

**GALAXYBORN SATIN CUSHION NO 21- titanium dioxide, octinoxate, octisalate powder
DWAY 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 ingredients: Titanium Dioxide 11.38%, Ethylhexyl Methoxycinnamate 7.00%, Ethylhexyl Salicylate 3.00%

INACTIVE INGREDIENT

Inactive ingredients:

Water, Cyclopentasiloxane, Cyclohexasiloxane, Butylene Glycol, Diphenylsiloxy Phenyl Trimethicone, Isoamyl p-Methoxycinnamate, Cetyl PEG/PPG-10/1 Dimethicone, C12-15 Alkyl Benzoate, Niacinamide, Dicaprylyl Carbonate, Alcohol Denat., Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Trimethylsiloxysilicate, Sodium Chloride, Iron Oxides (CI 77492), Sorbitan Sesquioleate, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Sorbitan Oliviate, Beeswax, Disteardimonium Hectorite, Polypropylsilsesquioxane, Isododecane, Dimethicone, Iron Oxides (CI 77491), Dipropylene Glycol, Acrylates/Polytrimethylsiloxymethacrylate Copolymer, Chlorphenesin, Trihydroxystearin, 1,2-Hexanediol, Hydroxyacetophenone, Saccharum Officinarum (Sugar Cane) Extract, Sodium Hyaluronate, Mentha Rotundifolia Leaf Extract, Propylene Carbonate, Iron Oxides (CI 77499), Fragrance(Parfum), Dimethiconol, Adenosine, Triethoxycaprylylsilane, Disodium EDTA, Brassica Campestris (Rapeseed) Flower Extract, Narcissus Tazetta Extract, Calendula Officinalis Flower Extract, Freesia Alba Flower Extract, Taraxacum Officinale (Dandelion) Extract, Helianthus Annuus (Sunflower) Flower Extract, Oxalis Hedysaroides Extract, Papaver Rhoeas Flower Extract, Glycerin, Tocopherol

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

For external use only

- 1) It is recommend to stop using the product and talk to dermatologist immediately if you are suffering such conditions : rash, swell up, itchiness.
- 2) Do not apply this product on any skin trouble.
- 3) Caution for storage and handling; always recap after use. Keep this product out of the reach of children. Avoid extremely high and low temperature and direct sunlight.
- 4) For the cleanliness in using the product, do not share the puff with someone else and it is recommended to keep it clean.

DESCRIPTION

Uses:

Helps prevent sunburn.

Directions:

- 1) Use at the sunscreen step after your basic skin care routine (it works as a sunblock, makeup base, and foundation) or Make-up before and after can be used.
- 2) Using the puff applicator, press down on the cushion sponge to get the foundation on the puff.
- 3) Close the inner lid tightly after each use to preserve freshness. Not closing the lid may cause the beneficial ingredients to evaporate and make the cushion sponge to shrink.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



GALAXYBORN SATIN CUSHION NO 21

titanium dioxide, octinoxate, octisalate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72256-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	1.70 g in 15 g
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	1.05 g in 15 g
Octisalate (UNII: 4X49 Y059 6W) (OCTISALATE - UNII:4X49 Y059 6W)	Octisalate	0.45 g in 15 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:72256-010-02	1 in 1 CARTON	03/01/2019	
1	NDC:72256-010-01	15 g in 1 CONTAINER; 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	03/01/2019	

Labeler - DWAY CO LTD (694896351)

Registrant - DWAY CO LTD (694896351)

Establishment

Name	Address	ID/FEI	Business Operations
Cit Co., Ltd.		690081646	manufacture(72256-010)

Revised: 3/2019

DWAY CO LTD