

71-1

11-4-2008

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Devon Morgan  
Regulatory Affairs Manager  
L. Perrigo Company  
515 Eastern Ave.  
Allegan, Michigan 49010

NOV 4 2008

**SUBJECT:** Application for Pesticide Notification (PRN 98-10)  
Request General Label Change (Optional Claims)  
EPA Reg. No. 71-1  
Application Dated August 28, 2008

Dear Registrant:


The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 08/28/08 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 71-1	<b>2. EPA Product Manager</b> Mr. George LaRoccs	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> 0.5% Permethrin Aerosol Spray	<b>PM#</b> 13	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> L. Perrigo Company 515 Eastern Avenue Allegan, MI 49010 <input type="checkbox"/> Check if this is a new address		<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is <u>identical</u> to a registered product and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____

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**Section - II**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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**Explanation: Use additional page(s) if necessary. (For section I and Section II.)**

Notification of Minor Labeling Change: This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.76 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
<i>* Certification must be submitted</i>		If "Yes" Unit Packaging wgt.    No. per container	If "Yes" Package wgt    No. per container		
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 5 oz (142 g)		<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
<b>6. Manner in Which Label is Affixed to Product</b> <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

**Section - IV**

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>		
<b>Name</b> Brian Anson	<b>Title</b> Reg. Affairs Project Mgr.	<b>Telephone No. (Include Area Code)</b> 269 673 1375
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		<b>6. Date Application Received</b> (Stamped)
<b>2. Signature</b> 	<b>3. Title</b> Regulatory Affairs Manager	
<b>4. Typed Name</b> Devon Morgan	<b>5. Date</b> 08 - 26 - 08	

-----Original Message-----

From: LaRocca.George@epamail.epa.gov  
[mailto:LaRocca.George@epamail.epa.gov]  
Sent: Thursday, July 17, 2008 10:34 AM  
To: Bridget Lee  
Subject: RE: FW: EPA labeling requirements: OPTIONAL CLAIMS

Ms. Bridget,

After reviewing your e-mail and explanation of the 1-2-3 and step 3 terms we have no objection to use of these optional claims provided you qualify it to read "1-2-3- Lice Control System" (not elimination) and submit as a Notification the labeling for the lice kit label since it references the spray product. In the notification you need to certify that the labeling for the spray product is identical to the last acceptable labeling for the product. Thanks.

## NOTIFICATION

NOV 04 2008

George LaRocca, PM 13  
Insecticides Branch  
Registration Division  
Office of Pesticides Programs, US EPA  
703-305-6100  
larocca.george@epa.gov  
Visit: <http://www.epa.gov/pesticides/>

Mr. LaRocca,

As previously discussed, a number of Perrigo's lice bedding spray products are marketed both individually and as part of a 3-part kit.

The kit includes components intended to be used in a specific order.

"1-2-3" describes to the user the order in which the kit's three components are to be used.

Steps 1 and 2 are non-pesticide items intended to remove lice from the head:

\* Step 1 is a drug shampoo to kill lice and nits.

\* Step 2 is a combing gel used to make the combing process easier to remove lice and nits killed by the shampoo.

\* Step 3 is the pesticide spray used to kill lice on bedding in order to minimize re-infestation of humans by killing lice that might be surviving on the bedding.

This "1-2-3" system is clearly described on the kit labeling. Because the shampoo, combing gel and spray can be sold separately, the "Step"

designation on those individual items helps the user understand what product they are buying in the system and may also alert them to the possibility that they haven't purchased all of the products needed to fully implement the system.

The labeling provides detailed directions for each step and how they work together and outlines expectations for elimination and control of lice infestation.

Please see attached an example label for the lice treatment kit ("1-2-3" system) as well as the individual label for the lice bedding spray, which bears the term "step 3" only to indicate its inclusion in the kit.

Our goal is that labeling complies with all EPA and state agency requirements. The labeling was designed to provide consumers with all necessary information and to avoid any confusion. This labeling is based on the "brand standard", which has been approved and distributed without any reports of consumer confusion of which we are aware.

Please advise whether you believe the "1-2-3" designation outlined above is acceptable and in compliance with EPA policy. Also, please feel free to contact me to discuss at your convenience.

Thank you.

Bridget Lee

Sive, Paget & Riesel, P.C.  
460 Park Avenue  
New York, NY 10022  
blee@sprlaw.com  
(212) 421-2150 ext. 274



August 26, 2008

VIA OVERNIGHT DELIVERY

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Notification of Minor Labeling Change for EPA Registration Number 71-1

Dear Sir or Madam:

The L. Perrigo Company ("Perrigo") currently holds the EPA pesticide product registration for 0.5% Permethrin Aerosol Spray (EPA Reg. No. 71-1). On November 6, 2007, EPA found Perrigo's application for amendment to registration acceptable subject to four comments.

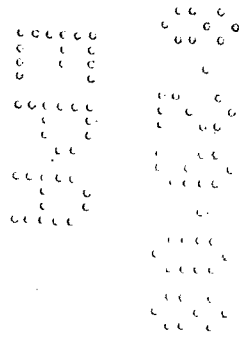
Following his review of final printed labeling, EPA Product Manager George LaRocca determined that the instruction in comment "2" to delete reference to "step 1-2-3" or "step 3" was unnecessary and that EPA had no objection to the use of these optional claims provided that the "step 1-2-3" claim, which appears on the labeling of Perrigo's kit containing the aerosol spray, read "1-2-3 Lice Control System", not "1-2-3 Lice Elimination System." During an August 22, 2008 telephone conversation with Bridget Lee, Perrigo's environmental counsel, Mr. LaRocca further confirmed that the inclusion of the term "step 3" on the individual aerosol spray labeling was acceptable and that the instruction to change "control" to "kill" found in comment "4" was unnecessary. The attached e-mail exchanges substantiate such understanding.

We therefore submit this Notification, pursuant to 40 C.F.R. § 152.46 and PR Notice 98-10, to document such confirmation of the acceptability of "1-2-3 Lice Control Spray." Please inform Perrigo of a determination of notification acceptability by returning the enclosed postcard. If you have any questions, please do not hesitate to contact Brian Anson directly at (269) 673-1375.

Sincerely,

Devon Morgan  
Regulatory Affairs Manager

cc: George LaRocca (via e-mail)



GOOD SENSE

In-Home Not For Use On Humans

# Bedding Spray

## Lice Treatment

### STEP 3

1-2-3 Lice Control System

**Kills lice and their eggs on bedding, furniture, car interiors and other non-washable items**

**ACTIVE INGREDIENT:**

Permethrin 0.50%

**OTHER INGREDIENTS:** 99.50%

100.00%

\* Cis/trans ratio: Min. 35% (±) cis and Max. 65% (±) trans.

\*\* Contains Petroleum distillate

KEEP OUT OF REACH OF CHILDREN  
**CAUTION**  
See side panel for additional precautions



READ ENTIRE LABEL BEFORE EACH USE

NET WT 5 OZ (142 g)

This product is Step 3 of a three step lice control system that includes a shampoo as Step 1 and a combing gel as Step 2.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**CAUTION:** Harmful if swallowed or absorbed through skin. Avoid inhalation of spray mist. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of feed and foodstuffs.

**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 (54°C) may cause bursting.

**FIRST AID**

Call a Poison Control Center or doctor immediately for treatment advice. Have product container or label with you when calling a Poison Control Center or doctor or going for treatment.

<b>If swallowed:</b>	<ul style="list-style-type: none"> <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>
<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>Hold eye 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> </ul>
<b>If inhaled:</b>	<ul style="list-style-type: none"> <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> </ul>
<b>If on skin or clothing:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>

**NOTE TO PHYSICIAN**

Contains petroleum distillate - vomiting may cause aspiration pneumonia.

EPA Reg. No. 71-1  
EPA Est. No. See Bottom or Top of Can  
DOT 2P

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Remove pets and birds and cover fish aquaria before space spraying or surface applications. **This product is not for use on humans.** If lice infestation occurs on humans, use a product labeled for use on humans. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry.

**SHAKE WELL BEFORE USING**

Remove protective cap. Hold container upright and spray from a distance of 8-10 inches. Individuals with asthma or severe allergies should consult their doctor before using this product and have someone else apply this product.

**To kill lice and louse eggs:** Spray in 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 to the point of dampness but not run-off. Spray only those articles and parts of bedding including mattresses and furniture, that cannot be either laundered or dry-cleaned. Do not use on pillowcases, sheets or clothing. Allow all sprayed articles to dry thoroughly before each use.

**STORAGE AND DISPOSAL**

**Storage:** Store in a cool, dry area away from children and pets and away from heat, sparks and open flame. Do not transport or store below 32°F (0°C).

**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 or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**NOTICE:** Purchaser assumes all responsibility for safety and use not in accordance with directions.

DISTRIBUTED BY  
L. Perrigo Co.  
515 Eastern Avenue  
Allagan, MI 49010



3 70030 14861 5

: 9K1C3 C2 FJ

NO TYPE AND NO COLOR AREA

NOTIFICATION

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