DERMA BRILLIANCE SUNSCREEN SPF 30- octinoxate, oxybenzone, octisalate, avobenzone and octocrylene cream
Allure Labs, Inc

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 Ingredients:

Octinaxate - 7.5%

Oxybenzone - 6.0%

Octisalate - 5.0%

Avobenzone - 2.0%

Octocrylene - 1.5%

Purpose: Sunscreen

Uses:
- This product is suited for broad spectrum UV protection.

Warnings:
- For external use only.

- Keep out of eyes.
- If, contacts occurs rinse with water.

Discontinue use if irritation or redness occurs.

Consult a doctor if sever irritation occurs.

Directions:
- Apply using fingertips 20-30 minutes before exposure to the sun.
- Gently massage into face and neck.
- Reapply as needed.

Water, Alkyl(C12-15) Benzoate, Butylene Glycol, Octyldodecyl Neopentanoate, Hyaluronate Sodium, Kiwi Fruit, Medium chain Triglycerides, Green Tea Leaf, Teprenone, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Cyclomethicone 5, Cyclomethicone 6, Algae Extract, Artemisia Vulgaris Root, Centella Asiatica, Echinacea Purpurea, Lauryl Methacrylate / Glycol Dimethacrylate, Crosspolymer, Carbomer, Yeast Polysaccharides, Triethanolamine,Acrylate/C10-30 Alkyl Acrylate Crosspolymer, Polyethylene Glycol 400, Tocopherol, Ascorbyl Palmitate, Ascorbic Acid, Citric Acid Monohydrate, Sorbitan Mono Oleate, Polysorbate 20, Palmitoyl Pentapeptide-4, Darutoside, Glycerin, Polygonum Aviculare Top, Arctostaphylos UVA-URSI Leaf, Mitracarpus Scaber Extract, Plankton Extract, Egg Phospholipids, Micrococcus Lysate, Arabidopsis Thaliana, Ubidecarenone, Edetate Disodium, Aloe Vera Leaf.

Distributed by:

ICTV, 150 Stewart Parkway,

Greensboro, GA 30642 USA 77 Humberline Drive, Toronto,

Ont, Canada M9W0B6.

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62742-4073
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
KIWI FRUIT (UNII: 71ES77LGJC)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TEPRENONE (UNII: S8S8451A4O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
UBIDECARENONE (UNII: EJ27X76M46)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Trolamine (UNII: 9O3K93S3TK)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4073-1	28.3 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/17/2015	

Labeler - Allure Labs, Inc (926831603)

Revised: 3/2015 Allure Labs, Inc