

**ZO SKIN HEALTH SHEER FLUID BROAD-SPECTRUM SUNSCREEN SPF 50- zinc oxide lotion**

**ZO Skin Health, 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.*

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**ZO® Skin Health Sheer Fluid Broad-Spectrum Sunscreen SPF 50  
National Drug Code 42851-091-50**

***Drug Facts***

***Active Ingredients***

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***Active Ingredients***

Zinc Oxide 22.0%

***Purpose***

Sunscreen

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***Uses***

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides high protection against 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***

- Apply liberally 15 minutes before sun exposure.
- Use a water-resistant sunscreen if swimming or sweating
  - Reapply: ■ 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.

### ***Inactive Ingredients***

Dimethicone, Water, C12-15 Alkyl Benzoate, Dicaprylyl Carbonate, Cetyl PEG/PPG-10/1 Dimethicone, Silica, Glycerin, Butylene Glycol, Argania Spinosa Kernel Oil, Tocopheryl Acetate, Polysorbate 20, Dimethicone Crosspolymer, Ethyl Ferulate, Triethoxycaprylylsilane, Bisabolol, Phenoxyethanol, Polymethyl Methacrylate, Caprylyl Glycol, Chlorphenesin, Sodium Chloride, Helianthus Annuus (Sunflower) Seed Oil, Sodium Citrate, Melanin, Pentylene Glycol, 1,2-Hexanediol, Ascorbic Acid, Retinyl Palmitate, Beta-Glucan, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, Ethylhexylglycerin, Iron Oxides.

### ***Principal Display Panel***

ZO® Skin Health

by Zein Obagi MD

NDC 42851-091-50

Sheer Fluid Broad-Spectrum Sunscreen SPF 50

ZOX12®

50 mL / 1.7 Fl. Oz.



|  |                               |
|--|-------------------------------|
| <b>ZO<sup>®</sup> SKIN HEALTH</b><br>BY ZEIN OBAGI MD                |                               |
| <b>PRODUCT</b><br>Sheer Fluid Broad-Spectrum<br>Sunscreen SPF 50, UC |                               |
| <b>CATEGORY:</b>   | Protect                       |
| <b>FORMULA NO.:</b>  | ZO-004-148                    |
| <b>CLASSIFICATION:</b>   | OTC                           |
| <b>ITEM TYPE:</b>  | Component                     |
| <b>SIZE:</b>   | Full - 50 ml                  |
| <b>PART NO.:</b>   | 216700                        |
| <b>UPC:</b>  | 810866011672                  |
| <b>REGION</b><br>GBL <b>US</b> INTL US+INTL CAN CHINA                |                               |
| <b>VENDOR</b><br>K1  | <b>TEMPLATE</b><br>28607A STE |
| <b>COLORS</b>  |                               |
|  | Spot White                    |
|  | Pantone Blue 072 C            |
|  | Black                         |
| <b>SUBSTRATE</b>   |                               |
|  | 18pt Silver Foil SBS C15      |

|   |                                      |
|---|--------------------------------------|
| <b>GRADE/A</b><br>DSGN / INSP-1, ◀PREM▶ QLT<br>PO BOX 431, FREEPORT, NY 11530   646-755-6235<br>GRADE DESIGN = DOT = COM  | <b>FINAL</b><br><b>2</b><br>10.27.22 |
| <b>FILE NAME</b><br>SheerFluidBroadSpectrum_50ml_Sec_US_ZOS275_MECH_F2  |                                      |
| <b>NOTES:</b><br>Created 09.20.22 rg; copy updates 09.26.22 rg; copy update 09.27.22 rg; Released final file 09.30.22 rg; copy update 10.25.22 rg; Released final file 10.27.22 rg; |                                      |

Mineral fluid sunscreen with a natural, bare-faced finish for all skin types. Antioxidant-rich formula defends skin against environmental aggressors. Provides broad-spectrum protection against UVA/UVB. Natural melanin shields skin from aging effects of high-energy visible (HEV) light.

Oxybenzone free.

Shake well before dispensing.

ZOX12<sup>®</sup>

12-hour, time-release ZOX12<sup>®</sup> complex, our sunscreens help shield the skin from harmful infrared (IR-A) rays.

Dist. by ZO Skin Health, Inc. Irvine, CA 92618 | Made in USA with US & imported materials zoskinhealth.com | 916700

**ZO SKIN HEALTH SHEER FLUID BROAD-SPECTRUM SUNSCREEN SPF 50**  
zinc oxide lotion

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:42851-091 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b>  |
|---|--------------------------|------------------|
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE               | 0.225 g in 50 mL |

## Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| <b>ETHYL FERULATE</b> (UNII: 5B8915UELW)   |                 |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  |                 |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)   |                 |
| <b>MELANIN SYNTHETIC (TYROSINE, PEROXIDE)</b> (UNII: O0CV1RMR44)                               |                 |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)   |                 |
| <b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)  |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)   |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)  |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |                 |
| <b>ARGAN OIL</b> (UNII: 4V59G5UW9X)  |                 |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)   |                 |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)   |                 |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)  |                 |
| <b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)                                 |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)  |                 |
| <b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)  |                 |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)  |                 |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)  |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)  |                 |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)                               |                 |
| <b>LEVOMENOL</b> (UNII: 24WE03BX2T)  |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |                 |
| <b>ROSEMARY</b> (UNII: IJ67X351P9)   |                 |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)   |                 |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |                 |
| <b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)   |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)   |                 |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)  |                 |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |                 |
| <b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)   |                 |
| <b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6) |                 |

## Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:42851-091-50 | 1 in 1 CARTON  | 04/01/2023           |                    |
| 1 |                  | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020                                     | 04/01/2023           |                    |

**Labeler** - ZO Skin Health, Inc. (826468527)

Revised: 1/2023

ZO Skin Health, Inc.