

**OBAGI SKINTRINSIQ ANTIOXIDANT PROTOCOL- avobenzene, homosalate, octisalate, octocrylene, and oxybenzone**  
**Obagi Cosmeceuticals LLC**

*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.*

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**Obagi® SkintrinsiQ™ Antioxidant Protocol Kit 15%**

**Obagi® Professional-C™ Suncare SPF 30**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
Avobenzene 3%	Sunscreen
Homosalate 8%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 2.79%	Sunscreen
Oxybenzone 3%	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

**When using this product** keep out of eyes. If product gets into eyes, rinse with water to remove.

**Stop use and ask a doctor if** rash occurs

**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**

ascorbic acid, citrus grandis (grapefruit) peel extract, dimethicone, dimethicone crosspolymer, fragrance, octoxynol-9

### **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**

SKINTRINSIQ™

ANTIOXIDANT 15%

PROTOCOL KIT

INCLUDES:

- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- Obagi Professional-C® Serum 15%, 1 FL. OZ.
- Obagi Professional-C® Peptide Complex, 1 FL. OZ.
- Obagi Professional-C® Suncare SPF 30, 1.7 OZ.

OBAGI®



OBAGI

SKINTRINSIQ™

2.742



# ANTIOXIDANT 15% PROTOCOL KIT

**INCLUDES:**

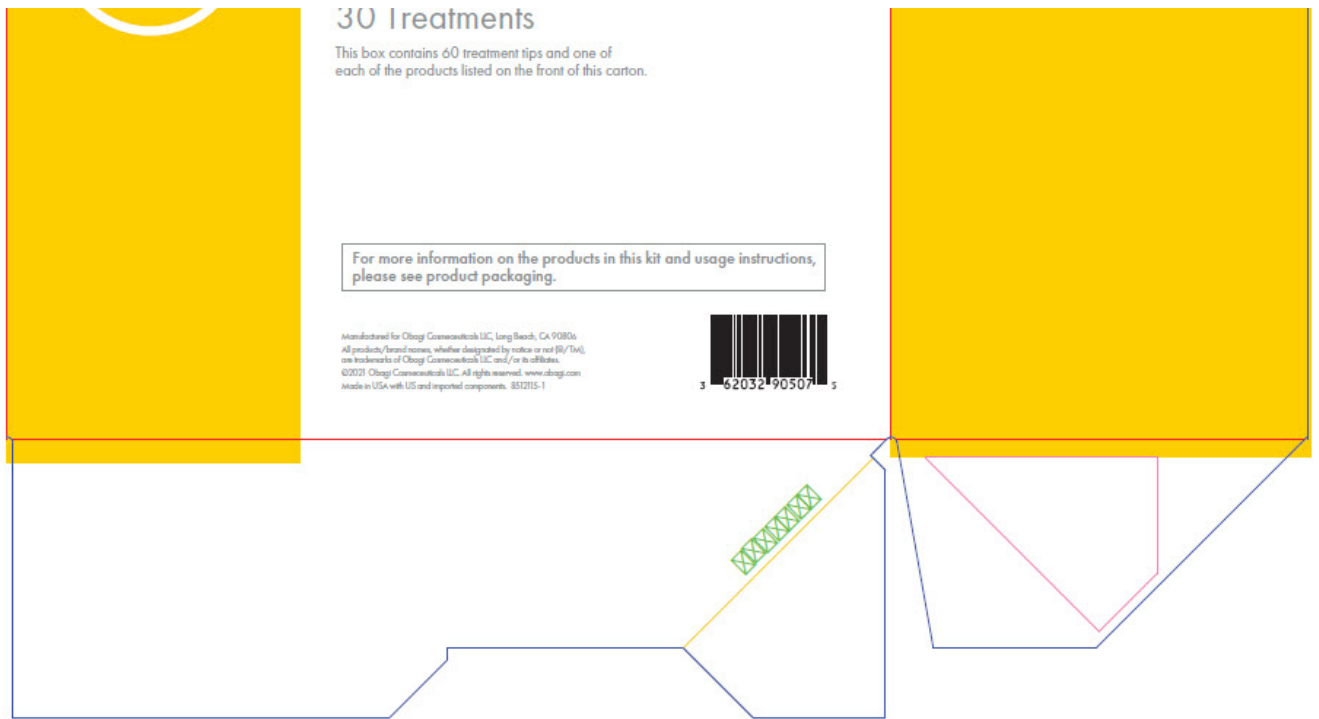
- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- Obagi Professional-C® Serum 15%, 1 FL. OZ.
- Obagi Professional-C® Peptide Complex, 1 FL. OZ.
- Obagi Professional-C® Suncare SPF 30, 1.7 OZ.

OBAGI

SKINTRINSIQ™



# ANTIOXIDANT 15% PROTOCOL KIT



## **PRINCIPAL DISPLAY PANEL - 48 g Bottle Carton**

**OBAGI<sup>®</sup>  
MEDICAL**

**Professional-C<sup>™</sup>**

**SUNCARE**

**BROAD SPECTRUM  
SPF 30**

**SUNSCREEN**

**Net wt. 1.7 oz. (48 g)**

NO COATING

**Professional-C™ Suncare  
Broad Spectrum SPF 30**

Obagi® Professional-C Suncare broad spectrum sunscreen is formulated with 10% L-ascorbic acid (Vitamin C) and provides protection against skin damage and signs of skin aging.

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  - wear long-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor ▶

**Drug Facts (continued)**

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- store at controlled room temperature: 15°C–25°C (59°F–77°F)
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**Questions or comments?**

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



Professional-C™

SUNCARE

BROAD SPECTRUM  
SPF 30

SUNSCREEN

Net wt. 1.7 oz. (48 g)

Distributed by Obagi Cosmeceuticals LLC,  
Long Beach, CA 90806

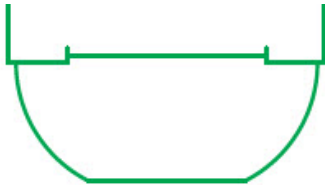
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Made in USA with US and imported components.  
9594102



The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen





## OBAGI SKINTRINSIQ ANTIOXIDANT PROTOCOL

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62032-907
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-907-07	1 in 1 BOX	08/01/2021	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	60 mL
Part 2	1 BOTTLE, PLASTIC	59 mL
Part 3	1 BOTTLE, DROPPER	30 mL
Part 4	1 BOTTLE, PUMP	30 mL
Part 5	1 TUBE	48 g

## Part 1 of 5

### OBAGI NU-DERM GENTLE CLEANSER

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

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
INGR	GLYCERETH-7 (UNII: 3D2Y91QZ2H)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
INGR	METHYLPARABEN (UNII: A2I8C7HI9T)	
INGR	OLEYL LACTATE (UNII: B3AWW0N3GM)	

INGR	<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
INGR	<b>SODIUM LAUROYL OAT AMINO ACIDS</b> (UNII: FSW2K9B9N5)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
INGR	<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
INGR	<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
INGR	<b>DIETHYLENE GLYCOL MONOETHYL ETHER</b> (UNII: A1A18X02B)	
INGR	<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 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		08/01/2021	

## Part 2 of 5

### OBAGI NU-DERM TONER

face and neck (excluding shaving preparations) liquid

### Product Information

**Route of Administration** TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
INGR	<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
INGR	<b>BORAGO OFFICINALIS SEED</b> (UNII: 2GXJ790US0)	
INGR	<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	

INGR	<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
INGR	<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>HAMAMELIS VIRGINIANA TOP WATER</b> (UNII: NT00Y05A2V)	
INGR	<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
INGR	<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
INGR	<b>POTASSIUM ALUM</b> (UNII: 1L24V9R23S)	
INGR	<b>SAGE</b> (UNII: 065C5D077J)	
INGR	<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 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		08/01/2021	

### Part 3 of 5

## OBAGI PROFESSIONAL-C SERUM

face and neck (excluding shaving preparations) liquid

### Product Information

<b>Route of Administration</b>	TOPICAL
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### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>ALCOHOL</b> (UNII: 3K9958V90M)	
INGR	<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
INGR	<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52RONHXW)	
INGR	<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

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

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		08/01/2021	

## Part 4 of 5

### OBAGI PROFESSIONAL-C PEPTIDE COMPLEX

moisturizing lotion

## Product Information

**Route of Administration** TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	ACETYL OCTAPEPTIDE-3 (UNII: 8K14HJF88S)	
INGR	ALMOND OIL (UNII: 66YXD4DKO9)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	HYDROCHLORIC ACID (UNII: QTT17582CB)	
INGR	IMIDUREA (UNII: M629807ATL)	
INGR	KINETIN (UNII: P39Y9652YJ)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	PEG-12 GLYCERYL DIMYRISTATE (UNII: VS4W16AQ3X)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
INGR	PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	SODIUM CARBOXYMETHYL .BETA.-GLUCAN (DS 0.65-0.85) (UNII: 2YGO1190AP)	

INGR	<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
INGR	<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
INGR	<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
INGR	<b>WATER</b> (UNII: 059QF0K00R)	
INGR	<b>ZEATIN</b> (UNII: 7160OJ9GR6)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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		08/01/2021	

### Part 5 of 5

## PROFESSIONAL-C SUNCARE BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream

### Product Information

<b>Item Code (Source)</b>	NDC:62032-050
<b>Route of Administration</b>	TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.9 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>CITRUS MAXIMA FRUIT RIND</b> (UNII: 5NX3G75CA6)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

**DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)**

**OCTOXYNOL-9 (UNII: 7JPC6Y25QS)**

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-050-54	1 in 1 CARTON		
1		48 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	M020	08/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/01/2021	

**Labeler - Obagi Cosmeceuticals LLC (790553353)**

### Establishment

Name	Address	ID/FEI	Business Operations
G.S.COSMECEUTICAL USA, INC.		017014734	manufacture(62032-907)

### Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(62032-907)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(62032-907)

### Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	pack(62032-907)