

SKINDOG - avobenzone, octocrylene, oxybenzone, homosalate, octisalate lotion

SkinDog, LLC

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:

Purpose

Avobenzone 3.0%.....	Sunscreen (A)
Octocrylene 4.0%.....	Sunscreen (B)
Oxybenzone 6.0%.....	Sunscreen (A)
Homosalate 15.0%.....	Sunscreen (B)
Octisalate 5.0%.....	Sunscreen (B)

Uses

- High UVB sunburn/UVA protection
- for skin highly sensitive to sunburn
- retains SPF after 80 minutes of activity

Warnings

For External use only

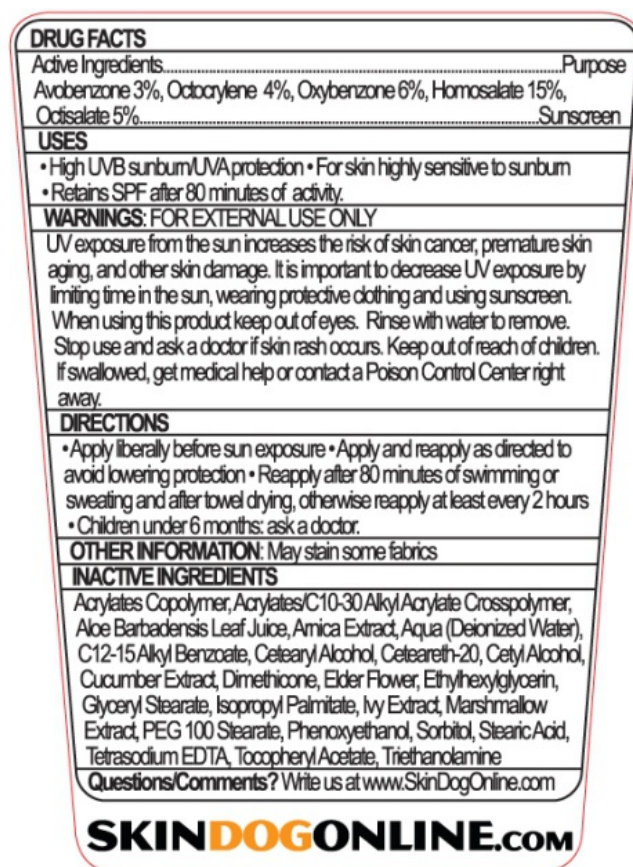
UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using sunscreen.

Directions

- Apply liberally before sun exposure.
- Apply and reapply as directed to avoid lowering protection.
- Reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise reapply at least every 2 hours.
- Children under 6 months; ask a doctor.

Inactive Ingredients

Aqua; Acrylates/C10-30 Alkyl Acrylate Crosspolymer; Sorbitol; Marshmallow Extract; Ivy Extract; Cucumber Extract; Elder Flower; Arnica Extract; EDTA; Aloe Barbadensis Leaf Juice; Isopropyl Palmitate; Stearic Acid; PEG100 Stearate; Dimethicone; Cetyl Alcohol; Glyceryl Stearate; C12-15 Alkyl Benzoate; Cetearyl Alcohol, Ceteareth-20; Phenoxyethanol Ethylhexyl Glycerin; Triethanolamine; Tetrasodium EDTA; Tocopheryl Acetate



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

May stain some fabrics

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if skin rash occurs.

SKINDOG

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42657-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	1.70 g in 56.7 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	8.5 g in 56.7 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	3.4 g in 56.7 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.8 g in 56.7 g

Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)		Octocrylene	2.27 g in 56.7 g	
Inactive Ingredients				
Ingredient Name			Strength	
Water (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
Isopropyl Palmitate (UNII: 8CRQ2TH63M)				
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)				
GLYCERYL DISTEARATE (UNII: 73071MW2KM)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
POLYOXYL 100 STEARATE (UNII: YD01N1999R)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
Dimethicone (UNII: 92RU3N3Y1O)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)				
CUCUMBER (UNII: YY7C30VXJT)				
HEDERA HELIX LEAF (UNII: ZP9XFG71A7)				
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)				
EDETATE SODIUM (UNII: MP1J8420LU)				
TROLAMINE (UNII: 9O3K93S3TK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42657-111-01	56.7 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		01/05/2012	

Labeler - SkinDog, LLC (078352090)

Revised: 1/2012

SkinDog, LLC