

**PHOTO FINISH PROTECT BROAD SPECTRUM SPF 45 PRIMER- avobenzone, homosalate, octinoxate, octisalate, and octocrylene cream**  
**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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**PHOTO FINISH PROTECT BROAD SPECTRUM SPF 45 PRIMER**

**Drug Facts**

**Active Ingredients**

Avobenzone 3.0%  
Homosalate 10.0%  
Octinoxate 7.0%  
Octisalate 4.0%  
Octocrylene 8.0%

**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
- 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

**Inactive Ingredients**

Dimethicone, Polymethylsilsesquioxane/Silica Crosspolymer, Talc, Stearyl Dimethicone, Polysilicone-11, Butyloctyl Salicylate, Silica, Dimethiconol, BHT, Phenoxyethanol, Mica <ILN46784>

**Other information**

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

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

smashbox

PHOTO FINISH

PROTECT

BROAD SPECTRUM

SPF 45

PRIMER

1 fl. oz. liq. / 30 ml e

CDW\_Smashbox\_DL581\_C55P  
14 PT. Invercote C1S

CREATED AT SMASHBOX  
PHOTO STUDIOS L.A.

Photo Finish Protect  
Broad Spectrum  
SPF 45 Primer

This silky SPF 45 primer blurs, preps & protects.

**NEVER STICKY, HEAVY OR GREASY**  
Lightweight, cushiony gel

**TRANSPARENT WITH NO WHITE CAST**  
Broad-spectrum UVA/UVB protection

**NATURAL MATTE FINISH**  
Blends easily & leaves skin smooth

**FOR:** All skin types

**TO USE:** Wear alone or under makeup.

**Drug Facts**

Active Ingredients	Purpose
Avobenzone 3.0%	} Sunscreen
Homosalate 10.0%	
Octinoxate 7.0%	
Octisalate 4.0%	
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**Drug Facts (continued)**

regularly use a sunscreen with a Broad Spectrum value of 15 or higher and other sun protection measures including:  
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**Other information**

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1 fl. oz. liq. / 30 ml e



smashbox  
©Smashbox Cosmetics, Dist.  
Culver City, CA 90232  
WLB Ltd. G132 30D, UK  
WLB NY, DEVEL BE-2260  
Made in USA / CAWT  
www.smashbox.com



C4WT-01-1111  
DL581

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avobenzone, homosalate, octinoxate, octisalate, and octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10348-017
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0303 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.101 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.0707 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.0404 g in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.0808 g in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
Dimethicone (UNII: 92RU3N3Y1O)	
Talc (UNII: 7SEV7J4R1U)	
Stearyl Dimethicone (400 MPA.S at 50 C) (UNII: R327X197HY)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4C00W6C5)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Mica (UNII: V8A1AW0880)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10348-017-01	1 in 1 CARTON	11/15/2019	
1		30 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	11/15/2019	

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

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(10348-017) , REPACK(10348-017)

**Establishment**

Name	Address	ID/FEI	Business Operations
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ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(10348-017)
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### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(10348-017) , REPACK(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(10348-017) , REPACK(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(10348-017)

### Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Laboratories, Inc.		001535103	MANUFACTURE(10348-017)