

**ZO SKIN HEALTH SMART TONE BROAD-SPECTRUM SUNSCREEN SPF 50-
avobenzene, homosalate, octisalate, octocrylene lotion
ZO Skin Health, Inc.**

Drug Facts

Active Ingredients

Ingredients	Purpose
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
- 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 and as needed.
- 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

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- Protect this product from excessive heat and direct sun.

Inactive Ingredients

Water, Dimethicone, Butyloctyl Salicylate, Styrene/Acrylates Copolymer, Dimethicone/Divinyldimethicone/Silsesquioxane Crosspolymer, Glyceryl Stearate, PEG-100 Stearate, Butylene Glycol, Mica, Polyamide-5, Steareth-21, Argania Spinosa Kernel Oil, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Petasites Japonicus Root Extract, Tocopheryl Acetate, Tocopherol, Ascorbic Acid, Retinyl Palmitate, Caprylyl Glycol, Hexylene Glycol, Propylene Glycol Stearate, Melanin, Pentylene Glycol, Tetrahexyldecyl Ascorbate, Beta-Glucan, Glycerin, Ethyl Linoleate, Oleyl Alcohol, Acrylates Crosspolymer-4, Dimethicone/Vinyl Dimethicone Crosspolymer, Magnesium Stearate, Panthenyl Triacetate, Cetearyl Alcohol, PEG-8 Laurate, Coco-Glucoside, Steareth-2, Polymethyl Methacrylate, Cellulose Acetate, Acrylates/Ammonium Methacrylate Copolymer, Simethicone, Disodium EDTA, Sodium Hydroxide, Ethyl Ferulate, Phenoxyethanol, 1,2-Hexanediol, Potassium Sorbate, Ethylhexylglycerin, Ethylene Brassylate, Fragrance, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, 77492, 77499).



ZO SKIN HEALTH by ZEIN OBAGI MD	
PRODUCT Smart Tone Broad-Spectrum SPF 50, UC	
CATEGORY:	Protect
FORMULA NO.:	ZO-004-185
CLASSIFICATION:	OTC
ITEM TYPE:	Component
SIZE:	Full - 45 ml
PART NO.:	2767/00/01
UPC:	810866017674
REGION GBL US INTL US+INTL CAN CHINA	
VENDOR K1	TEMPLATE Z1205A SITE
COLORS <input type="checkbox"/> Spot White <input checked="" type="checkbox"/> Pantone Blue 072 C <input type="checkbox"/> Black	
SUBSTRATE 18pt Silver Foil SBS C1S	

GRADE/A	FINAL 1
DSGN / INSP-1 • PREM • QLTY	03.06.24
FILE NAME SmartTone_45ml_Sec_US_ZOS450_MESH-F1	
NOTES: Created 02:29:24 jh; F1 Final Release 03:06:24 jh	

ZO® SKIN HEALTH
by ZEIN OBAGI MD

NDC 42851-096-45

Smart Tone Broad-Spectrum Sunscreen SPF 50

ZOX12 ®

45 mL / 1.5 Fl. Oz.

ZO SKIN HEALTH SMART TONE BROAD-SPECTRUM SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-096
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	68 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-100 STEARATE (UNII: YD01N1999R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PROPYLENE GLYCOL STEARATE (UNII: MZM1I680W0)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYL FERULATE (UNII: 5B8915UELW)	
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
ACRYLATES CROSSPOLYMER-4 (UNII: GEV2EL4D9G)	
PANTHENOL TRIACETATE, (+)- (UNII: 1206E8961B)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)
MICA (UNII: V8A1AW0880)
STEARETH-21 (UNII: 53J3F32P58)
ROSEMARY (UNII: IJ67X351P9)
PETASITES JAPONICUS ROOT (UNII: 6F650HF10T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
GLYCERIN (UNII: PDC6A3C0OX)
COCO-GLUCOSIDE (UNII: ICS790225B)
STEARETH-2 (UNII: V56DFE46J5)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0KO0R)
POLYAMIDE-5 (UNII: UEM62QMW5F)
ARGAN OIL (UNII: 4V59G5UW9X)
SUNFLOWER OIL (UNII: 3W1JG795YI)
TOCOPHEROL (UNII: R0ZB2556P8)
DIMETHICONE/DIVINYLDIMETHICONE/SILSESQUIOXANE CROSSPOLYMER (UNII: T3064TZ75A)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
DIMETHICONE (UNII: 92RU3N3Y1O)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-096-20	1 in 1 CARTON	04/19/2024	
1		45 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:42851-096-45	1 in 1 CARTON	04/19/2024	
2		45 mL in 1 TUBE; Type 0: Not a Combination Product		



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FORMULA NO.:	ZO-004-185
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SIZE:	Full - 45 ml
PART NO.:	276700-01
UPC:	810866017674
REGION GBL US INTL US+INTL CAN CHINA	
VENDOR K1	TEMPLATE 21205A STE
COLORS	
<input type="checkbox"/> Spot White	
<input checked="" type="checkbox"/> Pantone Blue 072 C	
<input type="checkbox"/> Black	
SUBSTRATE 18pt Silver Foil SBS C1S	

GRADE / A	FINAL 1
DSGN / INSP-1, PREM+ QTY P1 906 431, PREPARET W/ 1500 1648 700 8238 D R A S E A S I O N = D D T = C D M	03.06.24
FILE NAME SmartTone_45ml_Spc_US_ZO0660_MECH_F1	
NOTES: Created 02.29.24 jh; F1 Final Release 03.06.24 jh	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/19/2024	

Labeler - ZO Skin Health, Inc. (826468527)

Revised: 4/2024

ZO Skin Health, Inc.