

**OBAGI-C RX SYSTEM NORMAL-OILY 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.*

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**OBAGI-C® RX SYSTEM NORMAL-OILY 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-Balancing Toner 6.7 fl. oz. (198 mL.) 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 thoroughly removes impurities and dead skin cells to prepare the skin for the next step in your skin care regimen. s.

**Directions**

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

**Warnings**

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

**Keep out of reach of children.**

## **Ingredients**

water (aqua), hamamelis virginiana (witch hazel) water, propylene glycol, sodium pca, benzalkonium chloride, aloe barbadensis leaf juice (aloe barbadensis), panthenol, polyquaternium-10, phenoxyethanol, methylparaben

## **C-Clarifying Serum Normal to Oily (Skin Lightening Serum) NDC 62032-122-10 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 oily 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 Oily contains:

### **Active Ingredient**

Hydroquinone USP, 4% (40 mg/g)

### **Inactive Ingredients**

water, propylene glycol, alcohol denat., dipropylene glycol, ascorbic acid, propylene carbonate, sodium lauryl sulfate, fragrance

See enclosed Package Insert for full prescribing information.

**Rx ONLY. FOR EXTERNAL USE ONLY.**

## **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 Broad Spectrum SPF 50 Matte

Net wt. 3 oz. (85 g)

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

### Drug Facts

Active ingredients	Purpose
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, ceteareth-20, cetearyl alcohol, chlorphenesin, citric acid, cyclopentasiloxane, dimethicone, dimethicone crosspolymer-3, disodium EDTA, glycerin, hydrogenated palm glycerides, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, methylisothiazolinone, PEG-40 stearate, pentylene glycol, phenoxyethanol, phenyl trimethicone, polysilicone-11, polysorbate 60, potassium sorbate, sodium benzoate, sodium dihydroxycetyl phosphate, sodium polyacrylate, squalane, stearyl alcohol, tetrahexyldecyl ascorbate, tropolone, 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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obagi.com Made in USA 41502111Z 5021

**PRINCIPAL DISPLAY PANEL - Kit Carton**

NDC # 62032-523-04

**OBAGI®  
MEDICAL**

**OBAGI-C® RX SYSTEM**

**NORMAL OILY**

**Skin Intervention Kit**

NORMAL OILY

MEDICAL  
ARTS

第3章 4.2.3.3~5.2.3~5.6



**OBAGI-C® RX SYSTEM**

NORMAL OILY

## Skin Intervention Kit

NORMAL OILY

O B A G I<sup>®</sup>  
M E D I C A L

62032 52304 0

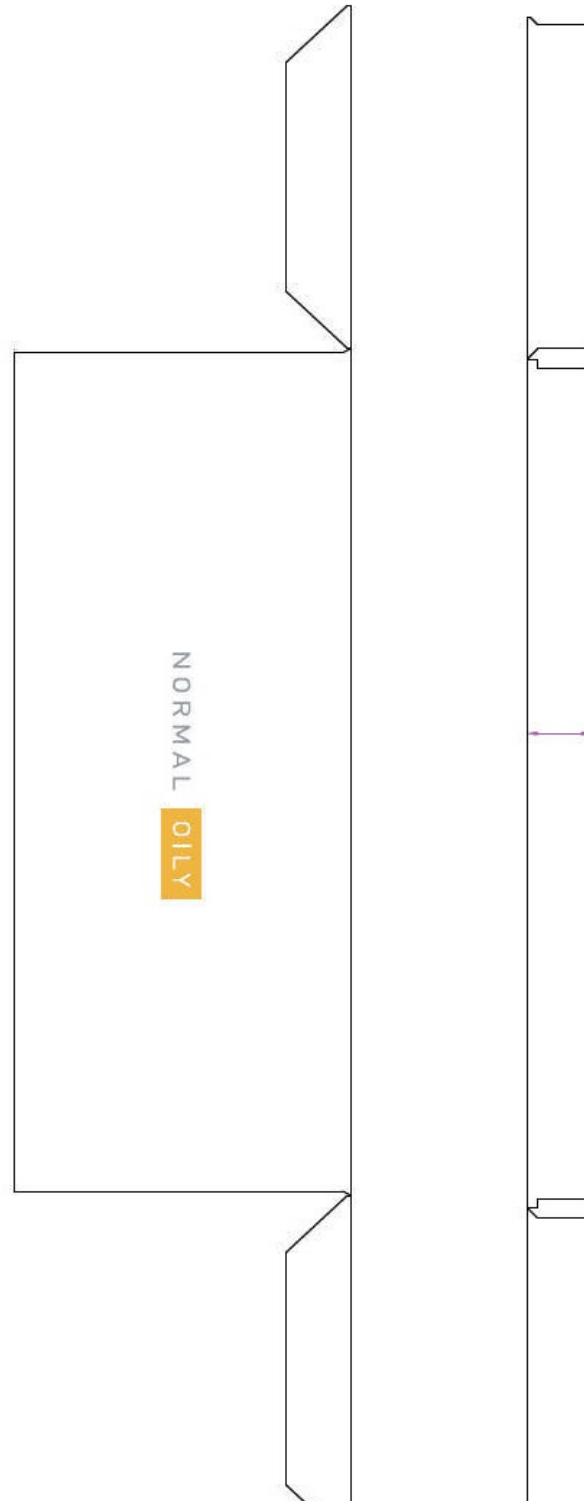
Skin Intervention Kit

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• **Other information**  
The following table summarizes the key information about the study:  
**Outcomes of treatment**  
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**Outcomes of treatment**

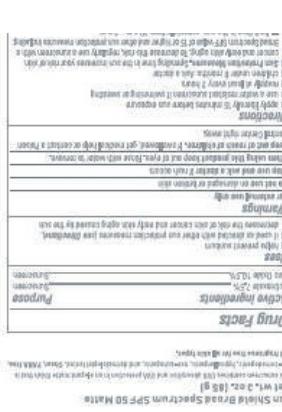
Travel Bag and Passport Instruction Guide  
for Oahu's Best Hotels and Lodging Properties

(-)-Clarityning Serum Normal to Only 5ml Lightening



## OBAGI-C RX SYSTEM

An advanced system that offers the benefits of both prescription-strength 4% hydroquinone and Vitamin C to help correct early signs of skin aging, and maintain younger-looking skin.



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

hydroquinone, octinoxate and zinc oxide kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62032-523
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-523-04	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	198 mL

### Part 1 of 5

## OBAGI C RX SYSTEM C CLARIFYING SERUM

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	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		01/01/2010	

### 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

### 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
EDETA 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.-TO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A218C7HI9T)	

**PROPYLPARABEN** (UNII: Z8IX2SC1OH)

**BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K)

**PHENYL TRIMETHICONE** (UNII: DR0K5NOJ4R)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:62032-105-36	57 g in 1 BOTTLE, PLASTIC		

### Marketing Information

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

### Part 3 of 5

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

octinoxate and zinc oxide lotion

### Product Information

<b>Item Code (Source)</b>	NDC:62032-121
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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

<b>Ingredient Name</b>	<b>Strength</b>
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

**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)**

**DIMETHICONE (UNII: 92RU3N3Y1O)**

**SODIUM DIHYDROXYCETYLL PHOSPHATE (UNII: YWI33EV595)**

**HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)**

**CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)**

**CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)**

**.ALPHA.-TO COPHEROL 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)**

**EDETADE DISODIUM (UNII: 7FLD91C86K)**

**METHYLISOTHIAZOLINO NE (UNII: 229D0E1QFA)**

**HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%)  
(UNII: 86FQE96TZ4)**

**SQUALANE (UNII: GW89575KF9)**

**POLYSORBATE 60 (UNII: CAL22UVI4M)**

**SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)**

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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	02/12/2013	

### 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	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	COCAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
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-BALANCING TONER FOR NORMAL TO OILY SKIN

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

#### Product Information

Route of Administration	TOPICAL
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#### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	METHYLPARABEN (UNII: A2I8C7H9T)	
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 MPA.S At 2%) (UNII: HB1401PQFS)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		198 mL in 1 BOTTLE, PLASTIC		

#### 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		04/02/2013	

#### Labeler - OMP, INC. (790553353)

#### Establishment

Name	Address	ID/FEI	Business Operations
PURETEK CORPORATION		785961046	MANUFACTURE(62032-523), LABEL(62032-523), PACK(62032-523)

#### Establishment

Name	Address	ID/FEI	Business Operations
Ei INC.		105803274	MANUFACTURE(62032-523) , LABEL(62032-523) , PACK(62032-523) , ANALYSIS(62032-523)

## Establishment

Name	Address	ID/FEI	Business Operations
MILBAR LABORATORIES		195556790	MANUFACTURE(62032-523)

## Establishment

Name	Address	ID/FEI	Business Operations
Bay Cities Container Corporation		066229618	RELABEL(62032-523) , REPACK(62032-523)

## Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-523)

Revised: 8/2013

OMP, INC.