

TOTAL SUN PROTECTION- octinoxate, octisalate, oxybenzone, zinc oxide lotion
Cosmed Dermaceuticals, 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.

Clinicians Complex Total Sun Protection SPF 30+

Active Ingredients

Octinoxate 7.5% w/w

Octisalate 3.0% w/w

Oxybenzone 3.0% w/w

Zinc Oxide 4.0% w/w

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.

Keep out of reach of children.

Directions

- Apply liberally 15 minutes before sun exposure and as needed
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours

- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10am to 2pm
 - Wear long sleeve shirts, pants, hats, and sun glasses
 - Children under 6 months: Ask a doctor

Other Information

Protect this product from excessive heat and direct sun

Questions or Comments:

Call 770-965-1022

Inactive Ingredients

Water, PPG-3 Myristyl Ether, Aloe Barbadensis Leaf Extract, Glycol Stearate, Cetyl Alcohol, Polyacrylamide, PVP/Hexadecene Copolymer, White Tea (Camellia Oleisera) Leaf Extract, Green Tea (Camellia Sinensis) Leaf Extract, Tocopheryl Acetate, Propylene Glycol, C13-14 Isoparaffin, Decyl Glucoside, Silica, Cetyl Phosphate, Glyceryl Stearate, PEG 100 Stearate, Glycerin, Diazolidinyl Urea, Triethoxycaprylylsilane, Methylparaben, Disodium EDTA, Propylparaben, Laureth-7

CLINICIANS COMPLEX®



TOTAL SUN PROTECTION SPF 30+

- OIL-FREE FORMULA
- UVA/UVB PROTECTION
- CONTAINS GREEN & WHITE TEA EXTRACT

4.5 OZ.

Drug Facts

Active Ingredients	Percentages	Purpose
Octinoxate	7.5%w/w	Sunscreen
Octisalate	8.0%w/w	Sunscreen
Oxybenzone	8.0%w/w	Sunscreen
Zinc Oxide	4.0%w/w	Sunscreen

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Distributed By: Cosmed Dermaceuticals, Braselton, GA 30517

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61352-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZ ONE - UNII:95OOS7VE0Y)	OXYBENZ ONE	30 mg in 1 g
zinc oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PPG-3 MYRISTYL ETHER (UNII: 7913J43WZ5)	

GLYCOL STEARATE (UNII: 0324G66D0E)
CETYL ALCOHOL (UNII: 936JST6JCN)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
HEXADECYL POVIDONE (4 HEXADECYL BRANCHES/REPEAT) (UNII: AG75W62QYU)
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CETYL PHOSPHATE (UNII: VT07D6X67O)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
GLYCERIN (UNII: PDC6A3C0OX)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
METHYLPARABEN (UNII: A2I8C7HI9T)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
LAURETH-7 (UNII: Z95S6G8201)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61352-004-01	127.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2013	

Labeler - Cosmed Dermaceuticals, Inc. (967008038)

Registrant - A.I.G. Technologies, Inc. (086365223)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies, Inc.		086365223	manufacture(61352-004) , label(61352-004)