

**ZO SKIN HEALTH BROAD-SPECTRUM SUNSCREEN SPF 50- titanium dioxide,
zinc oxide cream
ZO Skin Health, Inc.**

**ZO® Skin Health Broad-Spectrum Sunscreen SPF 50
42851-064**

Drug Facts

Active Ingredients

<i>Active Ingredient</i>	<i>Purpose</i>
Titanium Dioxide 6.4%	Sunscreen
Zinc Oxide 15.0%	Sunscreen

Uses

- Helps prevent sunburn

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.
- Use a water-resistant sunscreen if 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

1,2-Hexanediol, Alumina, Aqua/Water/Eau, Ascorbic Acid, Beta-Glucan, Bisabolol, Butylene Glycol, Calcium Chloride, Cetyl PEG/PPG-10/1 Dimethicone, Cordyceps Militaris Mycelium Extract, Dimethicone, Dimethicone Crosspolymer, Erythritol, Ethylhexylglycerin, Glycerin, Glycine Soja (Soybean) Seed Extract, Glycyrrhiza Uralensis (Licorice) Root Extract, Hexyl Laurate, Homarine HCL, Iron Oxides, Lactobacillus Ferment, Melanin, PEG-10 Dimethicone, Pentylene Glycol, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethyl Methacrylate, Potassium Sorbate, Retinyl Palmitate, Scutellaria Baicalensis Root Extract, Silica, Sodium Benzoate, Sodium C14-16 Olefin Sulfonate, Sodium Chloride, Sodium Citrate, Squalane, Stearic Acid, Tocopheryl Acetate, Tribehenin.

Outer Package Label



ZO[®] SKIN HEALTH by ZEIN OBAGI MD	
PRODUCT Broad-Spectrum Sunscreen SPF 50	
CATEGORY: PROTECT FORMULA NO.: ZO-004-161 CLASSIFICATION: OTC ITEM TYPE: Component SIZE: Full - 118g / 4 Oz PART NO.: 241400 UPC: 810866014048	
REGION GBL US INTL US+INTL CAN CHINA	
VENDOR K1	TEMPLATE Z0263A2 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 2
DSGN / INSP-1 • PREM • QLTLY	07.20.22
GRADE/DESIGN • ROT • COM	
FILE NAME BroadSpectrumSunscreenSPF50_118g_Sun_US_ZO3210_MCH_F2	
NOTES: Formula number update & released final files 07.20.22 igp	

ZO[®] Skin Health
by **ZEIN OBAGI MD**
NDC 42851-064-04

BROAD-SPECTRUM SUNSCREEN SPF 50

For sensitized skin

ZOX 12®

Lightweight, non-irritating mineral sunscreen for the most sensitive skin types and post-procedure skin. Provides broad-spectrum protection against UVA/UVB rays. Natural melanin shields skin from aging effects of high-energy visible (HEV) light. Oxybenzone free.

ZOX 12®

Engineered with our exclusive 12-hour, time-release ZOX12® 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

ZO SKIN HEALTH BROAD-SPECTRUM SUNSCREEN SPF 50

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-064
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.552 mg in 118 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.7 mg in 118 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
ERYTHRITOL (UNII: RA96B954X6)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	

ASCORBIC ACID (UNII: PQ6CK8PD0R)
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)
DIMETHICONE (UNII: 92RU3N3Y1O)
HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SOLANUM ANOMALUM WHOLE (UNII: 7J95G4E8OY)
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
FERRIC OXIDE RED (UNII: 1K09F3G675)
SCUTELLARIA LATERIFLORA TOP (UNII: C6CNB75R61)
STEARIC ACID (UNII: 4ELV7Z65AP)
SQUALANE (UNII: GW89575KF9)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LEVOMENOL (UNII: 24WE03BX2T)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
TRIBEHENIN (UNII: 80C9U7TQZ0)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-064-04	1 in 1 CARTON	08/15/2022	
1		118 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 Drug	M020	08/15/2022	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
LIFETECH RESOURCES LLC		622559110	manufacture(42851-064)