

BLEVE BVIBRANT- octyl methoxycinnamate lotion
TOPCO ASSOCIATES LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

ACTIVE INGREDIENT

OCTYL METHOXYCINNAMATE 2%

AVOBENZONE 0.5%

PURPOSE

SKIN PROTECTANT

SKIN PROTECTANT

USES

HELPS PREVENT SUNBURN.

WARNINGS

FOR EXTERNAL USE ONLY.

SKIN CANCER/SKIN AGING ALERT

SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY SKIN AGING. THIS PRODUCT HAS BEEN SHOWN ONLY TO HELP PREVENT SUNBURN, NOT SKIN CANCER OR EARLY SKIN AGING.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

APPLY LIBERALLY 15 MINUTES BEFORE EXPOSURE TO SUN. USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING. REAPPLY AT LEAST EVERY TWO HOURS. FOR CHILDREN UNDER 6 MONTHS, ASK A DOCTOR.

INACTIVE INGREDIENTS

WATER (AQUA), CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES, GLYCINE SOJA (SOYBEAN) OIL, C12-15 ALKYL BENZOATE, POLYGLYCERYL-3 METHYLGLUCOSE DISTEARATE, GLYCERYL STEARATE, CETYL ALCOHOL, STEARYL ALCOHOL, DIMETHICONE, VITIS VINIFERA (GRAPE) FRUIT CELL EXTRACT, ISOMALT, LECITHIN, SODIUM BENZOATE, PALMITOYL TRIPEPTIDE-38, GLYCERIN, HYDROXYPROPYL CYCLODEXTRIN, INULIN, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, FRAGRANCE (PARFUM), PHENOXYETHANOL, TROPOLONE.

LABEL COPY



BLEVE BVIBRANT

octyl methoxycinnamate lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:36800-353

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 2 mL in 100 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 0.5 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309) | |
| SOYBEAN OIL (UNII: 241ATL177A) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| POLYGLYCERIN-3 (UNII: 4A0NCJ6RD6) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| VITIS VINIFERA FLOWERING TOP (UNII: 6TG3V35HTV) | |
| ISOMALT (UNII: S870P55O2W) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROXYPROPYLBETADEX (0.58-0.68 MS) (UNII: 1I96OHX6EK) | |
| INULIN (UNII: JOS53KRJ01) | |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| TROPOLONE (UNII: 7L6DL16P1T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:36800-353-04 | 118 mL in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 03/19/2012 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|---------------------|
| APOLLO HEALTH AND BEAUTY CARE | | 201901209 | manufacture |

Revised: 3/2012

TOPCO ASSOCIATES LLC