

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 26 1995

Primavera Laboratories, Inc.
99 Biltmore Ave., Suite 260
Rye, NY 10580

Dear Mr. Beldock

Re: Your Request for Label Amendment dated 6/14/94 and Alternate Formulation Dated 5/5/95 for Treo SPF 8, EPA Reg. No. 65233-4

The formula statement referred to above is acceptable as an alternate formula under this registration and has been included in our files. I have enclosed a copy of the evaluation of the alternate formulation for your records.

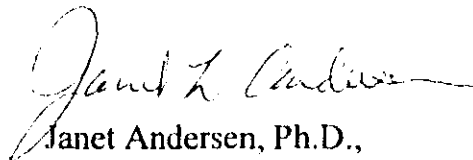
The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments below. A disposal statement is required and the statement submitted by your agent is acceptable.

- ◆ On the front panel, the signal word "CAUTION" must appear centered in the text above the sentence "Keep out of reach of children".
- ◆ The percentages representing the amounts of active and inert ingredients should be aligned by the decimal points.
- ◆ A disposal statement must be included which states, "DISPOSAL: Do not reuse empty container. Put in trash".

A stamped copy of the label is enclosed for your records. You must incorporate any comments noted on your label. This label must be on products released for shipment within 1 year or by the next printing, which ever occurs first.

Five copies of the finished labeling must be submitted prior to releasing the product for shipment.

Sincerely,



Janet Andersen, Ph.D.,
Acting Director,
Biopesticides & Pollution Prevention
Division (7501W)
Office of Pesticide Programs

Enclosures

TICE/7501-W/703-308-8295/CITRONELLA/09-22-95/EPA REG. # 65233-4

CONCURRENCES

SYMBOL	7501-W	7501W	7501W				
SURNAME	TICE	TICE	Andersen				
DATE	9/24/95	9/20/95	9/28/95				

TREO® 3-WAY OUTDOOR PROTECTION LOTION SPF 8

FRONT OF BOTTLE:

TREO®
3-WAY OUTDOOR
PROTECTION

MOISTURIZING
SUNCARE

MOSQUITO, FLEA & DEER TICK
REPELLENT

SPF 8
PABA-FREE
SUNSCREEN LOTION

ACTIVE INGREDIENT: *
OIL OF CITRONELLA .05%
INERT INGREDIENTS: 99.95%
* INSECT REPELLENT
CAUTION: KEEP OUT OF
REACH OF CHILDREN.

118 ml 4 FL. OZ.

**ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 26 1995**

*Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.*

65233-4

BACK OF BOTTLE:

TREO® 3-Way Outdoor Protection 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 UV rays. TREO® is effective against fleas, mosquitoes and deer ticks. Protection from peeling, drying and cracking skin. 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.

BACK OF BOTTLE:
CON'T:

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 INGREDIENTS: OCTYL
METHOXYCINNAMATE,
OCTYL SALICYLATE.

OTHER INGREDIENTS:

WATER, GLYCERIN, PVP/EICOSENE COPOLYMER, OCTYL PALMITATE, STEARIC ACID, DEA-CETYL PHOSPHATE, CETYL ALCOHOL, STEAPYRIUM CHLORIDE, GLYCERYL STEARATE, IMIDAZOLIDINYL UREA, DIMETHICONE, METHYLPARABEN, PROPYLPARABEN, FRAGRANCE, BHT, DISODIUM EDTA

EPA Reg. No. 65233-4
EPA Est. No. [To be assigned]
U.S. Pat. No. 5,227,406
Primavera Laboratories, Inc.
Rye, NY 10580