NO-AD 45 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: 15% Octisalate: 5% Oxybenzone: 5% 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

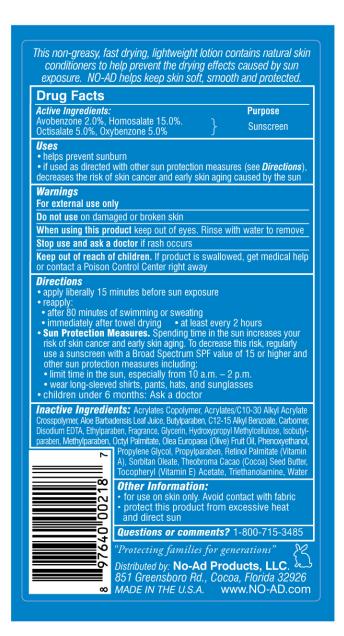
For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

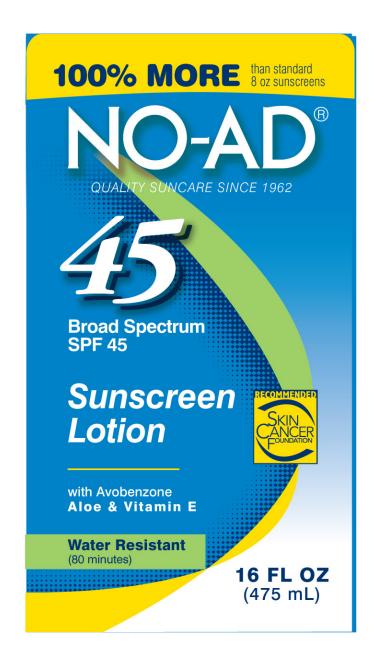
Directions

- 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





black

UV white R. Screen White Pms 375 PMS 288 PMS 109 PMS 425 dieline

NO-AD 45 SUNSCREEN avobenzone, homosalate, octisalate, oxybenzone lotion Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 mL in 100 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	5 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mL in 100 mL

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HO MO PO LYMER TYPE C (UNII: 4Q93RCW27E)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
COCOA BUTTER (UNII: 5120 YT1CRR)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A218 C7H19 T)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:62802-218-16	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	0 1/0 1/20 12		

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

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