

**OBAGI-C RX SYSTEM NORMAL-DRY SKIN INTERVENTION- hydroquinone, octinoxate and zinc oxide
OMP, INC.**

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 NORMAL-DRY
SKIN INTERVENTION KIT**

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

A gel-based facial cleanser that clarifies and prepares your skin for absorption of the system's product ingredients. This concentrated cleanser gently removes excess oil, makeup, and other everyday impurities, and rinses clean, leaving your skin feeling fresh and clear.

Directions

Use twice daily, morning and evening. Massage a small amount of cleanser and lukewarm water onto skin, rubbing gently in a circular motion. Rinse completely with lukewarm water and gently pat dry.

Warnings

Avoid getting into eyes. **For external use only.**

Keep out of reach of children.

Ingredients

water (aqua), sodium laureth sulfate, sodium lauroyl oat amino acids, cocamidopropyl betaine, aloe barbadensis leaf juice (aloe barbadensis), ascorbic acid, glycerin, medicago sativa (alfalfa) extract, borago officinalis extract, chamomilla recutita (matricaria) flower extract (chamomilla recutita extract), sodium chloride, saponins, xanthan gum, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum), red 33 (CI 17200), yellow 5 (CI 19140)

**C-Clarifying Serum Normal to Dry (Skin Lightening Serum) NDC 62032-106-10 1 fl. oz. (30 mL.)
Hydroquinone USP, 4% Rx Only AM**

Antioxidant serum containing Vitamin C and prescription-strength hydroquinone. This patented formulation for normal to dry skin reduces the appearance of dark spots for a lighter, brighter complexion.

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

Use once daily in the morning. Apply 5-7 drops to the entire face, or as directed by your skin care physician. Massage in gently. 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Warnings

Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

Each gram of Obagi-C Rx C-Clarifying Serum Normal to Dry contains:

Active Ingredient

Hydroquinone USP, 4% (40 mg/g)

Inactive Ingredients

propylene glycol, water, ascorbic acid, propylene carbonate, sodium lauryl sulfate.

See enclosed Package Insert for full prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

C-Exfoliating Day Lotion Net wt. 2 oz. (57 g.) AM

A smooth, lightweight moisturizer that not only hydrates, but also gently exfoliates the skin, revealing a brighter, healthier-looking complexion.

Directions

Use once daily in the morning. Squeeze a small amount (approximately 1-2 pea-sized drops) onto your hands. Using your fingertips, apply evenly to the entire face. Massage gently until completely absorbed.

Warnings

Avoid getting into eyes. **For external use only.**

Keep out of reach of children.

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.

Ingredients

water (aqua), ethylhexyl palmitate, ethylhexyl stearate, glycolic acid, caprylic/capric triglyceride, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isopropyl palmitate, sodium hyaluronate, squalane, PEG-8 dimethicone, glyceryl stearate, PEG-100 stearate, glycerin, sodium hydroxide, PEG-8 ricinoleate, ascorbyl glucoside, tocopheryl acetate, dimethicone, arginine, cetearyl alcohol, cetareth-20, steareth-2, bisabolol, tetrasodium EDTA, polysorbate 60, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance (parfum)

C-Therapy Night Cream (Skin Lightener) NDC 62032-105-36 Net wt. 2 oz. (57 g.) Hydroquinone USP, 4% Rx Only PM

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 the appearance of dark spots and delivers Vitamins C and E during the skin's nightly renewal process.

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

Use daily in the evening. Dispense a small amount (approximately 1-2 pea-sized drops) and apply to the entire face. Massage in gently. 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, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring.

Warnings

Avoid contact with eyes, nose, mouth, or lips. In case of accidental contact, patient should rinse eyes thoroughly with water and contact physician. Sunscreen use is an essential aspect of hydroquinone therapy because even minimal sunlight exposure sustains melanocytic activity.

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, 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, saponins, BHT

See enclosed Package Insert for full prescribing information.

Rx ONLY. FOR EXTERNAL USE ONLY.

Travel Bag and Patient Instruction Guide

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

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

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Octinoxate 7.5%	Sunscreen
Zinc Oxide 10.5%	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
- 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

Inactive ingredients

1,2-hexanediol, caprylyl glycol, cetareth-20, cetearyl alcohol, chlorphenesin, citric acid, cyclopentasiloxane, dimethicone crosspolymer-3, disodium EDTA, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-10 dimethicone, PEG-40 stearate, pentylene glycol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tocopheryl acetate, tropolone, ubiquinone, water, xanthan gum

Other information

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

Questions or comments?

1.800.636.7546

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

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

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PRINCIPAL DISPLAY PANEL - Kit Carton

NDC# 62032-518-04

**OBAGI®
MEDICAL**

OBAGI-C® RX SYSTEM

NORMAL DRY
Skin Intervention Kit

OBAGI-C[®] RX SYSTEM



NDC# 43032-616-04



OBAGI-C[®] RX SYSTEM

NORMAL DRY

Skin Intervention Kit

OBAGI-C[®] RX SYSTEM



NORMAL DRY
Skin Intervention Kit



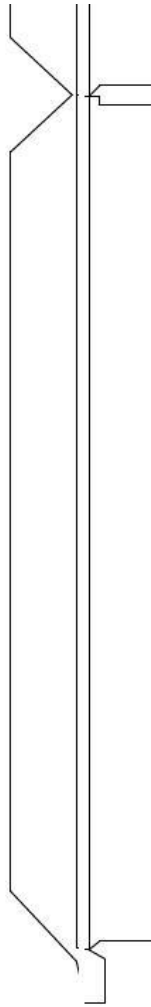
Treatment Bag and Patient Instruction Guide

This system is designed to provide a comprehensive skin care regimen for normal to dry skin. The kit includes four products: Sun Shield, OBAGI-C, OBAGI-C, and OBAGI-C. Each product is designed to work together to improve skin texture, reduce signs of aging, and provide long-term hydration. The OBAGI-C products are formulated with a unique blend of active ingredients, including retinol, to stimulate collagen production and improve skin firmness. Sun Shield provides broad-spectrum protection against UV rays, helping to prevent further skin damage and maintain the results of your treatment. For best results, use the products in the order listed below and follow the instructions provided for each product.

Active Ingredients: Retinol, Vitamin C, Hyaluronic Acid, Niacinamide, and other skin care ingredients. **Other Information:** Avoid sun exposure, tanning beds, and waxing/wax removal treatments while using this system. **Questions or comments?** Contact our customer support team at 1-800-438-7777. **Warnings:** Do not use if you are pregnant or breastfeeding. **Store at controlled room temperature 18°C-25°C (64°F-77°F).**

FPO
Barcelona Area
6203251804

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OBAGI-C RX SYSTEM NORMAL-DRY SKIN INTERVENTION

hydroquinone, octinoxate and zinc oxide kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-518
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-518-04	1 in 1 CARTON		

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

Item Code (Source) NDC:62032-106

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	NDC:62032-106-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, GLASS		

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 SKIN LIGHTENING WITH VITAMINS C AND E

hydroquinone cream

Product Information

Item Code (Source) NDC:62032-105

Route of Administration	TOPICAL
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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)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

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		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		01/01/2004	

SUNSCREEN

octinoxate and zinc oxide lotion

Product Information

Item Code (Source) NDC:62032-121

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	105 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
WATER (UNII: 059QF0K00R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
SODIUM DIHYDROXYCETYL PHOSPHATE (UNII: YWI33EV595)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TROPOLONE (UNII: 7L6DL16P1T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
UBIDECARENONE (UNII: EJ27X76M46)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
SQUALANE (UNII: GW89575KF9)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-121-90	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/07/2012	

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
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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: 3QP1U3FV8)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	METHYLPARABEN (UNII: A28C7H9T)	
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	ALFALFA (UNII: DJO934BRBD)	
INGR	CHAMOMILE (UNII: FGL3685T2X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	ORANGE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		177 mL in 1 BOTTLE, PLASTIC		

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
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PHENOXYETHANOL (UNII: HE492ZZ3T)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	BUTYLPARABEN (UNII: 3QPIIU3FV8)	
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 (4500 MPA.S AT 1%) (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	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		

Marketing Information

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		11/07/2012	

Labeler - OMP, INC. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-518) , LABEL(62032-518) , PACK(62032-518)

Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-518) , LABEL(62032-518) , PACK(62032-518) , ANALYSIS(62032-518)

Establishment

Name	Address	ID/FEI	Business Operations
MILBAR LABORATORIES		195556790	MANUFACTURE(62032-518)

Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-518) , REPACK(62032-518)

Revised: 1/2013

OMP, INC.