

PROTECT THE TRUTH SPF 50 OLE HENRIKSEN- avobenzone,homosalate, octisalate,octocrylene,oxybenzone lotion
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.

Protect the Truth SPF 50

Active ingredients	Purpose
Avobenzone 3%	Prevention of Sunburn
Homosalate 10%	Prevention of Sunburn
Octisalate 5%	Prevention of Sunburn
Octocrylene 2.7%	Prevention of Sunburn
Oxybenzone 5%	Prevention of Sunburn

prevention of sunburn

Keep out of reach of children

provides high protection

helps protect against sunburn

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

apply smoothly and evenly to face and neck. repeat as necessary

children under 6 months of age: ask doctor

Water (Aqua/Eau), Butyloctyl Salicylate, Styrene/Acrylates Copolymer, Thermus Thermophilus Ferment, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Vitis Vinifera (Grape) Fruit Cell Extract, Algae Extract, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Camellia Oleifera Leaf Extract, Pullulan, Isomalt, Lecithin, Glycerin, Dimethicone, Silica, Ceteareth-20, Sodium Phytate, Xanthan Gum, Citric Acid, Sodium Benzoate, Ethylhexylglycerin, Phenoxyethanol, Potassium Sorbate, Fragrance (Parfum).

NEW



OLEHENRIKSEN

all skin types/anti-aging

**protect the
truth™ SPF 50+**

broad spectrum
UV protection with
Solar Active Complex™



Sunscreen Lotion

1.7 fl. oz./ 50 ml

Drug Facts

Active ingredients

Avobenzone	3%
Homosalate	10%
Octisalate	5%
Octocrylene	2.7%
Oxybenzone	5%

Purpose

Prevention of Sunburn

Uses

- Provides high protection.
- Helps protect against sunburn.

Warnings

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

Keep out of reach of children.

Directions

- Apply smoothly and evenly to face and neck. Repeat as necessary.
- Children under 6 months of age: ask doctor.

Inactive ingredients

Water (Aqua/Eau), Butyloctyl Salicylate, Styrene/Acrylates Copolymer, Thermus Thermophilus Ferment, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Vitis Vinifera (Grape) Fruit Cell Extract, Algae Extract, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Camellia Oleifera Leaf Extract, Pullulan, Isomalt, Lecithin, Glycerin, Dimethicone, Silica, Ceteareth-20, Sodium Phytate, Xanthan Gum, Citric Acid, Sodium Benzoate, Ethylhexylglycerin, Phenoxyethanol, Potassium Sorbate, Fragrance (Parfum).

OleHenriksen

all skin type/ Anti Aging

Protect the truth SPF 50+

broad spectrum UV Protection with Solar Active Complex

Sunscreen Lotion

1.7 fl.oz./ 50 ml

PROTECT THE TRUTH SPF 50 OLE HENRIKSEN

avobenzene,homosalate, octisalate,octocrylene,oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51770-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.7 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
ISOMALT (UNII: S870P55O2W)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:51770-222-02	1 in 1 BOX		
1	NDC:51770-222-01	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/15/2011	

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(51770-222)

Revised: 7/2013

Ole Henriksen of Denmark