

**SMASHBOX HALO HEALTHY GLOW ALL-IN-ONE TINTED MOISTURIZER BROAD SPECTRUM SPF 25- octinoxate, titanium dioxide, and zinc oxide liquid**  
**SMASHBOX BEAUTY COSMETICS, INC**

*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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**SMASHBOX HALO HEALTHY GLOW ALL-IN-ONE TINTED MOISTURIZER BROAD SPECTRUM SPF 25**

**Drug Facts**

**Active Ingredients**

Octinoxate 6.7%  
Titanium Dioxide 3.1%  
Zinc Oxide 1.3%

**Purpose**

Sunscreen

**Uses**

helps prevent sunburn

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

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

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**For sunscreen use:**

- apply liberally and evenly 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- **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 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 of age: ask a doctor

**Inactive Ingredients**

Water\Aqua\Eau, Octyldodecyl Neopentanoate, Butyloctyl Salicylate, Dimethicone, Butylene Glycol, Methyl Trimethicone, Niacinamide, Cetyl PEG/PPG-10/1 Dimethicone, Lauryl PEG-9 Polydimethylsiloxylethyl Dimethicone, Diethylhexyl Succinate, Laureth-4, Tocopheryl Acetate, Sodium Hyaluronate, Lecithin, Rosa Hybrid Flower Extract, Pyrus Malus (Apple) Fruit Extract, Lens Esculenta (Lentil) Fruit Extract, Citrullus Lanatus (Watermelon) Fruit Extract, Lycium Chinense (Wolfberry) Fruit Extract, Palmitoyl Hexapeptide-14, Peat Extract, Gold, Sodium Lactate, Methicone, Sodium PCA, Hydrolyzed Wheat Protein/PVP Crosspolymer, Glycerin, Barium Sulfate, Magnesium Sulfate, Dimethyl Isosorbide, Maltodextrin, Triethoxycaprylylsilane, Dimethicone Crosspolymer-3, Silica, Aluminum Hydroxide, Dimethicone/PEG-10/15 Crosspolymer, Trimethylsiloxysilicate, Hexylene Glycol, Isostearic Acid, Caprylyl Glycol, Stearic Acid, Polyglyceryl-2 Triisostearate, Dipentaerythrityl Tri-Polyhydroxystearate, Dipropylene Glycol, Sodium Citrate, BHT, Disodium EDTA, Sodium Benzoate, Potassium Sorbate, Phenoxyethanol, [+/- Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Bismuth Oxochloride (CI 77163)] <ILN48115>

### **Other Information**

protect the product in this container from excessive heat and direct sun

### **PRINCIPAL DISPLAY PANEL - 40 ml Tube Carton**

smashbox

HALO

HEALTHY GLOW

ALL-IN-ONE

TINTED MOISTURIZER

BROAD SPECTRUM SPF 25

1.4 fl. oz./ 40 ml e

Smashbox\_DL588A\_C5JK\_Halo Hybrid Tinted Moisturizer  
17.1 Pt Inercote C1S

Our studio artists love this weightless tinted moisturizer, which is infused with primer so it lasts all day. It melts in effortlessly, enhancing skin with light, natural-looking coverage & a longwearing glow.

**ALL IN ONE**

Primes, perfects, protects & hydrates

**HEALTHY GLOW, DEWY FINISH**

No creasing, caking or settling

**PACKED WITH SKIN-LOVING INGREDIENTS**

Infused with goji berries, gold & peptide

**WITH SPF 25**

For environmental protection

**TO USE:**

Shake well. Tap on with fingers & blend.

**Drug Facts**

Active Ingredients	Purpose
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**Drug Facts (continued)**

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Water\Aqua\Eau, Octyldodecyl Neopentanoate, Butyloctyl Salicylate, Dimethicone, Butylene Glycol, Methyl Trimethicone, Niacinamide, Cetyl PEG/PPG-10/1 Dimethicone, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Diethylhexyl Succinate, Laureth-4, Tocopheryl Acetate, Sodium Hyaluronate, Lecithin, Rosa Hybrid Flower Extract, Pyrus Malus (Apple) Fruit Extract, Lens Esculenta (Lentil) Fruit Extract, Citrullus Lanatus (Watermelon) Fruit Extract, Lycium Chinense (Wolfberry) Fruit Extract, Palmitoyl Hexapeptide-14, Peat Extract, Gold, Sodium Lactate, Methicone, Sodium PCA, Hydrolyzed Wheat Protein/PVP Crosspolymer, Glycerin, Barium Sulfate, Magnesium Sulfate, Dimethyl Isosorbide, Maltodextrin, Triethoxycaprylylsilane, Dimethicone Crosspolymer-3, Silica, Aluminum Hydroxide, Dimethicone/PEG-10/15 Crosspolymer, Trimethylsiloxy silicate, Hexylene Glycol, Isostearic Acid, Caprylyl Glycol, Stearic Acid, Polyglyceryl-2 Triisostearate, Dipentaerythryl Tri-Polyhydroxy-

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FAIR

stearate, Dipropylene Glycol, Sodium Citrate, BHT, Disodium EDTA, Sodium Benzoate, Potassium Sorbate, Phenoxyethanol, (+/- Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Bismuth Oxychloride (CI 77163)) <LN48115>

**Other Information**

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smashbox HALO

**HEALTHY GLOW ALL-IN-ONE TINTED MOISTURIZER**  
BROAD SPECTRUM SPF 25

1.4 fl.oz. / 40 ml e

smashbox  
©Smashbox Cosmetics, Dist.  
Culver City, CA 90232  
WLB Ltd, GU32 3DD, UK  
WLB NV, OEVEL BE-2260  
Made in Canada / C5JK



C5JK-01-1111  
DL588A

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NOTRE SITE INTERNET.



# SMASHBOX HALO HEALTHY GLOW ALL-IN-ONE TINTED MOISTURIZER BROAD SPECTRUM SPF 25

octinoxate, titanium dioxide, and zinc oxide liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10348-018
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Methyl Trimethicone (UNII: S73ZQI0GXM)	
Niacinamide (UNII: 25X51I8RD4)	
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: 25G622K2RA)	
Diethylhexyl Succinate (UNII: 69W9UMG3P8)	
Laureth-4 (UNII: 6HQ855798J)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Apple (UNII: B423VGH5S9)	
Lens Culinaris Fruit (UNII: ZYZ076G9JH)	
Watermelon (UNII: 231473QB6R)	
Gold (UNII: 79Y1949PYO)	
Sodium Lactate (UNII: TU7HW0W0QT)	
Methicone (20 Cst) (UNII: 6777U11MKT)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Glycerin (UNII: PDC6A3C0OX)	
Barium Sulfate (UNII: 25BB7EKE2E)	
Magnesium Sulfate, Unspecified Form (UNII: DE08037SAB)	
Dimethyl Isosorbide (UNII: SA6A6V432S)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	

Hexylene Glycol (UNII: KEH0A3F75J)
Isostearic Acid (UNII: X33R8U0062)
Caprylyl Glycol (UNII: 00YIU5438U)
Stearic Acid (UNII: 4ELV7Z65AP)
Polyglyceryl-2 Triisostearate (UNII: 68DUY2D39A)
Dipentaerythrityl Tri-Polyhydroxystearate (UNII: D21K655H52)
Dipropylene Glycol (UNII: E107L85C40)
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)
Sodium Benzoate (UNII: OJ245FE5EU)
Potassium Sorbate (UNII: 1VPU26JZZ4)
Phenoxyethanol (UNII: HIE492ZZ3T)
Mica (UNII: V8A1AW0880)
Ferric Oxide Red (UNII: 1K09F3G675)
Ferric Oxide Yellow (UNII: EX438O2MRT)
Ferrosoferric Oxide (UNII: XM0M87F357)
Bismuth Oxychloride (UNII: 4ZR792I587)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10348-018-01	1 in 1 CARTON	04/02/2020	
1		40 mL 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 NOT FINAL	part352	04/02/2020	

**Labeler** - SMASHBOX BEAUTY COSMETICS, INC (945344414)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(10348-018) , REPACK(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
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ESTEE LAUDER N.V.		370 151326	MANUFACTURE(10348-018)
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### Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(10348-018) , REPACK(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(10348-018) , REPACK(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(10348-018)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(10348-018)

Revised: 4/2020

SMASHBOX BEAUTY COSMETICS, INC