DR NIKKO SHEER SUNSCREEN- octinoxate cream
Cit 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.

---

octinoxate, octisalate, ensulizole

water, glycerin, dipropylene glycol, etc.

helps prevent sunburn

1. If the following symptoms occur after product use, stop using the product immediately and consult a dermatologist (continuous use can exacerbate the symptoms).
1) Occurrence of red spots, swelling, itchiness, and other irritation
2) If the symptoms above occur after the application area is exposed to direct sunlight

2. Do not use on open wounds, eczema, and other irritations
3. Precaution for Storage and Handling
1) Close the lid after use
2) Keep out of reach of infants and children
3) Do not to store in a place with high/low temperature and exposed to direct sunlight

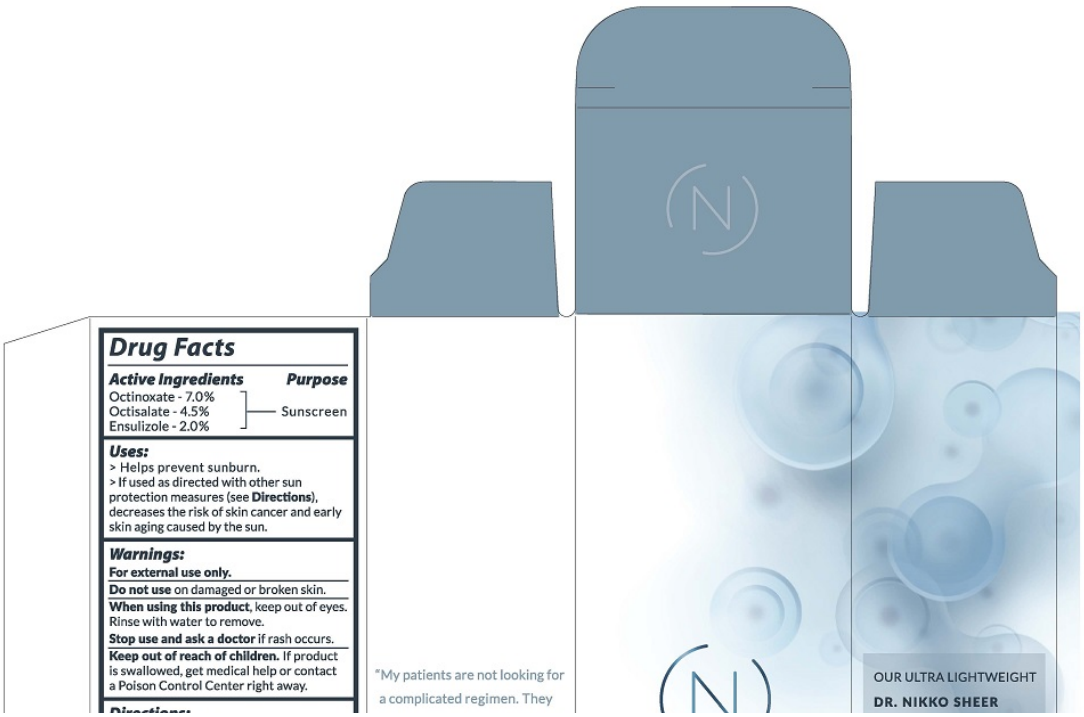
4. Use as avoiding eye areas.

Keep out of reach of children.

Apply liberally 15 minutes before sun exposure

external use only

[DR NIKKO] Sheer Sunscreen Unit Box_50ml



DR NIKKO SHEER SUNSCREEN

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69133-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	2 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69133-050-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/13/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/13/2018	

Labeler - Cit Co., Ltd. (690081646)

Registrant - Cit Co., Ltd. (690081646)

Establishment

Name	Address	ID/FEI	Business Operations
Cit Co., Ltd.		690081646	label(69133-050) , manufacture(69133-050)

Revised: 8/2018 Cit Co., Ltd.