OBAGI-C RX SYSTEM NORMAL-DRY SKIN INTERVENTION- hydroquinone, homosalate, octisalate, and zinc oxide
Obagi Cosmeceuticals LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

OBAGI-C® RX SYSTEM

WELCOME TO THE OBAGI-C® Rx SYSTEM OF SKIN CARE PRODUCTS!

PATIENT INFORMATION—For Topical Use Only

Complete skin care regimen formulated with 4% hydroquinone to reduce hyperpigmentation and other essential ingredients to help address the signs of skin aging caused by photoaging.

Please read this product information prior to use of the Obagi-C® Rx System. Any questions regarding your particular skin care regimen should be directed to your physician. More information about the Obagi-C® Rx System or other Obagi® systems is available on our website at www.obagi.com.

PHYSICIAN PRESCRIBING INFORMATION

Rx only

FOR EXTERNAL USE ONLY

62032-106-10 Obagi-C® Rx System C-Clarifying Serum for Normal to Dry Skin

Each gram of **Obagi-C® Rx System C-Clarifying Serum** for Normal to Dry Skin contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, propylene carbonate, propylene glycol, sodium lauryl sulfate, water

62032-122-10 Obagi-C® Rx System C-Clarifying Serum for Normal to Oily Skin

Each gram of **Obagi-C® Rx System C-Clarifying Serum** for Normal to Oily Skin contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, dipropylene glycol, fragrance, propylene carbonate, propylene glycol, SD alcohol-39-C, sodium lauryl sulfate, water

62032-105-36 Obagi-C® Rx System C-Therapy Night Cream

Each gram of **Obagi-C® Rx System C-Therapy Night Cream** contains:

Active: Hydroquinone, USP 4% (40 mg per g)

Inactives: ascorbic acid, BHT, cetyl alcohol, disodium EDTA, glycerin, lactic acid, methylparaben, phenyl trimethicone, PPG-2 myristyl ether propionate, propylparaben, saponins, sodium lauryl sulfate, sodium metabisulfate, TEA-salicylate, tocopheryl acetate, water

DESCRIPTION

Hydroquinone is 1,4-benzenediol. Hydroquinone occurs as fine, white needles. The drug is freely soluble in water and in alcohol. Chemically, hydroquinone is designated as p-dihydroxybenzene; the empirical formula is $C_6H_6O_2$; molecular weight is 110.11 g per mol.

The chemical structure is in the diagram.

CLINICAL PHARMACOLOGY

Topical application of hydroquinone produces a reversible depigmentation of the skin by inhibition of the enzymatic oxidation of tyrosine to 3, 4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic processes. Exposure to sunlight or ultraviolet light will cause repigmentation of the bleached areas, which may be prevented by the use of sunscreen agents contained in the Obagi-C® Rx System Sun Shield Matte Broad Spectrum SPF 50.

INDICATIONS AND USAGE

The gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of melanin hyperpigmentation.

DOSAGE AND ADMINISTRATION

A thin application should be applied once or twice daily or as directed by a physician. If no improvement is seen after three (3) months of treatment, use of this product should be discontinued. Sun exposure should be limited by using a sunscreen agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

WARNINGS

- Hydroquinone is a skin-bleaching agent, which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this product.
- Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin and check within 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, the product should be discontinued and a physician consulted. Close patient supervision is recommended.
- Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, the patient should rinse thoroughly with water and contact a physician.
- Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

The Obagi-C® Rx System C-Therapy Night Cream contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and lifethreatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

PRECAUTIONS

(See WARNINGS.)

Treatment should be limited to relatively small areas of the body at one time since some patients experience a transient skin reddening and a mild burning sensation, which does not preclude treatment.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with topical hydroquinone. It is also not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used on pregnant women only when clearly indicated.

Nursing Mothers

It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

Pediatric Use

Safety and effectiveness in children, below the age of 12 years, have not been established.

ADVERSE REACTIONS

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur, in which case the product should be discontinued and physician notified immediately.

To report SUSPECTED ADVERSE REACTIONS, contact Obagi Cosmeceuticals LLC, at 1-800-636-7546 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CONTRAINDICATIONS

People with prior history of sensitivity or allergic reaction to this product or any of its ingredients should not use it. The safety of topical hydroquinone use during pregnancy or in children (12 years and under) has not been established.

HOW SUPPLIED

Obagi-C® Rx System C-Clarifying Serum
(Hydroquinone, USP 4%) for Normal to Dry Skin is available as follows:

1 fl. oz. (30 mL) bottle
NDC 62032-106-10

Obagi-C® Rx System C-Clarifying Serum
(Hydroquinone, USP 4%) for Normal to Oily Skin is available as follows:

1 fl. oz. (30 mL) bottle
NDC 62032-122-10

Obagi-C® Rx System C-Therapy Night Cream
(Hydroquinone, USP 4%) is available as follows:

Net wt. 2 oz. (57 g) bottle
NDC 62032-105-36

Store at controlled room temperature: 15° to 25°C (59° to 77°F). Keep out of direct sunlight.

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

U.S. Patent 6,299,889

www.obagi.com
9578903 Revised: 1/2019

Sun Shield Matte Broad Spectrum SPF 50

Net wt. 3 oz. (85 g) AM

Drug Facts

Active ingredients	***Purpose***
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Zinc Oxide 16.5%	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 use 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
- **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
- children under 6 months: Ask a doctor

Other information

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivate, Silica, Polyglyceryl-6 Polyrininoleate, Sodium Chloride, Xanthan Gum,

Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Questions or comments?

1.800.636.7546
Monday–Friday 9 a.m.–4 p.m. Pacific Time

Distributed by Obagi Cosmeceuticals LLC,
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 62032-535-04

OBAGI®
MEDICAL

OBAGI-C® RX SYSTEM

NORMAL DRY
Skin Intervention Kit

NORMAL DRY

NDC# 62032-535-04

OBAGI® MEDICAL

OBAGI-C® RX SYSTEM

NORMAL DRY

Skin Intervention Kit

NORMAL DRY

OBAGI® MEDICAL

NORMAL DRY

Skin Intervention Kit

other essential ingredients to help address the signs of sun exposure caused by photaging.

Travel Bag and Patient Instruction Guide

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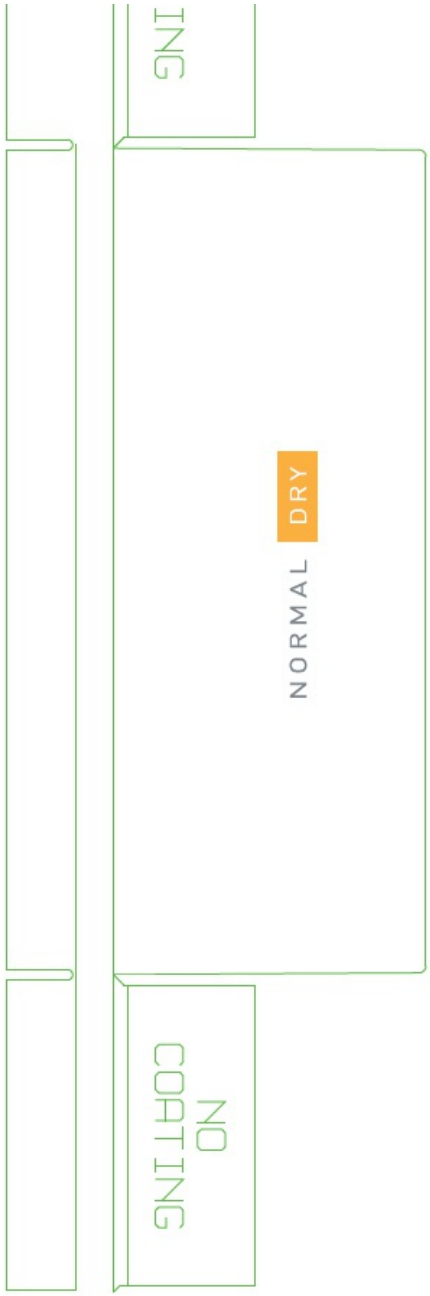
Long Beach, CA 90806



NO COATING

OBAGI®
MEDICAL

OBAGI-C® RX SYSTEM

Complete skin care system specifically formulated for normal to dry skin with 4% hydroquinone to reduce hyperpigmentation and

C-Cleansing Gel 6 fl. oz. (177 mL) AM•PM

C-Clarifying Serum Normal to Dry (Skin Lightening Serum) NDC 620 32-106-10 1 fl. oz. (30 mL) Hydroquinone USP, 4 % Rx Only AM

C-Exfoliating Day Lotion 2 fl. oz. (59 mL) AM

C-Therapy Night Cream (Skin Lightener) NDC 620 32-105-36 Net wt. 2 oz. (57 g) Hydroquinone USP, 4% Rx Only PM

Sun Shield Matte Broad Spectrum SPF 50 Net wt. 3 oz. (85 g) AM

Drug Facts

Active Ingredients	Purpose
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Zinc Oxide 16.5%	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 use 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.

OBAGI-C RX SYSTEM NORMAL-DRY SKIN INTERVENTION

hydroquinone, homosalate, octisalate, and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62032-535

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-535-04	1 in 1 CARTON	12/02/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, GLASS	30 mL
Part 2	1 BOTTLE, PLASTIC	57 g
Part 3	1 TUBE	85 g
Part 4	1 BOTTLE, PLASTIC	177 mL
Part 5	1 BOTTLE, PLASTIC	57 g

Part 1 of 5

OBAGI-C RX SYSTEM C-CLARIFYING SERUM SKIN LIGHTENING SERUM WITH VITAMIN C

hydroquinone liquid

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2004	

Part 2 of 5

OBAGI-C RX SYSTEM C-THERAPY NIGHT SKIN LIGHTENING WITH VITAMINS C AND E

hydroquinone cream

Product Information

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
TROLAMINE SALICYLATE (UNII: H8O4040BHD)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2004	

Part 3 of 5

OBAGI-C RX SYSTEM SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information	
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
Hydroxyacetophenone (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
C15-19 Alkane (UNII: CI87N1IM01)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
Sorbitan Olivate (UNII: MDL271E3GR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Candelilla Wax (UNII: WL0328HX19)	
Yellow Wax (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		85 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	12/02/2019	

Part 4 of 5

OBAGI-C RX SYSTEM C-CLEANSING WITH VITAMIN C

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

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**FD&C YELLOW NO. 5** (UNII: I753WB2F1M)	
INGR	**ASCORBIC ACID** (UNII: PQ6CK8PD0R)	
INGR	**SODIUM LAUROYL OAT AMINO ACIDS** (UNII: FSW2K9B9N5)	
INGR	**COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX)	
INGR	**SODIUM LAURETH-3 SULFATE** (UNII: BPV390UAP0)	
INGR	**ALOE VERA LEAF** (UNII: ZY81Z83H0X)	
INGR	**SODIUM CHLORIDE** (UNII: 451W47IQ8X)	
INGR	**MEDICAGO SATIVA WHOLE** (UNII: DJO934BRBD)	
INGR	**CHAMOMILE** (UNII: FGL3685T2X)	
INGR	**XANTHAN GUM** (UNII: TTV12P4NEE)	
INGR	**D&C RED NO. 33** (UNII: 9DBA0SBB0L)	
INGR	**BORAGE** (UNII: PB618V0K2W)	

Product Characteristics		
color	ORANGE	C48331

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/01/2004	

Part 5 of 5

OBAGI-C RX SYSTEM C-EXFOLIATING DAY WITH VITAMIN C

face and neck (excluding shaving preparations) lotion

Product Information	
Route of Administration	TOPICAL

Other Ingredients		
Ingredient Kind	**Ingredient Name**	**Quantity**
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**PHENOXYETHANOL** (UNII: HIE492ZZ3T)	
INGR	**ETHYLPARABEN** (UNII: 14255EXE39)	
INGR	**ISOBUTYLPARABEN** (UNII: 0QQJ25X58G)	
INGR	**BUTYLPARABEN** (UNII: 3QPI1U3FV8)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**POLYSORBATE 60** (UNII: CAL22UVI4M)	
INGR	**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)	
INGR	**PEG-100 STEARATE** (UNII: YD01N1999R)	
INGR	**ETHYLHEXYL PALMITATE** (UNII: 2865993309)	
INGR	**SQUALANE** (UNII: GW89575KF9)	
INGR	**HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)** (UNII: 86FQE96TZ4)	
INGR	**PEG-8 DIMETHICONE** (UNII: GIA7T764OD)	
INGR	**PEG-8 RICINOLEATE** (UNII: DM36F4D2OU)	

INGR	**GLYCOLIC ACID** (UNII: 0WT12SX38S)	
INGR	**ARGININE** (UNII: 94ZLA3W45F)	
INGR	**ETHYLHEXYL STEARATE** (UNII: EG3PA2K3K5)	
INGR	**MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U)	
INGR	**ISOPROPYL PALMITATE** (UNII: 8CRQ2TH63M)	
INGR	**HYALURONATE SODIUM** (UNII: YSE9PPT4TH)	
INGR	**SODIUM HYDROXIDE** (UNII: 55X04QC32I)	
INGR	**CETOSTEARYL ALCOHOL** (UNII: 2DMT128M1S)	
INGR	**POLYOXYL 20 CETOSTEARYL ETHER** (UNII: YRC528SWUY)	
INGR	**DIMETHICONE** (UNII: 92RU3N3Y1O)	
INGR	**STEARETH-2** (UNII: V56DFE46J5)	
INGR	**ASCORBYL GLUCOSIDE** (UNII: 2V52R0NHXW)	
INGR	**LEVOMENOL** (UNII: 24WE03BX2T)	
INGR	**EDETATE SODIUM** (UNII: MP1J8420LU)	
INGR	**.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0)	

Product Characteristics

color	WHITE	C48325

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
COSMETIC		01/02/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/02/2019	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
G. S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-535)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Packaging Systems, Inc. (DBA Paklab)		177711082	MANUFACTURE(62032-535) , PACK(62032-535)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-535)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-535) , LABEL(62032-535) , PACK(62032-535)