

SERUM CREMA BROAD SPECTRUM SPF20 SUNSCREEN- zinc oxide lotion
Pure on Purpose, 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.

Serum Crema Broad Spectrum SPF20 Sunscreen

Active Ingredient

Zinc Oxide (non-nano uncoated) 13.5%

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.

WARNINGS

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.

DIRECTIONS

- Apply liberally 15 minutes before sun exposure
- 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 & other sun protection measures including:
 - limit time in the sun, especially from 10am–2pm
 - wear long-sleeved shirts, pants, hats & sunglasses
 - use a water-resistant sunscreen if swimming or sweating
 - reapply at least every 2 hours

OTHER INFORMATION

Protect this product from excessive heat & direct sunlight.

INACTIVE INGREDIENTS

Argania Spinosa Kernel Oil* (Argan), Camellia Sinensis (Green Tea) Seed Oil*, Carthamus Tinctorius (Safflower) Seed Oil*, Cera Alba (Beeswax)*, Glycerin*, Glycyrrhiza Glabra (Licorice) Root Extract, Haematococcus Pluvialis Extract (Astaxanthin derived from Plankton), Helianthus Annuus (Sunflower) Seed Oil*, Iron Oxides (CI 77491) & (CI 77492), Jojoba Esters, Persea Gratissima (Avocado) Oil*, Prunus Armeniaca (Apricot) Kernel Oil*, Rosmarinus Officinalis (Rosemary) Leaf Extract, Rubus

Idaeus (Raspberry) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil*, Tocopherol (Vitamin E).
***denotes certified organic**

Package/Label Principal Display Panel

VIVE SANA
ORGANIC SUNCARE

SERUM CREMA

PREPARE-DEEPLY NOURISHING ARGAN
PROTECT-NON-NANO UNCOATED ZINC
REBUILD-GREEN TEA & RED RASPBERRY
IMPROVE-PLANKTON & LICORICE ROOT

BROAD SPECTRUM

-SPF 20-

SHEER BRIGHTENING FINISH

100% NATURAL

NET WEIGHT 2 FL. OZ / 59 ML



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SERUM CREMA BROAD SPECTRUM SPF20 SUNSCREEN

zinc oxide lotion

Product Information

| | | | | |
|--|--|---|-----------------------------|---------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71556-200 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 13.5 g in 100 g | |
| Inactive Ingredients | | | | |
| | Ingredient Name | | Strength | |
| | ARGAN OIL (UNII: 4V59G5UW9X) | | | |
| | CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K) | | | |
| | SAFFLOWER OIL (UNII: 65UEH262IS) | | | |
| | GLYCERIN (UNII: PDC6A3C0OX) | | | |
| | GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | | | |
| | HAEMATO COCCUS PLUVIALIS (UNII: 31T0FF0472) | | | |
| | SUNFLOWER OIL (UNII: 3W1JG795Y) | | | |
| | AVOCADO OIL (UNII: 6VNO72PFC1) | | | |
| | APRICOT KERNEL OIL (UNII: 54JB35T06A) | | | |
| | ROSEMARY (UNII: IJ67X351P9) | | | |
| | RASPBERRY SEED OIL (UNII: 9S8867952A) | | | |
| | JOJOBA OIL (UNII: 724GKU717M) | | | |
| | TOCOPHEROL (UNII: R0ZB2556P8) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71556-200-01 | 1 in 1 CARTON | 07/10/2017 | |
| 1 | | 59 g 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 | 07/10/2017 | |

Labeler - Pure on Purpose, LLC (080668430)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing, Inc. | | 793406000 | MANUFACTURE(71556-200) |