

SURFERS BARRIER- zinc oxide stick

Avasol 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

Zinc Oxide (non-nano, Uncoated) 24.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

- **For external use only.**
- **Keep out of eyes. Rinse with water to remove.**

Stop use and ask a doctor if rash or irritation occurs.

Do not use if allergic to ingredients, or nuts. Test small area first.

Keep out of reach of children. If swallowed, get medical help right away.

Directions

- apply liberally before sun
- reapply: after 80 min. of swimming or sweating, immediately after towel drying, or as needed
- children under 6 months: Ask a doctor.

Inactive ingredients

*Cocos Nucifera (Coconut) Oil,*Simmondsia Chinensis (Jojoba) Seed Oil, *Helianthus annuus (Sunflower) Oil, **Euphorbia Cerifera (Candelilla) wax, *Calophyllum Inophyllum (Tamanu) Oil, *Argania spinosa (Argan) Oil, Silica, **Theobroma Grandiflorum (Cupuacu) Butter, **Mauritia Flexuosa (Buriti) Fruit Oil, *Butyrospermum Parkii (Shea Butter), Rubus idaeus (Raspberry) Seed Oil, *Beeswax, Tocopherol (Vitamin E), Iron oxides, *Vanilla Planifolia (Vanilla) Fruit Extract, *Propolis, Plankton Extract, Mica, **Leptospermum scoparium (Manuka) Oil, *Rosmarinus Officinalis (Rosemary) Leaf Extract, *Cinnamomum Zeylanicum (Cinnamon) Bark Oil. ****Organic **Wildcrafted**

Other information

- protect package from moisture & extreme heat

Questions?

visit www.avasol.com

Principal Display Panel - 1oz Tube Label

avasol®

mineral sunscreen

30 SPF

Surf & Sport Barrier Water-resistant (80 min.)

Broad Spectrum (UVA/UVB) People-safe

- Ocean-safe Authentic
- 100% Bio-based

Net Wt 1oz (28 g)



Surf & Sport Barrier
Water-resistant (80 min.)
Broad Spectrum (UVA/UVB)
Safer for People & the Ocean
USDA Certified 100% Biobased

← Twist to Open → Tamper Evident Seal

avasol[®]

mineral sunscreen

30 SPF



Net Wt 1 OZ (28 g)

Mfg. in the USA by AVASOL Post Office Box 50516 Santa Barbara, CA 93150

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SURFERS BARRIER

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58518-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CANDELILLA WAX (UNII: WL0328HX19)	
TAMANU OIL (UNII: JT3LVK84A1)	
ARGAN OIL (UNII: 4V59G5UW9X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THEOBROMA GRANDIFLORUM SEED (UNII: Q7RNT1G37V)	
SHEANUT (UNII: 84H6HBP32L)	
MAURITIA FLEXUOSA WHOLE (UNII: 83ULF8L5FI)	
RUBUS IDAEUS SEED (UNII: M3CL7US2ZG)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERROUS OXIDE (UNII: G7036X8B5H)	
VANILLA BEAN (UNII: Q74T35078H)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
MICA (UNII: V8A1AW0880)	
HAEMATOCOCCUS PLUVIALIS (UNII: 31T0FF0472)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
ROSEMARY (UNII: IJ67X351P9)	
CINNAMON BARK OIL (UNII: XE54U569EC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58518-020-03	28 g in 1 TUBE; Type 0: Not a Combination Product	07/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/18/2013	

Labeler - Avasol LLC (078822898)

Establishment

Name	Address	ID/FEI	Business Operations
Avasol LLC		078822898	MANUFACTURE(58518-020)