MUSTELA MINERAL SUNSCREEN BROAD SPECTRUM SPF 50- zinc oxide lotion
Expanscience Laboratories d/b/a Mustela

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.

MUSTELA MINERAL SUNSCREEN BROAD SPECTRUM SPF 50

Drug Facts

Active Ingredient

Zinc Oxide 24%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed wtih other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only.

Do not use on damaged or broken skin.

When using this product keep out of the eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Apply liberally to exposed areas 15 minutes before sun exposure.
- Reapply: after 80 minutes of swimming or sweating.
- immediately after towel drying.
- at least every 2 hours.
- **Sun protection measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
- limit time in the sun, expecially from 10 a.m. - 2 p.m.
- wear long-sleeved shirt, pants, hat and sunglasses
- children under 6 months: ask a doctor

Inactive ingredients

WATER, C15-19 ALKANE, GLYCERIN, POLYGLYCERYL-3 POLYRICINOLEATE, ETHYL MACADAMIATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, STYRENE/ACRYLATES COPOLYMER,

STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PROPANEDIOL, POLYHYDROXYSTEARIC ACID, TRIETHOXYCAPRYLYLSILANE, 1,2-HEXANEDIOL, HYDROXYACETOPHENONE, MAGNESIUM SULFATE, SODIUM CHLORIDE, CAPRYLHYDROXAMIC ACID, TOCOPHERYL ACETATE, SODIUM HYALURONATE, TOCOPHEROL, MALIC ACID

Other information

Protect this product from excessive heat and direct sun. May stain some fabrics. You may report a serious adverse event to the phone number or address provided below.

Questions or comments?

Call toll free 1-800-422-2987 Monday-Friday 9:00am - 5:00pm EST

Company Information

MADE IN THE USA from globally sourced materials for Expanscience Laboratories Inc., Dba Mustela, 60 E. 56th St. 6th Floor, New York, New York 10022

www.MustelaUSA.com

Product Packaging - 100ml

Mustela

baby - child

MINERAL SUNSCREEN

FACE + BODY

DERMATOLOGIST TESTED

BROAD SPECTRUM

SPF 50

WATER RESISTANT

(80 MINUTES)

FOR BABIES, CHILDREN AND THE ENTIRE FAMILY

SAFE FOR SENSITIVE SKIN TYPES

0% FRAGRANCE AND PARABENS

100ml - 3.38 US FL.OZ.

EXPANSCIENCE LABORATOIRES

MUSTELA MINERAL SUNSCREEN BROAD SPECTRUM SPF 50

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64768-2924
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	240 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII:	

V5RS026Q0H)	
PROPANEDIOL (UNII: 5965N8W85T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
MALIC ACID (UNII: 817L1N4CKP)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
C15-19 ALKANE (UNII: CI87N1IM01)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64768-2924-1	100 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2019	
2	NDC:64768-2924-2	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2019	

Labeler - Expanscience Laboratories d/b/a Mustela (181191057)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(64768-2924)

Revised: 4/2020 Expanscience Laboratories d/b/a Mustela