

**SMASHBOX HIGH DEFINITION HEALTHY FX FOUNDATION SPF 15- 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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**SMASHBOX**

**HIGH DEFINITION HEALTHY FX FOUNDATION SPF 15**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 5.00%	Sunscreen
Titanium Dioxide 3.20%	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, PEG/PPG-18/18 Dimethicone, Polysilicone-11, Coco-Caprylate/Caprates, Quaternium-90 Bentonite, Hexyl Laurate, Polyglyceryl-4 Isostearate, Propylene Carbonate, Dimethicone/Divinyldimethicone Silsesquioxane Crosspolymer, Cetyl PEG/PPG-10/1 Dimethicone, Ascorbyl Palmitate, PEG-10 Dimethicone, Alumina, Silica, Magnesium Aluminum Silicate, Dimethylacrylamide/Acrylic Acid/Polystyrene Ethyl Methacrylate Copolymer, Sodium Chloride, Caprylyl Glycol, Stearic Acid, Palmitic Acid, C12-16

Alcohols, Hydrogenated Lecithin, Disodium EDTA, Phenoxyethanol, Sodium Dehydroacetate, [+/- Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)] <ILN38702>

**Other information**

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

Dist. Smashbox  
Beauty Cosmetics, Inc.  
Culver City, CA 90232

**PRINCIPAL DISPLAY PANEL - 30ml Cylinder Carton**

**smashbox**

**HIGH DEFINITION**

HEALTHY FX FOUNDATION

SPF 15

OIL-FREE

BROAD SPECTRUM SPF 15

1 fl. oz. / 30ml e

HIGH DEFINITION  
HEALTHY FX FOUNDATION  
BROAD SPECTRUM SPF 15

FAIR F0

Formulated to get skin close-up ready, this oil-free foundation creates natural looking, flawless skin. The buildable formula with SPF 15 contains antioxidant vitamin C to help combat against environmental aggressors. Pair with your favorite Photo Finish Foundation Primer for complexion perfection.

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#### Drug Facts (continued)

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BROAD SPECTRUM SPF 15  
1 fl. oz. / 30ml e

smashbox  
Dist: Smashbox  
Beauty Cosmetics, Inc.  
Culver City, CA 90232  
LONDON, MILK S3E0  
Made in USA / CA 11  
www.smashbox.com



C511-69-1112  
DL131

# SMASHBOX HIGH DEFINITION HEALTHY FX FOUNDATION SPF 15

octinoxate and titanium dioxide liquid

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10348-005
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.2 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PALMITIC ACID (UNII: 2V16EO95H1)	
C12-16 ALCOHOLS (UNII: S4827SZE3L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:10348-005-01	1 in 1 CARTON		
1		30 mL in 1 CYLINDER		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2012	

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

## Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(10348-005) , REPACK(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(10348-005) , RELABEL(10348-005) , REPACK(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(10348-005) , RELABEL(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(10348-005)

## Establishment

Name	Address	ID/FEI	Business Operations
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LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(10348-005)
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### Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(10348-005) , RELABEL(10348-005) , REPACK(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(10348-005) , RELABEL(10348-005) , REPACK(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(10348-005) , RELABEL(10348-005) , REPACK(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(10348-005) , RELABEL(10348-005)

### Establishment

Name	Address	ID/FEI	Business Operations
NU-WORLD CORPORATION		628045858	MANUFACTURE(10348-005)