

SPF 30 BODY SUNSCREEN- avobenzene, octinoxate, octisalate, octocrylene, oxybenzone cream

Alure Labs, 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.

Drug Facts

Active Ingredients:

Avobenzene - 2%

Octinoxate - 7.5%

Octisalate - 5%

Octocrylene - 1.5%

Oxybenzone - 6%

Purpose: Sunscreen

Uses:

- High protection against sunburn.
- Higher SPF gives more sunburn protection.

Warnings: For external use only.

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

Stop use and ask a doctor if rash occurs.

Do not use on damaged or broken skin.

Keep out of reach of children.

Directions:

- Apply generously 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply as needed or after towel drying, swimming or perspiring.
- children under 6 months of age: ask a doctor.

Protect the product in in this container from excessive heat and direct sun.

Inactive Ingredients: Water (Aqua), C12-15 Alkyl Benzoate, Butylene Glycol, Octyldodecyl Neopentanoate, Cyclopentasiloxane, Cyclohexaciloxane, Caprylic/Capric Triglyceride, Glycerin, Sorbitan Oleate, Ubiquinone, Physalis Angulata Extract, Teprenone, Sodium Hyaluronate, Organic Camellia Sinensis Leaf Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Algae Extract, Artemisia Vulgaris Extract, Centella Asiatica Extract, Echinacea Purpurea Extract, Palmitoyl Pentapeptide-4, Leontopodium Alpinum Meristem Cell Culture, Plankton Extract, Micrococcus Lysate, Arabidopsis Thaliana Extract, Organic Aloe Barbadosensis Leaf Juice, Polygonum Aviculare Extract, Xanthan Gum, Lecithin, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Triethanolamine, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, PEG-8, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid, Fragrance, Disodium EDTA.

Made in USA

Distributed By OJAS, LLC

SPF 30 BODY SUNSCREEN

avobenzone, octinoxate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
UBIDECARENONE (UNII: EJ27X76M46)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
TEPRENONE (UNII: S8S8451A4O)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ACTINIDIA CHINENSIS ROOT (UNII: 1L6O0O338I)	
ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
LEONTOPODIUM ALPINUM FLOWER (UNII: MWN6IZU3XM)	
ARABIDOPSIS THALIANA (UNII: A13L60HQ81)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4079-2	1 in 1 CARTON		
1	NDC:62742-4079-1	120 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/03/2015	

Labeler - Alure Labs, Inc. (926831603)

Revised: 11/2015

Alure Labs, Inc.