

OARS AND ALPS SPF 70 HYDRATING ANTIOXIDANT SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene spray

Oars and Alps 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.

Oars & Alps SPF 70 Hydrating Antioxidant Sunscreen Spray

Avobenzone - 2.9%

Homosalate - 9.8%

Octisalate - 4.9%

Octocrylene - 9.5%

Sunscreen

Uses

- 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.
 - **For external use only.**
 - **Flammable.** Contents under pressure. Keep away from fire, smoke, other sources of ignition or while smoking. Do not puncture or incinerate can. Do not store above 120 F.
 - **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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply generously and evenly 15 minutes before sun exposure
- Hold container 4-6 inches from the skin to apply
- Do not spray directly onto the face. Spray onto hands and rub onto face. Do not inhale.
- Do not apply in windy conditions.
- Use in well ventilated area.
- 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 six months: Ask a doctor.

Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Butyloctyl Salicylate, Citrus Paradisi (Grapefruit) Peel Oil, Cladonia Stellaris Extract, Diisopropyl Adipate, Ethyl Ferulate, Ethylhexyl Methoxycrylene, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Tetrahexyldecyl Ascorbate, Tocopherol

- Protect the product in this container from excessive heat and direct sun
- Avoid spraying on fabrics - may cause discoloration

Contact Hi@oarsandalps.com

Hydrating Antioxidant Sunscreen Spray SPF 70 is a lightweight spray developed with less alcohol than the traditional SPF spray. Formulated to moisturize while also protecting you from harmful UV radiation. Designed for those who live an active, on-the-go life style, with 80 min water-resistance that can be used on wet or sweaty skin.

Active ingredients	Purpose
Avobenzone 2.9%, Homosalate 9.8%, Octisalate 4.9%, Octocrylene 9.5%	Sunscreens

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Inactive ingredients Acrylates/Octylacrylamide Copolymer, Alcohol Denat., Butyloctyl Salicylate, Citrus Paradisi (Grapefruit) Peel Oil, Cladonia Stellaris Extract, Diisopropyl Adipate, Ethyl Ferulate, Ethylhexyl Methoxycrylene, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Tetrahexyldecyl Ascorbate, Tocopherol

Other Information Protect the product in this container from excessive heat and direct sun • Avoid spraying on fabrics—may cause discoloration.

Questions or comments? Contact Hi@oarsandalps.com

OARSANDALPS.CO
 #TAKETOTHEOARS
 Manufactured for
 Oars + Alps LLC
 Chicago, IL 60661

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83046-370
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.9 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.8 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALCOHOL (UNII: 3K9958V90M)	
ETHYL FERULATE (UNII: 5B8915UELW)	
GRAPEFRUIT OIL (UNII: YR377U58W9)	
CLADONIA RANGIFERINA WHOLE (UNII: O21ZF987XQ)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83046-370-13	177 mL in 1 CAN; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/01/2023	

Labeler - Oars and Alps LLC (040241941)