

SS-TMPFL- bs spf30 spray - dl spray
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 BROAD SPECTRUM SPRAY
FORMULA #SS-TMPFL

DOSAGE AND ADMINISTRATION

Directions: Apply liberally and evenly 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying, **AND** at least every 2 hours.

Inactive Ingredients: Alcohol Denatured, Sorbeth-2 Hexaoleate, Acrylates/, Octylacrylamide Copolymer

Other Information:

Protect product from excessive heat and direct 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: Skin Cancer/Skin 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.

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

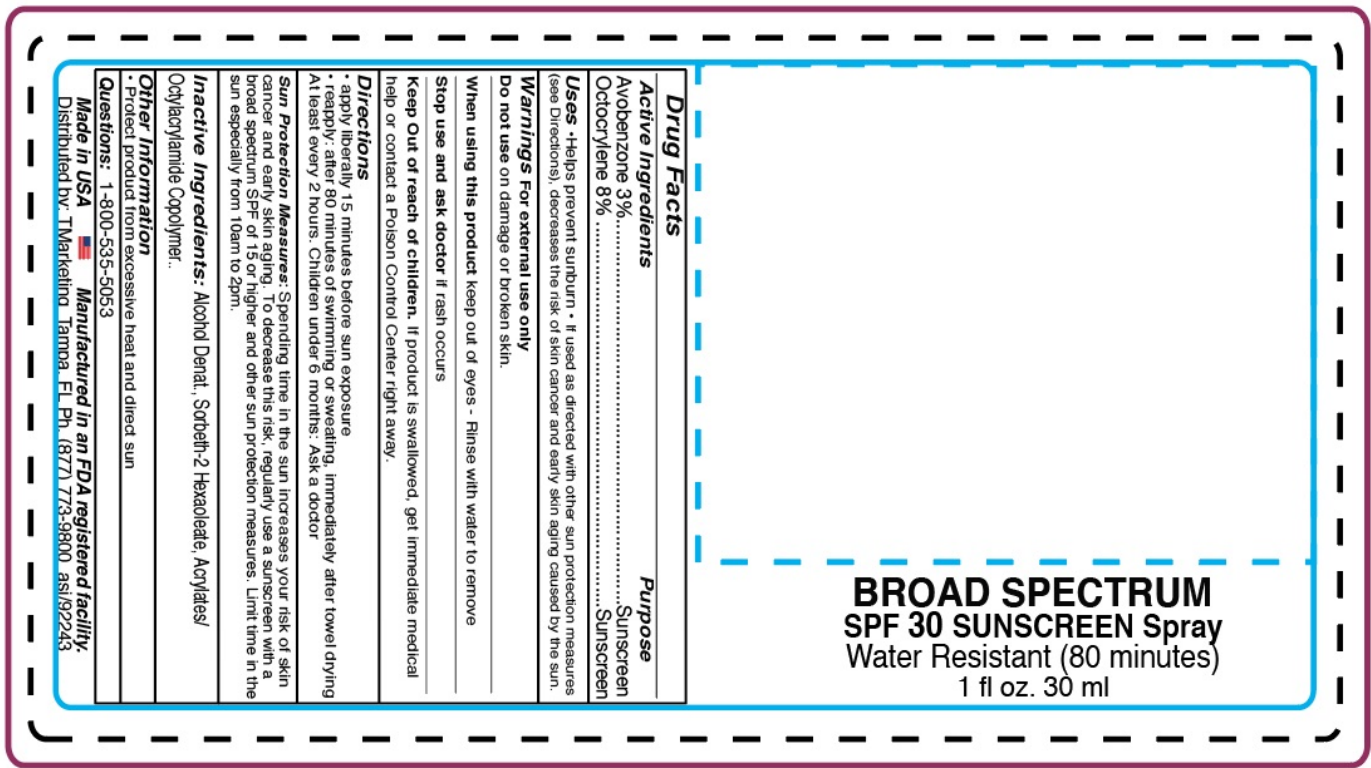
Stop use and ask a doctor if irritation or rash develops and persists.

Active Ingredients

Avobenzone 3%

Octocrylene 8%

Questions? Call



SS-TMPFL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.98 g in 30 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.7425 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)	
SORBETH-12 HEXAOLEATE (UNII: F3ECF77W74)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	Score
white	
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-001-10	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/01/2018	
2	NDC:58418-001-01	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/01/2018	
3	NDC:58418-001-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/01/2018	
4	NDC:58418-001-04	120 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/01/2018	
5	NDC:58418-001-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018	
6	NDC:58418-001-08	240 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/01/2018	
7	NDC:58418-001-16	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018	
8	NDC:58418-001-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018	
9	NDC:58418-001-28	3840 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018	
10	NDC:58418-001-70	211200 mL in 1 DRUM; Type 0: Not a Combination Product	10/01/2018	
11	NDC:58418-001-32	1228800 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	10/01/2018	
12	NDC:58418-001-25	960000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2018	

Labeler - Tropical Enterprises International, Inc. (091986179)**Registrant** - Tropical Enterprises International, Inc. (091986179)**Establishment**

Name	Address	ID/FEI	Business Operations
Tropiical Enterprises International, Inc.		091986179	manufacture(58418-001) , label(58418-001) , pack(58418-001)

Revised: 3/2020

Tropical Enterprises International, Inc.