

SKIN CRAVE BROAD SPECTRUM SPF30- spf30 broad spectrum sunscreen lotion lotion
Tropical Enterprises International 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.

Spf 30 Broad Spectrum Sunscreen - water based

Directions: Apply liberally and evenly 15 minutes before sun exposure.

Reapply every 2 hours as needed, after 40 minutes of swimming or sweating, or immediately after towel drying.

Inactive Ingredients:

Water, Polyester-7, Neopentyl Glycol Diheptanoate, Triethanolamine, Hypromellose, Acrylic Polymer, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben, Disodium EDTA

Uses: Helps prevent sunburn. If used as directed with other sun protection measures, decreases the risk of skin cancer and early aging caused by the sun.

Keep out of reach of children. If product is swallowed, seek immediate medical attention or contact a Poison Control Center right away.

Purpose: Sunscreen

WARNINGS:

For external use only.

When using this product avoid contact with eyes. If contact with eyes occurs, flush with water to remove.

Stop use and **ask a doctor** if irritation or rash develops and persists.

Keep out of reach of children. If product is swallowed, seek immediate medical attention or contact a Poison Control Center right away.

Active Ingredients:

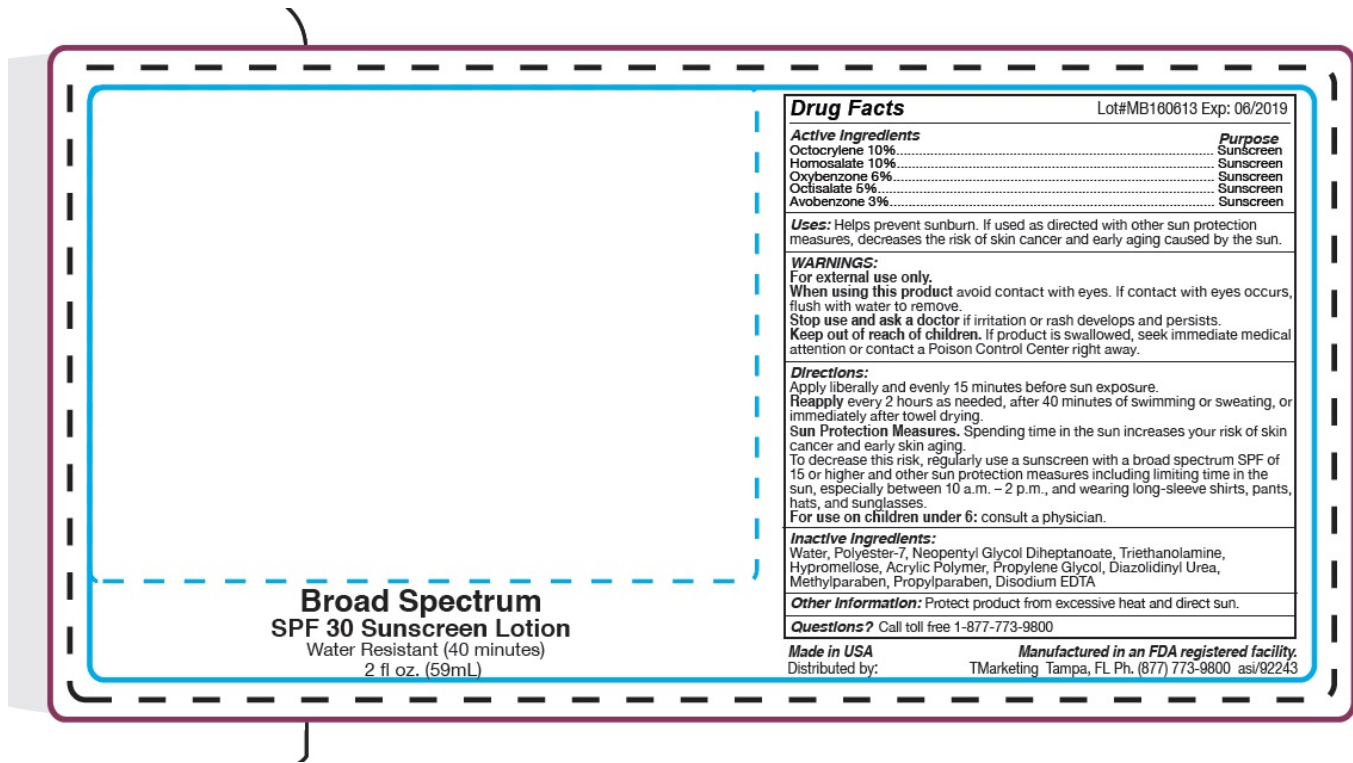
Octocrylene 10%

Homosalate 10%

Oxybenzone 6%

Octisalate 5%

Avobenzone 3%



SKIN CRAVE BROAD SPECTRUM SPF30

spf30 broad spectrum sunscreen lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-224
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
CUPRIC TRIETHANOLAMINE (UNII: 6NU949U74E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-224-10	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
2	NDC:58418-224-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
3	NDC:58418-224-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
4	NDC:58418-224-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
5	NDC:58418-224-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
6	NDC:58418-224-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
7	NDC:58418-224-28	3840 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
8	NDC:58418-224-08	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2012	

Labeler - Tropical Enterprises International Inc (091986179)

Registrant - Tropical Enterprises International Inc (091986179)

Revised: 12/2014

Tropical Enterprises International Inc