

TRUTH REVEALED SUPER CREME SPF 15 OLE HENRIKSEN- octinoxate, avobenzone, oxybenzone, octocrylene cream

Ole Henriksen

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.

Truth Revealed Super Creme with SPF 15

Active Ingredient	Purpose
Octinoxate 7.5%	Sunscreen
Avobenzone 2.0%	Sunscreen
Oxybenzone 2.0%	Sunscreen
Octocrylene 1.9%	Sunscreen

Uses:

Helps prevent sunburn.

Higher SPF gives more sunburn protection.

Keep out of reach of children

Stop use and ask a doctor if rash or irritation develops and lasts

Warnings

For external use only

When using this product keep out of eyes. Rinse with water to remove.

If swallowed, get immediate medical help or contact a poison control center right away.

Directions

Massage into skin in upward motion, outward circular motions

For children under 6 months, ask a doctor.

Inactive Ingredients

Water (Aqua,Eau), cocoglycerides, Glycerin, Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Dimethicone, Palmitoyl Tripeptide-5, Algae Extract, Pullulan, Chondrus Chripus (Carrageenan), Plukenetia Volubilis Seed Oil, Schinus Terebinthifolius Seed Extract, Tetrahexyldecyl Ascorbate, calcium Ascorbate, Sodium Hyaluronate, Chamomilla Recutita (Matricaria) Flower Extract, Daucus Carota Sativa (Carrot) Extract, Corylus Avellana (Hazelnut) extract, Avena Sativa (Oat) Meal Extract. Vaccinum Myrtillus Extract, Saccharum Officinarum (Sugar Cane) Extract, Acer Saccharinum (Sugar Maple) Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Citrus Medica Limonium (Lemon) Fruit Extract, Bisabolol, Allantoin, Tocopheryl Acetate, Carbomer, Cetareth-20, Aminomethyl Propanol, sodium Phytate, Citric Acid, Polyacrylate-13/polyisobutene/polysorbate 20, Phenoxy ethanol, Ethylhexylglycerin, Potassium Sorbate, Fragrance (Parfum)



Elevate your skin to a new level of textural refinement and firmness with this highly concentrated, anti-aging moisturizer.
DIRECTIONS: Massage an even layer into face and neck. Apply daily and prior to sun exposure.
 Elevez votre peau à un nouveau niveau de raffinement et de fermeté grâce à cette super crème hautement concentrée.
MODE D'EMPLOI: Appliquez en massant une couche uniforme sur le visage et le cou. Utilisez quotidiennement, avant l'exposition au soleil.
WARNINGS: Discontinue use if irritation develops or increases. If irritation persists, consult a health care practitioner.
AVERTISSEMENTS: Arrêtez l'utilisation si une irritation se présente ou s'accroît. Si l'irritation persiste, consultez un médecin.
ACTIVE INGREDIENTS/INGRÉDIENTS ACTIFS: Octinoxate 7.5%, Avobenzone 2.0%, Oxybenzone 2.0%, Octocrylene 1.86%
OLE HENRIKSEN DIST. DISTRIBUTÉ - VAN NUYS, CA 91406 USA.
EU dist. by/Distribué en Europe par: OH Europe - Avedareholmen 78A - 2650 Hvidovre Denmark
www.olehenriksen.com Made in USA/Fabriqué aux E.-U.

OLEHENRIKSEN
 all skin types/anti-aging
truth revealed™
super crème with SPF 15
 reveal your perfect skin
 révélez la perfection de votre peau
 Net Wt. 1.7 oz / 50 g e

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Truth Revealed Super Creme with SPF 15

Net. Wt. 1.7 oz/ 50g

TRUTH REVEALED SUPER CREME SPF 15 OLE HENRIKSEN			
octinoxate, avobenzone, oxybenzone, octocrylene cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51770-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	2 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)		OXYBENZONE	2 g in 100 g

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)

OCTOCRYLENE

1.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
PLUKENETIA VOLUBILIS SEED OIL (UNII: 8ED72Z8J1Z)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CALCIUM ASCORBATE (UNII: 183E4W213W)	
CHAMOMILE (UNII: FGL3685T2X)	
CARROT (UNII: L56Z1JK48B)	
AVENA SATIVA LEAF (UNII: 206PI19V7R)	
VACCINIUM MYRTILLUS LEAF (UNII: Y4U591OU70)	
SUCROSE (UNII: C151H8M554)	
ACER SACCHARUM BARK/SAP (UNII: Z120VL0KAC)	
ORANGE (UNII: 5EVU04N5QU)	
LEMON (UNII: 24RS0A988O)	
LEVOMENOL (UNII: 24WE03BX2T)	
ALLANTOIN (UNII: 344S277G0Z)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER 934 (UNII: Z135WT9208)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PHYTIC ACID (UNII: 7IGF0S7R8I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51770-001-02	1 in 1 PACKAGE		
1	NDC:51770-001-01	50 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/15/2010	

Labeler - Ole Henriksen (133369058)

Registrant - Ole Henriksen (133369058)

Establishment

Name	Address	ID/FEI	Business Operations
HB GORDON MANUFACTURING INC		008328619	manufacture(51770-001)

Revised: 7/2013

Ole Henriksen