NO-AD 85 SUNSCREEN - avobenzone, homosalate, octisalate, oxybenzone, octocrylene 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%
Oxybenzone: 6%
Octisalate: 5%
Octocrylene: 5%
Avobenzone: 3%

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

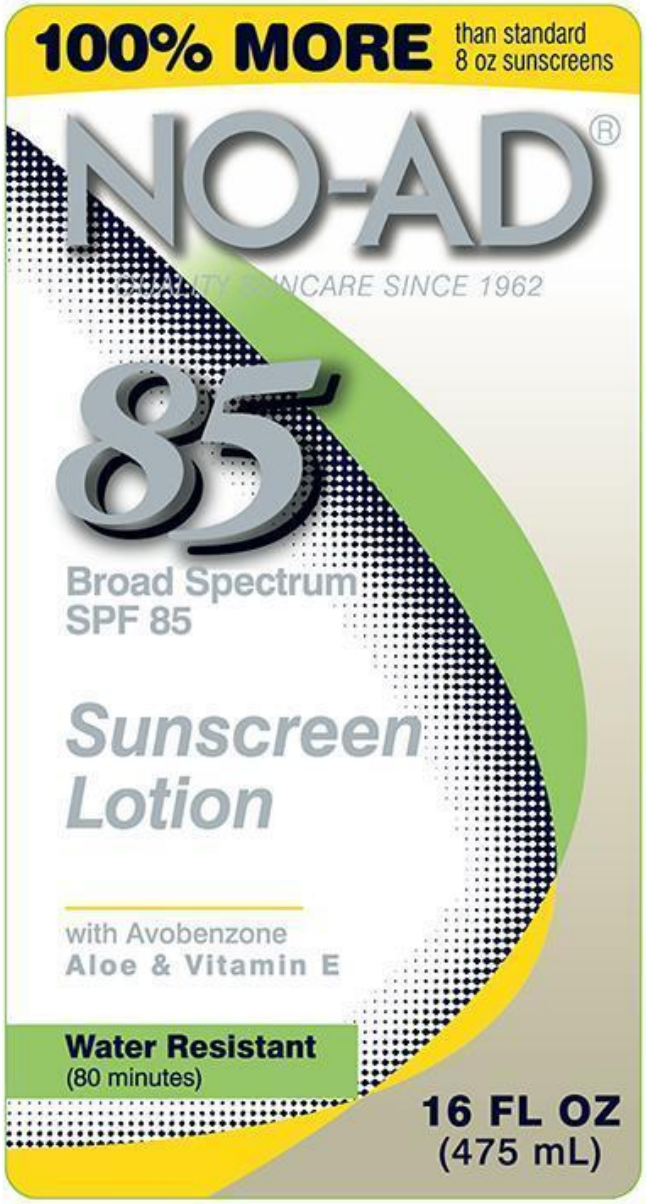
For external use only. Do not use on damaged or broken skin. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

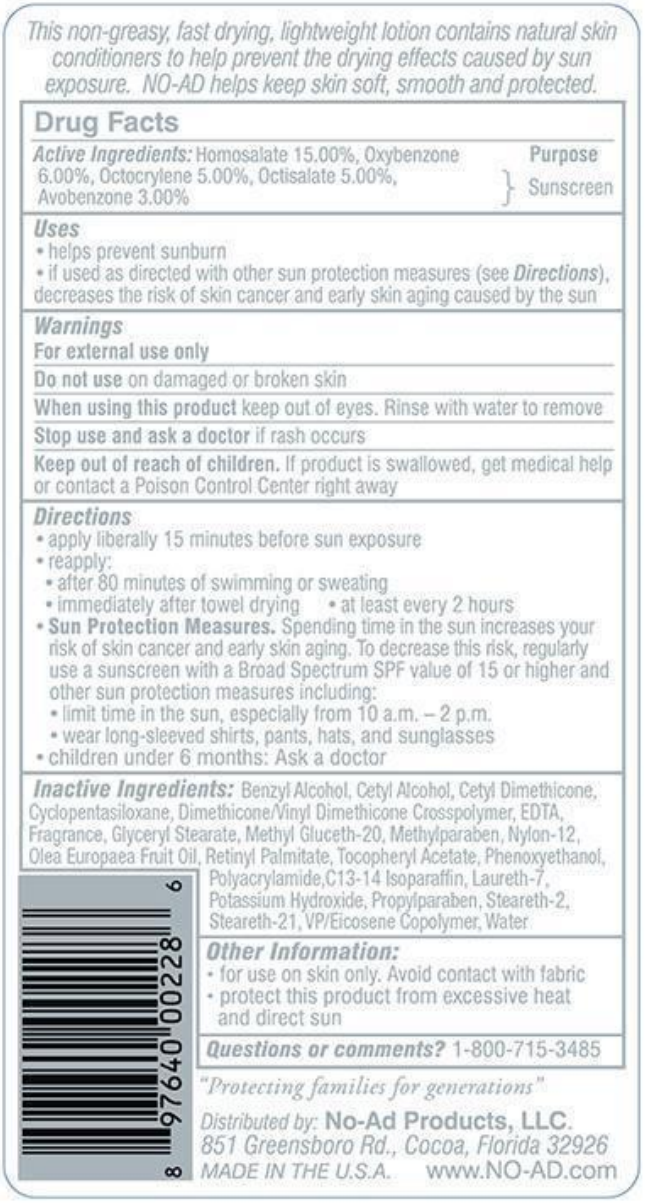
Directions

- 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





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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62802-228
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
NYLON-12 (UNII: 446U8J075B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARETH-2 (UNII: V56DFE46J5)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
STEARETH-21 (UNII: 53J3F32P58)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PVP/VA COPOLYMER (UNII: D9C330MD8B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-228-16	475 g 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(62802-228)