NATURAL SUNSCREEN- zinc oxide cream MooGoo USA 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.

Active Ingredient Purpose

Zinc Oxide 24.96%

□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

IKeep out of reach of children.

Natural Sunscreen

MooGoo

"Zinc only thanks"

SPF 30

Rubs in Clear

Water Based (Less Greasy)

UVA + UVB Broad Spectrum

For Children & Adults

WATER RESISTANT 40MIN

Active Ingredient

Zinc Oxide 24.96% w/w

Directions

Apply liberally 15 minutes before sun exposure

Reapply:

- after 40 minutes of swimming or sweating
- immediately after towel drying
- if rubbed off by clothing or water

□**Sun Protection Measures:**□ This Zinc based sunscreen reflects and scatters more than 97% of UV rays. In addition to sunscreen, limit time in peak sun and wear a hat. All natural products should be patch tested before use.

□ 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.
- **All natural products should be patch tested before use. Stop use if rash occurs.**

Inactive Ingredients

water, jojoba oil, galactoarabinan, beeswax, coco caprylate, sorbitan olivate & lecithin & polyglyceryl-2 dipolyhydroxystearate & cetyl phosphate & polyglyceryl-3 polyricinoleate, & oleic acid, glycerin, tropolone, capryl glycol, sodium chloride (salt).

LABEL



NATURAL SUNSCREEN

zinc oxide cream

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:69788-000

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)ZINC CATION24.96 g in 100 g

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| GALACTO ARABINAN (UNII: SL4SX1O487) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| COCO-CAPRYLATE (UNII: 4828G836N6) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| EGG PHO SPHO LIPIDS (UNII: 1Z74184RGV) | |
| POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229 XJ4V12) | |
| CETYL PHO SPHATE (UNII: VT07D6X67O) | |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZO63P0N0W) | |

| OLEIC ACID (UNII: 2UMI9 U37CP) | |
|--------------------------------------|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| TROPOLONE (UNII: 7L6 DL16 P1T) | |
| CAPRYLYL GLYCOL (UNII: 00 YIU5438 U) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

| | Packaging | | | |
|---|-------------------|---|-----------------------------|--------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 NDC:69788-000-0 | 1 120 g in 1 PACKAGE; Type 0: Not a Combination Product | 04/05/2016 | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part352 | 05/07/2015 | | |
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Labeler - MooGoo USA LLC (076343899)

| Establishment | | | | |
|----------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| MooGoo USA LLC | | 076343899 | manufacture(69788-000) | |

Revised: 4/2016 MooGoo USA LLC