

**ZO SKIN HEALTH DAILY SHEER BROAD-SPECTRUM SUNSCREEN SPF 45-  
avobenzene, homosalate, octisalate, octocrylene 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 Daily Sheer Broad-Spectrum Sunscreen SPF 45  
National Drug Code 42851-094-45  
Formula No. ZO-004-171 Bentley (Homosalate Reformulation)**

**Drug Facts**

**Active Ingredients**

| <b>Active Ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
| Avobenzene 3.0% .....     | Sunscreen      |
| Homosalate 6.8% .....     | Sunscreen      |
| Octisalate 5.0%.....      | Sunscreen      |
| Octocrylene 10.0% .....   | Sunscreen      |

**Uses**

- helps prevent sunburn
- higher SPF gives more sunburn protection
- provides high protection against sunburn
- retains SPF after 40 minutes of perspiring
- 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

**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.

**Warnings**

**For external use only.**

## ***Directions***

- Apply liberally 15 minutes before sun exposure
- Reapply: ■ at least every 2 hours ■ after 40 minutes of swimming or sweating
- 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***

Water, Butyloctyl Salicylate, Silica, Dimethicone, Cetearyl Alcohol, Diethylhexyl 2,6-Naphthalate, Triaccontanyl PVP, Argania Spinosa Kernel Oil, Glyceryl Stearate, PEG-100 Stearate, Tocopheryl Acetate, Isododecane, Glycerin, Bisabolol, Propanediol, Steareth-21, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, Ascorbic Acid, Retinyl Palmitate, Dipotassium Glycyrrhizate, Squalane, Beta-Glucan, Melanin, Cetearyl Glucoside, Steareth-2, Polysorbate 60, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Acrylates Copolymer, Polymethyl Methacrylate, Disodium EDTA, Ethyl Ferulate, Sodium C14-16 Olefin Sulfonate, Sodium Hydroxide, Phenoxyethanol, Ethylhexylglycerin, Pentylene Glycol, 1,2-Hexanediol, Fragrance, Iron Oxides.

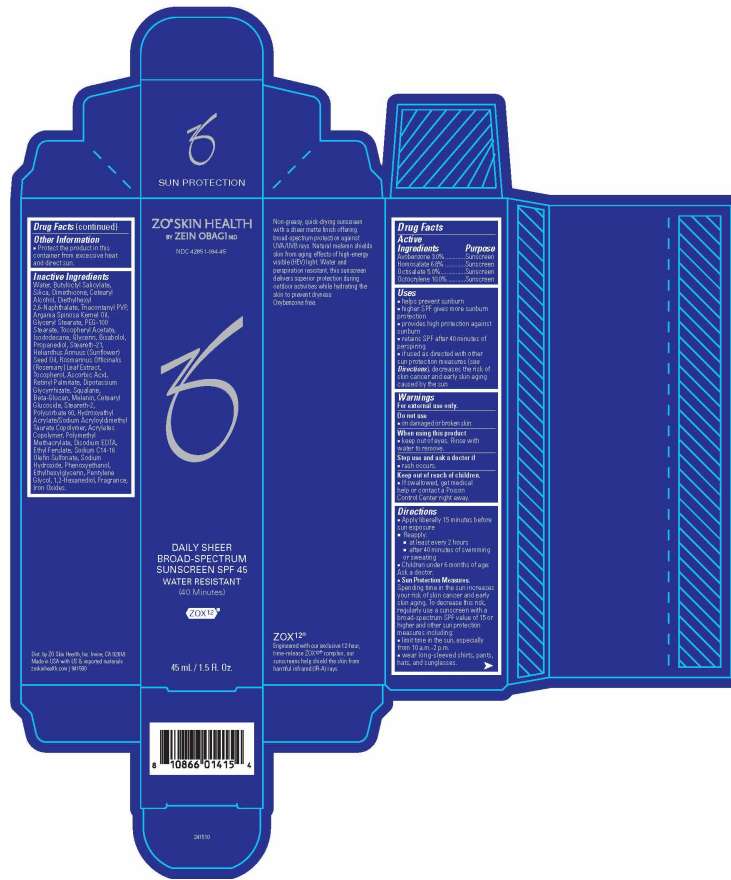
## ***Principal Display Panel***

ZO® Skin Health

by Zein Obagi, MD

NDC 42851-094-45

DAILY SHEER BROAD-SPECTRUM SUNSCREEN SPF 45 WATER RESISTANT  
(40 Minutes)



|  |   |
|--|---|
| <b>ZO SKIN HEALTH</b><br>By ZEIN OBAGI MD                  |   |
| <b>PRODUCT</b><br>UC, Daily Sheer Broad-Spectrum<br>SPF 45 |   |
| <b>CATEGORY:</b>   | Protect                                   |
| <b>FORMULA NO.:</b>  | ZO-004-171                                |
| <b>CLASSIFICATION:</b>                                     | OTC                                       |
| <b>ITEM TYPE:</b>  | Component                                 |
| <b>SIZE:</b>   | Full - 45 mL                              |
| <b>PART NO.:</b>   | 241510                                    |
| <b>UPC:</b>  | 810866014154                              |
| <b>REGION</b><br>GBL US INTL US+INTL CAN CHINA             |   |
| <b>VENDOR</b><br>K1  | <b>TEMPLATE</b><br>21207A1 STE V Internal |
| <b>COLORS</b>  |   |
| <input type="checkbox"/>                                   | Spot White                                |
| <input checked="" type="checkbox"/>                        | Pantone Blue 072 C                        |
| <input type="checkbox"/>                                   | Black                                     |
| <b>SUBSTRATE</b><br>18pt Silver Foil SBS C1S               |   |

|   |  |                                      |
|---|--|--------------------------------------|
| <b>GRADE/A</b>  |  | <b>FINAL</b><br><b>1</b><br>01.04.23 |
| DSGN / INSP-1 - PREM - QLT<br>All labels and packaging for ZOX12 are subject to change<br>B R A D E A S I O N - P O T - C O M   |  |                                      |
| <b>FILE NAME</b><br>DailySheerSPF45_45ml_Sac_US_ZOX12_MEGH_F1   |  |                                      |
| <b>NOTES:</b><br>created 12.14.22 kj; Revised copy 12.21.22 kj; Updated<br>barcode 12.22.22 kj; Released final file 01.04.23 kj |  |                                      |

## ZOX12®

Engineered with our exclusive 12-hour, time-release ZOX12® complex, our sunscreens help shield the skin from harmful infrared (IR-A) rays.

Non-greasy, quick-drying sunscreen with a sheer matte finish offering broad-spectrum protection against UVA/UVB rays. Natural melanin shields skin from aging effects of high-energy visible (HEV) light. Water and perspiration resistant, this sunscreen delivers superior protection during outdoor activities while hydrating the skin to prevent dryness. Oxybenzone free.

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

# ZO SKIN HEALTH DAILY SHEER BROAD-SPECTRUM SUNSCREEN SPF 45

avobenzone, homosalate, octisalate, octocrylene lotion

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:42851-094 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE        | 3060 mg in 45 mL |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE        | 1350 mg in 45 mL |

|   |             |                  |
|---|-------------|------------------|
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE  | 2250 mg in 45 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 4500 mg in 45 mL |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>LEVOMENOL</b> (UNII: 24WE03BX2T)   |          |
| <b>ROSEMARY</b> (UNII: IJ67X351P9)  |          |
| <b>DIMETHICONE 100</b> (UNII: RO266O364U)   |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |          |
| <b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)  |          |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)  |          |
| <b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)  |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)  |          |
| <b>ETHYL FERULATE</b> (UNII: 5B8915UELW)  |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)   |          |
| <b>ARGAN OIL</b> (UNII: 4V59G5UW9X)   |          |
| <b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)  |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)  |          |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)  |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |          |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)   |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |          |
| <b>WATER</b> (UNII: 059QF0K0OR)   |          |
| <b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)  |          |
| <b>STEARETH-21</b> (UNII: 53J3F32P58)   |          |
| <b>MELANIN SYNTHETIC (TYROSINE, PEROXIDE)</b> (UNII: O0CV1RMR44)  |          |
| <b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4) |          |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)   |          |
| <b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)   |          |
| <b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGXM)  |          |
| <b>STEARETH-2</b> (UNII: V56DFE46J5)  |          |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)  |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)   |          |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)   |          |
| <b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)   |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)  |          |
| <b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)  |          |
| <b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)   |          |
| <b>SQUALANE</b> (UNII: GW89575KF9)  |          |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)  |          |
| <b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)   |          |
| <b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)  |          |

## Packaging

| # | Item Code     | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------|---------------------|----------------------|--------------------|
|   | NDC 43351-004 |                     |                      |                    |

|                              |   |  |                             |                           |
|------------------------------|---|--|-----------------------------|---------------------------|
| <b>1</b>                     | NDC:42851-094-45                                | 1 in 1 CARTON                                      | 08/01/2023                  |                           |
| <b>1</b>                     |   | 40 mL in 1 TUBE; Type 0: Not a Combination Product |                             |                           |
| <b>Marketing Information</b> |   |  |                             |                           |
| <b>Marketing Category</b>    | <b>Application Number or Monograph Citation</b> |  | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| OTC monograph final          | M020  |  | 08/01/2023                  |                           |

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

Revised: 2/2023

ZO Skin Health, Inc.