

71-1

03-31-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 31 2010

Mr. Brian Anson
L. Perrigo Company
515 Eastern Avenue
Allegan, MI 49010

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Mr. Anson:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated February 23, 2010 for the following product(s):

0.5% Permethrin Aerosol Spray (EPA Reg. No. 71-1)
Alternate Brand Name: "Up & Up Lice Bedding Spray Step 3"

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN-98-10. The label has been date-stamped "Notification" and will be placed in our records.

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 nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact Regina Foushee'-Smith at 703-605-0780.

Sincerely,

A handwritten signature in cursive script that reads "Richard J. Gebken".

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

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

	United States Environmental Protection Agency 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

1. Company/Product Number 71-1-13344	2. EPA Product Manager Mr. Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 0.5% permethrin aerosol spray	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) L. Perrigo Company 515 Eastern Avenue Allegan, MI 49010 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>71-1</u> Product Name <u>Up & Up Lice Bedding Spray Step 3</u>

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name: Per 40 CFR 152.46 and PR Notice 98-10, this is to notify EPA of the addition of a new alternate brand name to the brand names already under Perrigo. Labeling meets the requirements of 40 CFR 156.10. (See attachment for additional information)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt No. per container	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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* Certification must be submitted

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 5 oz (142g)	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Brian Anson	Title Reg Affairs Proj Manager	Telephone No. (Include Area Code) 269 673 1375
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Certification

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 or both under applicable law.

2. Signature 	3. Title Regulatory Affairs Project Manager	6. Date Application Received (Stamped)
4. Typed Name Brian Anson	5. Date Feb 23, 2010	

lice bedding spray
step 3

not for use on humans
for bedding and furniture
kills lice and their eggs on mattresses,
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

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.

If swallowed:	<ul style="list-style-type: none"> • Immediately call a Poison Control Center or doctor. • Do not induce vomiting unless told to do so by a Poison Control Center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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.
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 by mouth-to-mouth, if possible.
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.

NOTE TO PHYSICIAN

Contains petroleum distillate – vomiting may cause aspiration pneumonia.

EPA Reg. No. 71-1-13344
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.

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NO TYPE AND NO COLOR AREA