

AGATHA FITTING TOUCH MAKE UP SET- octinoxate, titanium dioxide, octisalate, zinc oxide powder

Coson Co., Ltd.

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.

ACTIVE INGREDIENT

Active Ingredient: Ethylhexyl Methoxycinnamate 7.5%, Titanium Dioxide 8.65755%, Ethylhexyl Salicylate 5.0%, Zinc Oxide 3.52%

INACTIVE INGREDIENT

AGATHA FITTING TOUCH MAKE UP FOUNDATION PACT - Inactive Ingredients: Water, Cyclopentasiloxane, Cyclohexasiloxane, Butylene Glycol, PEG-10 Dimethicone, Trimethylsiloxysilicate, Phenyl Trimethicone, Glycerin, Niacinamide, Diglycerin, Lauryl Peg-9 Polydimethylsiloxyethyl Dimethicone, Polymethylsilsesquioxane, Distearidimonium Hectorite, Diisostearyl Malate, Sodium Chloride, Sorbitan Sesquioleate, Helianthus Annuus (Sunflower) Seed Oil, Oenothera Biennis(Evening Primrose) Oil, Anthemis Nobilis Flower Water, Rosa Damascena Flower Water, Panax Ginseng Root Extract, Tocopherol, Centella Asiatica Extract, Sodium Hyaluronate, Olea Europaea(Olive) Fruit Oil, Lecithin, Lilium Candidum Flower Extract, Leontopodium Alpinum Flower/Leaf Extract, Convallaria Majalis Bulb/Root Extract, Magnolia Liliflora Flower Extract, Phytosterols, Squalane, Hydrolyzed Collagen, Tocopheryl Acetate, Paeonia Lactiflora Root Extract, Hydrolyzed Pea Protein, Saussurea Involucrata Extract, Citrus Aurantium Dulcis(Orange) Flower Extract, Dioscorea Japonica Root Extract, Plumeria Rubra Flower Extract, Tremella Fuciformis (Mushroom) Extract, Butyrospermum Parkii(Shea Butter), Ceramide 3, Mica(CI77019), Polymethyl Methacrylate, Aluminum Hydroxide, Ozokerite, Polyhydroxystearic Acid, Dimethicone, Stearic Acid, Triethoxycaprylylsilane, Dimethicone Crosspolymer, Disodium EDTA, Adenosine, Linoleic Acid, Phenoxyethanol, Ethylhexylglycerin, 1,2-Hexanediol, Iron Oxides(CI77492), Iron Oxides(CI77491), Iron Oxides(CI77499), Fragrance

AGATHA TINTED LIP GLOW - Ingredients: Diisostearyl Malate, Limnanthes Alba(Meadowfoam) Seed Oil, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Hydrogenated Polyisobutene, Methyl Hydrogenated Rosinate, Hydrogenated Castor Oil Dimer Dilinoleate, Synthetic Fluorphlogopite, Hydrogenated Vegetable Oil, Astrocaryum Murumuru seed Butter, Euphorbia Cerifera(Candelilla) Wax, Polyethylene, Butyrospermum Parkii(Shea Butter), Tocopheryl Acetate, Ceresin, Ethylene/Propylene Copolymer, Synthetic Wax, Copernicia Cerifera(Carnauba) Wax, Sucrose Tetrastearate Triacetate, Triethoxycaprylylsilane, Fragrance, Red 27 (CI45410:1)

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. If following symptoms occur, stop use and consult a doctor: red spots, swelling, itching, irritation, or symptoms where product has been applied under direct sunlight. 2. Do not use on scarred skin or if you have dermatitis or eczema. 3. Keep the cap closed on this product. 4. Keep away from direct sunlight or heat. 5. Keep out of reach of children.

How to use

How to use: Once an appropriate amount has accumulated, use the included puff to smooth it out onto your face by patting it in an outward motion.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



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octinoxate, titanium dioxide, octisalate, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62171-070
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	0.67 g in 9 g	
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	0.77 g in 9 g	
Octisalate (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	Octisalate	0.45 g in 9 g	
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8 SF37)	ZINC CATION	0.31 g in 9 g	
Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Butylene Glycol (UNII: 3XUS85K0RA)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62171-070-01	9 g in 1 CARTON; 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	12/01/2015	

Labeler - Coson Co., Ltd. (689835593)

Registrant - Coson Co., Ltd. (689835593)

Establishment

Name	Address	ID/FEI	Business Operations
Coson Co., Ltd.		689835593	manufacture(62171-070)

Revised: 1/2016

Coson Co., Ltd.