

ZO SKIN HEALTH ZO FAVORITES (MOTHERS DAY GWP)- titanium dioxide
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 ZO[®] Favorites (Mother's Day GWP)
NDC 42851-162

Drug Facts

Active ingredients

Titanium Dioxide 8.2%

Purpose

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 use and ask a doctor if

- 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 of age: 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 Polydimethylsiloxyethyl Dimethicone, Dimethiconol, Aluminum Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehenin, Helianthus Annuus Seed Oil, Polymethyl Methacrylate, Water, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Polyglyceryl-4 Isostearate, Glycerin, Glycine Soja Seed Extract, Caprylic/Capric Triglyceride, Behenyl Behenate, Squalane, Tocopheryl Acetate, Melanin, Ethyl Ferulate, Polyglyceryl-5 Trioleate, Triethoxycaprylylsilane, Ascorbic Acid, Methylisothiazolinone, Retinyl Palmitate, Pentylene Glycol, Rosmarinus Officinalis Leaf Extract, Ethylhexylglycerin, Disodium Uridine Phosphate, Tocopherol, Myristoyl Pentapeptide-8, Iron Oxides.

DIST BY ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] SKIN HEALTH
BY ZEIN OBAGI, MD

NDC 42851-162-01

ZO[□] FAVORITES

OFFECTS[®] EXFOLIATING CLEANSER

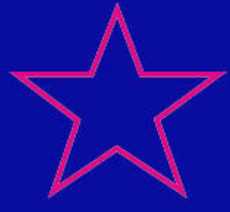
40 mL / 1.5 Fl. Oz.

OSSENTIAL[®] DAILY POWER DEFENSE

30 mL / 1 Fl. Oz.

OCLIPSE[®] SUNSCREEN + PRIMER SPF 30

15 mL / 0.5 Fl. Oz.



ZO[®] SKIN HEALTH

BY ZEIN OBAGI, MD

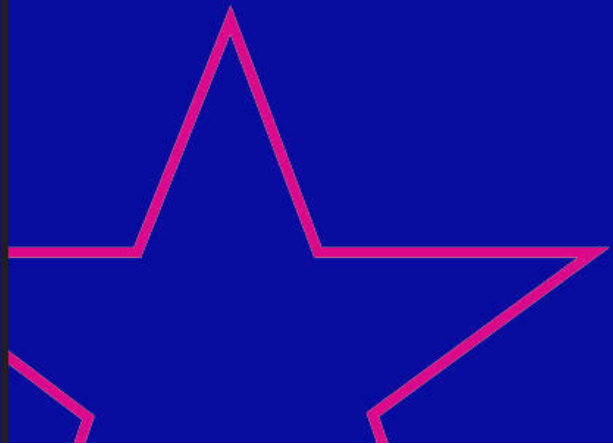
NDC 42851-162-01



ZO[★] FAVORITES

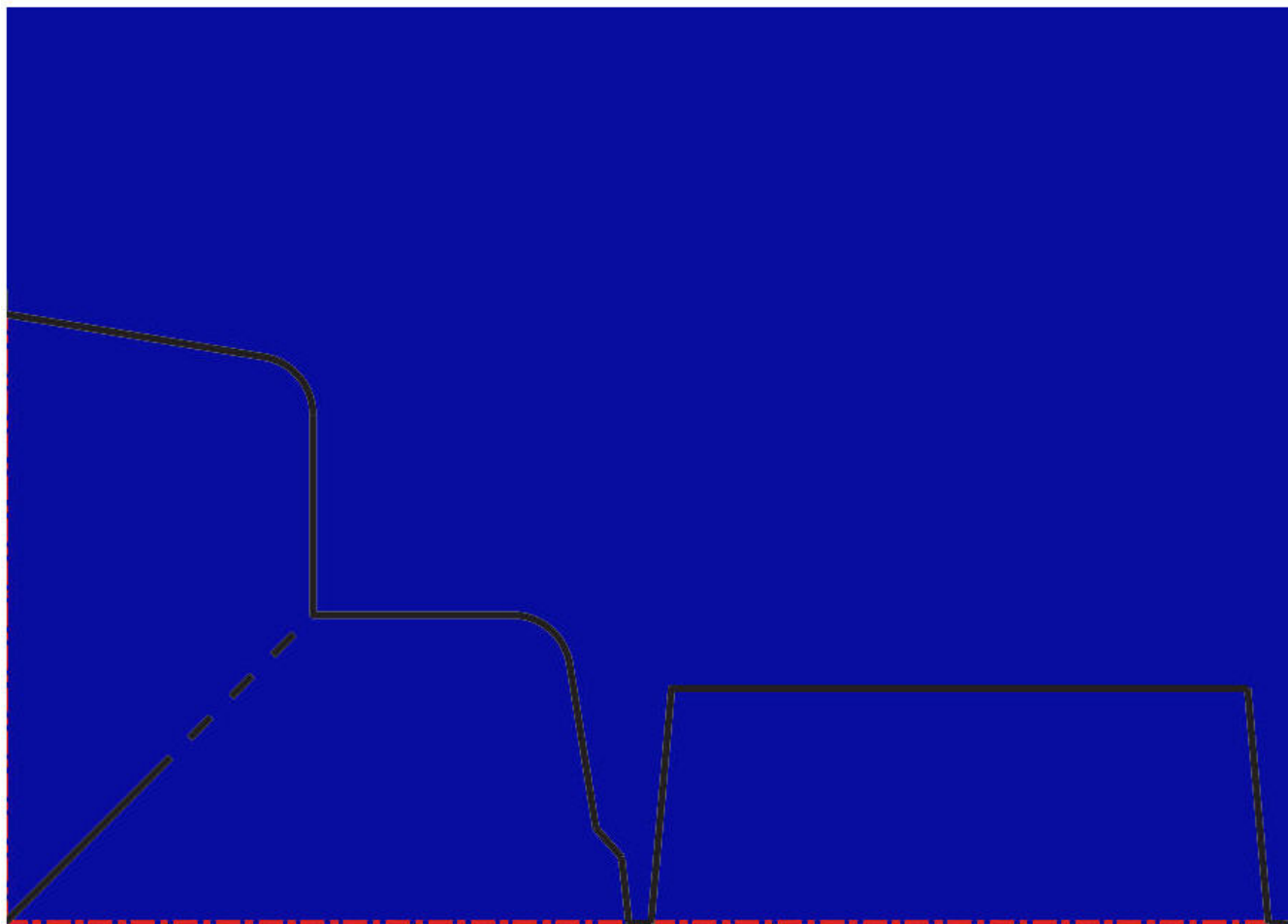
OFFECTS[®] EXFOLIATING CLEANSER

40 mL / 1.5 FL. OZ.



OSSENTIAL® DAILY POWER DEFENSE
OCLIPSE® SUNSCREEN + PRIMER SPF 30

30 mL / 1 Fl. Oz.
15 mL / 0.5 Fl. Oz.



Experience some of our favorite products!
Cleanse with Effects® Exfoliating Cleanser, strengthen your skin with Ossential® Daily Power Defense, and protect with Oclipse® Sunscreen + Primer SPF 30. Plus, included is a satin drawstring bag to hold your favorite products.

EFFECTS® EXFOLIATING CLEANSER

OCLIPSE® SUNSCREEN + PRIMER
BROAD-SPECTRUM SPF 30 UVA/UVB PROTECTION
15 mL / 0.5 Fl. Oz. (NDC 42851-053-01)

Drug Facts

Active ingredients	Purpose
Titanium Dioxide 8.2%	Sunscreen

Uses

- helps prevent sunburn.
- if used as directed with other sun protection measures (see *Directions*)

40 mL / 1.5 Fl. Oz.

Moisten hands with lukewarm water; apply a small amount to damp face and neck. To help increase penetration of the active ingredients, rub one minute.

INGREDIENTS Water (Aqua), Sodium Laureth Sulfate, Acrylates Copolymer, Cocamidopropyl Betaine, Polyethylene, Glycerin, Cocamidopropyl Hydroxysultaine, Disodium Cocoamphodiacetate, Mannitol, Cellulose, Fragrance (Parfum), Sodium Hydroxide, Myristoyl Pentapeptide-8, Butylene Glycol, Spiraea Ulmaria Extract, Melaleuca Alternifolia Leaf Oil, Salicylic Acid, Sodium PCA, Niacin, Niacinamide, Ammonium Lactate, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Biosaccharide Gum-1, Disodium EDTA, Sodium Chloride, Sodium Carbonate, Methylchloroisothiazolinone, Methylisothiazolinone, Magnesium Chloride, Magnesium Nitrate, Limonene, Chromium Hydroxide Green (CI 77289).

ESSENTIAL® DAILY POWER DEFENSE

30 mL / 1 Fl. Oz.

Following cleansing, apply 2 - 3 pumps on face and neck every morning. Massaging skin increases absorption, penetration and stimulation. Follow with Occlipse® Sunscreen + Primer Broad-Spectrum SPF 30.

INGREDIENTS Water (Aqua), Cetearyl Isononanoate, Cyclopentasiloxane, Cyclohexasiloxane, Pentylene Glycol, Cetearyl Alcohol, Glycerin, Steareth-20, Jojoba Esters, Carbomer, C14-22 Alcohols, Phenoxyethanol, Cetearyl Glucoside, Safflower Oil/Palm Oil Aminopropanediol Esters, Polysorbate 20, Butylene Glycol, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Hydroxide, Caprylyl Glycol, C12-20 Alkyl Glucoside, Ethylhexylglycerin, Lactose, Disodium EDTA, Cellulose, Hexylene Glycol, Potassium Sorbate, Beta-Glucan, 1,2-Hexanediol, Methylparaben, Lecithin, Hydroxypropyl Methylcellulose, Sorbitol, EDTA, Benzoic Acid, Sodium Benzoate, Arabidopsis Thaliana Extract, Micrococcus Lysate, Retinol, Retinyl Palmitate, Tocopheryl Acetate, Citrus Aurantium Dulcis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Reticulata Peel Oil, Mentha Piperita Oil, Mimosa Tenuiflora Bark Extract, Tocopherol, Limonene, CI 77007 (Ultramarines), CI 60730 (Ext. Violet 2).

CAUTION Stop use if rash or irritation develops and persists. Keep out of eyes. Keep out of reach of children. Products may make your skin more sensitive to the sun; wear a sunscreen with SPF 30 daily.

EFFECTS® EXFOLIATING CLEANSER SUNBURN ALERT This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

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zoskinhealth.com

Use 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

• 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 of age: 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 Polydimethylsiloxyethyl Dimethicone, Dimethiconol, Aluminum Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Tribehnenin, Helianthus Annuus Seed Oil, Polymethyl Methacrylate, Water, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Polyglyceryl-4 Isostearate, Glycerin, Glycine Soja Seed Extract, Caprylic/Capric Triglyceride, Behenyl Behenate, Squalane, Tocopheryl Acetate, Melanin, Ethyl Ferulate, Polyglyceryl-5 Trioleate, Triethoxycaprylylsilane, Ascorbic Acid, Methylisothiazolinone, Retinyl Palmitate, Pentylene Glycol, Rosmarinus Officinalis Leaf Extract, Ethylhexylglycerin, Disodium Uridine Phosphate, Tocopherol, Myristoyl Pentapeptide-8, Iron Oxides.

DIST BY ZO Skin Health, Inc. Irvine, CA 92618

MADE IN USA 092400



ZO SKIN HEALTH ZO FAVORITES (MOTHERS DAY GWP)

titanium dioxide kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:42851-162

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:42851-162-01	1 in 1 CARTON	04/01/2015
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	40 mL
Part 2	1 BOTTLE, PUMP	30 mL
Part 3	1 BOTTLE, PUMP	15 mL

Part 1 of 3

ZO SKIN HEALTH EFFECTS EXFOLIATING CLEANSER

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	TEA TREE OIL (UNII: VIF565UC2G)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	CO CAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
INGR	HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CO CAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)	
INGR	DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
INGR	MANNITOL (UNII: 3OWL53L36A)	
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	FILIPENDULA ULMARIA ROOT (UNII: 997724QNDS)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	NIACIN (UNII: 2679MF687A)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	AMMONIUM LACTATE (UNII: 67M901L9NQ)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	HYPROMELLOSES (UNII: 3NXW29V3WO)	
INGR	BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	SODIUM CARBONATE (UNII: 45P3261C7T)	
INGR	METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
INGR	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

INGR	MAGNESIUM CHLORIDE (UNII: 02F3473H9O)	
INGR	MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	CHROMIUM HYDROXIDE GREEN (UNII: RV8FT8XF5R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		04/01/2015	

Part 2 of 3

ZO SKIN HEALTH OSSENTIAL DAILY POWER DEFENSE

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: P5O01U99NI)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	C14-22 ALCOHOLS (UNII: B1K89384RJ)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

INGR	LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)
INGR	POWDERED CELLULOSE (UNII: SMD1X3XO9M)
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)
INGR	METHYL PARABEN (UNII: A218C7HI9T)
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
INGR	HYPROMELLOSES (UNII: 3NXW29V3WO)
INGR	SORBITOL (UNII: 506T60A25R)
INGR	EDETIC ACID (UNII: 9G34HU7RV0)
INGR	BENZOIC ACID (UNII: 8SKN0B0MIM)
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)
INGR	ARABIDOPSIS THALIANA (UNII: A13L60HQ81)
INGR	RETINOL (UNII: G2SH0XKK91)
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
INGR	LEMON OIL (UNII: I9GRO824LL)
INGR	MANDARIN OIL (UNII: NJO720F72R)
INGR	PEPPERMINT OIL (UNII: AV092KU4JH)
INGR	MIMOSA TENUIFLORA BARK (UNII: 515MQE449I)
INGR	TOCOPHEROL (UNII: R0ZB2556P8)
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)
INGR	ULTRAMARINE BLUE (UNII: I39WR998BI)
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; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		04/01/2015	

Part 3 of 3

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

titanium dioxide lotion

Product Information

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
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
WATER (UNII: 059QF0K00R)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
SQUALANE (UNII: GW89575KF9)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
ETHYL FERULATE (UNII: 5B8915UELW)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ROSEMARY (UNII: IJ67X351P9)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
URIDINE MONOPHOSPHATE DISODIUM (UNII: KD8E20071T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-053-01	15 mL in 1 BOTTLE, PUMP; 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	04/01/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2015	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment			
Name	Address	ID/FEI	Business Operations
Lifetech Resources, LLC.		081239587	manufacture(42851-162)

Establishment			
Name	Address	ID/FEI	Business Operations
Thibiant International, Inc.		083913913	manufacture(42851-162)

Establishment			
Name	Address	ID/FEI	Business Operations
PakLab		790530976	manufacture(42851-162)

Revised: 6/2020

ZO Skin Health, Inc.