BONDI SANDS SPORT SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion BONDI SANDS (USA) INC.

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.

BONDI SANDS SPORT SPF 50 SUNSCREEN LOTION

Drug Facts

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 8%

Purpose

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.
- Retains SPF after 80 minutes of activity in the water.

Warnings

For external use only

Do not use

on damaged or broken skin.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash or irritation develops and lasts.

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.

Other information

- Protect the product in this container from excessive heat and direct sun.
- You may report a serious adverse reaction to 888-266-0772; Monday Friday, 9 am – 5 pm.

Inactive Ingredients

Water/Aqua/Eau, Beeswax/Cera Alba/Cire d'abeille, Aloe Barbadensis Leaf Juice, Isopropyl Palmitate, Cetearyl Alcohol, Cyclopentasiloxane, Cyclohexasiloxane, Ceteareth-20, Hydroxyacetophenone, Carbomer, Benzyl Alcohol, Saccharide Isomerate, Phenoxyethanol, Sodium Stearoyl Glutamate, Triethanolamine, Tocopheryl Acetate, Sodium Chloride, Citric Acid.

Questions?

888-266-0772 or visit bondisands.com

Company Information

Made in Australia. Distributed by Bondi Sands USA Wilmington, 19808, DE. bondisands.com

Product Packaging

bondi sands The Australian tan BROAD SPECTRUM SPORT SPF 50

SUNSCREEN LOTION

VERY WATER RESISTANT 80 MINUTES

SWEAT RESISTANT

COOL MOTION TECHNOLOGY

Australian Made

5.07 FL. OZ. (150mL)



BONDI SANDS SPORT SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79950-007		
Route of Administration	TOPICAL				

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 m
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
Inactive Ingredients		
Ingredient Name		Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)		
SACCHARIDE ISOMERATE (UNII: W8K377W98I)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)		
CYCLOMETHICONE 6 (UNII: XHK3U310BA)		
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)		
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
TROLAMINE (UNII: 903K93S3TK)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79950- 007-01	150 mL in 1 TUBE; Type 0: Not a Combination Product	05/23/2021	
2	NDC:79950- 007-02	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/02/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/23/2021	

Labeler - BONDI SANDS (USA) INC. (117596864)