

PRO FORMULA- zinc oxide, titanium dioxide 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%

Titanium Dioxide (non-nano, Uncoated) 6%

Purpose

Sunscreen

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

*Caprylic/Capric Triglyceride (Coconut), *Cocos Nucifera (Coconut) Oil,*Helianthus annuus (Sunflower) Oil, **Euphorbia cerifera (Candelilla) wax, *Calophyllum Inophyllum (Tamanu)Oil,*Beeswax,**Theobroma Grandiflorum (Cupuacu) Seed Butter, Mica, Tocopherol (Vitamin E),*Aloe Vera Leaf, Iron oxides, *Propolis, *Rosmarinus Officinalis (Rosemary) Leaf Extract, **Leptospermum scoparium (Manuka) Oil,*Cinnamomum

Zeylanicum(Cinnamon) Bark Oil.

***Organic **Wildcrafted**

Other information

- protect package from moisture & extreme heat.

Questions?

visit www.avasol.com

Principal Display Panel - 28 g Tube Label

avasol®

mineral sunscreen

PRO 50+SPF

Net Wt 1 oz (28 g)

Pro-Grade Skin Barrier

Water-resistant (80 min.)

Broad Spectrum (UVA/UVB)

Safer for People & the Ocean

USDA Certified 100% Biobased



**Pro-Grade Skin 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
PRO 50+SPF



Net Wt 1 oz (28 g)

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

Drug Facts

| Active Ingredients | Purpose |
|--|-----------|
| Zinc Oxide (non-nano, Uncoated) 24.5% | Sunscreen |
| Titanium Dioxide (non-nano, Uncoated) 6% | 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 *Caprylic/Capric Triglyceride (Coconut), *Cocos Nucifera (Coconut) Oil, *Helianthus annuus (Sunflower) Oil, **Euphorbia cerifera (Candelilla) wax, *Calophyllum Inophyllum (Tamanu) Oil, *Beeswax, **Theobroma Grandiflorum (Cupuacu) Seed Butter, Mica, Tocopherol (Vitamin E), *Aloe Vera Leaf, Iron oxides, *Propolis, *Rosmarinus Officinalis (Rosemary) Leaf Extract, **Leptospermum scoparium (Manuka) Oil, *Cinnamomum Zeylanicum (Cinnamon) Bark Oil.

***Organic **Wildcrafted**

Other information • protect package from moisture & extreme heat.

Questions? visit www.avasol.com

PRO FORMULA

zinc oxide, titanium dioxide stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58518-030 |
| 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 |

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | **TITANIUM DIOXIDE** | 6 g in 100 g

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| TAMANU OIL (UNII: JT3LVK84A1) | |
| CANDELILLA WAX (UNII: WL0328HX19) | |
| THEOBROMA GRANDIFLORUM SEED (UNII: Q7RNT1G37V) | |
| MICA (UNII: V8A1AW0880) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| FERROUS OXIDE (UNII: G7036X8B5H) | |
| PROPOLIS WAX (UNII: 6Y8XYV2NOF) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| 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:58518-030-03 | 28 g in 1 TUBE; Type 0: Not a Combination Product | 05/01/2023 | |
| 2 | NDC:58518-030-04 | 224 g in 1 POUCH; Type 0: Not a Combination Product | 05/01/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 05/01/2023 | |

Labeler - Avasol LLC (078822898)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|------------------------|
| Avasol LLC | | 078822898 | MANUFACTURE(58518-030) |

Revised: 4/2023

Avasol LLC