

PM-90

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States
 Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
 250108

Application for Pesticide - Section I

1. Company/Product Number Primavera Laboratories, Inc. / 65233-4	2. EPA Product Manager John Tice	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Bath & Body Works Outdoors 3 in 1 Suncare	PM# 90	
5. Name and Address of Applicant (include ZIP Code) Primavera Laboratories, Inc. 99 Biltmore Ave., Suite 254 Rye, NY 10580-1891 <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. 65233-4 Product Name TREO [®] SPF 8	

Section - II

Amendment - Explain below.
 Resubmission in response to Agency letter dated _____
 Notification - Explain below.

Final printed labels in response to Agency letter dated _____
 "Me Too" Application.
 Other - Explain below.

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

LABELING CHANGES: Miscellaneous Labeling Statement Changes (see additional sheets)

NOTIFICATION
 BPPD
 APR 18 1996

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <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) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. 4 fluid oz. No. per container 1	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container H-4.95" x W-2.25" x TH-1.41" top-.90" bottom (tapered)		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 type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other Pressure sensitive adhesive, clear plastic label		

Section - IV

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

Name Matthew R. Schneider	Title Authorized Representative	Telephone No. (Include Area Code) 202-965-7880
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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 <i>Matthew R. Schneider</i>	3. Title Authorized Representative	6. Data Application Received (Stamped)
4. Typed Name Matthew R. Schneider	5. Date April 3, 1996	

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9. Product Description:

"Bath & Body Works Outdoors 3 in 1 Suncare

- A PABA free, waterproof sunscreen that retains its degree of protection for at least 80 minutes in the water. It offers full-spectrum protection against both UVA and UVB rays and their skin damaging effects. Regular use may reduce the risks of skin cancer, premature aging and wrinkling due to prolonged sun exposure.
- An insect repellent effective against mosquitoes, deer ticks and fleas.
- A moisturizer that helps protect the skin against drying, peeling and cracking."

substituted for entire Product Description.

10. Directions: "Bath & Body Works Outdoors" substituted for each occurrence of "TREO".

11. Disposal Statement: "DISPOSAL: DO NOT REUSE EMPTY CONTAINER. PUT IN TRASH." added.

12. Other Ingredients: Isostearyl alcohol, Tocopheryl acetate, Propylene Glycol, Carbomer, Triethanolamine, Diazolidinyl urea added; Cetyl alcohol, Steapyrium chloride, Glyceryl monostearate, Imidazolidinyl urea, BHA subtracted.

13. Regulatory Information: "EPA Reg. No. 65233-4-697773" substituted for "EPA Reg. No. 65233"

"EPA Est. No. 12483-NY-002" substituted for "EPA Est. No. 059368-SC-001".

"US Pat. no. 5,227,406" added.

14. Manufacturing Data: "CREATED IN THE HEARTLAND
Manufactured for Bath & Body Works
97 West Main Street
New Albany, OH 43054
USA"
substituted for "Primavera Laboratories, Inc."

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L65

Bath & Body Works

 Outdoors

S 3^N1
SUNCARE
 SPF 8

Paba Free
 Waterproof Sunscreen

◆
 Mosquito, Deer Tick
 & Flea Repellent

◆
 Light Moisturizer

ACTIVE INGREDIENT:*
 OIL OF CITRONELLA 05%
 INERT INGREDIENTS: 99.95%
 *INSECT REPELLENT

KEEP OUT OF REACH
 OF CHILDREN.
CAUTION

4 FL.OZ./118mLe

Bath & Body Works
Outdoors
3 IN 1 SUNCARE

- A PABA free, waterproof sunscreen that retains its degree of protection for at least 80 minutes in the water. It offers full-spectrum protection against both UVA and UVB rays and their skin damaging effects. Regular use may reduce the risks of skin cancer, premature aging and wrinkling due to prolonged sun exposure.
- An insect repellent effective against mosquitoes, deer ticks and fleas.
- A moisturizer that helps protect the skin against drying, peeling and cracking.

DIRECTIONS: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply Bath & Body Works Outdoors liberally and evenly before exposure to sun or mosquitoes, deer ticks and fleas. Reapply after 80 minutes in the water, excessive perspiration, or prolonged activity. For longer lasting mosquito protection, apply a heavier initial dose of Bath & Body Works Outdoors to exposed skin. Reapply when effectiveness diminishes. For continued flea and deer tick protection, reapply frequently to maintain repellency.

DISPOSAL: DO NOT REUSE EMPTY CONTAINER. PUT IN TRASH.
CAUTION: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. DISCONTINUE USE IF IRRITATION OR RASH APPEARS. USE ON CHILDREN UNDER 6 MONTHS OF AGE ONLY WITH ADVICE OF PHYSICIAN.

ACTIVE SUNSCREEN INGREDIENTS: OCTYL METHOXYCINNAMATE, OCTYL SALICYLATE. OTHER INGREDIENTS: WATER, OCTYL PALMITATE, GLYCERIN, PVP/EICOSENE COPOLYMER, STEARIC ACID, DEA-CETYL PHOSPHATE, ISOSTEARYL ALCOHOL, TOCOPHERYL ACETATE, DIMETHICONE, PROPYLENE GLYCOL, CARBOMER, TRIETHANOLAMINE, DIAZOLIDINYL UREA, METHYLPARABEN, PROPYPARABEN, FRAGRANCE.

EPA REG. NO. 65233-4-69773 EPA EST. NO. 12483-NY-002
US PAT. NO. 5,227,406

CREATED IN THE HEARTLAND
Manufactured for Bath & Body Works
97 West Main Street
New Albany, Ohio 43054
USA

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FRONT LABEL

TREO®

3-WAY OUTDOOR
PROTECTION

PABA FREE
SUNSCREEN

MOSQUITO, FLEA &
DEER TICK REPELLENT

SOOTHING
MOISTURIZER

ACTIVE INGREDIENT*:
OIL OF CITRONELLA .05%
INERT INGREDIENTS* 99.95%

*Insect Repellent

CAUTION:
KEEP OUT OF REACH OF CHILDREN

SPF 8

4 FL. OZ. (118 ml)

ACCEPTED
with COMMENTS
in EPA Letter Dated

11 MAY 1994

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
I recommend, for the reasons
stated above, EPA Reg. 156
65233-4

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BACK LABEL

PLEASANT HERBAL SCENT

TREO® Lotion is waterproof. It retains its degree of sunscreen protection for at least 80 minutes in the water. TREO® provides full-spectrum protection from the damaging effects of both UVA and UVB rays. TREO® is effective against fleas, mosquitoes and deer ticks. Protection from peeling, drying and cracking skin. TREO® is non-comedogenic. It moisturizes dry skin and helps prolong your tan. The liberal and regular use over the years of this product may also help reduce the chance of premature aging and wrinkling caused by exposure to the sun.

DIRECTIONS: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apply TREO® liberally and evenly before exposure to sun or mosquitoes, deer ticks and fleas. Reapply after 80 minutes in the water, excessive perspiration or prolonged activity. For longer lasting mosquito protection apply a heavier initial dose of TREO® to exposed skin. Reapply when effectiveness diminishes. For continued flea and deer tick protection, reapply frequently to maintain repellency.

CAUTION: For external use only. Avoid contact with eyes. Discontinue use if irritation or rash appears. Use on children under 6 months of age only with the advice of a physician.

ACTIVE SUNSCREEN INGREDIENT: OCTYL METHOXYCINNAMATE, OCTYL SALICYLATE

OTHER INGREDIENTS: Water, Glycerin, PVP/Eicosene Copolymer, Octyl Palmitate, Stearic Acid; DEA-Cetyl Phosphate, Cetyl Alcohol, Steapyrium Chloride, Glyceryl Monostearate, Dimethicone, Imidazolidinyl Urea, Methylparaben, Propylparaben, Fragrance, BHA.

EPA Reg. No. 65233-
EPA Est. No. 059368-SC-001
Primavera Laboratories, Inc.
New York, New York 10019

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Term of Issuance: **Conditional**

NOTICE OF PESTICIDE:
 X Registration
 Reregistration

Name of Pesticide Product: **TREO SPF 8**

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

**Primavera Laboratories, Inc.
730 Fifth Avenue, Suite 1804
New York, New York 10019**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 65233-4".
- b. The term active ingredients and inert ingredients must be aligned to the same margin.
- c. Add the statement, " DISPOSAL: Do not reuse empty container. Wrap container and put in trash collection."

Signature of Approving Official:

Date: **11 MAY 1994**

3. Submit one (1) copy of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

This registration is being granted at this time on the express condition that EPA shall have the right at any time to designate certain ingredients in this product as active ingredients either in addition to or as an alternative to the designation of citronella as an active ingredient and require the submission of additional supporting data. Premavera Laboratories, Inc. shall have 30 days to submit an appropriate amendment after being notified by EPA in writing of any new designation of active ingredients along with any required supporting data and shall not apply any labels not containing such new designation to the product after being notified by EPA of the acceptance of the new designation. If Premavera Laboratories, Inc. fails to submit an appropriate application for amendment in a timely manner, applies labels not containing the new designation of active ingredients to the product after being notified of the acceptance of the new designation, or fails to submit or commit to the submission of any required data, EPA shall have the authority to cancel this registration by order and without hearing. Any such cancellation will be effective immediately upon written notification to Premavera Laboratories, Inc.

Sincerely,



Robert S. Brennis
Acting Product Manager 10
Insecticide & Rodenticide Branch
Registration Division (7505C)

9/23

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FRONT LABEL

TREO®

3-WAY OUTDOOR
PROTECTION

PABA FREE
SUNSCREEN

MOSQUITO, FLEA &
DEER TICK REPELLENT

SOOTHING
MOISTURIZER

ACTIVE INGREDIENT*:
OIL OF CITRONELLA .05%
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*Insect Repellent

CAUTION:
KEEP OUT OF REACH OF CHILDREN

SPF 8

4 FL. OZ. (118 ml)

ACCEPTED
with COMMENTS
in EPA Letter Dated

11 MAY 1994

U.S. Environmental Protection Agency
Office of Pesticide Programs
Washington, D.C. 20460
65233-4

4 3 4

BACK LABEL

PLEASANT HERBAL SCENT

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EPA Reg. No. 65233-

EPA Est. No. 059368-SC-001

Primavera Laboratories, Inc.

New York, New York 10019