

**ZO SKIN HEALTH SMART TONE BROAD-SPECTRUM SUNSCREEN SPF 50-  
avobenzone, 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 Smart Tone Broad-Spectrum Sunscreen SPF 50  
National Drug Codes 42851-055-45, 42851-055-20**

***Drug Facts***

***Active Ingredients***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Avobenzone 3% .....	Sunscreen
Homosalate 10%.....	Sunscreen
Octisalate 5%.....	Sunscreen
Octocrylene 10% .....	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.
- 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***

Water, Dimethicone, Butyloctyl Salicylate, Styrene/Acrylates Copolymer, Dimethicone/Divinyldimethicone/Silsesquioxane Crosspolymer, Glyceryl Stearate, Mica, PEG-100 Stearate, Butylene Glycol, Polyamide-5, Steareth-21, Argania Spinosa Kernel Oil, Helianthus Annuus (Sunflower) Seed Oil, Petasites Japonicus Root Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopheryl Acetate, Tocopherol, Ascorbic Acid, Retinyl Palmitate, Caprylyl Glycol, Hexylene Glycol, Melanin, Pentylene Glycol, Boron Nitride, Ethyl Ferulate, C12-15 Alkyl Benzoate, Tetrahexyldecyl Ascorbate, Beta-Glucan, Ethylene Brassylate, Polymethyl Methacrylate, Acrylates/Ammonium Methacrylate Copolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Disodium EDTA, Acrylates Crosspolymer-4, Panthenyl Triacetate, Glycerin, Aluminum Hydroxide, Simethicone, Ethyl Linoleate, Oleyl Alcohol, Cetearyl Alcohol, PEG-8 Laurate, Steareth-2, Coco-Glucoside, Isostearic Acid, Sodium Hydroxide, Phenoxyethanol, 1,2-Hexanediol, Potassium Sorbate, Ethylhexylglycerin, Fragrance, Titanium Dioxide, Iron Oxides.

### **Principal Display Panel**

ZO® SKIN HEALTH

by ZEIN OBAGI MD

NDC 42851-055-45

Smart Tone Broad-Spectrum Sunscreen SPF 50

ZOX12®



<b>ZO SKIN HEALTH</b> BY ZEIN OBAGI MD	
<b>PRODUCT</b> Smart Tone Broad-Spectrum SPF 50	
<b>CATEGORY:</b>	Protect
<b>FORMULA NO.:</b>	ZO-004-111 Rev. 2
<b>CLASSIFICATION:</b>	OTC
<b>ITEM TYPE:</b>	Component
<b>SIZE:</b>	Full - 45 ml
<b>PART NO.:</b>	24100-01
<b>UPC:</b>	810866017377
<b>REGION</b> GBL US INTL US+INTL CAN CHINA	
<b>VENDOR</b> K1	<b>TEMPLATE</b> 21205A-STE
<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 C15	

<b>GRADE/A</b>		<b>FINAL</b> <b>1</b> 02.24.22
DSGN / INSP-1 - PREM - QLT © 2022 ZEIN OBAGI MD B R A D E A D E S I G N - P D T - C O M		
<b>FILE NAME</b> SmartTone_45ml_Sec_US_ZOX12_MECH_F1		
<b>NOTES:</b> Created 02.14.22 kj; Revised copy 02.22.22 kj; Released final file 02.24.22 kj		

Ultra-lightweight sunscreen with customizable color beads designed to blend into most skin tones. Provides broad-spectrum protection against UVA/UVB rays. Natural melanin helps shield skin from the aging effects of high-energy visible (HEV) light. Oxybenzone free.

### ZOX12<sup>®</sup>

Engineered with our exclusive 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 | 973380

## ZO SKIN HEALTH SMART TONE BROAD-SPECTRUM SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42851-055
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	100 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85KORA)	
<b>ETHYL FERULATE</b> (UNII: 5B8915UELW)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>PETASITES JAPONICUS ROOT</b> (UNII: 6F650HF10T)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>BORON NITRIDE</b> (UNII: 2U4T60A6YD)	
<b>DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER</b> (UNII: T3064TZ75A)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>ETHYLENE BRASSYLATE</b> (UNII: 9A87HC7ROD)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>OLEYL ALCOHOL</b> (UNII: 172F2VN8DV)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PANTHENOL TRIACETATE, (+)-</b> (UNII: 1206E8961B)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>ETHYL LINOLEATE</b> (UNII: MJ2YTT4J8M)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	

<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-055-45	1 in 1 CARTON	06/01/2022	
1		45 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:42851-055-20	1 in 1 CARTON	06/01/2022	
2		20 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	part352	06/01/2022	

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

Revised: 4/2022

ZO Skin Health, Inc.