

CLEAR DEFENSE SPF 45- zinc oxide, octinoxate cream
Private Label Skin Care

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.

Clear Defense SPF 45

Drug Facts

Active ingredient

Zinc Oxide 12%

Octinoxate 7.5%

Purpose

Sunscreen

Use Helps prevent sunburn • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings For external use only.

When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician.

Reapply after 80 minutes of swimming or sweating. Reapply immediately after towel drying at least every 2 hours.

Precautions • 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 value of SPF 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m.–2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a physician.

Inactive Ingredients: Water, Cyclopentasiloxane, Niacinamide (Vitamin B3), Oleth-3 Phosphate, Octyldodecyl Neopentanoate, Hydroxyethyl Acrylate/Sodium

Acryloyldimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylolpropane Coconut Ether, Glycerin, Tocopheryl Acetate (Vitamin E), Polygonum Aviculare (Knotweed) Extract, Sodium Hyaluronate (Hyaluronic Acid), Disodium EDTA, Sodium Hydroxide, Citric Acid, Phenoxyethanol, Ethylhexylglycerin, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Triethoxycaprylylsilane

brand MD®

SKIN CARE

SUN DEFENSE

medical grade

✓ Fast-absorbing SPF features a high level of Niacinamide

✓ Oil-free and lightweight

brandMD®

Chatsworth, CA 91311

www.brandMD.com

Toll Free: (877) 252-7546

Packaging



Clear Defense SPF 45

SUN DEFENSE
medical grade

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- Oil-free and lightweight

2 oz | 57 g

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 Chatsworth, CA 91311
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 Made in USA

CLEAR DEFENSE SPF 45

zinc oxide, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72957-003(NDC:39765-016)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	12 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
NIACINAMIDE (UNII: 25X51I8RD4)
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)
GLYCERIN (UNII: PDC6A3C00X)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72957-003-01	57 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/27/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/27/2020	

Labeler - Private Label Skin Care (116996962)

Establishment			
Name	Address	ID/FEI	Business Operations
Private Label Skin Care		116996962	relabel(72957-003)