2000DL-CL30- promo spf30 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 BROAD SPECTRUM LOTION FORMULA #2000-DL-CL30 Oxybenzone free/Octinoxate free

Directions:

- apply liberally 15 minutes before sun exposure
- reapply:

*after 80minutes of swimming or sweating * immediately after towel drying

*at least every 2 hours

*children under 6 months: Ask a doctor

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.

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.

Purpose:

Sunscreen

Active Ingredients:

Avobenzone 3%

Octocrylene 8%

<u>WARNINGS</u>: 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.

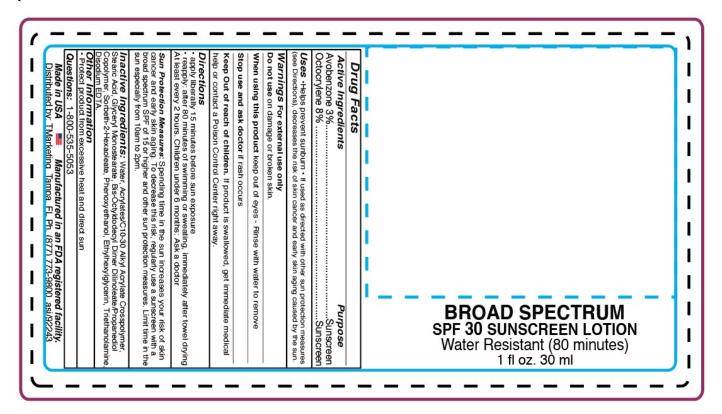
When using this product keep out of eyes. Rinse with water to remove.

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.

*Protect product from excessive heat and direct sun



2000DL-CL30

promo spf30 lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-002
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		
WATER (UNII: 059QF0KO0R)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
SORBETH-12 HEXAOLEATE (UNII: F3ECF77W74)			
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TROLAMINE (UNII: 903K93S3TK)			

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:58418-002- 06	177 mL in 1 TUBE; Type 0: Not a Combination Product	10/01/2018	

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	
Tropical Enterprises International, Inc.		091986179	manufacture(58418-002)	

Revised: 8/2023 Tropical Enterprises International, Inc.