

MD GLAM SPF 50- octinoxate lotion Spa de Soleil

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.

MD Glam SPF 50

Active Ingredients

Octinoxate 7.5%

Zinc oxide 9.5%

Purpose

Sunscreen

Warnings

Warnings

- For external use only
- Do not use on damaged or broken skin

When using this product

- keep out of the eye area
- rinse with water to remove
- stop use and ask a doctor if rash or irritation develops
- for external use only
- keep out of reach of children

Jar is glass and may shatter if dropped

Keep out of the reach of children.

Directions

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Apply generously and evenly thirty minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating. Children under 6 months of age: Ask a doctor.

Inactive Ingredients

Inactive Ingredients:

aqua, cocos nucifera (coconut) oil, carthamus tinctoris (safflower) seed oil, heptyl undecylenate, caprylic/capric triglyceride, cetyl alcohol, glycerin

Principal Display Panel



MD GLAM SPF 50

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
HEPTYL UNDECYLENATE (UNII: W77QUB6GXO)	
SAFFLOWER SEED (UNII: 8FCL6A31TX)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
WATER (UNII: 059QF0KOOR)	
COCONUT OIL (UNII: Q9L0O73W7L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9000-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/14/2022	

Labeler - Spa de Soleil (874682867)**Establishment**

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9000)

Revised: 12/2022

Spa de Soleil