

MAKETA SUNSCREEN WITH ALOE VERA SPF 30- octinoxate, octisalate, and oxybenzone lotion

Makéta™ Sunscreen Lotion with Aloe Vera SPF 30

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.

Makéta™ Sunscreen Lotion with Aloe Vera SPF 30

Drug Facts

Active Ingredients:		Purpose
Octinoxate	7.5%	Sunscreen
Octisalate	5.0%	Sunscreen
Oxybenzone	6.0%	Sunscreen

Uses

- * Helps prevent sunburn

Warnings

Skin Cancer/ Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

For External Use Only

Do Not Use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children.

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

Directions

- * Apply liberally 15 minutes before sun exposure.
- * Use a water resistant sunscreen if swimming or sweating.
- * Reapply at least every 2 hours.
- * Children under 6 months: Ask a Doctor

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredients

Allantoin, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Brassica Campestris/Aleurites Fordi Oil Copolymer, Butylparaben, Carbomer, Dimethicone, Ethylparaben, Fragrance, Glyceryl Stearate SE, Isobutylparaben, Lanolin Alcohol, Methylparaben, Mineral Oil, Phenoxyethanol, Propylparaben, Stearic Acid, Water.

Distributed By Makéta, LLC • Chicago, Illinois

PRINCIPAL DISPLAY PANEL - 532 ml Bottle Label

SPF 30

ALOE

Makéta™
sunscreen
LOTION

Aloe Vera
 Sun Screen Lotion

NET WT. 18 FL. OZ. (532 ml)

Makéta, LLC



MAKETA SUNSCREEN WITH ALOE VERA SPF 30

octinoxate, octisalate, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72102-047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 mL

Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Allantoin (UNII: 344S277G0Z)	
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)	
Gulose, L- (UNII: J96E9Q45N7)	
Mineral Oil (UNII: T5L8T28FGP)	
Hexamethyldisiloxane (UNII: D7M4659BPU)	
Aminomethylpropanol (UNII: LU49E6626Q)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Aloe vera leaf (UNII: ZY81Z83H0X)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
Cetostearyl alcohol (UNII: 2DMT128M1S)	
Polysorbate 60 (UNII: CAL22UVI4M)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72102-047-06	177 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2018	
2	NDC:72102-047-18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	06/01/2018	

Labeler - Makéta™ Sunscreen Lotion with Aloe Vera SPF 30 (081031516)

Establishment

Name	Address	ID/FEI	Business Operations
BMC 1092, Inc. dba Solo Laboratories, Inc		078831987	MANUFACTURE(72102-047) , LABEL(72102-047)

