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



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 29, 2011

Nasser A. Assaf, Ph.D Manager, Product Safety & Regulatory Affairs Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048

Subject:

**Amended Reregistration Label** 

Product Name: PYRAPERM® Total Release Indoor Fogger WBA P61

EPA Registration Number: 73049-348

EPA Decision Numbers: 410084, 411554, 413107, and 458900 (fogger

mitigation)

Dear Dr. Assaf:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Permethrin, Pyrethrins, and Piperonyl Butoxide REDs, and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 15 April, 2010
- Alternate CSF, dated 15 April, 2010

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Clayton Myers at 703-347-8874 or myers.clayton@epa.gov.

Sincerely,

Richard J. Gebken Product Manager

Insecticide Branch

Registration Division (7505P)

Enclosures: Label stamped "Accepted," dated December 29, 2011

Acute Toxicity Review, dated January 6, 2011 Product Chemistry Review, dated August 16, 2011

## 3048

# PYRAPERM® TOTAL RELEASE INDOOR FOGGER WBA P61

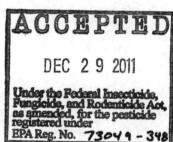
- [Contains Pyrenone® And Permanone®
- · Seeks Out Bugs Where They Hide
- Kills On Contact
- · Non-Staining
- No Unpleasant Odor
- · Water-Based Formula
- Kills Exposed Or Accessible Stages Of These Insects: Ants, Booklice, Carpet Beetles, Centipedes, Cockroaches, Confused Flour Beetles, Crickets, Earwigs, Firebrats, Fleas (Adults And Larvae), Flies, Fruit Flies, Gnats, Grasshoppers, Hornets, Houseflies, Midges, Millipedes, Mole Crickets, Mosquitoes, Palmetto Bugs, Pillbugs, Rice Weevils, Saw-Toothed Grain Beetles, Scorpions, Silverfish, Small Flying Moths, Sowbugs, Spiders, Stable Flies (Dog Flies), Ticks (Including Those Which May Cause Lyme Disease), Wasps, Waterbugs And Yellow Jackets]

{The entire label is printed in Spanish language [inside/outside the box][on peel out booklet] [or insert]}.

#### **ACTIVE INGREDIENTS:**

Pyrethrins	0.2%
Piperonyl Butoxide*	1.0%
Permethrin**	
OTHER INGREDIENTS†:	98.4%
	100.0%

<sup>\* (</sup>butyl carbityl)(6-propylpiperonyl) ether and related compounds.



**PRECAUCION AL CONSUMIDOR:** 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. 73049-348

EPA EST. NO.

## KEEP OUT OF REACH OF CHILDREN CAUTION

See Side/Back Panel For Additional Precautions

	FIRST AID
If Swallowed:	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>

#### **HOT LINE NUMBER**

Have the product container or label with you 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 1-877-315-9819.

#### NOTE TO PHYSICIAN

Contains petroleum distillate - vomiting may cause aspiration pneumonia.

**NET WEIGHT:** 

<sup>\*\*</sup>Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

<sup>†</sup>Contains Petroleum Distillate

## PRECAUTIONARY STATEMENTS Hazards To Humans & Domestic Animals

#### CAUTION

Harmful if swallowed. Breathing spray mist may be harmful. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

#### [Alternate text required for professional use products]

#### [PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers, must wear the following:

- Long-sleeved shirt
- Long pants
- · Shoes plus socks

#### **User Safety Recommendations:**

- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

#### **Physical and Chemical Hazards**

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Do not place on stove or radiator. 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 very carefully.

Highly Flammable Ingredient Ingrediente Altamente Inflamable



#### **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 remain in treated area. Exit area immediately and do not re-enter or allow adults, children, or pets to enter until vapors, and/or mist have dispersed and the treated area has been thoroughly ventilated.
- Wait two (2) hours after application, then open windows, vents and doors for two hours. There
  should be no remaining trace of pesticide fog or aerosol. If an odor is still detected additional
  ventilation is required.
- Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.
- Do not apply when food is present. Exposed food should be covered or removed. All food
  preparation surfaces and utensils should be covered during treatment or thoroughly washed
  before use.
- Do not use in greenhouses where plants are grown for food.
- Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental
  fish ponds) before application. Turn off aquarium filtering systems before spraying and wait
  approximately 15 minutes after application before turning the filter back on.
- Do not contaminate animal feed or water during application.
- [Alternate text: When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.]

#### [Alternate Use Restrictions for - Professional Use Labeling:]

- [Do not remain in treated area. Exit area immediately and do not re-enter or allow adults, children, or pets to enter until vapors, and/or mist have dispersed and the treated area has been thoroughly ventilated.
- Do not apply this product in a way that will contact workers or other persons, either directly or through drift.

Wait two (2) hours after application, then open windows, vents and doors for two (2) hours.
 There should be no remaining trace of pesticide fog or aerosol. If an odor is still detected, continue ventilating until no remaining trace or odor of pesticide remains.

Do not apply when food is present. Exposed food should be covered or removed. All food
preparation surfaces and utensils should be covered during treatment or thoroughly washed
before use.

Do not use in greenhouses where plants are grown for food.

Do not use in food areas of food handling establishments, restaurants, or other areas where
food is commercially prepared or processed. Do not use in serving areas while food is exposed
or facility is in operation. Serving areas are areas where prepared foods are served, such as
dining rooms, but excluding areas where foods may be prepared or held.

 May be applied in non-food/feed areas. Non-food/feed establishment areas are areas such as garbage rooms, lavatories, entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, mop closets and storage (after canning or bottling).

 Commercial food/feed areas where the product cannot be used include areas for receiving, serving, storage (Dry, Cold, Frozen, Raw), packaging (Cleaning, Slicing, Cooking, Grinding), edible, waste storage, enclosed processing systems (Mills, Dairies, Edible Oils, Syrups).

Do not use in aircraft cabins.

Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental
fish ponds) before application. Turn off aquarium filtering systems before spraying and wait
approximately 15 minutes after application before turning the filter back on.

Remove poultry before treating poultry houses.

 When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.]

For use in apartments, attics, basements, boats, cabins, campers, closed barns, day camps, garages, homes, horse stables, household storage areas, kennels, pet sleeping areas, rooms, non-commercial greenhouses, ship cabins, lathouses, seed houses, washrooms and the non-food/feed areas of schools, theaters, trucks, warehouses, boxcars, hospitals, hotels, industrial plants, motels and preschools.

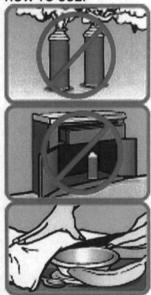
[One 2 ounce aerosol can treats up to 2,000 cubic feet of unobstructed area (a room 10= x 25= with an 8 foot ceiling).]

[To calculate cubic feet, multiply height x width x length.]

For Fleas and Ticks, use one 2 ounce can for every 2,000 cubic feet of room space.

Does not control bed bugs.

#### HOW TO USE:



To use this product correctly:

{graphic size 2.25 cm x 3.5 cm minimum}

DO NOT use multiple canisters in a room.

{graphic size 2.25 cm x 3.5 cm minimum}

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}

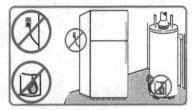
#### [Step 1:] BEFORE YOU FOG:

REMOVE or cover exposed foods, dishes, utensils, food processing equipment and surfaces. OPEN cabinets, cupboards, trunks, drawers, closets and doors in area to be treated to allow maximum kill in all areas where insects can hide and breed. Cover waxed wood floors, waxed furniture and other plastic surfaces near the fogger (newspaper may be used). CLOSE outside doors and windows to maximize killing power of fog. Cover or remove plants. SHUT OFF fans and air conditioners.



{graphic size 2.25 cm x 3.5 cm minimum}

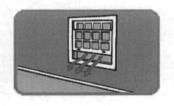
Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames or running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc). Call your gas utility or management company if you need assistance.



{graphic size 2.25 cm x 4 cm minimum}

[Step 2:] TO START FOGGING:

SHAKE WELL JUST BEFORE USING. Do not place on water stainable surface. Place a chair or table in the center of area to be fogged 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. Vacate the treated house, individual apartment unit, or other structure immediately. Do not re-enter for 2 hours. [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.]



{graphic size 2.25 cm x 3.5 cm minimum} [Step 3:1 AIRING OUT:

Before reoccupying the area, open all doors and windows and allow treated area to air for two (2) hours.

#### STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children and pets and away from heat, sparks or open flame.

Pesticide Disposal and Container Handling: 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.

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.]

#### 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.

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[Or alternate text

Note [Notice]: Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, seller shall have no liability for consequential damages.

Or

Notice: to the extent consistent with applicable law, buyer assumes all responsibility for safety and use not in accordance with directions.]

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PyraPerm is a registered trademark of Valent BioSciences Corporation. Pyrenone and Permanone are registered trademarks of Bayer AG.

 Piperonyl Butoxide\*
 1.0%

 Permethrin\*\*
 0.4%

 OTHER INGREDIENTS†:
 98.4%

\* (butyl carbityl)(6-propylpiperonyl) ether and related compounds. \*\*Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

†Contains Petroleum Distillate

Valent BioSciences Corporation Environmental Science Division 870 Technology Way Libertyville, IL 60048

#### **{TEXT ON DOOR KNOB HAND TAG}**

[Attention:] [Notice:] Fogger In Use			
[Area has been treated with [PyraPerm Total Release Indoor Fogger	WBA P61] [Fogge	er.]	
Note to User: Fill out and place hang-tag on the door to the treated a to the treated area not to enter for 2 hours.	area to alert family	and others v	vith access
[Do not enter [re-enter] treated [house] [apartment] [premises] until _	AM/PM on	1	_date]
[Do not return to [enter] treated premises for 2 hours [until 2 hours ha	ave expired	_AM/PM	[day]]
[Air out the room] [Wait 2 hours after application, then open windows, detectable.]	, vents and doors	if an odor is	still
Area may begin airing out at:onon(time-2 hours after activation)	ate)		
Area may be re-entered after airing out time:(2 hours minimum)	on		
[cut here [scissors illustration] and hang on your door]			
{TEXT ON CAN}			
PyraPerm Total Release Indoor Fogger WBA P61			
ACTIVE INGREDIENTS: Pyrethrins			

### Page 6 of 6

#### 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]

#### STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area inaccessible to children and pets and away from heat, sparks or open flame. Pesticide Disposal and Container Handling: 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

Harmful if swallowed. Breathing spray mist may be harmful. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID		
If Swallowed:	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	

#### HOT LINE NUMBER

Have the product container or label with you 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 1-877-315-9819.

#### NOTE TO PHYSICIAN

Contains petroleum distillate - vomiting may cause aspiration pneumonia.

#### Physical And Chemical Hazards

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Do not place on stove or radiator. Exposure to temperatures above 130°F may cause bursting. Do not use this unit in less than 100 cubic feet. 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.

Highly Flammable Ingredient Ingrediente Altamente Inflamable



Valent BioSciences Corporation Environmental Science Division 870 Technology Way Libertyville, IL 60048

EPA Reg. No: 73049-348 EPA Est. No:

NET Wt::

[Questions? Comments? See code on the bottom of can then call (xxx) xxx-xxxx or E-mail xxx@xxx.com]

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

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