SMASHBOX PHOTO FINISH FOUNDATION PRIMER SPF 20- avobenzone, homosalate, and octis alate 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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Drug Facts

Active Ingredients

Avobenzone 2.00% Homosalate 15.00% Octisalate 5.00%

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
- apply to all skin exposed to the sun
- 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

Cyclopentasiloxane, Polysilicone-11, Dimethicone Crosspolymer, C12-15 Alkyl Benzoate, Tocopheryl Acetate, Cola Acuminata (Kola) Seed Extract, Vitis Vinifera (Grape) Seed Extract, Carthamus Tinctorius (Safflower) Seed Oil, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Octyldodecyl Neopentanoate, Tribehenin, Ceramide 2, PEG-10 Rapeseed Sterol, Palmitoyl Oligopeptide, Acetyl Hexapeptide-8, Phenyl Trimethicone, Water\Aqua\Eau, Silica, Laureth-12, Hexyl Laurate, VP/Hexadecene Copolymer, Triethoxycaprylylsilane, Caprylyl Glycol, Hexylene Glycol, Hydrogenated Polydecene, Phenoxyethanol, Potassium Sorbate, Iron Oxides (CI 77491) <ILN39369>

Other information

protect the product in this container from excessive heat and direct sun Smashbox Cosmetics, Dist.
Culver City, CA 90232

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton

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PHOTO FINISH FOUNDATION PRIMER

SPF 20 WITH DERMAXYLTM COMPLEX

BROAD SPECTRUM SPF 20 1 fl. oz. / 30 ml e



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avobenzone, homosalate, and octisalate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10348-006

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mL in 100 mL			
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL			
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 mL in 100 mL			

Inactive Ingredients			
Ingredient Name	Strength		
Cyclomethicone 5 (UNII: 0THT5PCI0R)			
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)			
.AlphaTocopherol Acetate (UNII: 9E8X80D2L0)			
cola acuminata seed (UNII: 1F8 VIW1479)			
Vitis Vinifera Seed (UNII: C34U15ICXA)			
Safflower Oil (UNII: 65UEH262IS)			
Polyglyceryl-4 Isostearate (UNII: 820 DPX33S7)			
Octyldodecyl Neopentanoate (UNII: X8725R883T)			
Tribehenin (UNII: 8OC9U7TQZ0)			
Ceramide 2 (UNII: C04977SRJ5)			
PEG-10 Rapeseed Sterol (UNII: 258O76T85M)			
Palmitoyl Oligopeptide (UNII: HO4ZT5S86C)			
Acetyl Hexapeptide-8 (UNII: L4EL31FWIL)			
Phenyl Trimethicone (UNII: DR0K5NOJ4R)			
Water (UNII: 059QF0KO0R)			
Silicon Dioxide (UNII: ETJ7Z6XBU4)			
Laureth-12 (UNII: OAH19558U1)			
Hexyl Laurate (UNII: 4CG9F9W01Q)			
Triethoxycaprylylsilane (UNII: LDC331P08E)			
Caprylyl Glycol (UNII: 00 YIU5438 U)			
Hexylene Glycol (UNII: KEH0 A3F75J)			
Phenoxyethanol (UNII: HIE492ZZ3T)			
Potassium Sorbate (UNII: 1VPU26JZZ4)			
Ferric Oxide Red (UNII: 1K09F3G675)			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:10348-006-01	1 in 1 CARTON					
1		50 mL in 1 TUBE					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part352	05/27/2012			

Labeler - SMASHBOX BEAUTY COSMETICS, INC (945344414)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(10348-006), REPACK(10348-006)

Establishment

Name	Address	ID/FEI	Business Operations			
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(10348-006), RELABEL(10348-006), REPACK(10348-006)			

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(10348-006)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(10348-006), RELABEL(10348-006)

Establishment

Listabiliment					
Name	Address	ID/FEI	Business Operations		
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(10348-006)		

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(10348-006)

Establishment

Listabilianicit				
Name	Address	ID/FEI	Business Operations	
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(10348-006)	

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(10348-006)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(10348-006)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(10348-006), RELABEL(10348-006), REPACK(10348-006)

Establishment

Name	Address	ID/FEI	Business Operations

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(10348-006), RELABEL(10348-006), REPACK(10348-006)

Establishment				
Name	Address	ID/FEI	Business Operations	
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(10348-006)	

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(10348-006)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pennsylvania Logistics Center		078364654	REPACK(10348-006), RELABEL(10348-006)	

Establishment			
Name	Address	ID/FEI	Business Operations
MANA Cosmetics Inc		078870292	MANUFACTURE(10348-006)

SMASHBOX BEAUTY COSMETICS, INC Revised: 7/2012