

TOTAL TRUTH EYE CREME SPF 15 OLE HENRIKSEN- avobenzene, octinoxate, octisalate cream

Ole Henriksen of Denmark

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.

Total Truth Eye Cream SPF 15

Active Ingredients	Purpose
Avobenzene 2.0%	prevention of sunburn
Octinoxate 4.0%	prevention of sunburn
Octisalate 4.0%	prevention of sunburn

prevention of sunburn

keep out of reach of children

provides moderate protection

helps against sunburn

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

apply smoothly and evenly to face and neck

repeat as necessary

children under 6 month of age , ask doctor.

Water (Aqua, Eau), Glycerin, C12-15 Alkyl Benzoate, Dimethicone, Helianthus Annuus (Sunflower) Seed Oil, Stearic Acid, Stearyl Alcohol, Glyceryl Stearate SE, Vitis Vinifera (Grape) Seed Oil, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Limnanthes Alba (Meadowfoam) Seed Oil, Cetareth-20, Phenoxyethanol, Algae Extract, Pullulan, Palmitoyl Tripeptide-5, Sodium Hyaluronate, Tocopheryl Acetate, Retinyl Palmitate, Allantoin, Volubilis (Mountain Peanut) Seed Oil, Schinus Terebinthifolius Seed Extract, Magnesium Ascorbyl Phosphate, Triethanolamine, Carbomer, Potassium Sorbate, Alcohol, Lecithin.

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Repeat as necessary. Children under 6 months of age, ask doctor. <p>Inactive ingredients Water (Aqua, Eau), Glycerin, C12-15 Alkyl Benzoate, Dimethicone, Helianthus Annuus (Sunflower) Seed Oil, Stearic Acid, Stearyl Alcohol, Glyceryl Stearate SE, Vitis Vinifera (Grape) Seed Oil, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Limnanthes Alba (Meadowfoam) Seed Oil, Cetareth-20, Phenoxyethanol, Algae Extract, Pullulan, Palmitoyl Tripeptide-5, Sodium Hyaluronate, Tocopheryl Acetate, Retinyl Palmitate, Allantoin, Volubilis (Mountain Peanut)</p>	<p>Revitalize and protect with <i>total truth eye crème</i> SPF 15. Omega 3 extracts nourish and hydrate to diminish the appearance of fine lines and wrinkles while micro algae and tri-peptide 5 help strengthen and firm for total age-defying results.</p> <p>Drug Facts (continued)</p> <p>Seed Oil, Schinus Terebinthifolius Seed Extract, Magnesium Ascorbyl Phosphate, Triethanolamine, Carbomer, Potassium Sorbate, Alcohol, Lecithin.</p> <p>Mixed Sources Recycled post-consumer material Contains 100% recycled material www.fsc.org Cert no. COC-1024 © 2006 Forest Stewardship Council</p> <p>Made in USA OLE HENRIKSEN DIST.-VAN NUYS, CA 91406 USA EU dist. by: OH Europe - Avedareholms all 78A - 2 650 Hvidovre Denmark www.olehenriksen.com</p>	<p>NEW</p> <p>OLEHENRIKSEN</p> <p>all skin types anti-aging</p> <p>total truth™ eye crème SPF15</p> <p>offers complete age-defying eye care with vitamin c, micro algae and omega 3 extracts</p> <p>Net Wt. 0.5 oz./ 15 g</p>	<p>Drug Facts</p> <p>Active ingredients Avobenzene 2.0% Octinoxate 4.0% Octisalate 4.0%</p> <p>Purpose prevention of Sunburn</p> <p>Uses <ul style="list-style-type: none"> Provides moderate protection. Helps protect against sunburn. </p> <p>Warnings Stop use and ask a Doctor if rash or irritation develops and lasts. Keep out of reach of children.</p> <p>Directions <ul style="list-style-type: none"> Apply smoothly and evenly to face and neck. </p>
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NEW



OLEHENRIKSEN

all skin types/anti-aging

total truth™
eye crème SPF15

offers complete age-defying eye care
with vitamin c, micro-algae
and omega 3 extracts



Net Wt. 0.5 oz./ 15 g

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OleHenriksen
total truth
eye creme SPF 15
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TOTAL TRUTH EYE CREME SPF 15 OLE HENRIKSEN

avobenzone, octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51770-154
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

DIMETHICONE (UNII: 92RU3N3Y1O)
SUNFLOWER OIL (UNII: 3W1JG795YI)
STEARIC ACID (UNII: 4ELV7Z65AP)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PULLULAN (UNII: 8ZQ0AYU1TT)
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
ALLANTOIN (UNII: 344S277G0Z)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
TROLAMINE (UNII: 9O3K93S3TK)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
ALCOHOL (UNII: 3K9958V90M)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51770-154-02	1 in 1 BOX		
1	NDC:51770-154-01	15 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/14/2011	

Labeler - Ole Henriksen of Denmark (133369058)

Registrant - Ole Henriksen of Denmark (133369058)

Establishment

Name	Address	ID/FEI	Business Operations
HB Gordon Manufacturing Inc.		008328619	manufacture(51770-154)