

**HALO HD FOUNDATION BROAD SPECTRUM SPF 15 OIL FREE- octinoxate and titanium dioxide 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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**LIQUID HALO HD FOUNDATION BROAD SPECTRUM SPF 15 OIL FREE**

**Drug Facts**

**Active Ingredients**

Octinoxate 4.90%

Titanium Dioxide 2.90%

**Purpose**

Sunscreen

**Use**

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, Isododecane, Cyclopentasiloxane, Dimethicone, Butylene Glycol, Polymethyl Methacrylate, Trioctyldodecyl Citrate, Polysilicone-11, Coco-Caprylate/Caprates, PEG/PPG-18/18

Dimethicone, Polyglyceryl-4 Isostearate, Sodium Hyaluronate, Ascorbyl Palmitate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Quaternium-90 Bentonite, Dimethicone Silylate, Magnesium Aluminum Silicate, Alumina, Silica, Propylene Carbonate, Sodium Chloride, Caprylyl Glycol, Hexylene Glycol, Stearic Acid, Palmitic Acid, C12-16 Alcohols, Hydrogenated Lecithin, Disodium EDTA, Phenoxyethanol, [+/- Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499)] <ILN39852>

**Other information**

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

**PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton**

**smashbox**

**LIQUID**

**HALO**

**HD FOUNDATION**

**BROAD SPECTRUM**

**SPF 15**

**OIL-FREE**

**1 fl. oz./30 ml e**

LIQUID HALO  
HD FOUNDATION  
BROAD SPECTRUM SPF 15

1

Get a totally even, radiant finish that feels fresh and alive. Each pigment is encapsulated in a translucent gel to create that coveted, natural lit-from-within glow.

- Oil-free
- Patent-pending technology
- Light to medium coverage

**Drug Facts**

| Active Ingredients     | Purpose   |
|------------------------|-----------|
| Octinoxate 4.90%       | Sunscreen |
| Titanium Dioxide 2.90% |           |

**Use** helps prevent sunburn

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**Directions**

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•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: ▶

**Drug Facts (continued)**

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
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**Inactive Ingredients**

Water/Aqua/Eau, Isododecane, Cyclopentasiloxane, Dimethicone, Butylene Glycol, Polymethyl Methacrylate, Trioctyl/dodecyl Citrate, Polysilicone-11, Coco-Caprylate/Caprate, PEG/PPG-18/18 Dimethicone, Polyglyceryl-4 Isostearate, Sodium Hyaluronate, Ascorbyl Palmitate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Quaternium-90 Bentonite, Dimethicone Silylate, Magnesium Aluminum Silicate, Alumina, Silica, Propylene Carbonate, Sodium Chloride, Caprylyl Glycol, Hexylene Glycol, Stearic Acid, Palmitic Acid, C12-16 Alcohols, Hydrogenated Lecithin, Disodium EDTA, Phenoxyethanol, [+/- Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499)] <LN3985>

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1 fl. oz. / 30 ml e

smashbox  
Smashbox Cosmetics, Dist.  
Culver City, CA 90232  
London W1K 3BQ  
Made in Belgium / C199  
www.smashbox.com



C199-01-1111

DL287K

12/12

# HALO HD FOUNDATION BROAD SPECTRUM SPF 15 OIL FREE

octinoxate and titanium dioxide liquid

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10348-010 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength            |
|---|-------------------|---------------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE        | 0.05635 g in 100 mL |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 0.03335 g in 100 mL |

## Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>Water</b> (UNII: 059QF0KO0R)                       |          |
| <b>Isododecane</b> (UNII: A8289P68Y2)                 |          |
| <b>Cyclomethicone 5</b> (UNII: 0TH5PCI0R)             |          |
| <b>Dimethicone</b> (UNII: 92RU3N3Y1O)                 |          |
| <b>Butylene Glycol</b> (UNII: 3XUS85K0RA)             |          |
| <b>Trioctyldodecyl Citrate</b> (UNII: 35X8CT063R)     |          |
| <b>Coco-Caprylate/Caprate</b> (UNII: 8D9H4QU99H)      |          |
| <b>PEG/PPG-18/18 Dimethicone</b> (UNII: 9H0AO7T794)   |          |
| <b>Polyglyceryl-4 Isostearate</b> (UNII: 820DPX33S7)  |          |
| <b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)          |          |
| <b>Ascorbyl Palmitate</b> (UNII: QN83US2B0N)          |          |
| <b>Hexyl Laurate</b> (UNII: 4CG9F9W01Q)               |          |
| <b>Magnesium Aluminum Silicate</b> (UNII: 6M3P64V0NC) |          |
| <b>Aluminum Oxide</b> (UNII: LMI26O6933)              |          |
| <b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)             |          |
| <b>Propylene Carbonate</b> (UNII: 8D08K3S51E)         |          |
| <b>Sodium Chloride</b> (UNII: 451W47IQ8X)             |          |
| <b>Caprylyl Glycol</b> (UNII: 00YIU5438U)             |          |
| <b>Hexylene Glycol</b> (UNII: KEH0A3F75J)             |          |
| <b>Stearic Acid</b> (UNII: 4ELV7Z65AP)                |          |
| <b>Palmitic Acid</b> (UNII: 2V16EO95H1)               |          |
| <b>C12-16 Alcohols</b> (UNII: S4827SZE3L)             |          |
| <b>Edetate Disodium</b> (UNII: 7FLD91C86K)            |          |
| <b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)              |          |
| <b>Mica</b> (UNII: V8A1AW0880)                        |          |
| <b>Ferric Oxide Red</b> (UNII: 1K09F3G675)            |          |

|   |  |
|---|--|
| <b>Ferric Oxide Yellow</b> (UNII: EX438O2MRT) |  |
| <b>Ferrosoferric Oxide</b> (UNII: XM0M87F357) |  |

| <b>Packaging</b> |                  |                     |                      |                    |
|------------------|------------------|---------------------|----------------------|--------------------|
| #                | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1                | NDC:10348-010-01 | 1 in 1 CARTON       |                      |                    |
| 1                |                  | 30 mL in 1 BOTTLE   |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL      | part352                                  | 04/01/2013           |                    |

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

| <b>Establishment</b> |         |           |  |
|----------------------|---------|-----------|--|
| Name                 | Address | ID/FEI    | Business Operations                    |
| ELGC K.K.            |         | 712808195 | RELABEL(10348-010) , REPACK(10348-010) |

| <b>Establishment</b>                                     |         |           |   |
|--|---------|-----------|---|
| Name   | Address | ID/FEI    | Business Operations   |
| Estee Lauder Pennsylvania Distribution Center 2 (PADC 2) |         | 828534516 | MANUFACTURE(10348-010) , RELABEL(10348-010) , REPACK(10348-010) |

| <b>Establishment</b>                       |         |           |  |
|--|---------|-----------|--|
| Name                                       | Address | ID/FEI    | Business Operations                    |
| ESTEE LAUDER COSMETICS DISTRIBUTION CENTER |         | 208579636 | REPACK(10348-010) , RELABEL(10348-010) |

| <b>Establishment</b>        |         |           |                        |
|-----------------------------|---------|-----------|------------------------|
| Name                        | Address | ID/FEI    | Business Operations    |
| ESTEE LAUDER COSMETICS, LTD |         | 244669714 | MANUFACTURE(10348-010) |

| <b>Establishment</b>         |         |           |                        |
|------------------------------|---------|-----------|------------------------|
| Name                         | Address | ID/FEI    | Business Operations    |
| ESTEE LAUDER COSMETICS, LTD. |         | 205952385 | MANUFACTURE(10348-010) |

| <b>Establishment</b> |         |           |                        |
|----------------------|---------|-----------|------------------------|
| Name                 | Address | ID/FEI    | Business Operations    |
| ESTEE LAUDER N.V.    |         | 370151326 | MANUFACTURE(10348-010) |

| <b>Establishment</b>                         |         |           |                        |
|--|---------|-----------|------------------------|
| Name   | Address | ID/FEI    | Business Operations    |
| LEN-RON MANUFACTURING DIVISION OF ARAMIS INC |         | 809771152 | MANUFACTURE(10348-010) |

## Establishment

| Name            | Address | ID/FEI    | Business Operations   |
|-----------------|---------|-----------|---|
| NORTEC KEYSTONE |         | 943871157 | MANUFACTURE(10348-010) , RELABEL(10348-010) , REPACK(10348-010) |

## Establishment

| Name             | Address | ID/FEI    | Business Operations   |
|------------------|---------|-----------|---|
| NORTHTEC BRISTOL |         | 959338336 | MANUFACTURE(10348-010) , RELABEL(10348-010) , REPACK(10348-010) |

## Establishment

| Name              | Address | ID/FEI    | Business Operations   |
|-------------------|---------|-----------|---|
| NORTHTEC KEYSTONE |         | 949264774 | MANUFACTURE(10348-010) , RELABEL(10348-010) , REPACK(10348-010) |

## Establishment

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| WHITMAN LABORATORIES, LTD. |         | 216866277 | MANUFACTURE(10348-010) |

## Establishment

| Name              | Address | ID/FEI    | Business Operations    |
|-------------------|---------|-----------|------------------------|
| Aveda Corporation |         | 071352058 | MANUFACTURE(10348-010) |

## Establishment

| Name                          | Address | ID/FEI    | Business Operations                    |
|-------------------------------|---------|-----------|--|
| Pennsylvania Logistics Center |         | 078364654 | REPACK(10348-010) , RELABEL(10348-010) |

Revised: 4/2013

SMASHBOX BEAUTY COSMETICS, INC