OARS AND ALPS SPF 50 100% MINERAL ANTIOXIDANT SUNSCREEN- titanium dioxide, zinc oxide 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 50 100% Mineral Antioxidant Sunscreen Spray

Titanium Dioxide - 3.4%

Zinc Oxide - 15.7%

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.
- 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

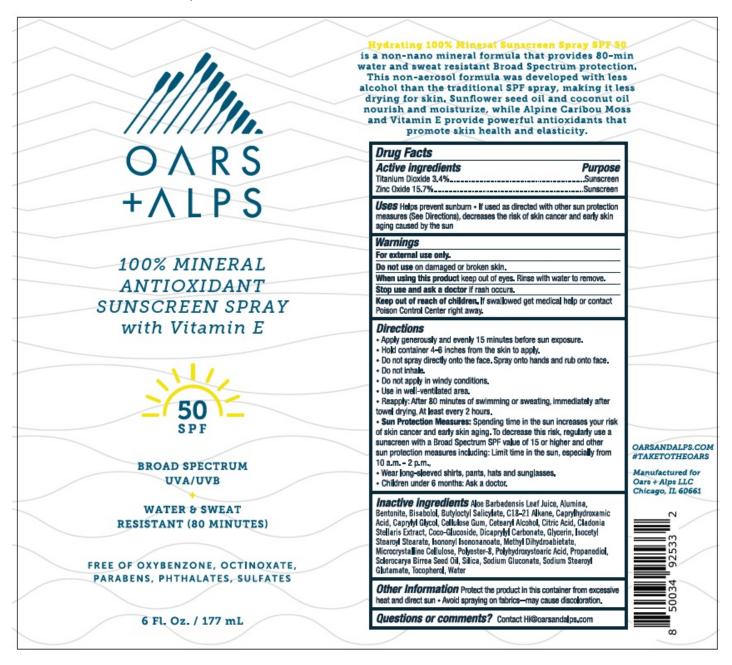
- Apply generously and evenly 15 minutes before sun exposure
- Hold container 4-6 inches from the skin to apply
- Do not spray directly onto the face. Spray onto hands and rub onto face. Do not inhale.
- Do not apply in windy conditions.
- Use in well ventilated area.
- Reapply: After 80 minutes of swimming or sweating, immedately after towl 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.

Aloe Barbadensis Leaf Juice, Alumina, Bentonite, Bisabolol, Butyloctyl Salicylate, C18-21 Alkane, Caprylhydroxamic Acid, Caprylyl Glycol, Cellulose Gum, Cetearyl Alcohol, Citric Acid, Cladonia Stellaris Extract, Coco-Glucoside, Dicaprylyl Carbonate, Glycerin, Isocetyl

Stearoyl Stearate, Isononyl Isononanoate, Methyl Dihydroabietate, Microcrystalline Cellulose, Polyester-8, Polyhydroxystearic Acid, Propanediol, Sclerocarya Birrea Seed Oil, Silica, Sodium Gluconate, Sodium Stearoyl Glutamate, Tocopherol, Water

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

Contact Hi@oarsandalps.com



OARS AND ALPS SPF 50 100% MINERAL ANTIOXIDANT SUNSCREEN

titanium dioxide, zinc oxide spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83046-369

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15.7 g in 100 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.4 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SCLEROCARYA BIRREA SEED OIL (UNII: WDO4TLS35F)	
BENTONITE (UNII: A3N5ZCN45C)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
WATER (UNII: 059QF0KO0R)	
C18-C21 ALKANE (UNII: 33822S0M40)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CLADONIA RANGIFERINA WHOLE (UNII: O21ZF987XQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM OXIDE (UNII: LMI2606933)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
COCO GLUCOSIDE (UNII: ICS790225B)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
LEVOMENOL (UNII: 24WE03BX2T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:83046-369- 13	177 mL in 1 CAN; Type 0: Not a Combination Product	12/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/01/2022	

Labeler - Oars and Alps LLC (040241941)

Revised: 1/2023 Oars and Alps LLC