

NO-AD SPLASH 30 SUNSCREEN - avobenzone, homosalate, octisalate, oxybenzone lotion
Sun & Skin Care Research, 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

Homosalate: 10%

Octisalate: 5%

Oxybenzone: 3%

Avobenzone: 2%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- If used as directed with other skin 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. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply after 80 minutes of swimming or sweating and 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 value of 15 or higher and other sun protection measures including limiting time in the sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants, hats and sunglasses.
- children under 6 months: Ask a doctor

Other Information

- For use on skin only
- Avoid contact with fabric
- Protect this product from excessive heat and direct sun

Drug Facts	
Active ingredients: Avobenzone 2.0%, Homosalate 10.0% Octisalate 5.0%, Oxybenzone 3.0%	Purpose Sunscreen
Uses • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), 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 • apply liberally 15 minutes before sun exposure • reapply: • after 80 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 value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor	
Inactive Ingredients: Acrylates / C10-30 Alkyl Acrylate Copolymer, Acrylates Copolymer, Aloe Barbadosensis Leaf Extract, Butylparaben, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylparaben, Glycerin, Hydroxypropyl Methylcellulose, Isobutylparaben, Methylparaben, Octyl Palmitate, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Propylene Glycol, Propylparaben, Retinyl Palmitate (Vitamin A), Sorbitan Oleate, Tocopheryl Acetate (Vitamin E), Triethanolamine, Water	
	Other Information: • for use on skin only. Avoid contact with fabric • protect this product from excessive heat and direct sun
	Questions or comments? Call toll free 1-800-715-3485
<p>This non-greasy, water resistant sunscreen lotion is perfect for any water sport activity. Contains aloe vera and vitamin E to help soften the sun's drying effect on your skin. Provides up to 30 times your natural degree of sunburn protection.</p> <p><i>Distributed by: No-Ad Products, LLC.</i> 851 Greensboro Rd., Cocoa, Florida 32926 MADE IN THE U.S.A. www.NO-AD.com</p>	



16oz SUPER SIZE

NO-AD[®]

SPLASH

30 Broad Spectrum SPF 30

WATER SPORT Sunscreen Lotion

with WetSkin Tech™

contains Avobenzone
Aloe & Vitamin E

Water Resistant
(80 minutes)

16 fl oz
(475 mL)

UV white R. Screen White PMS 109 Pms 1675
PMS 294 Black dieline

NO-AD SPLASH 30 SUNSCREEN

avobenzone, homosalate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	3 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYL PARABEN (UNII: 14255EXE39)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
METHYL PARABEN (UNII: A218C7HI9T)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-213-16	475 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2012	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture

