

**ZO SKIN HEALTH GEL SUNSCREEN BROAD-SPECTRUM SPF 50- avobenzone, octisalate, octocrylene gel**  
**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 Gel Sunscreen Broad-Spectrum SPF 50**  
**National Drug Code 42851-092-45**

**Drug Facts**

**Active Ingredients**

<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3.0%.....	Sunscreen
Octisalate 5.0%.....	Sunscreen
Octocrylene 10.0%	Sunscreen

**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.
- 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***

Isododecane, Silica, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Ethylhexyl Palmitate, Caprylic/Capric Triglyceride, Polyamide-8, Polyester-8, Isodecyl Neopentanoate, Polyamide-3, Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer, Polymethylsilsesquioxane/Trimethylsiloxysilicate, Diethylhexyl 2,6-Naphthalate, Diisopropyl Sebacate, Lauryl Lactate, Hydrogenated Poly(C6-20 Olefin), Bisabolol, Lupinus Albus Seed Oil, Triticum Vulgare (Wheat) Germ Extract, Glycine Soja (Soybean) Oil, Leontopodium Alpinum Meristem Cell Culture, Marrubium Vulgare Meristem Cell Culture, Tocopherol, Tocopheryl Acetate, Ascorbic Acid, Retinyl Palmitate, Melanin, Pentylene Glycol, Lecithin, Caprylyl Glycol, Glycerin, Diethylhexyl Syringylidenemalonate, HDI/Trimethylol Hexyllactone Crosspolymer, Polymethyl Methacrylate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Water, Ethylhexylglycerin.

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

ZO® Skin Health Gel Sunscreen Broad-Spectrum SPF 50

Water-Resistant

(40 Minutes)



<b>ZO° SKIN HEALTH</b> BY ZEIN OBAGI MD	
<b>PRODUCT</b> Gel Sunscreen Broad-Spectrum SPF 50, UC	
<b>CATEGORY:</b> Protect <b>FORMULA NO.:</b> ZO-004-156 <b>CLASSIFICATION:</b> OTC <b>ITEM TYPE:</b> Component <b>SIZE:</b> Full - 45g <b>PART NO.:</b> 216400 <b>UPC:</b> 810866011641	
<b>REGION</b> GBL US INTL US+INTL CAN CHINA	
<b>VENDOR</b> K1	<b>TEMPLATE</b> 28608A STE
<b>COLORS</b>	
	Spot White
	Pantone Blue 072 C
	Black
<b>SUBSTRATE</b> 18pt Silver Foil SBS C1S	

<b>GRADE/A</b> DSGN / INSP-1 • PREM • QLTY PO BOX 431, FREEPORT, NY 11560 (646) 755-6235 GRADE DESIGN • DOT • COM	<b>READER</b> <b>3</b> 09.27.22
<b>FILE NAME</b> GelSunscreen_50mL_Sec_US_ZO274_MECH_R3	
<b>NOTES:</b> Created 09.16.22 rg; copy updates 09.26.22 rg; copy updates 09.27.22 rg;	

## ZOX12®

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

A clear and unscented gel sunscreen with a complexion smoothing finish for all skin types. Exclusive antioxidant + plant stem cell complexes minimize the aging effects of environmental aggressors. Provides broad-spectrum protection against UVA/UVB. Natural melanin shields skin from aging effects of high-energy visible (HEV) light. Oxybenzone free.

Dist. by ZO Skin Health, Inc. Irvine, CA 92618

Made in USA with US & imported materials

zoskinhealth.com

**ZO SKIN HEALTH GEL SUNSCREEN BROAD-SPECTRUM SPF 50**  
avobenzone, octisalate, octocrylene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42851-092
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4.5 g in 45 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.35 g in 45 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 45 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>POLYAMIDE-8 (4500 MW)</b> (UNII: 77723GV81A)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER</b> (UNII: O4I3UFO6ZF)	
<b>WHEAT GERM</b> (UNII: YR3G369F5A)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIETHYLHEXYL 2,6-NAPHTHALATE</b> (UNII: I0DQJ7YGXM)	
<b>POLYAMIDE-3 (12000 MW)</b> (UNII: L7P3YWF22X)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>POLYMETHYLSILSESQUIOXANE/TRIMETHYLSILOXYSILICATE</b> (UNII: X2PZH4Y6HT)	
<b>LAURYL LACTATE</b> (UNII: G5SU0BFBK7O)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>LUPINUS ALBUS SEED OIL</b> (UNII: 958BJW095Q)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYDROGENATED C6-20 POLYOLEFIN (100 CST)</b> (UNII: 39EYQ1W9RB)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-092-45	1 in 1 CARTON	04/01/2023	
1		45 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 final	M020	04/01/2023	

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

Revised: 11/2022

ZO Skin Health, Inc.