

**ZO SKIN HEALTH DAILY SHEER BROAD-SPECTRUM SUNSCREEN SPF 50 WATER RESISTANT (40 MINUTES)- avobenzone, homosalate, octisalate, octocrylene cream**  
**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 50 Water Resistant (40 Minutes)**  
**NDC 42851-095-45**  
**Formula No. ZO-004-186**

***Drug Facts***

***Active Ingredients***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Avobenzone 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

***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

■ 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 this product 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, Tocopheryl Acetate, Glyceryl Stearate, PEG-100 Stearate, 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 42851-095-45

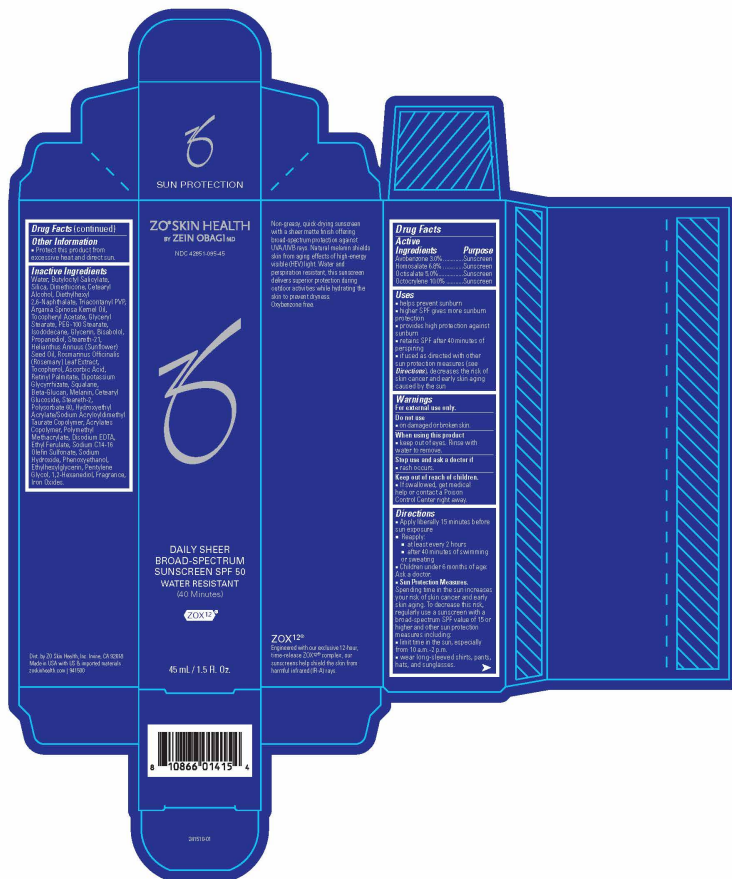
Daily Sheer Broad-Spectrum Sunscreen SPF 50

*Water Resistant*

*(40 Minutes)*

ZOX12®

45 mL / 1.5 Fl. Oz.



<b>ZO SKIN HEALTH</b> BY ZEIN OBAGI MD	
<b>PRODUCT</b> Daily Sheer Broad-Spectrum SPF 50, UC	
<b>CATEGORY:</b>	Protect
<b>FORMULA NO.:</b>	ZO-004-186
<b>CLASSIFICATION:</b>	OTC
<b>ITEM TYPE:</b>	Component
<b>SIZE:</b>	Full - 45 mL 241510-01
<b>PART NO.:</b>	810866014154
<b>UPC:</b>	810866014154
<b>REGION</b>	
GBL US INTL US+INTL CAN CHINA	
<b>VENDOR</b>	<b>TEMPLATE</b>
K1	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>	
18pt Silver Foil SBS C1S	

<b>GRADE/A</b>		<b>FINAL</b>
DSGN / INSP-1 - PREM - QLTY		1
05.16.23		
<b>FILE NAME</b>		
DailySheerSPF50_45ml_Sac_US_ZO5347_MECH_F1		
<b>NOTES:</b>		
created 05.12.23 kj; Released final file 05.16.23 kj		

# ZO SKIN HEALTH DAILY SHEER BROAD-SPECTRUM SUNSCREEN SPF 50 WATER RESISTANT (40 MINUTES)

avobenzone, homosalate, octisalate, octocrylene cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42851-095
<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>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4500 mg in 45 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2250 mg in 45 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1350 mg in 45 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>TRIACONTANYL PVP (WP-660)</b> (UNII: N0SS3Q238D)
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)
<b>STEARETH-2</b> (UNII: V56DFE46J5)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>MELANIN SYNTHETIC (TYROSINE, PEROXIDE)</b> (UNII: O0CV1RMR44)
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>ISODODECANE</b> (UNII: A8289P68Y2)
<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)
<b>ETHYL FERULATE</b> (UNII: 5B8915UELW)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>STEARETH-21</b> (UNII: 53J3F32P58)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)
<b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGXM)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-095-45	1 in 1 CARTON	10/01/2023	
1		45 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 final	M020	10/01/2023	

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

Revised: 7/2023

ZO Skin Health, Inc.