

**BROAD SPECTRUM SPF 30 TROPICAL SUNSCREEN- broad spectrum spf 30 tropical
sunscren lotion**

Raining Rose, 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.

Active Ingredients

Avobenzone 3.0%

Homosalate 7.5%

Octisalate 5.0%

Octocrylene 2.5%

Oxybenzone 6.0%

Purpose

Sunscreen

Warnings

For external use only

Do not use

on damaged or broken skin.

Stop Use and ask a doctor if

Rash Occurs

When Using this Product

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

Keep out of reach of children

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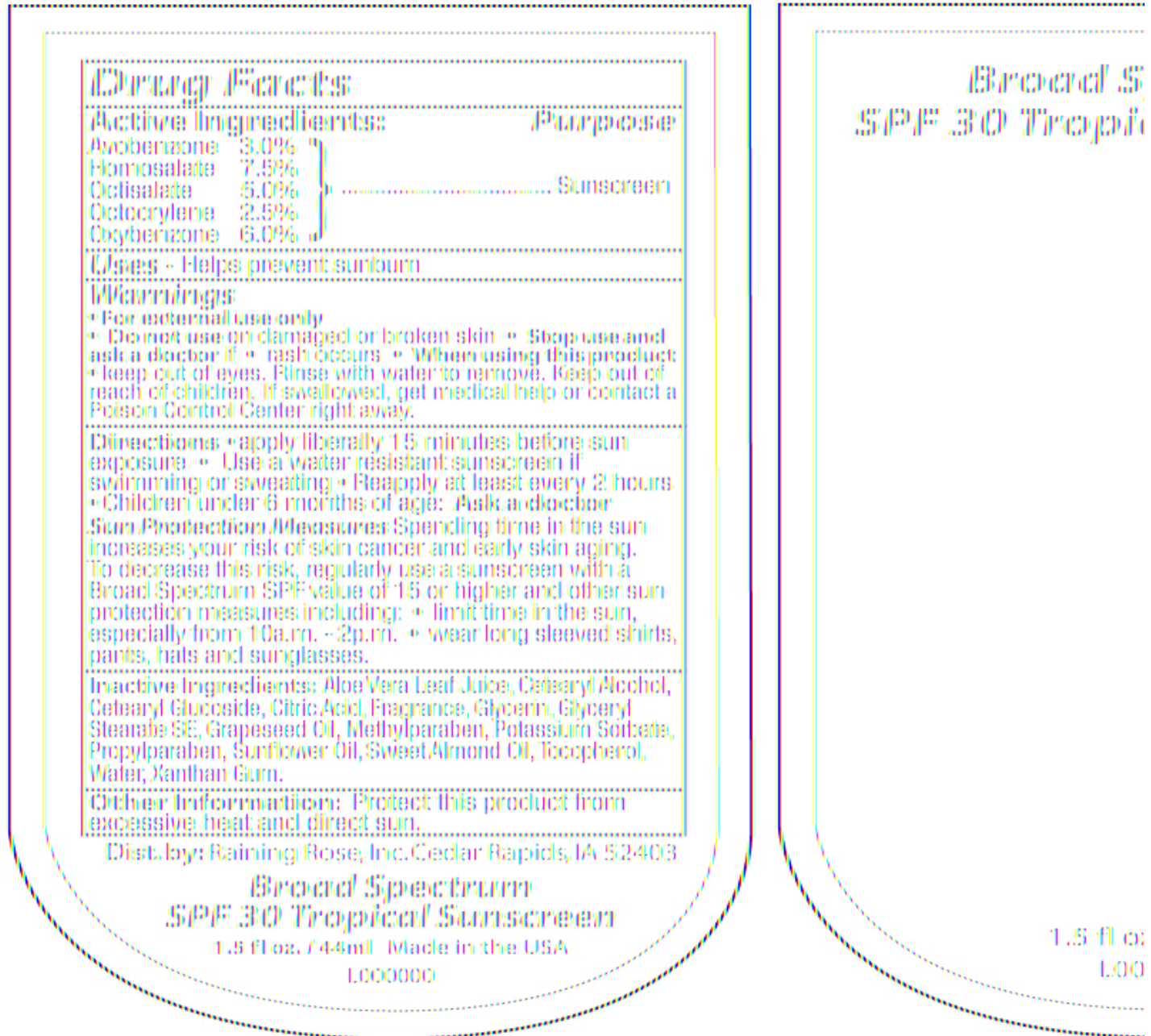
If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Inactive ingredients:

Aloe Vera Leaf Juice, Cetearyl Alcohol, Cetearyl Glucoside, Citric Acid, Fragrance, Glycerin, Glyceryl Stearate SE, Grapeseed Oil, Methylparaben, Potassium Sorbate, Propylparaben, Sunflower Oil, Sweet Amond Oil, Tocopherol, Water, Xanthan Gum.

Package Label



BROAD SPECTRUM SPF 30 TROPICAL SUNSCREEN

broad spectrum spf 30 tropical sunscreen lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0519
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2.64 g in 44 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	2.2 g in 44 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.32 g in 44 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.1 g in 44 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3.3 g in 44 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALMOND OIL (UNII: 66YXD4DKO9)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CETEARYL GLUCO SIDE (UNII: 09FUA47KNA)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0519-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/17/2020	

Labeler - Raining Rose, Inc (083819404)