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PM-90 NOTIFICATION OF LABELING STATEMENT CHANGES PER PR NOTICE 95-2 19 7	
Please read instructions on reverse before completing form.	Form Approved. OMB No. 2070-0060. Approvel expires 05-31-98
SEPA Environmental Protection Ag Washington, DC 20460	· · · · · · · · · · · · · · · · · · ·
Application for Pesticide - Section I Application for Pesticide - Section for Pesticide - Sectio	
1. Company/Product Number Primavera Laboratories, Inc. / 65233-6	2. EPA Product Manager John Tice 3. Proposed Classification
4. Company/Product (Name) SPF 30 Bath & Body Works Outdoors 3 in 1 Suncare	PM# - Restricted
5. Name and Address of Applicant (Include ZIP Code) Primavera Laboratories, Inc. 99 Biltmore Ave., Suite 254 Rye, NY 10580-1891 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. TREO SPF 30
[A 12 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
Amendment - Explain below. Resubmission in response to Agency letter dated	
LABELING CHANGES: Miscellaneous Labeling Statement Changes (see attached sheers). APR 1 8 1996 BPPD	
Section - III	
1. Material This Product Will Be Packaged In:	
Yes X No X Yes X X Yes X X X Yes X X X Yes X X X X X X Yes X X X X X X X X X X X X X X X X X X X	J " Glass
3. Location of Net Contents Information X Label Conteiner 4. Size(s) Retail Contents TH bottom (tape:	tainer H _{ff} 4,95" x -1.41" top90" S. Location of Label Directions red) On Label On Label On Label On Label On Label On Labeling accompanying product
6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled	xx Other <u>Pressure sensitive adhesi</u> ye 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 Title Matthew R. Schneider Aut	horized Representative Telephone No. (Include Area Code) 202-965-7880
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. 6. Date Application Received (Stamped)	
2. Signature 3. Title Au	thorized Representative

Matthew R. Schneider

4. Typed Name

5. Date

April 3, 1996

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PRIMAVERA LABORATORIES EPA REG. NO. 65233

LABEL CHANGES FOR

BATH & BODY WORKS OUTDOORS 3 in 1 SUNCARE SPF 30

{As compared to attached EPA stamped label dated May 11, 1994}

FRONT LABEL

- 1. Brand Name: "Bath & Body Works Outdoors" substituted for "TREO*".
- 2. Product Name: "3 in 1 Suncare SPF 30" substituted for "3-Way Outdoor Protection SPF 30".
- 3. Sunscreen Description: "Paba Free Waterproof Sunscreen" substituted for "Paba Free Sunscreen".
- 4. Insects Repelled: "Mosquito, Deer Tick & Flea Repellent" substituted for "Mosquito, Flea & Deer Tick Repellent".
- 5. Moisturizer Type: "Light Moisturizer" substituted for "Soothing Moisturizer".
- 6. Percentage of Ingredients: Decimals aligned.
- 7. Signal: "KEEP OUT OF THE REACH OF CHILDREN" placed over "CAUTION". No colon after "CAUTION".
- 8. Quantity: "4 FL.OZ./118mle" substituted for "4 FL. OZ (118 ml)".

BACK LABEL Page 2

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, Propylene Glycol, Carbomer,
 Triethanolamine, Diazolidinyl urea, BHT added; Cetylalcohol, Steapyrium chloride, Glyceryl monostearate,
 Imidazolidinyl urea, BHA subtracted.
- 13. Regulatory Information: "EPA Reg. No. 65233-6-69773" substituted for "EPA Reg. No. 65233"

"EPA Est. No. 12483-NY-002" substituted for "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.".

LABEL CHANGES - SPF 30

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This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, 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 95-2 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.



SPF 30

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.0Z/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 production 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: OCTOCRYLENE, OCTYL METHOXYCINNAMATE, OXYBENZONE, OCTYL SALICYLATE. OTHER INGREDIENTS: WATER, GLYCERIN, OCTYL PAL MITATE, PVP/ECOSENE COPPLYMER, STEARIC ACID, DEA-CETYL PHOSPHATE, ISOSTEARYL ALCOHOL, DIMETHICONE, PROPYLENE GLYCOL, CARBOMER, TRIETHANOLAMINE, DIAZOLIDINYL UREA, METHYL PARABEN, PROPYL PARABEN, BHT, FRAGRANCE.

EPA REG. NO. 65233-6-69773 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 Onto 43054 USA

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 30

4 FL. OZ. (118 ml)

ACCEPTED
with COMMENTS
in EPA Latter Dates

11 MAY 1994

Under the Federal Insecticids. Persipide, and Medical Science Action Community Services and Services Services and Services Servic

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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: OCTOCRYLENE, GCTYL METHOXYCINNAMATE, OCTYL SALICYLATE, BENZOPHENONE-3

OTHER INGREDIENTS: Water, Glycerin, Octyl Palmitate, PVP/Eicosene Copolymer, 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