

SPF 50 FACIAL SUNSCREEN- homosalate, octocrylene, octisalate, titanium dioxide, zinc oxide lotion

Beauty Architects, LLC

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.

SPF 50 FACIAL SUNSCREEN LOTION

Drug Facts

Active Ingredients

Homosalate 7%
Octocrylene 3%
Octisalate 2%
Titanium Dioxide 2.058%
Zinc Oxide 5.91%

Purpose

Sunscreen

Uses

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

Directions

For sunscreen use

- Apply generously 15 minutes before sun exposure
- Children under 6 months of age: Ask a doctor

Other Information

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

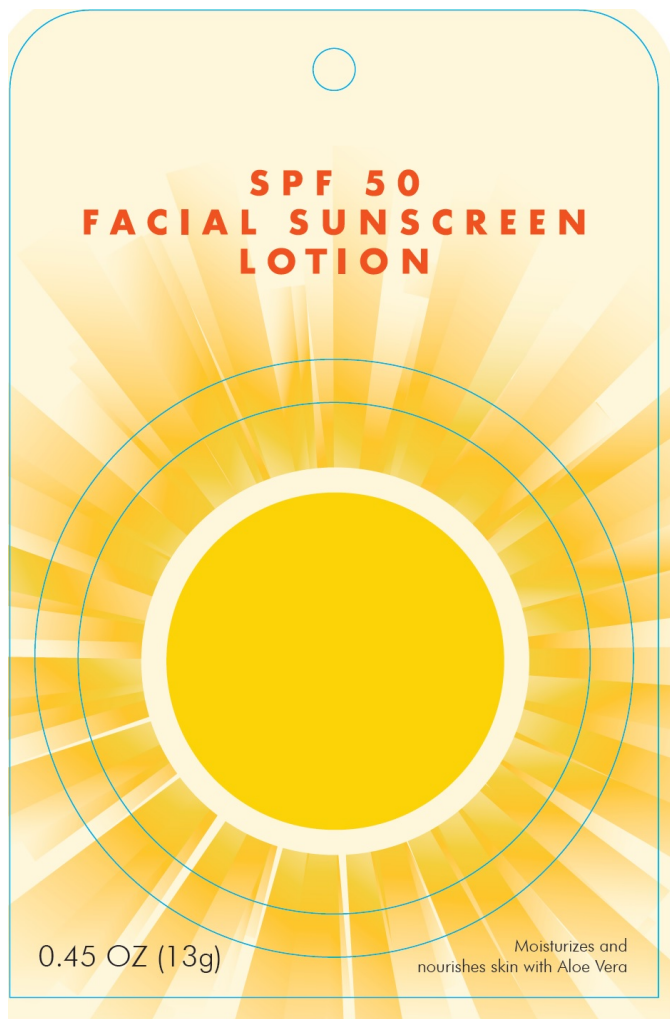
Inactive Ingredients

Water, Cetyl Ethylhexanoate, Glycerin, Dibutyl Adipate, Lauryl PEG-10 Tris(Trimethylsiloxy)silylethyl Dimethicone, Niacinamide, Sorbitan Sesquioleate, Silica, Diatomaceous Earth, Cetyl PEG/PPG-10/1 Dimethicone, Sodium Chloride, Ethyl Hexanediol, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Benzotriazolyl Dodecyl p-Cresol, Distearidimonium Hectorite, Fragrance, Glyceryl Caprylate, Allantoin, Triethoxycaprylsilane, Lauroyl Lysine, Disodium EDTA, Adenosine, 1,2-Hexanediol, Hyaluronic Acid, Tea Tree (Melaleuca Alternifolia) Leaf Water, Witch Hazel (Hamamelis Virginiana) Extract, Aloe Vera (Aloe Barbadensis) Leaf Extract, Butylene Glycol, Ethylhexylglycerin, Tea (Camellia Sinensis) Leaf Extract

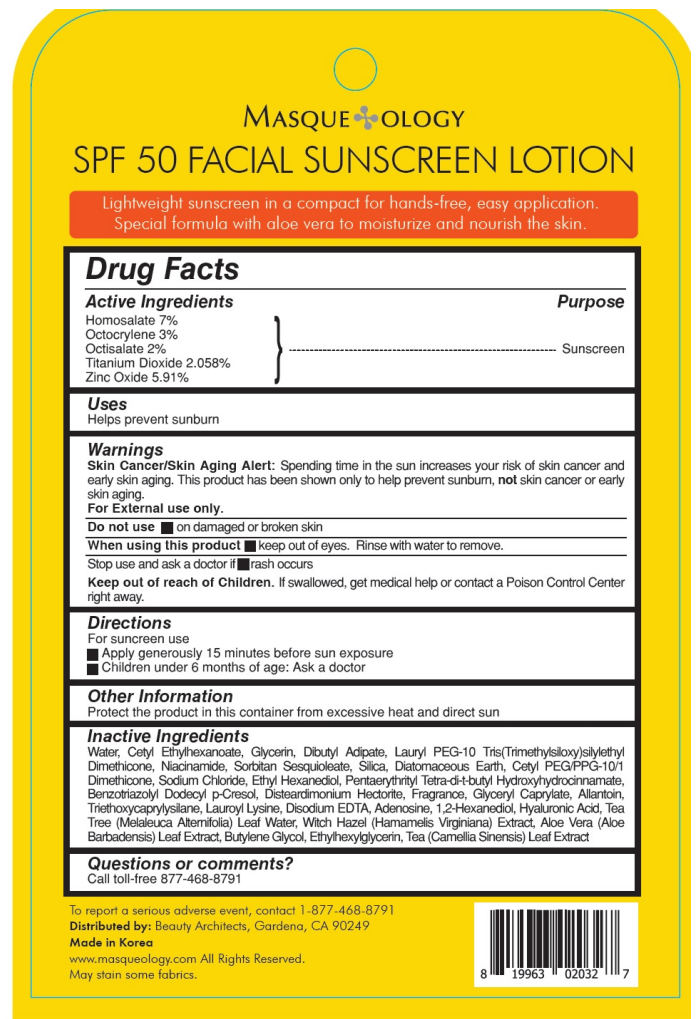
Questions or comments?

Call toll-free 877-468-8791

Package Labeling:



FRONT



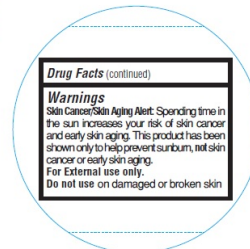
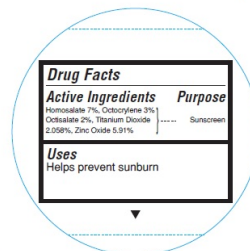
BACK



Label Cover



Label Inside Top



Label Inside Bottom

SPF 50 FACIAL SUNSCREEN			
homosalate, octocrylene, octisalate, titanium dioxide, zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72860-000
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	70 mg in 1 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 g	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20.58 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	59.1 mg in 1 g	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)			
GLYCERIN (UNII: PDC6A3C0OX)			
DIBUTYL ADIPATE (UNII: F4K100DXP3)			
NIACINAMIDE (UNII: 25X51I8RD4)			
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ETHOHEXADIOL (UNII: M9JGK7U88V)			
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)			

BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
ALLANTOIN (UNII: 344S277G0Z)
TRIETHOXYCAPRYL SILANE (UNII: LDC331P08E)
LAUROYL LYSINE (UNII: 113171Q70B)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
ADENOSINE (UNII: K72T3FS567)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
HYALURONIC ACID (UNII: S270N0TRQY)
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72860-000-13	13 g in 1 CONTAINER; Type 0: Not a Combination Product	02/21/2019	06/30/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/21/2019	06/30/2021

Labeler - Beauty Architects, LLC (078391941)