SUNSCREEN- zinc oxide cream
Oxygen development

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 FACE+BODY SPF50

Active Ingredient

Zinc Oxide 24%

Purpose

Sunscreen

Uses

Helps to prevent the sunburn. If used as directed with 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

Do not use on damaged or broken skin.

When Using

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

Stop Use

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

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

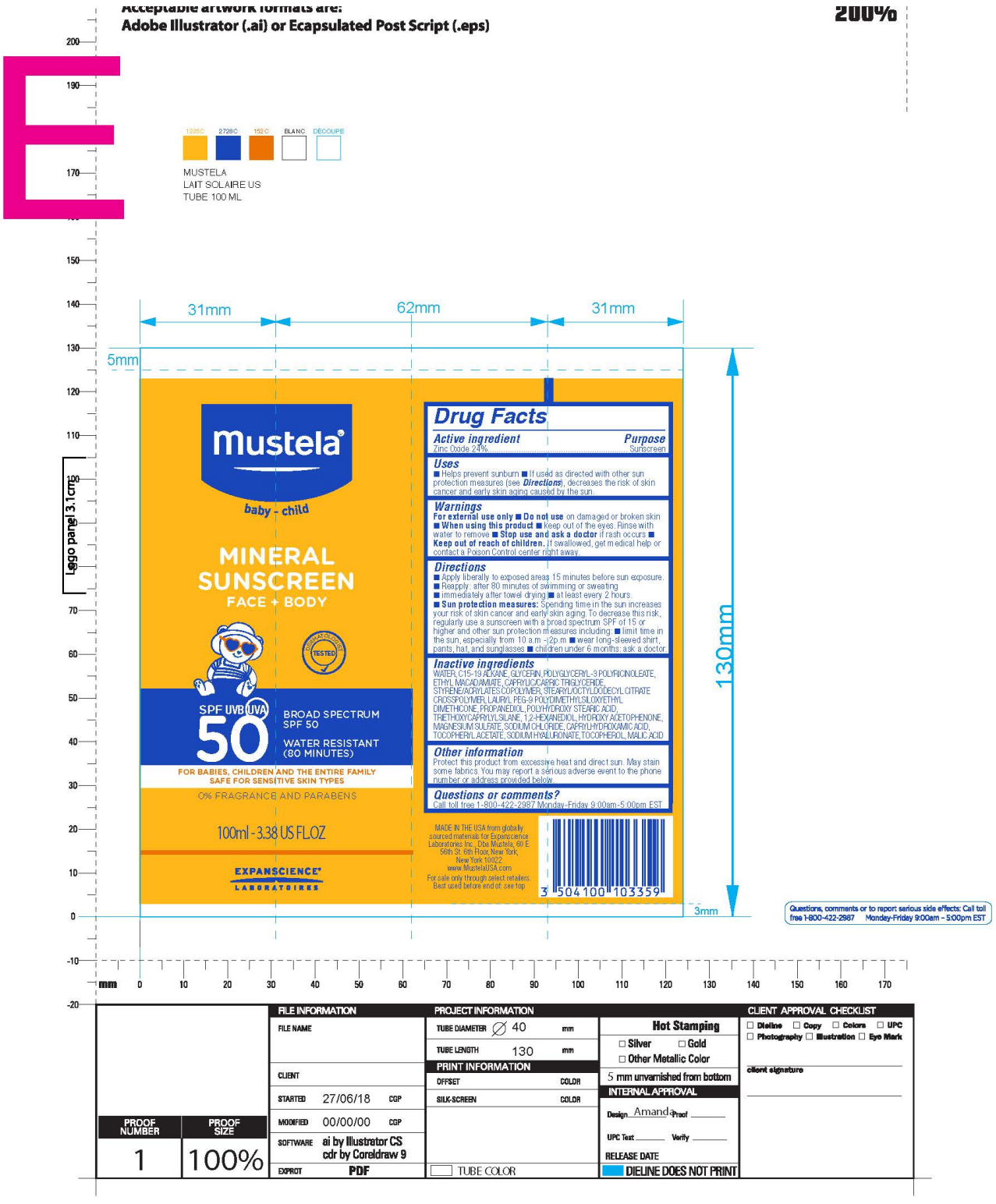
Other Information

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

Primary Package



Primary Package 500ml


Family Size
mustela
MINERAL
SUNSCREEN
FACE + BODY
ACCEPTED
National Eczema Association
SPF UVA+UVB
50
SPF 50 BROAD SPECTRUM
WATER RESISTANT
(80 MINUTES)
FOR BABIES, CHILDREN AND THE ENTIRE FAMILY
SAFE FOR SENSITIVE SKIN TYPES
0% FRAGRANCE AND PARABENS
500mL - 16.90 fl oz

500ml, 61354-070-02

SUNSCREEN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
C15-19 ALKANE (UNII: CI87N1IM01)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
ETHYL MACADAMIATE (UNII: ANA2NCS6V1)	
PROPANEDIOL (UNII: 5965N8W85T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-090-01	100 mg in 1 TUBE; Type 0: Not a Combination Product	02/22/2021	
2	NDC:61354-090-02	500 mg in 1 TUBE; Type 0: Not a Combination Product	02/22/2021	02/10/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2021	

Labeler - Oxygen development (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development		137098492	manufacture(61354-090)

Revised: 2/2023 Oxygen development