

BELO SUN EXPERT TINTED SUNSCREEN- octyl methoxycinnamate, titanium dioxide, octocrylene cream
Intelligent Skin Care 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.

Intelligent Skin Belo private labeled

Active Ingredients

Active Ingredients Purpose

Octyl methoxycinnamate 5% Sunscreen

Titanium dioxide 6.13%

Octocrylene .8%

Use

Use

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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 Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure.
- reapply at least every 2 hours.
- use a water-resistant sunscreen if swimming or sweating.
- children under 6 months of age: Ask a doctor.

Other Information

Other Information

protect the product in this container from excessive heat and direct sun

- high sun protection product

Inactive Ingredients

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water, aluminum hydroxide, lauroyl lysine, cyclotetrasiloxane, cyclopentasiloxane, cetyl alcohol, glyceryl stearate, cetareth-20, ceteraeth-12, cetearyl alcohol, cetyl palmitate, butylene glycol, bee venom, dimethicone, cetearyl dimethicone crosspolymer, methylsisesquioxane resin, niacinamide, alumina, simethicone, ethylhexyl methoxycrylene, avobenzone, butyrospermum parkii, hydrogenated dimer dilinoleyl/dimethylcarbonate copolymer, sorbitan palmitate, sorbitan olivate, benzyl alcohol, glyceryl caprylate, glyceryl undecylenate, iron oxides lauroyl lysine (CI 77492), fragrance, iron oxides lauroyl lysine (CI 66491), iron oxides lauroyl lysine (CI 77499) bisabolol, tetrasodium EDTA, citric acid

Questions or Comments?

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+63 2 7500 3825 or inquiries@iskincareinc.com

Purpose

Purpose

Helps prevent sunburn

label

octyl methoxycinnamate, titanium dioxide, octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82701-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.065 mg in 50 mg
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.4 mg in 50 mg
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 mg in 50 mg

Inactive Ingredients	
Ingredient Name	Strength
APIS MELLIFERA VENOM (UNII: 76013O881M)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
NIACINAMIDE (UNII: 25X51I8RD4)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
LAUROYL LYSINE (UNII: 113171Q70B)	
POLYMETHYLSILSESQUIOXANE/TRIMETHYLSILOXYSILICATE (UNII: X2PZH4Y6HT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LEVOMENOL (UNII: 24WE03BX2T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AVOBENZONE (UNII: G63QQF2NOX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PEG-80 SORBITAN PALMITATE (UNII: 4NR71FN0IA)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	

POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82701-001-01	50 mg in 1 TUBE; Type 0: Not a Combination Product	06/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/20/2022	

Labeler - Intelligent Skin Care Inc. (719667461)

Registrant - A.M. Rieta Corporation (727672787)

Revised: 11/2022

Intelligent Skin Care Inc.