

ZO SKIN HEALTH SUNSMART TRIPLE PROTECTION PROGRAM NATURAL MELANIN AND ANTIOXIDANT DEFENDERS WITH SUNSCREEN PLUS PRIMER SPF 30- titanium dioxide and zinc oxide
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.

ZO[®] SKIN HEALTH
SunSmart Triple Protection Program Natural Melanin and Antioxidant Defenders with Sunscreen + Primer SPF 30

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 10.2%	Sunscreen
Zinc Oxide 3.7%	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.

Stop and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

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: 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.
- Apply to all skin exposed to the sun

Other information

- Protect the product in this container from excessive heat and direct sunlight.

- You may report a serious adverse reaction to:
1 Technology Dr. B123, Irvine, CA 92618

Inactive ingredients

Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, Dimethicone Crosspolymer, Melanin, Tribehenin, Calcium Behenate, Sorbitan Isostearate, Dimethiconol, Alumina, Laureth-23, Methicone, PEG-10 Dimethicone, PPG-2 Myristyl Ether Propionate, Propylparaben, Methylparaben, Myristoyl Pentapeptide-8, Iron Oxide (CI 77492).

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO® SKIN HEALTH
BY ZEIN OBAGI, MD

SunSmart

TRIPLE PROTECTION PROGRAM

Natural Melanin and Antioxidant
Defenders with Sunscreen + Primer
SPF 30

NDC 42851-157-03

beverly hills

ANTI-AGING COMBO PACK

zoskinhealth.com



ZO[®] SKIN HEALTH
BY ZEIN OBAGI, MD



SunSmart
TRIPLE PROTECTION PROGRAM

Natural Melanin and Antioxidant

OSSENTIAL[®] DAILY POWER DEFENSE
30 mL / 1 Fl. Oz.

CAUTION For external use only. Stop use if rash or irritation develops and persists. Keep out of eyes. Keep out of reach of children. Product may make your skin more sensitive to the sun; always use sunscreen protection.

INGREDIENTS Water (Aqua), Cetearyl Isononanoate, Cyclopentasiloxane, Cyclohexasiloxane, Pentylene Glycol, Retinol, Lecithin, Polysorbate 20, Glycerin, Steareth-20, Cetearyl Alcohol, Jojoba Esters, Retinyl Palmitate, Tocopheryl Acetate, Beta-Glucan, Lactose, Citrus Aurantium Dulcis (Orange) Peel Oil, Citrus Nobilis (Mandarin Orange) Peel Oil, Citrus Limon (Lemon) Peel Oil, Citrus Reticulata (Tangerine) Peel, Mentha Piperita (Peppermint) Oil, Mimosa Tenuiflora Bark Extract, Arabidopsis Thaliana Extract, Micrococcus Lysate, C14-22 Alcohols, Safflower Oil/Palm Oil Aminopropanediol Esters, Cetearyl Glucoside, C12-20 Alkyl Glucoside, Cellulose, Butylene Glycol, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Hydroxide, Carbomer, Hydroxypropyl Methylcellulose, Hexylene Glycol, Disodium EDTA, Caprylyl Glycol, Ethylhexylglycerin, Phenoxyethanol, Limonene, Ultramarines (CI 77007), Ext. Violet 2 (CI 60730).

Natural Melanin and Antioxidant
Defenders with Sunscreen + Primer
SPF 30

NDC 42851-157-03

beverly hills

ANTI-AGING COMBO PACK

No matter what time of year or where you live, you must protect your skin everyday to prevent premature aging. These two powerhouse anti-aging formulas by Zein Obagi, M.D. are designed to work together, offering maximum protection

OCCLIPSE® SUNSCREEN + PRIMER
BROAD-SPECTRUM SPF 30, UVA/UVB PROTECTION
30 mL / 1 Fl. Oz. (NDC 42851-051-03)

Drug Facts

Active ingredients

Purpose

from the damaging effects of sun exposure and environmental pollutants and irritants.

OSSENTIAL® DAILY POWER DEFENSE

Retinol, enzymes and antioxidants help repair damaged cells and protect against future damage. It encourages cellular activity to aid in skin cell rejuvenation.

OCLIPSE® SUNSCREEN + PRIMER SPF 30

Using titanium dioxide and zinc oxide—two physical sunscreens—this sunscreen provides full spectrum UV protection. Melanin, nature's best protectant, works to neutralize free radicals generated by sunlight. A tint and a silky matte finish help the sunscreen reduce the appearance of skin imperfections and create the perfect primer for make-up application.

Following cleansing, apply 2-3 pumps of Ossential® Daily Power Defense over your face and neck every morning. Massaging skin increases absorption, penetration and stimulation. Follow with Oclipse® Sunscreen + Primer SPF 30.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

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

zoeskinhealth.com



MADE IN USA
095900

Titanium Dioxide 10.2%.....Sunscreen
Zinc Oxide 3.7%.....Sunscreen

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ZO SKIN HEALTH SUNSMART TRIPLE PROTECTION PROGRAM NATURAL MELANIN AND ANTIOXIDANT DEFENDERS WITH SUNSCREEN PLUS PRIMER SPF 30

titanium dioxide and zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-157
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-157-03	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PUMP	30 mL
Part 2	1 BOTTLE, PUMP	30 mL

Part 1 of 2**OCLIPSE SUNSCREEN PLUS PRIMER BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION**

titanium dioxide and zinc oxide lotion

Product Information

Item Code (Source)	NDC:42851-051
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	102 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	ZINC OXIDE	37 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CALCIUM BEHENATE (UNII: J5VFA9V6YG)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONOL (40 CST) (UNII: 343C7U75XW)	
ALUMINUM OXIDE (UNII: LM26O6933)	
LAURETH-23 (UNII: N72LMW566G)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7H9T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-051-03	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2012	

Part 2 of 2

OSSENTIAL DAILY POWER DEFENSE ANTI-AGING FORMULA

cleansing (cold creams, cleansing lotions, liquids, and pads) lotion

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0K00R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99N)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	JOJOBA BUTTER (UNII: XIA46H803R)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CURDLAN (UNII: 6930DL209R)	
INGR	LACTOSE (UNII: J2B2A4N98G)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	MANDARIN OIL (UNII: NJO720F72R)	
INGR	LEMON OIL (UNII: I9GRO824LL)	

INGR	PEPPERMINT OIL (UNII: AV092KU4JH)	
INGR	MIMOSA TENUIFLORA BARK (UNII: 515MQE449I)	
INGR	ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
INGR	C14-22 ALCOHOLS (UNII: B1K89384RJ)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
INGR	HYPROMELLOSES (UNII: 3NXW29V3WO)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	LIMONENE, (+/-)- (UNII: 9MC3B4447)	
INGR	ULTRAMARINE BLUE (UNII: B9WR998BI)	
INGR	EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/01/2014	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Owen Biosciences		790003045	MANUFACTURE(42851-157)

Establishment

Name	Address	ID/FEI	Business Operations
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PakLab, Inc.

177711082

MANUFACTURE(42851-157)

Revised: 4/2014

ZO Skin Health, Inc.