

ALOE UP SUNSCREEN SPF 50- avobenzene, homosalate, octisalate, octocrylene, octinoxate lotion
Aloe Care International, LLC

ALOE UP - SPF 50 LOTION (61477-213)

ACTIVE INGREDIENTS:

AVOBENZONE (3%)

HOMOSALATE (5%)

OCTINOXATE (6%)

OCTISALATE (5%)

OCTOCRYLENE (10%)

PURPOSE:

SUNSCREEN

INDICATIONS:

HELPS PREVENT SUNBURN.

DIRECTIONS:

APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.

REAPPLY: AFTER 40 MINUTES OF SWIMMING OR SWEATING; IMMEDIATELY AFTER TOWEL DRYING; AT LEAST EVERY 2 HOURS.

KEEP OUT OF REACH OF CHILDREN.

WARNINGS:

FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. STOP USE AND ASK A DOCTOR IF RASH OCCURS. KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

Other Ingredients:

ACRYLATES/C10-30 ALKYL ACRYLATES CROSSPOLYMER, ALLANTOIN, ALOE BARBADENSIS LEAF JUICE, ALUMINUM STARCH OCTENYLSUCCINATE, BUTYLOCTYL SALICYLATE, C12-15 ALKYL BENZOATE, CAMELLIA SINENSIS LEAF EXTRACT, CARBOMER, IODOPROPYNYL BUTYLCARBAMATE, ISODECYL NEOPENTANOATE, METHYLISOTHIAZOLINONE, PHENOXYETHANOL, POLYETHYLENE, POLYSORBATE 20, PROPANEDIOL, SORBITOL, THEOBROMA CACAO (COCOA) SEED BUTTER, TOCOPHERYL ACETATE, TRIETHANOLAMINE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, WATER



BROAD SPECTRUM
SPF 50

4 FL OZ (118 mL)

Mixed with
ALOE VERA GEL,
COCOA BUTTER,
TEA TREE OIL
& VITAMIN E



BASED WITH 3.5% PURE ALOE VERA GEL - REEF FRIENDLY
REFRESHING FRAGRANCE - ALCOHOL & MINERAL OIL FREE

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3.0% Homosalate 3.0% Octisalate 6.0% Octocrylene 5.0% Octinoxate 12%	Sunscreen
Uses	
<ul style="list-style-type: none"> helps prevent sunburn if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun 	
Warnings	
For external use only	
Do not use on damaged or broken skin	
When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure reapply <ul style="list-style-type: none"> after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours 	
Sun Protection Measures. 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 SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. – 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses children under 6 months. Ask a doctor 	
Inactive ingredients	
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbardensis Leaf Juice, Aluminum Starch Octylsuccinate, Butylacetyl Salicylate, C12-15 Alkyl Benzoate, Gamella Sinensis Leaf Extract, Carbomer, Fragrance, Isododecane, Isopropyl Myristate, Isodecyl Neopentanoate, Methylisothiazolinone, Phenoxyethanol, Polyethylene, Polyoctylate 20, Propylene Glycol, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Trioleum Ethylhexylamine Disuccinate, Water	
Other information	
protect this product from excessive heat and direct sun	
Questions or comments?	
Call toll free 1-800-856-2568 • www.aloeup.com	

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ALOE UP SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene, octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61477-213
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	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	

ALLANTOIN (UNII: 344S277G0Z)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPANEDIOL (UNII: 5965N8W85T)
SORBITOL (UNII: 506T60A25R)
COCOA BUTTER (UNII: 512OYT1CRR)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61477-213-14	118 mL in 1 TUBE; Type 0: Not a Combination Product	02/24/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/24/2014	

Labeler - Aloe Care International, LLC (938242187)