ROCCOS OLD SCHOOL SUNSCREEN SPF 30- octinoxate cream Rocco's Old School

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.

Drug Facts

Active Ingredient

Octinoxate 7.5%	Sunscreen agent
Benzophenone-3 6%	Sunscreen agent
Titanium Dioxide 1.5%	Sunscreen agent

Use

 To help prevent sunburn from UVB radiation and protect against long-UVA rays linked to deep premature skin-aging.

Warnings

For external use only.

When using this product

- Keep out of eyes.
- Rinse with water to remove.

Stop use and ask doctor if

rash or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally on face, neck and other exposed areas every morning after cleansing or at least 15 minutes before sun exposure, or as needed.
- Reapply if excess perspiration or product wear occurs, and after swimming or towel drying.
 For children under six months

For children under six months of age

- Consult a doctor.
- Store at controlled room temperature 15° 30° C (59° 86°F).

Inactive ingredients

Purified Water/Aqua/Eu, Allantoin, Glyceryl Stearate and PEG-100 Stearate, Stearic Acid, Squalene, Beeswax, Aloe Barbadensis Leaf Juice, Sodium Hyaluronate, Carbomer, Potassium sorbate, Sodium Benzoate

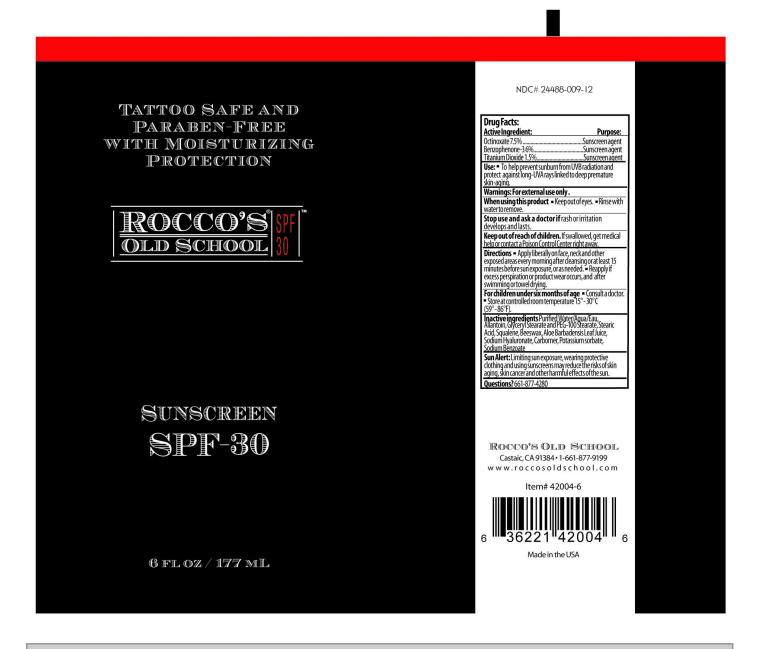
Sun Alert

Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

Questions?

661-877-4280

Place Holder Text



octinoxate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	13.275 mL in 177 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	10.62 mL in 177 mL
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	2.655 mL in 177 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALLANTO IN (UNII: 344S277G0Z)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SQUALENE (UNII: 7QWM220FJH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:24488-009-12	177 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/16/2011	

Labeler - Rocco's Old School (961956229)

Registrant - Creations Garden Natural Products Inc. (961956229)

Establishment			
Name	Address	ID/FEI	Business Operations

Creations Garden Natural Products Inc.	961956229	manufacture
Cicutions durach natural froducts inc.	001000220	manaracture

Revised: 2/2011 Rocco's Old School