

SPF 50- zinc oxide lotion
Cosmetic Specialty Labs, Inc.

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.

Active Ingredients

Zinc Oxide

Titanium Dioxide

Purpose

Sunscreen

Sunscreen

Sun Alert:

Limiting sun exposure, wearing protective clothing, and using broad spectrum sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Uses

Helps prevent sunburn. Used as directed with other sun protection measures, decreases skin cancer risk and early skin aging, caused by the sun.

Caution

May stain some fabrics. Keep out of direct sunlight and excessive heat. Some natural separation may occur. Shake well before using.

Warnings

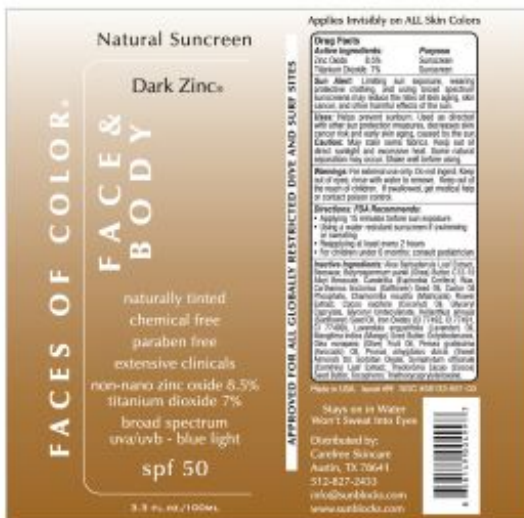
For external use only. Do not ingest. Keep out of eyes; rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact poison control.

Directions: FDA Recommends

- Applying 15 minutes before sun exposure
- Using a water resistant sunscreen if swimming or sweating
- Reapplying at least every 2 hours
- For children under 6 months: consult pediatrician

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Beeswax, Butyrospermum parkii (Shea) Butter, C12-15 Alkyl Benzoate, Candelilla (Euphorbia Cerifera) Wax, Carthamus tinctorius (Safflower) Seed Oil, Castor Oil Phosphate, Chamomilla recutita (Matricaria) Flower Extract, Cocos nucifera (Coconut) Oil, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus annuus (Sunflower) Seed Oil, Iron Oxides (CI 77492, CI 77491, CI 77499), Lavandula angustifolia (Lavender) Oil, Mangifera indica (Mango) Seed Butter, Octyldodecanol, Olea europaea (Olive) Fruit Oil, Persea gratissima (Avocado) Oil, Prunus amygdalus dulcis (Sweet Almond Oil), Sorbitan Oleate, Symphytum officinale (Comfrey) Leaf Extract, Theobroma cacao (Cocoa) Seed Butter, Tocopherol, Triethoxycaprylylsiloxane



SPF 50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58133-651
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8.5 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CHAMOMILE (UNII: FGL3685T2X)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
SHEA BUTTER (UNII: K49155WL9Y)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CANDELILLA WAX (UNII: WL0328HX19)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COMFREY (UNII: D05HXK6R3G)	
CASTOR OIL (UNII: D5340Y2I9G)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
--	--	------------------------	----------------------

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-651-03	100 mL in 1 TUBE; Type 0: Not a Combination Product	11/05/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/05/2021	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	label(58133-651) , manufacture(58133-651) , pack(58133-651)

Revised: 11/2021

Cosmetic Specialty Labs, Inc.