

THEFACESHOP NATURAL SUN LONG LASTING SUNSCREEN BROAD SPECTRUM SPF 50- ensulizole, octinoxate, octisalate, titanium dioxide, zinc oxide lotion
THEFACESHOP Co., Ltd.

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 11.65%

Octinoxate 7.00%

Titanium Dioxide 4.57%

Octisalate 4.5%

Ensulizole 3.5%

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 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 and as needed.
- Reapply as needed or after towel drying, swimming, or sweating.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. to 2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses
 - Children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

WATER, CYCLOPENTASILOXANE, DIPROPYLENE GLYCOL, GLYCERIN, DICAPRYLYL CARBONATE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, TROMETHAMINE, DIMETHICONE, PANTHENOL, DISTEARDIMONIUM HECTORITE, ALUMINUM HYDROXIDE, ZINC STEARATE, SORBITAN SESQUIOLEATE, DIMETHICONE/PEG-10/15 CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, STEARIC ACID, GLYCERYL CAPRYLATE, HYDROGEN DIMETHICONE, DISTEARYLDIMONIUM CHLORIDE, MICA, NYLON 12, ETHYLHEXYLGLYCERIN, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, TRIETHOXYCAPRYLYLSILANE, TRISODIUM EDTA, HELIANTHUS ANNUS (SUNFLOWER) SRPOUT EXTRACT, MENTHYL PCA, SODIUM PCA, SODIUM BENZOATE, TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499), FRAGRANCE

OTHER INFORMATION

Protect this product from excessive heat and direct sun

QUESTIONS OR COMMENTS?

Call toll free **1-888-498-9004**

PRINCIPAL DISPLAY PANEL

**NATURAL SUN
LONG LASTING SUNSCREEN**

**BROAD SPECTRUM
SPF 50**

1.69 fl. oz. 50 mL



THEFACESHOP NATURAL SUN LONG LASTING SUNSCREEN BROAD SPECTRUM SPF 50

ensulizole, octinoxate, octisalate, titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-196
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.285 g in 50 mL
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	1.75 g in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.825 g in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
MENTHYL DL-PYRROLIDONECARBOXYLATE (UNII: 8P18J856U2)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
ZINC STEARATE (UNII: H92E6QA4FV)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
TROMETHAMINE (UNII: 023C2WHX2V)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
MICA (UNII: V8A1AW0880)	
NYLON-12 (UNII: 446U8J075B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51523-196-01	2 in 1 BOX	01/01/2018	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2018	

Labeler - THEFACESHOP Co., Ltd. (688329416)

Establishment

Name	Address	ID/FEI	Business Operations
THEFACESHOP Co., Ltd.		688329416	label(51523-196)

Establishment

Name	Address	ID/FEI	Business Operations
ZENISCE Co., Ltd.		690188305	manufacture(51523-196)

Revised: 3/2018

THEFACESHOP Co., Ltd.