

DR FROG INTENSIVE CALMING SUN BLOCK- titanium dioxide, zinc oxide cream
Charmzone 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 7.30%, ZINC OXIDE 6.99%

INACTIVE INGREDIENT

Inactive ingredients:

WATER,CYCLOPENTASILOXANE,BUTYLENE GLYCOL,LAMINARIA JAPONICA EXTRACT,CYCLOMETHICONE,ISODODECANE,HYDROGENATED POLY(C6-14 OLEFIN),PEG-10 DIMETHICONE,PHENYL TRIMETHICONE,DIMETHICONE,1,2-HEXANEDIOL,DISTEARDIMONIUM HECTORITE,PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE,ALUMINUM HYDROXIDE,SODIUM CHLORIDE,STEARIC ACID,CYCLOHEXASILOXANE,DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER,BEESWAX,GLYCERYL CAPRYLATE,FRAGRANCE,MYRISTIC ACID,TOCOPHERYL ACETATE,CETYL PEG/PPG-10/1 DIMETHICONE,ULMUS DAVIDIANA ROOT EXTRACT,BIFIDA FERMENT LYSATE,ALLIUM CEPA (ONION) BULB EXTRACT,CENTELLA ASIATICA EXTRACT,PANTHENOL,PROPYLENE GLYCOL,ETHYLHEXYLGLYCERIN,DISODIUM EDTA,GLYCERIN,ALPHA-GLUCAN OLIGOSACCHARIDE,CAPRYLIC/CAPRIC TRIGLYCERIDE,DIPROPYLENE GLYCOL,HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL,HYDROGENATED LECITHIN,ASCORBYL TOCOPHERYL ACETATE,SODIUM GUAIAZULENE SULFONATE,SUCROSE PALMITATE,ALCOHOL,SODIUM HYALURONATE,CRINUM ASIATICUM EXTRACT,POLYSORBATE 80,CERAMIDE NP,NELUMBO NUCIFERA LEAF EXTRACT,CHOLESTEROL,PHYTOSPHINGOSINE

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

- 1) Please stop using the product if the following symptoms occur or appear when the skin is exposed to direct sunlight: red blotches, swelling, itchiness or other irritations while using product. Then, consult a dermatologist or a specialist.
- 2) Please do not apply the product on wound or any of skin irritation, such as eczema or dermatitis.
- 3) Precaution during storage/handling. a) Keep the product closed after using b) Keep out of reach of children c) Avoid storing in high and low temperature and areas exposed to direct sunlight

DESCRIPTION

Uses:

[UV PROTECTION]



DR FROG INTENSIVE CALMING SUN BLOCK				
titanium dioxide, zinc oxide cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:2220 1-10 30	
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	3.65 g in 50 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8 SF37)		ZINC CATION	3.49 g in 50 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:22201-1030-2	1 in 1 CARTON	03/01/2018	
1	NDC:22201-1030-1	50 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	03/01/2018	

Labeler - Charmzone Co Ltd (689049765)

Registrant - Charmzone Co Ltd (689049765)

Establishment

Name	Address	ID/FEI	Business Operations
Charmzone Co., Ltd._Wonju Factory		688238394	manufacture(22201-1030)

Revised: 4/2018

Charmzone Co Ltd