

**SRB 3 LIGHTING WHITE SUN- octinoxate, octisalate, avobenzone cream
CASINBIO 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.

ACTIVE INGREDIENT

Active Ingredient: Ethylhexyl Methoxycinnamate 7.50%, Ethylhexyl Salicylate 5.00%, Butyl Methoxydibenzoylmethane 3.00%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Butylene Glycol, Caprylic/Capric Triglyceride, Phenylbenzimidazole Sulfonic Acid, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Niacinamide, Cetearyl Alcohol, Methyl Methacrylate Crosspolymer, Cyclopentasiloxane, Glyceryl Stearate, Cetearyl Oliviate, Glycerin, Sorbitan Oliviate, Oryza Sativa (Rice) Bran Extract, Sodium Hydroxide, Cyclohexasiloxane, Nylon-12, Polyacrylate-13, Sorbitan Stearate, Dimethicone, PEG-100 Stearate, Caprylyl Glycol, Polyisobutene, Ethylhexylglycerin, Tocopheryl Acetate, Fragrance, Disodium EDTA, Dextrin, 1,2-Hexanediol, Polysorbate 20, Sorbitan Isostearate, BHT, Citrus Aurantifolia (Lime) Flower Extract, Prunus Persica (Peach) Flower Extract, Propylene Glycol, Pyrus Malus (Apple) Flower Extract, Ananas sativus (pineapple) fruit Extract, Actinidia Chinensis (Kiwi) Fruit Extract, Alchemilla Vulgaris Extract, Arnica Montana Flower Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Adansonia Digitata Seed Extract, Equisetum Arvense Extract, Olea Europaea (Olive) Leaf Extract, Punica Granatum Flower Extract, Prunus Avium (Sweet Cherry) Flower Extract, Citrus Aurantium Dulcis (Orange) Flower Extract, Sophora Japonica Flower Extract, Fructan, Phenoxyethanol

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. If the following side effects occur, immediately discontinue use. Before resuming use, consult a dermatologist as continual use may worsen symptoms. A) If red spots, swelling, itching, irritation, or other discomforts occur after using the product. B) If the above symptoms occur on the applied area after exposure to direct sunlight. 2. Do not use on open wounds or on areas of skin exhibiting signs of eczema or dermatitis. 3. Storage and handling precautions A) Keep product out of reach of infants and children. B) Ensure that lid is closed after use. C) Do not store in places subject to high or cold temperatures or under exposure to direct sunlight. D) Use care to avoid eye contact when using this product.

DESCRIPTION

How to use: Apply an appropriate amount to areas exposed to sunlight such as the face, neck, arms, legs, and spread evenly.

Recommended dosage: Spread an appropriate amount over areas exposed to sunlight such as the face, neck, arms, and legs

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 mg in 50 mL	
	OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.50 mg in 50 mL	
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.50 mg in 50 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	Water (UNII: 059QF0KO0R)			
	Butylene Glycol (UNII: 3XUS85K0RA)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70218-030-01	50 mL in 1 CARTON; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part352	10/01/2015	

Labeler - CASINBIO CO., LTD. (557830673)

Registrant - CASINBIO CO., LTD. (557830673)

Establishment

Name	Address	ID/FEI	Business Operations
CASINBIO CO., LTD.		557830673	repack(70218-030)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(70218-030)

Revised: 11/2015

CASINBIO CO., LTD.