

ALMAY HEALTHY BIOME MAKEUP- homosalate, octisalate, octocrylene, titanium dioxide, zinc oxide emulsion

Almay

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.

Almay Skin Perfacting Healthy Biome Makeup

Active Ingredient Section

Homosalate 5.0%

Octisalate 5.0%

Octocrylene 5.0%

Titanium Dioxide 5.8%

Zinc Oxide 3.94%

Uses

Helps prevent sunburn. if used as directed with other sun protection measures decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use on damaged skin or broken skin

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 SPF value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10am- 2pm. Wear long-sleeved shirts, pants, hats and sunglasses.

When using this product

Keep out of the eyes, Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

If product is swalled get medical help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure. Use water resistant sunscreen is swimming or sweating. Reapply at least ever 2 hours. Children under 6 months; Ask a doctor.

Drug Facts (con't.)

Tetrapeptide-10, Polyglyceryl-3 Diisostearate, Polymnia Sonchifolia Root Juice, Polysorbate 80, Propylene Carbonate, Simethicone, Sorbitan Stearate, Tetrasodium EDTA, Tocopheryl Acetate, Triethoxycaprylsilane, Phenoxethanol, **May Contain** [+/-: Iron Oxides (CI 77491), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Titanium Dioxide (CI 77891)]. B01001

Drug Facts (con't.)

QUESTIONS? 1-800-473-8566

ACTIVE INGREDIENTS:
HOMOSALATE 5.00%
OCTISALATE 5.00%
OCTOCRYLENE 5.00%
TITANIUM DIOXIDE 5.80%
ZINC OXIDE 3.94%

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MADE IN U.S.A. WITH U.S. AND NON-U.S. COMPONENTS.
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Drug Facts (con't.)

and other sun protection measures including: • Limit time in the sun, especially from 10 am – 2 pm • Wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients: Aqua/Water/Eau, Cyclopentasiloxane, Butyloctyl Salicylate, Cetyl PEG/PPG-10/1 Dimethicone.

Drug Facts (con't.)

Trimethylsiloxyoctylsilicate, Glycerin, Isododecane, Alumina, Magnesium Sulfate, Silica, Alpha-Glucan Oligosaccharide, Caprylic/Capric Triglyceride, Caprylyl Glycol, Cetyl Palmitate, Distearidimonium Hectorite, Hydrogen Dimethicone, Hydrogenated Lecithin, Lactobacillus, Maltodextrin, Ophiopogon Japonicus Root Extract, Palmitoyl

Drug Facts (con't.)

broken skin. • **When using this product** keep out of the 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 • Apply liberally 15 minutes before sun

Drug Facts (con't.)

exposure • Use a water resistant sunscreen if swimming or sweating • Reapply at least every 2 hours • Children under 6 months: Ask a doctor. • **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 SPF value of 15 or higher

Drug Facts

Active ingredients	Purpose
Homosalate 5.00%.....	Sunscreen
Octisalate 5.00%.....	Sunscreen
Octocrylene 5.00%.....	Sunscreen
Titanium Dioxide 5.80%.....	Sunscreen
Zinc Oxide 3.94%.....	Sunscreen

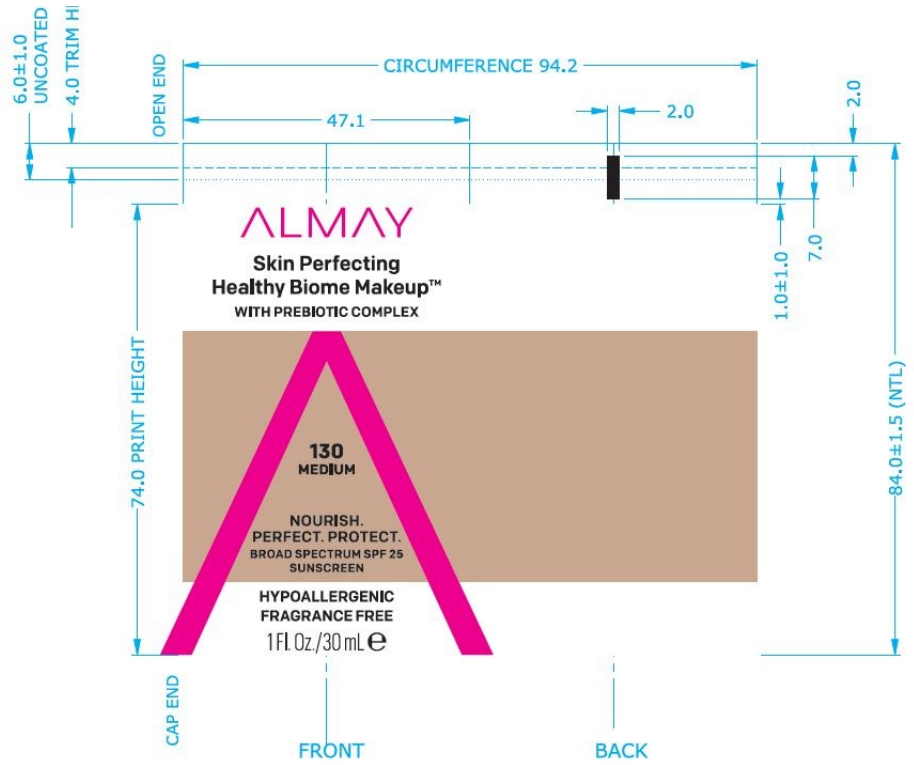
Drug Facts (con't.)

Uses • Helps prevent sunburn. • If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

• **For external use only.** • **Do not use** on damaged or

**FOR POSITION ONLY
DOES NOT PRINT**



WPP World Wide Packaging	UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS TOLERANCES:	Part Name: 30mm Tube	Supplier: WPP Suzhou
	LINEAR: X = ±0.2 ANGULAR: ±0°30'	Drawn By: DECO 30x84	

ALMAY HEALTHY BIOME MAKEUP

homosalate, octisalate, octocrylene, titanium dioxide, zinc oxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0311-0723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.94 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIMETHYLSILOXYLSILICATE (M/Q 0.66) (UNII: 5041RX63GN)	
MAGNESIUM SULFATE ANHYDROUS (UNII: ML30MJ2U7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

PALMITOYL TETRAPEPTIDE-10 (UNII: 6Q6H1PKC05)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DIMETHICONE (UNII: 92RU3N3Y1O)
EDETATE SODIUM (UNII: MP1J8420LU)
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
OPHIOPOGON JAPONICUS ROOT (UNII: 90PS6JV9GZ)
WATER (UNII: 059QF0K00R)
GLYCERIN (UNII: PDC6A3C0OX)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
ISODODECANE (UNII: A8289P68Y2)
ALUMINUM OXIDE (UNII: LM26O6933)
.ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PEG-20 SORBITAN STEARATE (UNII: HD40WR33LC)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
SMALLANTHUS SONCHIFOLIUS WHOLE (UNII: 4P5T8DTR73)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0311-0723-01	1 mL in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/01/2020	

Labeler - Almay (064988652)

Establishment

Name	Address	ID/FEI	Business Operations
Revlon, INC.		809725570	manufacture(0311-0723)