

**ZO SKIN HEALTH BROAD-SPECTRUM SUNSCREEN SPF 50- titanium dioxide,  
zinc oxide 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 Broad-Spectrum Sunscreen SPF 50**  
**42851-064**

***Drug Facts***

***Active Ingredients***

<b><i>Active Ingredient</i></b>	<b><i>Purpose</i></b>
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



<b>ZO SKIN HEALTH</b> by ZEIN OBAGI MD	
PRODUCT Broad-Spectrum Sunscreen SPF 50	
CATEGORY:	PROJECT
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 20263A2 STE
COLORS	
<input type="checkbox"/>	Spot White
<input checked="" type="checkbox"/>	Pantone Blue 072 C
<input type="checkbox"/>	Black
SUBSTRATE	
<input checked="" type="checkbox"/>	18pt Silver Foil SBS C15

<b>GRADE/A</b>	<b>FINAL</b> <b>2</b> 07.20.22
DESIGN INSP-1 • PREM • QLT 10/20/2022 PREPARED BY LISA HAN, 20/2022 GRADESIGN - DOT - COM	
FILE NAME BroadSpectrumSunscreenSPF50_118g_Seq_US_ZOX12_MECH_F2	
NOTES: Formula number update & released final files 07.20.22 rg.	

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**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>ERYTHRITOL</b> (UNII: RA96B954X6)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	

<b>GLYCYRRHIZA URALENSIS ROOT</b> (UNII: 42B5YD8F0K)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)
<b>CALCIUM CHLORIDE</b> (UNII: M4I0D6VV5M)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>HOMARINE HYDROCHLORIDE</b> (UNII: 8866LNG61N)
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>SOLANUM ANOMALUM WHOLE</b> (UNII: 7J95G4E8OY)
<b>SODIUM C14-16 OLEFIN SULFONATE</b> (UNII: O9W3D3YF5U)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>SCUTELLARIA LATERIFLORA TOP</b> (UNII: C6CNB75R61)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)
<b>TRIBEHENIN</b> (UNII: 8OC9U7TQZ0)

### 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 final	part352	08/15/2022	

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

### Establishment

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

