

NON-NANO SUNSCREEN SPF 40- zinc oxide lotion
ProCaps Laboratories, 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.

Solé non-nano zinc oxide SPF 40 sunscreen

ACTIVE INGREDIENT

Zinc Oxide 17.5%

PURPOSE

Sunscreen

USE

- 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

- For sunscreen use
- apply liberally and evenly 15minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: Ask a doctor.
- 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.

OTHER INFORMATION

- protect the product in this container from excessive heat and direct sun
- may stain some fabrics

QUESTIONS?

CALL 800.800.1200
www.ProCapsLabs.com

INACTIVE INGREDIENTS

Water (Aqua), Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Cetearyl Alcohol, Silica, Coco-Glucoside, Microcrystalline Cellulose, Glycerin, Pyrus Malus (Apple) Fruit Extract, Cocoyl Proline, Humulus Lupulus (Hops) Extract, Isostearic Acid, Phenylpropanol, Polyhydroxystearic Acid, Xanthan Gum

Solé's lightweight, non-greasy, water-based formula is ideal for daily use. It's smooth, transparent, non-whitening formula is designed for all skin types, including sensitive skin. Solé is the perfect way to both protect your skin and the planet at the same time.

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 17.5%	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.

Warnings

• 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 • For sunscreen use • apply liberally and evenly 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months of age: Ask a doctor. • **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.

Other information • protect the product in this container from excessive heat and direct sun • may stain some fabrics

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QUESTIONS? CALL 800.800.1200 www.PROCAPSLABS.com	
CAREFULLY CREATED BY 	

Manufactured for ProCaps Laboratories and EcoEcho
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Solé natural mineral-based sunscreen is the successful result of more than two decades of research seeking the safest, mildest and most effective sun protection. Its smooth, transparent, non-whitening zinc oxide provides powerful SPF 40 protection without synthetic chemical sunscreens.

Solé is dermatologist tested, hypoallergenic and non-comedogenic. It is also fragrance-free, preservative-free and chemical sunscreen free. Solé is vegan, cruelty-free and never tested on animals.

Solé's primary ingredients are water and non-nano zinc oxide making it the safest, gentlest and most responsible choice in skin protection. Solé is designed with not just your health, but that of the planet, in mind. Enjoy!

QUESTIONS? REORDERS?
888.888.2876 • SOLE.COM

earth friendly

solé™

non-nano
zinc oxide
SPF 40
sunscreen

hypoallergenic
broad spectrum

ecoecho™

6 fl oz. / 177 ml

Dermatologist Tested
Non-Comedogenic
For Sensitive Skin
Preservative Free
Fragrance-Free
Hypoallergenic

Paraben-Free
Phthalate-Free
Petrolatum-Free
Sulfate-Free
Gluten-Free

Mineral Based
Broad Spectrum
Smooth Transparent
Non-Nano Zinc Oxide
No Chemical Sunscreens

 MADE IN THE USA

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NON-NANO SUNSCREEN SPF 40

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72879-505
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	17.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
JOJOBA OIL (UNII: 724GKU717M)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
COCO-GLYCERIDES (UNII: ISE9I7DNUG)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
GLYCERIN (UNII: PDC6A3C0OX)
APPLE (UNII: B423VGH5S9)
COCOYL PROLINE (UNII: 0IH06971TF)
HOPS (UNII: 01G73H6H83)
ISOSTEARIC ACID (UNII: X33R8U0062)
PHENYLPROPANOL (UNII: 0F897O3O4M)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72879-505-02	1 in 1 BOX	03/29/2019	
1		59 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72879-505-04	1 in 1 BOX	03/29/2019	
2		118 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:72879-505-06	1 in 1 BOX	03/29/2019	
3		177 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/29/2019	

Labeler - ProCaps Laboratories, Inc. (144872652)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	manufacture(72879-505)

Revised: 2/2019

ProCaps Laboratories, Inc.