

**ZO SKIN HEALTH OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30
UVA/UVB PROTECTION- titanium dioxide 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.

**OCLIPSE[®] Sunscreen + Primer Broad-Spectrum SPF 30 UVA/UVB Protection
42851-053**

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 8.2%	Sunscreen

Uses

- Helps prevent 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 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.
- Children under 6 months: Ask a doctor.
- Reapply at least every two hours.
- **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 this product from excessive heat and direct sun.
- You may report a serious adverse reaction to: 5 Technology Dr., Irvine, CA 92618

Inactive ingredients

Cyclopentasiloxane, Dimethicone Crosspolymer, Phenyl Trimethicone, Polyglyceryl-3

Polydimethylsiloxylethyl Dimethicone, Stearic Acid, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehenin, Helianthus Annuus (Sunflower) Seed Oil, Polymethyl Methacrylate, Water, Polyglyceryl-4 Isostearate, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Dimethiconol, Phenoxyethanol, Squalane, Caprylic/Capric Triglyceride, Caprylyl Glycol, Chlorphenesin, Tocopheryl Acetate, Melanin, Behenyl Behenate, Triethoxycaprylylsilane, Polyglyceryl-5 Trioleate, Ethyl Ferulate, Glycine Soja (Soybean) Seed Extract, Calcium Chloride, Retinyl Palmitate, Pentylene Glycol, Ascorbic Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Potassium Sorbate, Ethylhexylglycerin, Myristoyl Pentapeptide-8, Tocopherol, Disodium Uridine Phosphate, Pentaerythrityl Tetra-di-t-butyl, Hydroxyhydrocinamate, Iron Oxides.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

ZO[®] SKIN HEALTH

BY ZEIN OBAGI, MD

OCLIPSE[®]

SUNSCREEN + PRIMER

BROAD-SPECTRUM SPF 30

UVA/UVB/HEV/IR-A PROTECTION

beverly hills

30 mL / 1 Fl. Oz.

zoskinhealth.com



Drug Facts (continued)

Inactive ingredients

Cyclopentasiloxane, Dimethicone, Crosspolymer, Phenyl Trimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Stearic Acid, Aluminum Hydroxide, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehenin, Helianthus Annuus (Sunflower) Seed Oil, Polymethyl Methacrylate, Water, Polyglyceryl-4 Isostearate, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Dimethiconol, Phenoxyethanol, Squalane, Caprylic/Capric Triglyceride, Caprylyl Glycol, Chlorphenesin, Tocopheryl Acetate, Melanin, Behenyl Behenate, Triethoxycaprylsilane, Polyglyceryl-5 Trioleate, Ethyl Ferulate, Glycine Soja (Soybean) Seed Extract, Calcium Chloride, Retinyl Palmitate, Pentylene Glycol, Ascorbic Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Potassium Sorbate, Ethylhexylglycerin, Myristoyl Pentapeptide-8, Tocopherol, Disodium Uridine Phosphate, Pentaerythrityl Tetra-di-t-butyl, Hydroxyhydrocinnamate, Iron Oxides.

ZO[®] SKIN HEALTH
BY ZEIN OBAGI MD

NDC 42851-053-03



OCLIPSE[®]
SUNSCREEN + PRIMER
BROAD-SPECTRUM SPF 30

UVA / UVB / HEV / IR-A
PROTECTION



30 mL / 1 Fl. Oz.

Oclipse[®] Sunscreen + Primer uses a multiple defense sun protection system that provides full spectrum UVA/UVB defense. Natural melanin shields skin from the aging effects of high-energy visible light (HEV). A universal tint and a silky matte finish help reduce the appearance of skin imperfections. Can be used alone or worn under makeup for a more even, long-lasting application. Oxygenzone free.

ZOX12[™]

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

Drug Facts

Active ingredient Purpose
Titanium Dioxide 8.2% Sunscreen

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"ZO" is a registered trademark of ZO Skin Health, Inc.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618
MADE IN USA 061800

zoskinhealth.com



SPF 30 UVA/UVB PROTECTION

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-053
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	82 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
SQUALANE (UNII: GW89575KF9)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
CALCIUM CHLORIDE (UNII: M4I0D6VV5M)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
URIDINE MONOPHOSPHATE DISODIUM (UNII: KD8E20071T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
WATER (UNII: 059QF0KO0R)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
ETHYL FERULATE (UNII: 5B8915UELW)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	

ROSEMARY (UNII: IJ67X351P9)	
SOYBEAN (UNII: L7HT8F1ZOD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-053-03	1 in 1 CARTON	01/02/2018	
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:42851-053-01	15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/02/2018	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	manufacture(42851-053)

Revised: 4/2020

ZO Skin Health, Inc.