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Janice K. Sharp, Ph.D. Valent BioSciences Corp. 870 Technology Way, Suite 100 Libertyville, IL 60048

Product Name: Pyrenone Lice Spray® FEB 2 4 2005 Company Name: Valent BioScience Corp EPA File Symbol: 73049-290 EPA Receipt Date: 10 August 2004 Subject: Amendment to a new Basic CSF to comply with CARB VOC regulations and labeling modifications associated with new CSF.

Dear Dr. Sharp,

The revised Basic confidential statement of formulas (CSF) dated 6 August 2004, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. This CSF has been added to the registration file for the aforementioned product. The revised and accepted CSF shall supersede any previous basic formulation on record.

The label amendment submitted meets the standards set forth in PR Notice 2001-1 and is accepted conditionally.

Submit two (2) copies of the revised final printed label for the record.

It has also come to the attention of the Agency that no data matrix is available for this product. Please provide a complete data matrix for this product within 120 days. If you have any questions, you may contact Mark E. Suarez, at (703) 305-0120.

Richard Gebken Acting Product Manager 10 Insecticide Branch Registration Division (7505C)

Enclosure 073049-00290 \$765622 <del>CSF.Accepted 29 September 2004</del> Fee Product Chemistry Review of EP 29 Septmeber 2004 Amended Label Conditionally Accepted 24 February 2005

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	H7505C				
•	MSUAREZ				
	Feb 24, 2005				

# **PYRENONE<sup>®</sup> LICE SPRAY**

• Contains Pyrenone

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- Provides Rapid Control of Lice (Body Lice, Head Lice, Crabs, Nits) and Chiggers on Personal Articles and Other Inanimate Surfaces. Not for Human Use.
- For Use in Homes. Office, Locker, Rest Rooms, and the Non-food Areas of Schools, Hospitals, Institutions, Motels and Restaurants.

### **ACTIVE INGREDIENTS:**

Pyrethrins	0.4 %
Piperonyl Butoxide*	
OTHER INGREDIENTS**:	
	100.0 %

\*Equivalent to min. 1.6% (butylcarbityl)(6-propylpiperonyl) ether and 0.4% related compounds. \*\*Contains Petroleum Distillate

**PRECAUCION AL CONSUMIDOR:** Sí 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.)

# EPA REG. NO. 73049-290

# EPA EST. NO.

with COMMENTS

In EPA Letter Dated:

FEB 2 4 2005 Under the Federal Insecticide,

# KEEP OUT OF REACH OF CHILDREN

# CAUTION

If Swallowed:	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
lf inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
If in eyes:	<ul> <li>Hold cyc open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
lf on skin or clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
	HOT LINE NUMBER

#### NOTE TO PHYSICIAN

Contains petroleum distillate - vomiting may cause aspiration pneumonia.

See Side Panel For Additional Precautions

**NET CONTENTS:** 

# PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals

#### CAUTION

Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing spray mist. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Use with adequate ventilation.

# **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 on or around 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.

SHAKE WELL BEFORE USING AND AT INTERVALS DURING PROLONGED USE

Do not apply this product in any rooms while occupied by patients, the elderly or infirm. Do not apply to classrooms when in use. Prevent re-entry of dogs and cats into treated area until spray deposits are dry.

Test product on an inconspicious area before applying. Spray until surface is slightly wet, but not to the point of runoff; over application may cause damage. Will not stain surfaces or fabrics where water alone causes no damage.

This product is for use on inanimate surfaces only. For control of lice on humans use a pediculicide (lice treatment) specifically designed for that purpose.

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 food may be prepared or held. Non-food areas include garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning and bottling). In the home, cover all food handling surfaces and cover or remove all food and cooking utensils or wash thoroughly after treatment. Cover or remove exposed food.

FOR USE ON INANIMATE SURFACES including garments, bedding, mattresses, furniture, floor and carpeting. Hold can upright with nozzle away from you. Press button and spray surface to be treated from a distance of 10 inches. Treat each square foot for 3 seconds, directing the spray to moisten all infested surfaces. In treating bedding, make sure the spray is directed into all corners of fitted sheets and blankets as well as the inside and outside of pillow cases. In treating garments and headgear, (including sports gear that may be passed from player to player) close attention should be given to seams, hems, cuffs, collars, and creases. After treatment, bedding and all garments must be either laundered in hot water or dry cleaned. For mattresses, furniture and carpeting: direct spray to moisten all folds, tucks, seams and crevices of infested areas. Allow the treated surface to dry completely before use.

# STORAGE AND DISPOSAL

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

Storage: Store in a cool dry area. Do not transport or store below 32°F. [Protect from freezing.] [Do not freeze.]

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 or 1-800-CLEANUP 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 should 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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