## 2000DL-CL30- promo spf30 lotion Tropical Enterprises International, Inc.

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# Promo SPF30 BROAD SPECTRUM LOTION FORMULA #2000-DL-CL30 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:

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

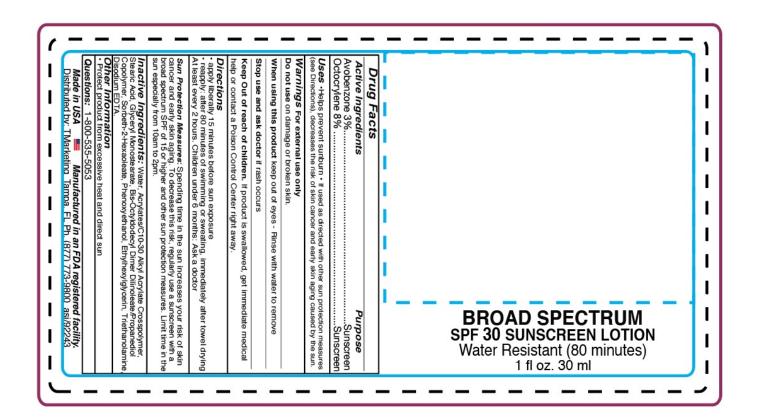
Inactive Ingredients: Water, Acrylates/C10-30, Alkyl Acrylate cross polymer, Stearic Acid, Glyceryl Monostearate, Bis-Octyldodecyl Dimer Dillinoleate/Propanediol Copolymer, Sorbeth-2-Hexaoleate, Phenoxylethanol, Ethylhexylglycerin, Triethanolamine, Disodium EDTA.

\*Protect product from excessive heat and direct sun

Questions: 1-877-773-9800

<sup>\*</sup>at least every 2 hours

<sup>\*</sup>children under 6 months: Ask a doctor



#### 2000DL-CL30

promo spf30 lotion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58418-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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			

Pā	Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58418- 002-10	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/01/2018		
2	NDC:58418- 002-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018		
3	NDC:58418- 002-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018		
4	NDC:58418- 002-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018		
5	NDC:58418- 002-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018		
6	NDC:58418- 002-80	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018		
7	NDC:58418- 002-12	360 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018		
8	NDC:58418- 002-16	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018		
9	NDC:58418- 002-64	1920 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018		
10	NDC:58418- 002-28	3840 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2018		
11	NDC:58418- 002-00	1.5 mL in 1 PACKET; Type 0: Not a Combination Product	02/02/2020		
12	002-70	211200 mL in 1 DRUM; Type 0: Not a Combination Product	02/02/2020		
	002-32	40960 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	02/02/2020		
	NDC:58418- 002-15	45 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/02/2020		
15	NDC:58418- 002-18	52 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/02/2020		
16	002-55	30 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/02/2020		
17	NDC:58418- 002-25	960000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/24/2020		
18	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 Drug	M020	10/01/2018	

## Labeler - Tropical Enterprises International, Inc. (091986179)

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

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Tropical Enterprises International, Inc.		035229882	manufacture(58418-002)	

Revised: 4/2024 Tropical Enterprises International, Inc.