

OBAGI-C C-RX SYSTEM NORMAL-OILY SKIN INTERVENTION- hydroquinone, homosalate, octisalate, 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® C-Rx System Normal-Oily Skin Intervention

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 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

Questions or comments?

1.800.636.7546 Monday-Friday 9 a.m.-4 p.m. PST

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - Kit Carton

OBAGI®
MEDICAL

OBAGI-C® RX SYSTEM

Complete skin care system specially formulated for normal to oily skin with hydroquinone to reduce hyperpigmentation and other essential ingredients to help address the signs of sun exposure caused by photoaging.

NORMAL OILY

Skin Intervention Kit



OBAGI-C® RX SYSTEM

Complete skin care system specifically formulated for normal to oily skin with hydroquinone to reduce hyperpigmentation and other essential ingredients to help address the signs of sun exposure caused by photoaging.



NORMAL OILY Skin Intervention Kit

C-Cleansing Gel

6 fl. oz. (177 mL)

Directions: Use twice daily, morning and evening. Apply to damp face and neck with moistened fingertips, rub in circular motion and rinse completely with lukewarm water.

Ingredients: Water (Aqua), Sodium Laureth Sulfate, Sodium Lauroyl Lactyl Amino Acids, Cocamidopropyl Betaine, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Sodium Chloride, Methylparaben, Glycerin, Saponine, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben, Xanthan Gum, Borago Officinalis Extract, Medicago Sativa (Alfalfa) Extract, Ascorbic Acid, Chamomilla Recutita (Matricaria) Flower Extract, Fragrance (Parfum), Red 33 (CI 17200), Yellow 5 (CI 19140)

C-Balancing Toner

6.7 fl. oz. (198 mL)

Directions: Use twice daily, in the morning and evening after cleansing. Pump a small amount (3 to 4 pumps) onto a cotton pad and gently wipe over entire face. Let air dry. Do not rinse.

Ingredients: Water (Aqua), Hamamelis Virginiana (Witch Hazel) Water, Propylene Glycol, Sodium PCA, Benzalkonium Chloride, Aloe Barbadensis Leaf Juice, Methylotetra, Panthenol, Polyguanidium-10, Phenoxyethanol, Methylparaben

C-Clarifying Serum Normal to Oily (Skin Lightening Serum)

NDC 62032-122-10 Hydroquinone USP, 4% Rx Only

1 fl. oz. (30 mL)

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.

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

Warnings: Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, 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 melanocyte activity.

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.

Active ingredient: Hydroquinone, USP 4% (40 mg/g)
Inactive ingredients: Water (Aqua), Propylene Glycol, Alcohol Denat, Dipropane Glycol, Ascorbic Acid, Propylene Carbonate, Sodium Lauryl Sulfate, Fragrance (Parfum)

Rx Only. FOR EXTERNAL USE ONLY.

C-Therapy Night Cream (Skin Lightener)

NDC 62032-105-36 Hydroquinone USP, 4% Rx Only

Net wt. 2 oz. (57 g)
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.

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

Warnings: Avoid contact with eyes, nose, mouth, and lips. In case of accidental contact, 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 melanocyte activity.

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.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening 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.

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

Active ingredient: Hydroquinone, USP 4% (40 mg/g)
Inactive ingredients: Water (Aqua), Glycerin, Cetyl Alcohol, PPG-2 Myristyl Ether Propionate, Sodium Lauryl Sulfate, TEA-Salicylate, Lactic Acid, Phenyl Trimethicone, Tocopheryl Acetate, Sodium Metabisulfite, Ascorbic Acid, Methylparaben, Disodium EDTA, Propylparaben, Saponine, BHT

Rx Only. FOR EXTERNAL USE ONLY.

See enclosed Package Insert for full prescribing information.

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

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www.obagi.com

Made in USA with US and imported components.

10481022-1

OBAGI-C® RX SYSTEM

Complete skin care system specifically formulated for normal to oily skin with hydroquinone to reduce hyperpigmentation and other essential ingredients to help address the signs of sun exposure caused by photoaging.

C-Cleansing Gel | AM+PM

Helps clarify and prepare your skin for the system's product ingredients, while also removing makeup and oil.

C-Balancing Toner | AM+PM

Specifically formulated for normal to oily skin, the C-Balancing Toner adjusts your skin's pH balance. As an essential step after cleansing, this alcohol-free, non-drying toner removes impurities and dead skin to prepare the skin for the next step in your skin care regimen.

C-Clarifying Serum Normal to Oily (Skin Lightening Serum) | AM

NDC 62032-106-10, Hydroquinone USP, 4% Rx Only

Antioxidant Serum containing Vitamin C and prescription-strength hydroquinone. This formulation for normal to dry skin corrects dark spots for a lighter, brighter complexion.

C-Therapy Night Cream (Skin Lightener) | PM

4% Rx Only, NDC 62032-101-36

A rich moisturizer that works while you sleep to renew and rejuvenate your skin. The C-Therapy Night Cream is uniquely formulated with prescription-strength hydroquinone to gradually diminish dark spots and provide Vitamins C and E during the skin's nightly renewal process.

Sun Shield Matte Broad Spectrum SPF 50 | AM

Obagi Nu-Derm® sunscreen combines UVB absorption and UVA protection in an elegant, matte finish that is non-comedogenic and dermatologist tested. Sheer and fragrance free for all skin types.



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

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

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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

Drug Facts (continued)

Inactive ingredients

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivate, Silica, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxycetophenone, Disodium EDTA, 1,2-Hexamethyl, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylylsilane, Polyhydroxystearic Acid, Dimethiconium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (Candelilla) Wax, Beeswax (Cera Alba), Dimethicone

Questions or comments?

1.800.636.7546 Monday–Friday 9 a.m.–4 p.m. PST

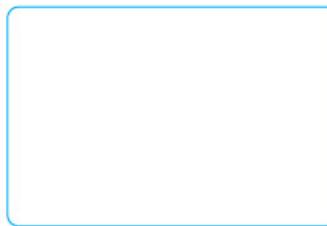
Store at controlled room temperature 15°–25°C (59°–77°F).

FOR ALL PRODUCTS

Warnings: Avoid getting into eyes.

If product gets into the eyes, thoroughly rinse with water.

For external use only. Keep out of reach of children.



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OBAGI-C C-RX SYSTEM NORMAL-OILY SKIN INTERVENTION

hydroquinone, homosalate, octisalate, zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-915
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-915-01	1 in 1 KIT	06/25/2021	

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	198 mL

Part 1 of 5

OBAGI-C RX SYSTEM C-CLARIFYING SERUM NORMAL TO OILY SKIN LIGHTENING SERUM WITH VITAMIN C

hydroquinone liquid

Product Information

Item Code (Source)	NDC:62032-122
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)	
ALCOHOL (UNII: 3K9958V90M)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-122-10	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		01/01/2010	

Part 2 of 5

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

hydroquinone cream

Product Information

Item Code (Source)	NDC:62032-105		
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: 368GB514J)	
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: PDC6A3C00X)	
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	NDC:62032-105-36	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

SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information

Item Code (Source)	NDC:62032-140
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: PDC6A3C00X)	
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, UNSPECIFIED (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	NDC:62032-140-09	1 in 1 CARTON		
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 DRUG	M020	12/02/2019	

Part 4 of 5

OBAGI-C C-CLEANSING WITH VITAMIN C

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] gel

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
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: DJ0934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	BORAGE (UNII: PB618V0K2W)	
COLR	ORANGE (UNII: 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 C-BALANCING TONER FOR NORMAL TO OILY SKIN

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

Product Information

Route of Administration

TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
INGR	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	POLYQUATERNIUM-10 (400 MPAS AT 2%) (UNII: HB1401PQFS)	
INGR	PANTHENOL (UNII: WV9CM0067Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 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		01/01/2009	

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
Bay Cities Container Corporation		118417470	PACK(62032-915) , LABEL(62032-915)

Establishment

Name	Address	ID/FEI	Business Operations
G. S. Cosmeceutical USA, Inc.		017014734	MANUFACTURE(62032-915)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-915)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Packaging Systems, Inc. (DBA Paklab)		177711082	MANUFACTURE(62032-915)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-915)

Revised: 10/2025

Obagi Cosmeceuticals LLC