, ill or aged persons are confined. Remove patients prior to treatment. Vacate treated areas for at least 2 hours and thoroughly ventilate before reoccupying.• For indoor agricultural premises, commercial animal housing and outdoor ornamental and lawns: Do not apply more than 1 time per day.• When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.• For post-harvest applications to stored grain and seed: Do not reapply within 30 days.• For food stored in bags: Direct application to food contact surfaces is prohibited.• Remove pets, birds and cover fish aquariums before application.

15. Delete the statement starting with "The insecticidal components of this concentrate ...," since this is an implied safety claim.

Directions for Use, INDOOR APPLICATION subsection comment(s):

16. In the 1st sentence of the 1st paragraph in this subsection, replace the word "control" with the word "kill."
17. In the 1st sentence of the 2nd paragraph in this subsection, replace the word "using" with the words "at a rate of."

Directions for Use, INDOOR APPLICATION subsection comment(s):

18. Revise the 2nd and 3rd sentences of the 2nd paragraph in this subsection to read "Close off and vacate treated areas for at least 10 minutes and thoroughly ventilate before reoccupying."
19. In the 2nd sentence of the 4th paragraph in this subsection, replace the words "using approximately" with the words "at a rate of."

Directions for Use, IN MILLS, ELEVATORS AND GRANARIES subsection comment(s):

20. In the 3rd sentence of the 1st paragraph in this subsection, replace the words "using approximately" with the words "at a rate of."
21. Immediately following the statement starting with "Sack surfaces of bagged grain ...," insert the following text as a 2nd sentence: "Direct application to food contact surfaces is prohibited."
22. In the 1st sentence of the 8th paragraph in this subsection, replace the word "control" with the word "kill."

Directions for Use, ON HORSES subsection comment(s):

23. In the 1st sentence of the 1st paragraph in this subsection, replace the word "control" with the word "kill" and replace the words "at the rate of" with the words "at a rate of."
24. In the 2nd sentence of the 1st paragraph in this subsection, replace the word "5to" with the words "5 to."
25. In the 1st sentence of the 2nd paragraph in this subsection, replace the word "control" with the word "kill."

Directions for Use, MOSQUITO CONTROL OUTDOORS subsection comment(s):

26. Revise the subsection heading to read "**MOSQUITO CONTROL OUTDOORS (NOT FOR WIDE AREA MOSQUITO CONTROL):**"
27. In the 1st sentence, replace the word "control" with the word "kill."

Storage and Disposal Statement section comment(s):

28. To facilitate inclusion of language from PR Notice 2007-4, replace

"STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in a cool, dry place. Keep container closed.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

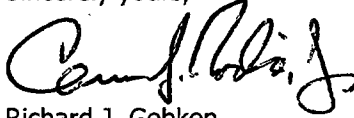
CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank for store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities."

Landis International, Inc. should note that a notice of availability of EPA's RED for products containing pyrethrins was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42387-42389). In addition, EPA's RED for products containing piperonyl butoxide was published in the *Federal Register* on July 26, 2006 (Volume 71, Number 143, Pages 42385-42386). As a result, additional data and/or labeling changes may be required for products containing pyrethrins and piperonyl butoxide.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the 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 amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov.

Sincerely yours,

FOR 

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure: *Copy of label stamped "Accepted with Comments"*
048665-00002 D411413

CONCENTRATE I

~~A Water Emulsifiable Insecticide Concentrate authorized by U.S.D.A. for use in all areas of official establishments operating under the Federal meat, poultry, shell egg grading, and egg products inspection programs. Category F-1~~

For use in Bakeries, Bottling Plants, canneries, Flour Mills, Food Processing Plants, Hospitals, Hotels, Restaurants, Schools, Horse Barns, Dairy and Hog Barns, Kennels and other Farm Structures or Buildings Housing Animals or Poultry and on Ornamental Plants in Homes, Gardens and Greenhouses.

Ingredients

Pyrethrins	3.00%
*Piperonyl butoxide, technical	30.00%
INERT INGREDIENTS	67.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN	
CAUTION! DANGER	
See Inside for Additional Precautionary Statements	
FIRST AID	
If In Eyes:	<ul style="list-style-type: none"> • 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 further treatment advice.
If On Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for further treatment advice.
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 poison control center or doctor for treatment advice.
If Swallowed:	<ul style="list-style-type: none"> • Call poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT UNE NUMBER - CHEMTREC (800) 424-9300	
(24 hours)	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Registration No. 48665-2

EPA Est. No. 1021-MN-02

NET CONTENTS 1 GALLON
MANUFACTURED FOR:

ACCEPTED
With COMMENTS
In EPA Letter Dated:
August 4, 2009
Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:
48665-2



10337 North US Hwy 27, Ocala, FL 34482 • (352) 351-5858 • 1-800-248-5858

**PRECAUTIONARY STATEMENT:
Hazard to Humans and Domestic Animals**

~~Gaution~~ **Danger**

Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS:

Do not apply outdoors when weather conditions favor drift from the area. **DO NOT APPLY DIRECTLY TO WATER** except as indicated in the Directions for Use. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

DIRECTIONS FOR USE

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

To prepare dilutions the concentrate should first be stirred or agitated well. Add the required amount of concentrate to water and blend thoroughly. This will produce a stable micro-emulsion.

~~The insecticidal components of this concentrate, pyrethrins and piperonyl butoxide, are classified as food additives, and when used as directed allowable tolerance levels will not be exceeded.~~

~~Do not apply directly to food. In commercial food handling facilities, cover or remove any food processing equipment during application. Do not apply while food processing is under way. After space spraying in plants, bakeries, and other food processing plants, wash with potable water all equipment, benches, shelving, etc., where exposed food will be handled. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use.~~

~~In hospitals, remove patients prior to treatment. Ventilate area for 2 hours before returning patients.~~

~~In horse barns, not for application if horses will be used for feed.~~

~~Remove pets and birds, cover fish aquariums before spraying.~~

INDOOR APPLICATION:

To ~~control~~ exposed stage of houseflies, including fruit flies, mosquitoes, gnats, and small flying moths dilute 1 part concentrate in 59 parts water (2.1 ounces per gallon). Close doors and windows and shut off ventilating systems. Apply as a fog or fine mist, directing the spray toward the upper portions of the room and toward windows and other light sources which attract these insects.

Thoroughly fill the area with mist ~~using~~ 1 to 2 ounces per 1000 cubic feet. Keep area closed for 10 minutes or more. Vacate after treatment and ventilate before reoccupying. Repeat treatment as needed.

For use through overhead applicators, dilute one part concentrate in 39 to 59 parts water (3.3 to 2.1 ounces per gallon). Use higher concentration under heavy infestation.

For initial clean-out of infestations of cockroaches, ants, spiders, silverfish, crickets, boxelder bugs, scorpions, and clovermites: Dilute 1 part concentrate in 14 parts water (8.5 fluid ounces per gallon). Apply as a coarse droplet surface spray ~~using approximately~~ 1 gallon to 750 square feet. Spray thoroughly all surfaces where these insects are usually found including walls, baseboards, moldings, doors, cabinets, shelves, sinks and pipes, with special attention to cracks and crevices, niches, dark comers, drains and similar hiding places. Treat ant trails, nests and runs. When possible, spray insects directly.

Repeat treatment using a dilution of 1 plus 29 (4.3 fluid ounces per gallon) at the same rate of application after an interval of one month or when reinfestation occurs.

IN MILLS, ELEVATORS AND GRANARIES:

For rapid initial kill of exposed or accessible stages of granary weevil, rice weevil, confused flour beetles, rust red flour beetle, cadelle, sawtoothed grain beetle, cheese mites and grain mites: dilute at a rate of 1 part concentrate to 29 parts water (4.3 fluid ounces per gallon). Clean out any waste grain, dust, dirt or debris and destroy before spraying. Apply as a coarse droplet spray ~~using approximately~~ 1 gallon to 750 square feet of surface.

Infested stored products should be fumigated or treated by other effective methods using an approved product intended for this use.

In mills, elevators, and granaries, thoroughly spray floors, walls and other surfaces of bins, storage and handling areas with particular attention to cracks, crevices, and similar protected locations. Treat unloading, handling and processing areas, and apply the insecticide to conveying, processing and handling equipment such as the inside of reel conveyors, purifier conveyors, sifters, roll housings and hoppers, pick-up conveyors, etc. Spray thoroughly around the base of heavy machinery and equipment.

Thoroughly treat walls, floors, shelves and other exposed surfaces, and lightly spray each layer of cartons or containers as stacked.

Sack surfaces of bagged grain can be sprayed lightly until slightly moist.

For protection in transit, treat truck beds, box cars, and ships' holds before loading.

Using a dilution of 1 part concentrate in 29 parts water (4.3 fluid ounces per gallon), apply at a rate 1 gallon to 750 square feet of surface with particular attention to cracks, crevices, and similar hiding places.

To ~~control~~ exposed accessible stages of Indian meal moth and Angor mois grain moth in stored grain: Dilute 1 part of concentrate in 17 parts of water (8.5 fluid ounces per gallon) and apply to the surface of the binned grain at a rate of 2 gallons per 1000 square feet (1.6 pints per 100 square feet). Apply at monthly intervals beginning with the first appearance of moths and continuing until early fall. In case of severe infestation, break up webbing with rake before spraying and make a second application in two weeks.

ON HORSES:

To ~~control~~ horn flies, house flies, mosquitoes and gnats, dilute ~~at the rate of~~ 1 part concentrate to 119 parts water (1 fluid ounce per gallon) and apply to wet the hair thoroughly with particular attention to the topline, underline, flanks, withers, and other infested areas. Repeat treatment at intervals of 5 to 12 days for small insect populations or as needed when flies are emerging in large numbers.

To ~~control~~ stable flies, horse flies, and deer flies, dilute 1 part concentrate to 29 parts water (4.3 fluid ounces per gallon) and apply a quart per adult animal to wet the hair thoroughly with particular attention to the legs, flanks, barrel, topline, and other body areas commonly attacked by these flies. Repeat treatment each week or as needed.

MOSQUITO CONTROL OUTDOORS:

To ~~control~~ adult mosquitoes, using ground application, dilute 1 part concentrate to 4 parts water (25.6 fluid ounces per gallon). Apply as a fine mist or fog. Treat shrubbery and vegetation where mosquitoes may rest. Shrubby and vegetation around stagnant pools, marshy areas, ponds and shore lines may be treated. ~~Application of this product to any body of water is prohibited, when used for adult mosquito control.~~ Repeat as necessary usually once or twice a week.

STORAGE AND DISPOSAL:

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

PESTICIDE DISPOSAL: Pesticide, spray mixture or rinsate that cannot be used according to label instructions may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available 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.

CONDITIONS OF SALE:

SHOOFLY warrants that this product in its unopened package conforms to the chemical description on the label and is reasonably fit for the purposes set forth on the label when used according to directions under normal use conditions. To the extent consistent with applicable law, there are no other warranties, expressed or implied, concerning the use of this product other than indicated on the label. To the extent consistent with applicable law, this warranty does not extend to the handling or use of this product contrary to label instructions or under abnormal conditions or conditions not reasonably foreseeable to seller, and buyer assumes all risk of any such use.

