SKIN CRAVE SPF30 SUNSCREEN- spf30 sunscreen lotion (non-broad spectrum) 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.

Spf30 Sunscreen lotion (non broad spectrum)

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

Reapply every 2 hours as needed, after 40 minutes of swimming or sweating, or immedaitely after towel dry9ing.

For use on children under 6 months: consult a physician

Inactive Ingredients: Acrylic Polymer, Diazolidinyl Urea, Disodium EDTA, Hypromellose, Methylparaben, Propylene Glycol, Propylparaben, PPG-15 Stearyl Ether Benzoate, Triethanolamine, Water

Uses: Helps prevent sunburn.

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

Purpose:

Sunscreen

Active Ingredients:

Octocrylene 7%, Octinoxate 6.5%

Oxybenone 5.5 %, Octisalate 4%

WARNINGS: **Skin Cancer/ Sking Aging Alert:** Spending time in the sun

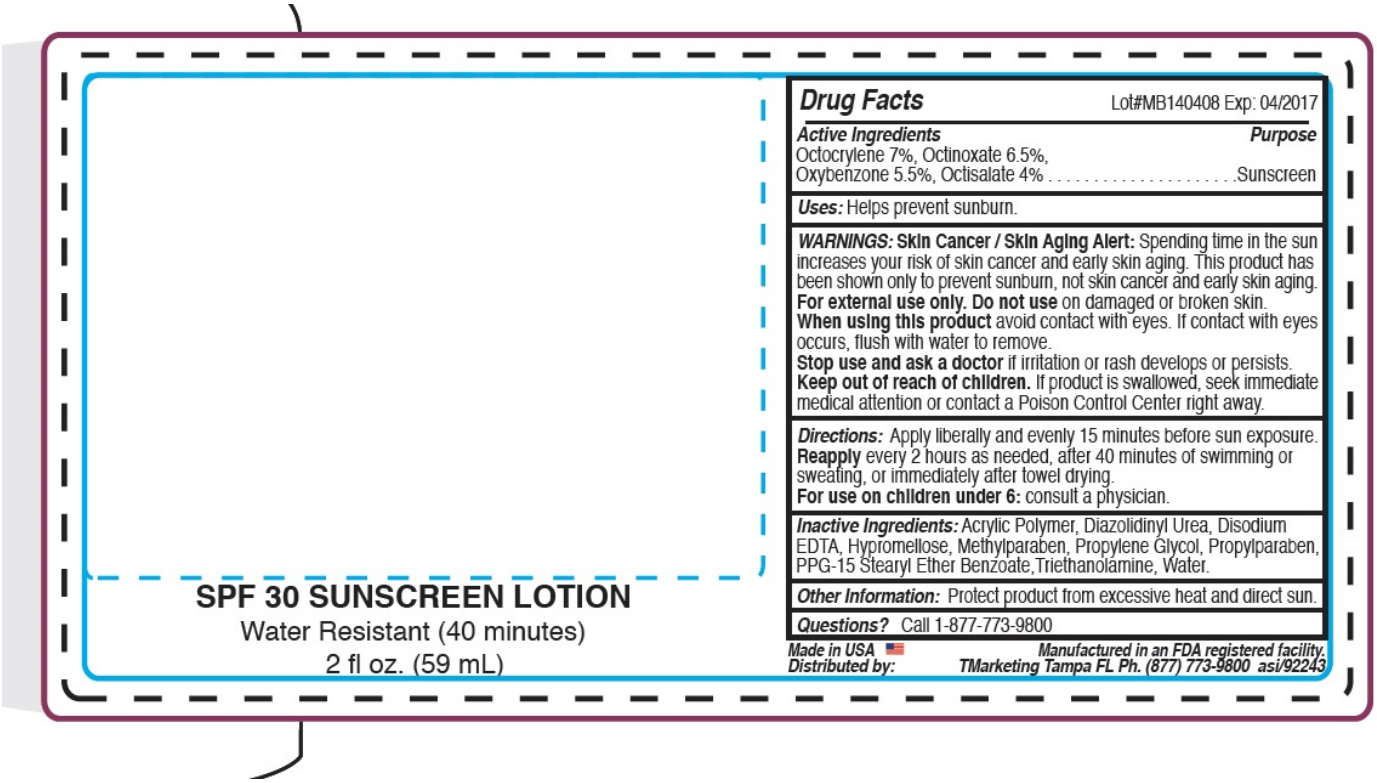
increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer and early skin aging.

For external use only. Do not use on damaged or broken skin.

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 or persists.

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



SKIN CRAVE SPF30 SUNSCREEN

spf30 sunscreen lotion (non-broad spectrum) lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58418-223
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	4 mg in 1 mL
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	5.5 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	7 mg in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PPG-15 STEARYL ETHER BENZOATE (UNII: 80D2J6361M)	
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:58418-223-10	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012	
2	NDC:58418-223-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
3	NDC:58418-223-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
4	NDC:58418-223-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
5	NDC:58418-223-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2012	
6	NDC:58418-223-80	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
7	NDC:58418-223-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
8	NDC:58418-223-16	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
9	NDC:58418-223-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012	
10	NDC:58418-223-28	3840 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.