TINTED SUNSCREEN CREAM SPF 30 4-DEEP AMBER- titanium dioxide, zinc oxide cream

C.F.E.B. - Sisley

Tinted Sunscreen Cream SPF 30 4-Deep Amber

Active ingredients

Titanium dioxide 12.93%

Zinc oxide 10.89%

Purpose

Sunscreen

Uses

- Helps prevent 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 on damaged or broken skin.

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

Stop use and ask a doctor if rash occurs

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating.
 - Immediately after towel drying.
 - At least every 2 hours.
- Children under 6 months of age: ask a doctor.
- Spending time in the sun increases your risk of skin cancern and early skin aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including: **Sun Protection Measures.**
 - Limit time in the sun, especially from 10 am to 2 pm.
 - Wear long-sleeved shirts, pants, hats and sunglasses.

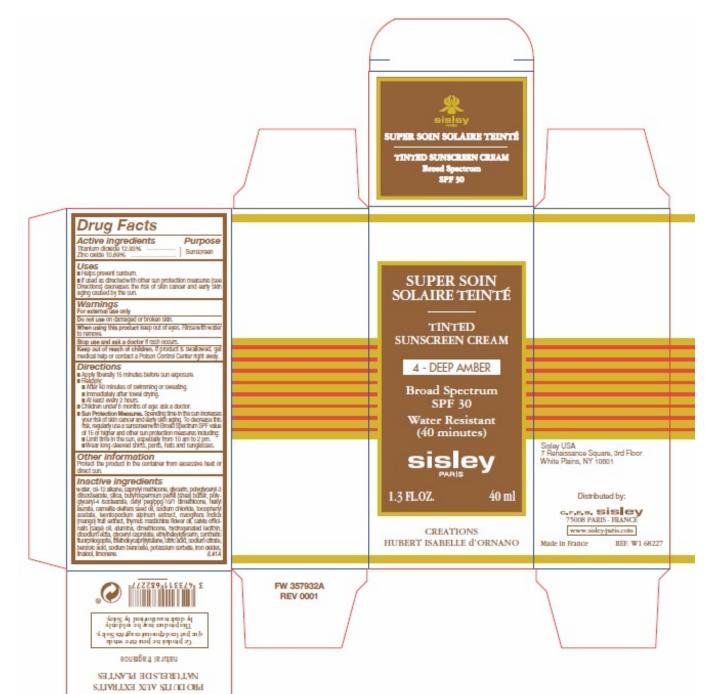
Other information

Protect the product in the container from excessive heat or direct sun.

Inactive ingredients

water, c9- 12 alkane, caprylyl methicone, glycerin, polyglyceryl-3 diisostearate, silica, butyrospermum parkii (shea) butter, polyglyceryl-4 isostearate, cetyl peg/ppg-10/1 dimethicone, hexyl laurate, camellia oleifera seed oil, sodium chloride, tocopheryl acetate, leontopodium alpinum extract, mangifera indica (mango) fruit extract, thymus mastichina flower oil, salvia officinalis (sage) oil, alumina, dimethicone, hydrogenated lecithin, disodium edta, glyceryl caprylate, ethylhexyglycerin, synthetic fluorphlogopite, triethoxycaprylylsilane, citric acid, sodium citrate, benzoic acid, sodium benzoate, potassium sorbate, iron oxides, linalool, limonene.

Package labeling





Drug Facts

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TINTED SUNSCREEN CREAM SPF 30 4-DEEP AMBER

titanium dioxide, zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66097-009

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	129.3 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	108.9 mg in 1 mL

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Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CAMELLIA OIL (UNII: T1PE06G0VE)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MANGO (UNII: 162913NR86)	
THYMUS MASTICHINA FLOWERING TOP OIL (UNII: 9NP0832457)	
SAGE OIL (UNII: U27K0H1H2O)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
DIMETHICONE (UNII: 92RU3N3Y10)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZ D4G4A)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:66097-009- 40	1 in 1 BOX	03/15/2017		
3		40 mL in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC Monograph Drug	M020	03/15/2017	

Labeler - C.F.E.B. - Sisley (262279246)

Revised: 11/2023 C.F.E.B. - Sisley