2011



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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 14, 2011

Ms. Sharon M. Johnston, Esq. Regulatory Consultant for Ultrasol Industries, Ltd. c/o RegGuide Regulatory Services 509 Tower Valley Drive Hillsboro, MO 63050-1216

Subject: Amending Labeling; Response to EPA Letters Dated March 23, 2010 and July 6, 2011 Ultrasol Total Release Fogger, EPA Reg. No. 72804-1 Your Submission Dated October 4, 2011

Dear Ms. Johnston:

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 label revision provision(s):

General Comment(s):

- 1. Delete all text throughout the label marked with "strikethrough."
- In accordance with the Agency's guidance documents entitled "Required Label Language for Indoor Total Release Fogger (TRF) Products," dated March 23, 2010, and "Update On Required Label Language for Indoor Total Release Fogger Products," dated July 6, 2011, please consider the following regarding the subject product:
 - Avoid multipacks for consumer use
 - Adopt smaller unit sizes (2 oz. versus the standard 6 oz.)
 - Utilize a time-delayed release mechanism (3-5 seconds)
 - Switch to non-flammable propellants

Optional Marketing Statements section comment(s):

3. Within the 8th optional marketing statement, revise "For control of fungus gnats" to read "To kill fungus gnats."

Directions for Use, Use Restrictions subsection comment(s):

- 4. To facilitate inclusion of required label language from the REDs for pyrethrins and piperonyl butoxide (updated label tables for pyrethrins/piperonyl butoxide combination products), you must incorporate the following changes into the subject label:
 - Insert the following new bulleted statement immediately preceding the 1st bulletized statement: "This product does not control bed bugs."
 - Revise the 4th bulleted statement to read "When using in homes: Remove or cover exposed food and drinking water, in the treatment area, before application. Remove or cover dishes, utensils, food processing equipment and food preparation surfaces, or wash them before use. Do not use in serving areas while food is exposed."
 - Insert the following new bulleted statement immediately following the revised 4th bulleted statement: "Do not allow adults, children or pets to enter until vapors, mists and/or aerosols 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 for at least 2 hours until aerosols, vapors and/or mists have dispersed."
 - Insert the following new bulleted statement immediately following the newly inserted bulleted statement above: "When using in food areas of food handling establishments: Do not make applications when facility is in operation. Avoid contamination of food or feedstuffs. During applications, cover or remove food. During applications, cover food processing surfaces and equipment or clean after treatment with a suitable detergent and rinse with potable water before use. Do not use in serving areas (dining areas where prepared foods are served) while food is exposed or facility is in operation."

Directions for Use, Use Restrictions subsection comment(s), continued:

- Within the 1st sentence of the 9th bulleted statement, replace the words "any person, pet, ..." with the words "adults, children, or pets, ..."
- Insert the following new bulleted statement immediately following the revised 9th bulleted statement: "Do not apply directly into sewers or drains, or to any areas like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow this product to enter and drain during or after application."

Directions for Use, HOW TO USE THIS PRODUCT PROPERLY subsection comment(s):

5. Revise the statement "Call your gas utility or management company if you need assistance." to read "Call your gas utility or Management Company if you need assistance with your pilot lights."

Directions for Use, BEFORE YOU FOG subsection comment(s):

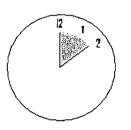
- In accordance with the Agency's March 23, 2010 and July 6, 2011 TRF quidance, you must insert the 6. following relocated text statement immediately following the 3rd sentence within this subsection: "Remove pets, birds, and cover fish aquariums before use."
- 7. Insert the following statement immediately following the last sentence within this subsection: "Immediately before activating fogger, complete the door hang-tag by filling in the time & date to instruct family and other people with access to the treated area (premises) not to enter for at least two (2) hours following the time of activation. Hang the tag on the door to the entrance."

Directions for Use, AIRING OUT subsection comment(s):

- In accordance with the Agency's March 23, 2010 and July 6, 2011 TRF guidance, you must:
 Use **boldface** type for the 1st and 4th sentences found within this subsection.

 - Revise the 5th sentence to read "Before re-occupying the treated area, open all doors and windows and allow the treated area to thoroughly ventilate (air out) for at least 2 hours."
 - Include a clock face pictogram shading the entry restriction immediately below the "AIRING OUT" subsection to appear as follows:

Example:



Storage and Disposal Statement section comment(s), pages 4-5 of 5:

- Revise the existing "Pesticide Storage:" subsection to read "Pesticide Storage: Store product in its original 9. container in a cool, dry (preferably locked) place away from heat or open flame in an area that is inaccessible to children and animals."
- 10. Insert the following text statement immediately following the revised "Pesticide Storage:" subsection above as follows: "Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility,"

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

11. Revise this subsection to read "CAUTION: Harmful if absorbed through the skin. Avoid contact with skin, eves, or clothing. Avoid breathing vapor or spray mist; breathing spray mist may be harmful. Wash hands thoroughly with plenty of soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes and gloves."

Precautionary Statements, Physical or Chemical Hazards subsection comment(s):

- 12. Revise the subsection heading to read "Physical and Chemical Hazards"
- 13. Revise this subsection to read "**Flammable**. Contents under pressure. Do not store near heat or open flame. Keep away from heat, sparks, and open flame. Do not apply this product around electrical equipment due to the possibility of shock hazard. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Never leave container in parked or unattended vehicles. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the Directions for Use on this label very carefully."
- 14. The "Highly Flammable Ingredient" pictogram, as shown below, must be displayed adjoining the revised "**Physical and Chemical Hazards**" subsection.



Highly Flammable Ingredient Ingrediente Altamente Inflamable

- Precautionary Statements, First Aid Statement subsection comment(s):
- 15. To facilitate inclusion of missing required label language from the original NOR for this product, you must reinsert the "**First Aid Statement**" subsection immediately following the revised "**Physical and Chemical Hazards**" subsection above, to read as follows:

	FIRST AID
If On Skin or Clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
cioting	 Call a poison control center or doctor immediately for further treatment advice.
	HOT LINE NUMBER
for treatment. For	t container or label with you when calling a poison control center or doctor, or going or additional information on this product (including health concerns, medical pesticide incidents), you may call 1-800-xxx-xxxx, twenty-four (24) hours per day, er week.

16. It is important to note that upon responding to this label review, you must substitute the "1-800-xxx-xxxx" notation with a valid phone number that is available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

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 section 6(e) of FIFRA. 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 <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yo

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7504P)

Copy of label stamped "Accepted with Comments"

Enclosure: 072804-00001 D456139

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Ultrasol Total Release Fogger

- For Residential/Homeowner Use Only
- [For Use in Homeowner Greenhouses
- For Use in Fruit & Vegetable Storage Areas
- May be Used on All Growing Plants
- For Use on Vegetable Plants
- For Use on Ornamental Plants and Flowers
- For Use on Fruits & Vegetables After Harvest
- 8 For Control of fungus gnats, spider mites, two-spotted spider mites, aphids, whiteflies, scale, mealy bugs & thrips
 - Contains No CFC's or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols]

Active Ingredients:	
Pyrethrins	0.40%
Piperonyl Butoxide*	
Other Ingredients:	
ould higher the	100.000%

*(butyl carbityl) (6-propylpiperonyl) ether and related compounds

EPA Reg. No.: 72804-1

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN CAUTION

See {appropriate location} for additional precautions

Ultrasol Industries, Ltd. 10755-69 Avenue Edmonton, Alberta T6H 2C9 Canada With COMMENTS In EPA Letter Dated: December 14, 2011 Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

ACCEPTED

72804-

Net Wt. 1.5 oz to 6.0 oz (xx g) Each. Total Net Wt. xx oz (xx g) Master label

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

Use Restrictions:

- Do not use multiple canisters in a room.
- Do not use in small confined areas
- Turn off ignition sources.
- Remove or cover exposed food.
- Air out the room before entering.
- Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for 2 hours.
- Vacate the treated house, individual apartment unit or other structure immediately. Do not re-enter for 2 hours
- Wait two (2) hours after application, then open windows, vents and doors for two hours. If an odor is still detected, additional ventilation is required.
- Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep
 people and pets out of the area during application.

{The following statements can be modified for larger size cans as long as the use rate remains 1 ounce per 1000 cu. ft.}

One 2 oz fogger treats up to 2000 cubic feet (a room up to 10 feet by 25 feet with an 8 foot ceiling) of unobstructed area. To calculate cubic feet. Multiply height x width x length.

General Use Instructions: For use in homeowner greenhouses and other indoor areas where plants are grown or produce is stored. Can be used on all ornamental and vegetable plants. Can also be used in storage areas where almonds, apples, beans, birdseed, blackberries, blueberries, boysenberries, cherries, corn (including popcorn), crabapples, currants, dewberries, figs, grapes, guavas, loganberries, mangoes, muskmelons, oranges, peaches, peanuts, pears, peas, pineapples, plums, potatoes, raspberries, sweet potatoes, tomatoes and walnuts are stored after harvest.

HOW TO USE THIS PRODUCT CORRECTLY:

DO NOT use multiple canisters in a room.

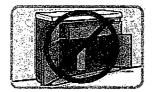


{graphic size 2.25 cm x 3.5 cm minimum}

Master label

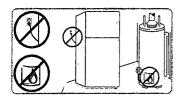
. . . .

DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. Use of a fogger in an enclosed space may cause the product to explode, resulting in injury to people or damage to property. DO NOT use in a room 5 ft x 5 ft or smaller; instead allow fog to enter from other rooms.



{graphic size 2.25 cm x 3.5 cm minimum}

Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames, or running electrical appliances that cycle on and off (i.e., refrigerators, thermostats, etc.) Call your gas utility or management company if you need assistance.



{graphic size 2.25 cm x 4 cm minimum}



{graphic size 2.25 cm x 3.5 cm minimum}

Step 1: BEFORE YOU FOG:

OPEN cabinets, cupboards, drawers, closets and doors in area to be treated. REMOVE or cover exposed foods, dishes, utensils, food processing equipment and surfaces. Cover waxed wood floors, waxed furniture and other plastic surfaces near the fogger (newspaper may be used). CLOSE outside doors and windows. SHUT OFF fans and air conditioners.



{graphic size 2.25 cm x 3.5 cm minimum}

Step 2: TO START FOGGING:

Do not place on water stainable surface. Place a chair or table in the center of area to be fogle() approximately 2 ft above the floor. Cover with several layers of newspaper or paper towels. Tilt can opening AWAY from face and depress tab firmly with thumb until it clicks in locked position. Set fogger on newspaper. Immediately leave the area.

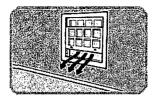
Master label

. . . .

. . .

Step 3: AIRING OUT

Vacate the treated house, individual apartment unit, or other structure immediately. Do not remain in the area during treatment. Keep treated area closed for 2 hours. Do not re-enter for 2 hours. Before reoccupying the area, open all doors and windows and allow to air for 2 hours.



{graphic size 2.25 cm x 3.5 cm minimum}

Repeat treatment in two weeks if insects return.

STORAGE AND DISPOSAL

Pesticide Storage: Store in a cool, dry place away from heat or open flame, preferably in a locked storage area. **Container Disposal:** Do Not Puncture or Incinerate! If Empty: Place in trash or offer for recycling if available. If Partly Filled: Call your local solid waste agency for disposal instructions.

PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

Caution: Breathing spray mist may be harmful.

Physical or 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. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the "Directions for Use" on this label carefully.

Highly Flammable Ingredient (FLAMMABILITY ICON) Ingrediente Altamente Inflamable

[Important Note: To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this product not in accordance with directions given herewith.]

[NOTICE: To the extent consistent with applicable law, buyer assumes all responsibility for use and storage of this product not in accordance with directions.]

[To the extent consistent with applicable law, seller warrants that the product conforms to the chemical description and is reasonabley fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, express or implied, extends to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to seller and buyer assumes all risk of any such use.]

{Entire label is printed in Spanish language inside the peel off label, inside and/or outside carton or box, on insert inside cap or box or on hang tag attached to can.}

[] Denote alternate text in addition to any directions for use.

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Text on Can

Ultrasol Total Release Fogger

0.40%
2.00%
7.60%
0.000%

*(butylcarbityl) (6-propylpiperonyl) ether and related compounds

Net Wt. 1.5 to 6.0 oz (xx g)

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel [insert inside cap] [insert inside box] [hang tag] [outside/inside box [carton] [peel out booklet] for complete directions for use, precautionary statements and first aid

[Available in English and Spanish]

[The entire label is [available] printed in Spanish [language] [inside the box] [on insert [found] [located] [inside cap] [inside box] [on hang tag] [on peel out booklet]

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Highly Flammable Ingredient (FLAMMABILITY ICON) Ingrediente Altamente Inflamable

Ultrasol Industries, Ltd. 10755-69 Avenue Edmonton, Alberta T6H 2C9 Canada EPA Reg. No: 72804-1 EPA Est. No:

{Additional information from the stamped accepted label may be provided on the can as space allows.}

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Text on Door Knob Hang Tag

[Attention:] [Notice:] Fogger In Use

Area has been treated with Ultrasol Total Release Fogger.

Note to User: Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for 2 hours.

[Do not enter [re-enter] treated [house] [apartment] [premises] until ______AM/PM on ______Ate]

Do not return to [enter] treated premises for 2 hours [until 2 hours have expired ______AM/PM _____[day]]

[Air out the room] [Wait 2 hours after application, then open windows, vents and doors if an odor is still detectable.]

Area may begin airing out at: ______ on______ (time-2 hours after activation) (date)

Area may be re-entered after airing out time: ______on _____on ______on ______

[cut here [scissors illustration] and hang on your door]

....

. . . .

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