SPF30- 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 Ingredient

Zinc Oxide

Purpose

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 proctection measures, decreases skin cancer risk and early skin aging, caused by the sun.

Caution

Keep out of direct sunlight and excessive heat. Some natural seperation 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.

Other Information

Protect this product from excessive heat or direct sun.

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

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Inactive Ingredients

Aloe Barbadensis Leaf Extract, Beeswax, Butyrospermum parkii (Shea) Butter, C12-15 Alkyl Benzoate, Candelilla (Euphorbia Cerifera) Wax, Carthamus tinctorius (Safflower) Seed Oil, Chamomilla recutita (Matricaria) Flower Extract, Cocos nucifera (Coconut) Oil, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus annuus (Sunflower) Seed Oil, Lavandula angustifolia (Lavender) Oil, Mangifera indica (Mango) Seed Butter, Olea europaea (Olive) Fruit Oil, Persea gratissima (Avocado) Oil, Symphytum officinale (Comfrey) Leat Extract, Theobroma cacao (Cocoa) Seed Butter, Tocopherol, Triethoxycaprylylsiloxane

Carefree Sunscreen™

Carefree Natural

Sold Thru
Skincare Professionals

FACE & BODY

un-tinted
chemical free
paraben free
extensive clinicals
non-nano zinc oxide 22.75%
broad spectrum
uva/uvb - blue light

spf 30+

3.3 FL.OZ./100ML

APPROVED FOR ALL GLOBALLY RESTRICTED DIVE AND SURF SITES

Applies Invisibly on ALL Skin Colors
Stays on in Water
Won't Sweat Into Eyes

Drug Facts

Active Ingredients:	Purpose
Zinc Oxide 22.75%	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 the reach of children. If swallowed, get medical help or contact poison control.

Other Information: Protect this product from excessive heat or direct sun.

Directions: FDA Recommends:

- Applying 15 minutes before sun exposure
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Inactive Ingredients: Aloe Barbadensis Leaf Extract, Beeswax, Butyrospermum parkii (Shea) Butter, C12-15 Alkyl Benzoate, Candelilla (Euphorbia Cerifera) Wax, Carthamus tinctorius (Safflower) Seed Oil, Chamomilla recutita (Matricaria) Flower Extract, Cocos nucifera (Coconut) Oil, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus annuus (Sunflower) Seed Oil, Lavandula angustifolia (Lavender) Oil, Mangifera indica (Mango) Seed Butter, Olea europaea (Olive) Fruit Oil, Persea gratissima (Avocado) Oil, Prunus amygdalus dulcis (Sweet Almond) Oil, Symphytum officinale (Comfrey) Leaf Extract, Theobroma cacao (Cocoa) Seed Butter, Tocopherol, Triethoxycaprylylsiloxane.

Made in USA NDC 58133-652-35

Item# 493

Distributed by:
Carefree Skincare
Austin, TX 78641
512-827-2433
info@sunblocks.com
www.sunblocks.com

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SPF30

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-652
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22.75 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:58133-652-35	100 mL in 1 TUBE; Type 0: Not a Combination Product	11/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/04/2021	

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	label(58133-652) , manufacture(58133-652) , pack(58133-652)

Revised: 11/2021 Cosmetic Specialty Labs, Inc.