

ZO MEDICAL ZO NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM FOR RESTORING EVEN SKIN TONE - 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[®] MEDICAL ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM For Restoring Even Skin Tone

Drug Facts

Active ingredient

Titanium Dioxide 8%

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.

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.

Other information

- Store product in a cool place away from direct heat and sunlight.
- You may report a serious adverse reaction to: 5 Technology Dr. #100, Irvine, CA 92618

Directions

- For full protection, apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- For 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.
- Apply to all skin exposed to the sun.

Inactive ingredients

Water, Aluminum Hydroxide, Stearic Acid, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cyclopentasiloxane, Phenyl Trimethicone, Styrene/Acrylates Copolymer, Pentylene Glycol, Dimethicone, Glycerin, Isodecyl Neopentanoate, Diisopropyl Sebacate, Lauryl Lactate, Polyacrylamide, Disodium EDTA, Phytosphingosine, Cetareth-20, Cetearyl Alcohol, PEG-100 Stearate, Glyceryl Stearate, Sodium Dihydroxycetyl Phosphate, Hydrogenated Palm Glycerides, Melanin, Ethylhexylglycerin, Erythritol, Homarine HCL, Sodium Benzoate, Potassium Sorbate, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Nephelium Lappaceum Peel Extract, Glycine Soja (Soybean) Extract, Silica, C13-14 Isoparaffin, Laureth-7.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - Kit Carton

ZO[®] MEDICAL
BY ZEIN OBAGI MD

NDC 42851-156-60

ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

For Restoring Even Skin Tone

ZO[®] MEDICAL

BY ZEIN OBAGI MD

For Restoring Even Skin Tone

ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

For Restoring Even Skin Tone

DESIGNED BY ZEIN OBAGI, MD To reduce the appearance of hyperpigmentation without the use of hydroquinone. This system is specifically designed to promote a smooth, blemish-free skin tone. Potent retinol, skin brighteners, vitamin C and antioxidants are released to rapidly brighten and even skin tone and improve the appearance of skin's texture and firmness.

• Ideal for improving the appearance of hyperpigmentation either when hydroquinone treatment is complete or contraindicated.

• Use when skin bleaching is not desired and even color tone is the objective

• Use after completing a course of hydroquinone for 4-5 months or as maintenance

• Ideal for improving the appearance of hyperpigmentation either when hydroquinone treatment is complete or contraindicated.

This system also reduces the appearance of fine lines & wrinkles

RIGHT EXEM™ Skin Brightener & Correcting Cream, Non-Hydroquinone
Net Wt. 1.7 oz. (48.5g)

DIRECTIONS Apply 1-2 pumps evenly on face and neck more as directed by your physician. Start with and build up gradually. Apply twice a week and increase frequency to alternate days and then daily. Hydroquinone use is contraindicated when using this product. Do not use on children or pregnant women.

CAUTION This active ingredient is not intended for use on children or pregnant women. Do not use on children or pregnant women. Do not use on children or pregnant women. Do not use on children or pregnant women.

RETINAX™ Active Vitamin A Micro Emulsion
Net Wt. 1.7 oz. (48.5g)

DIRECTIONS Apply 1-2 pumps twice a week and increase frequency to alternate days and then daily. Hydroquinone use is contraindicated when using this product. Do not use on children or pregnant women.

CAUTION This active ingredient is not intended for use on children or pregnant women. Do not use on children or pregnant women. Do not use on children or pregnant women.

RESTOPALAM™ Soothing Recovery Cream
Net Wt. 1.7 oz. (48.5g)

DIRECTIONS Use 1-2 pumps AM and PM or as needed to hydrate and soothe skin. Mix 1-2 pumps with Right Exem™ in AM or Retinax™ in PM to calm irritated reactions.

CAUTION Use only as directed. 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.

ONLY USE

10866-01990-6

ACTIVE INGREDIENTS:
 Hydroquinone 4.0% (w/w)
 Retinol 0.5% (w/w)
 Ascorbic Acid 5.0% (w/w)
 Vitamin C 1.0% (w/w)
 Alpha-Arbutin 2.0% (w/w)

OTHER INGREDIENTS:
 Water, Glycerin, N-Butyl Alcohol, Propylene Glycol, Stearic Acid, Cetyl Alcohol, Cetearyl Alcohol, Cetyl Stearate, Cetearyl Stearate, Cetyl Palmitate, Cetyl Myristate, Cetyl Laurate, Polysorbate 20, Polysorbate 80, Polysorbate 120, Polysorbate 150, Polysorbate 200, Polysorbate 400, Polysorbate 600, Polysorbate 800, Polysorbate 1200, Polysorbate 1400, Polysorbate 1600, Polysorbate 1800, Polysorbate 2000, Polysorbate 2200, Polysorbate 2400, Polysorbate 2600, Polysorbate 2800, Polysorbate 3000, Polysorbate 3200, Polysorbate 3400, Polysorbate 3600, Polysorbate 3800, Polysorbate 4000, Polysorbate 4200, Polysorbate 4400, Polysorbate 4600, Polysorbate 4800, Polysorbate 5000, Polysorbate 5200, Polysorbate 5400, Polysorbate 5600, Polysorbate 5800, Polysorbate 6000, Polysorbate 6200, Polysorbate 6400, Polysorbate 6600, Polysorbate 6800, Polysorbate 7000, Polysorbate 7200, Polysorbate 7400, Polysorbate 7600, Polysorbate 7800, Polysorbate 8000, Polysorbate 8200, Polysorbate 8400, Polysorbate 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ZO[®] NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

IMPORTANT When transitioning patients from the hydroquinone system to a non-hydroquinone system, gradually introduce Right Exem™ and Retinax™ on alternate days of hydroquinone use to avoid rebound pigmentation. Allow the skin to adjust then discontinue use of hydroquinone, usually in 1-2 months.

Use the ZO[®] GSRM Getting Skin Ready system to prepare the skin and optimize the effectiveness of this program as the first step in your skin health protocol.

DRUG FACTS (continued)

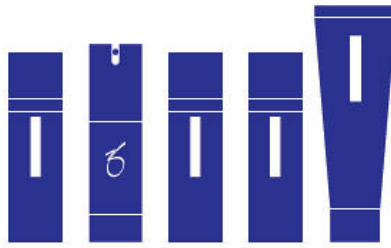
Directions For full directions, apply liberally 15 minutes before Power Defense. Apply at least every 2 hours.

Warnings Do not use on children or pregnant women. Do not use on children or pregnant women. Do not use on children or pregnant women.

Use Hydroquinone is a skin lightening agent. It may cause irritation and redness. Do not use on children or pregnant women. Do not use on children or pregnant women.

Drug Facts See the back of the box for complete directions. Do not use on children or pregnant women. Do not use on children or pregnant women.

NDC 42851-168-00



ZO® NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM

For Restoring Even Skin Tone

ZO MEDICAL ZO NON-HYDROQUINONE HYPERPIGMENTATION SYSTEM FOR RESTORING EVEN SKIN TONE

titanium dioxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42851-156
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-156-60	1 in 1 CARTON	06/01/2014	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	30 mL
Part 2	1 TUBE	30 mL
Part 3	1 TUBE	60 g
Part 4	1 TUBE	30 mL
Part 5	1 BOTTLE, PUMP	30 mL

Part 1 of 5

RETAMAX ACTIVE VITAMIN A MICRO EMULSION

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

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
INGR	BROCCOLI (UNII: UO14FT57BZ)	
INGR	POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	HYDROLYZED SERICIN (ENZYMATIC; 2500 MW) (UNII: 02EMA6F96C)	
INGR	SODIUM SULFITE (UNII: VTK01UQK3G)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	CYCLOMETHICONE 4 (UNII: CZ227117JE)	
INGR	STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	MYRISTYL ALCOHOL (UNII: V42034O9PU)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	LINALYL ACETATE (UNII: 5K47SSQ51G)	
INGR	CURDLAN (UNII: 6930DL209R)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
INGR	PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	
INGR	ETHYL NICOTINATE (UNII: NU3H353YH)	

INGR	Sodium Benzoate (UNII: OJ245FE5EU)	
INGR	Benzoic Acid (UNII: 8SKN0B0MIM)	
INGR	CARVOMENTHONE (UNII: D5PYY1B83Q)	
INGR	LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
INGR	.ALPHA.-OCIMENE, (3Z)- (UNII: LTP9229T5N)	
INGR	4-CARVOMENTHENOL (UNII: L65MV77ZG6)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
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 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/11/2012	

Part 2 of 5

BRIGHTENEX SKIN BRIGHTENER AND CORRECTING, NON-HYDROQUINONE

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: 059QF0KO0R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99ND)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ALMOND OIL (UNII: 66YXD4DKO9)	
INGR	CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	

INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	CYCLOMETHICONE 4 (UNII: CZ227117JE)	
INGR	CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	ASCORBYL PALMITATE (UNII: QN83US2B0N)	
INGR	GLUTATHIONE (UNII: GAN16C9B8O)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	N-ACETYLGLUCOSAMINE (UNII: V956696549)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	SOY ISOFLAVONES (UNII: 71B37NR06D)	
INGR	POLYSORBATE 61 (UNII: X9E1MY2JQG)	
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	NYLON-12 (UNII: 446U8J075B)	
INGR	SODIUM SULFITE (UNII: VTK01UQK3G)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	CORN OIL (UNII: 8470G57WFM)	
INGR	.BETA.-CAROTENE (UNII: 01YAE03M7J)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	GLUCONOLACTONE (UNII: WQ29KQ9POT)	
INGR	POLYISOBUTYLENE (1300 MW) (UNII: 241BN7J12Y)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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		01/11/2012	

Part 3 of 5

ZO MEDICAL OCLIPSE-C BROAD-SPECTRUM SUNSCREEN SPF 50

titanium dioxide lotion

Product Information

Item Code (Source) NDC:42851-052

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.08 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
MELAMINE (UNII: N3GP2YSD88)	
ERYTHRITOL (UNII: RA96B954X6)	
HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N)	
NEPHELIUM LAPPACEUM FRUIT RIND (UNII: Y0513T90FO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42851-052-60	60 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	06/01/2013	

Part 4 of 5

RESTORACALM SOOTHING RECOVERY

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

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	JOJOBA BUTTER (UNII: XIA46H803R)	
INGR	CURDLAN (UNII: 6930DL209R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
INGR	ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
INGR	ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
INGR	ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
INGR	DOCOSANOL (UNII: 9G1OE216XY)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	N-ACETYLTYROSINE (UNII: DA8G610ZO5)	
INGR	HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

INGR	HYDROLYZED SERICIN (ENZYMATIC; 2500 MW) (UNII: 02EMA6F96C)	
INGR	PHENOXYETHANOL (UNII: HE492ZZ3T)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	ETHYL FERULATE (UNII: 5B8915UELW)	
INGR	POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
INGR	ROSEMARY (UNII: IJ67X351P9)	
INGR	URIDINE MONOPHOSPHATE DISODIUM (UNII: KD8E20071T)	
INGR	SULFURYL FLUORIDE (UNII: 64B59K7U6Q)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
INGR	1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
INGR	PROLINE (UNII: 9DLQ4CIU6V)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
INGR	ANGELICA SINENSIS ROOT (UNII: B66F4574UG)	
INGR	ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE)	
INGR	HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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		01/11/2012	

Part 5 of 5

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

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Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
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: 2DMT128MIS)	
INGR	JOJOBA BUTTER (UNII: XIA46H803R)	
INGR	VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CURDLAN (UNII: 6930DL209R)	
INGR	LACTOSE, UNSPECIFIED FORM (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: AIBL60HQ81)	
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 HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CARBOMER HOMO POLYMER 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: IB9WR998BI)	
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		01/11/2012	

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
THIBIANT INTERNATIONAL, INC.		083913913	MANUFACTURE(42851-156)

Establishment

Name	Address	ID/FEI	Business Operations
SANTOR CORPORATION		797472792	MANUFACTURE(42851-156)

Establishment

Name	Address	ID/FEI	Business Operations
Lifetech Resources		622559110	MANUFACTURE(42851-156)

Establishment

Name	Address	ID/FEI	Business Operations
PAKLAB		790530976	MANUFACTURE(42851-156)

Revised: 4/2016

ZO Skin Health, Inc.