

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.

Obagi® Skintrinsiq Brightening Protocol Kit 10%

Obagi® Professional-C™ Suncare SPF 30

Drug Facts

Active ingredients	Purpose
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 10%
PROTOCOL KIT

INCLUDES:

- 60 Tips
- Obagi Nu-Derm® Gentle Cleanser, 2 FL. OZ.
- Obagi Nu-Derm® Toner, 2 FL. OZ.
- Obagi Professional-C® Serum 10%, 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



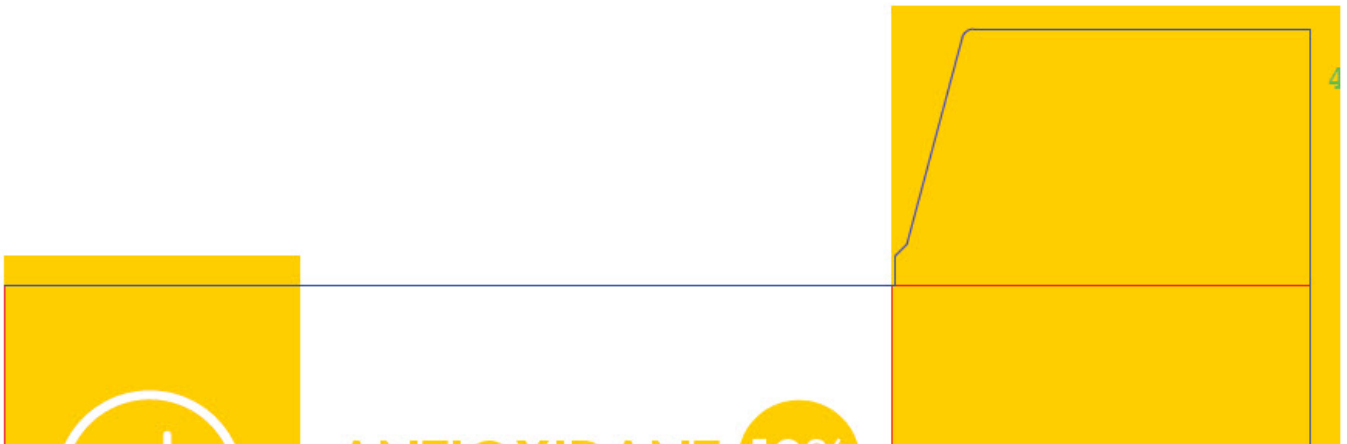
ANTIOXIDANT 10% PROTOCOL KIT

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- Obagi Professional-C® Suncare SPF 30, 1.7 OZ.

OBAGI

SKINTRINSIQ™





PRINCIPAL DISPLAY PANEL - 48 g Tube Carton

OBAGI[®]
MEDICAL

Professional-C[™]
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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Drug Facts (continued)

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Questions or comments?

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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.

9594 102



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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-906
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-906-06	1 in 1 BOX; Type 0: Not a Combination Product	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

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	APRICOT KERNEL OIL (UNII: 54JB35T06A)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	BUTYLPARABEN (UNII: 3QPI1U3FV8)	
INGR	CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
INGR	ETHYLPARABEN (UNII: 14255EXE39)	
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	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	PROPYLPARABEN (UNII: Z8IX2SC1OH)	
INGR	SAGE (UNII: 065C5D077J)	
INGR	SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM LAUROYL OAT AMINO ACIDS (UNII: FSW2K9B9N5)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	WATER (UNII: 059QF0KO0R)	

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	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)	
INGR	CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	

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

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		

1	30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
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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	STEARIC ACID (UNII: 4ELV7Z65AP)	

INGR	TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
INGR	TROLAMINE (UNII: 9O3K93S3TK)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	ZEATIN (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

Item Code (Source)	NDC:62032-050
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	27.9 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRUS MAXIMA FRUIT RIND (UNII: 5NX3G75CA6)	
DIMETHICONE (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(62032-906)

Establishment

Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals, LLC		001207208	manufacture(62032-906)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	manufacture(62032-906)

Establishment

Name	Address	ID/FEI	Business Operations
TENCO ASSEMBLIES, INC		075535609	pack(62032-906)