2000DL-CL30T- spf30 bs tropical lotion Tropical Enterprises International, Inc.

Tropical scented SPF30 BROAD SPECTRUM LOTION FORMULA #2000-DL-CL30V Oxybenzone free/Octinoxate free

Active Ingredients:

Avobenzone 3%

Octocrylene 8%

Purpose:

Sunscreen

Uses: Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk

of skin cancer and early skin aging caused by the sun.

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.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If product is swallowed, get immediate medical help or contact a Poison Control Center

right away.

Directions:

- apply liberally 15 minutes before sun exposure
- reapply:

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

Inactive Ingredients: Water, Acrylates/C10-30, Alkyl Acrylate cross polymer, Stearic Acid, Glyceryl Monostearate, Bis-Octyldodecyl Dimer Dillinoleate/Propanediol Copolymer, Sorbeth-2-Hexaoleate, Phenoxylethanol, Ethylhexylglycerin, Triethanolamine, Disodium EDTA.

^{*}after 80minutes of swimming or sweating * immediately after towel drying

^{*}at least every 2 hours

^{*}children under 6 months: Ask a doctor

^{*}Protect product from excessive heat and direct sun



2000DL-CL30T

spf30 bs tropical lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	2.34 g in 30 mL		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.9 g in 30 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
WATER (UNII: 059QF0KO0R)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
SORBETH-12 HEXAOLEATE (UNII: F3ECF77W74)				
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				

CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	

Product Characteristics			
Color	white (white to off-white)	Score	
Shape		Size	
Flavor	TROPICAL FRUIT PUNCH	Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:58418-004- 06	177 mL in 1 TUBE; Type 0: Not a Combination Product	10/02/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2023	

Labeler - Tropical Enterprises International, Inc. (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tropical Enterprises International, Inc.		035229882	manufacture(58418-004)	

Revised: 1/2024 Tropical Enterprises International, Inc.