

**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.*

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**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, Phenoxyethanol, 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%

**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.

\*Protect product from excessive heat and direct sun

Questions or comments? Call toll free 1-800-535-5053

**BROAD SPECTRUM  
SPF 30 SUNSCREEN LOTION**  
 Water Resistant (80 minutes)  
 1 fl oz. 30 ml

|  |   |
|--|---|
| <b>Drug Facts</b>  | <b>Purpose</b>  |
| <b>Active Ingredients</b>  | Avobenzone 3%.....Sunscreen<br>Octocrylene 8%.....Sunscreen |
| <b>Uses</b> -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.  |   |
| <b>Warnings For external use only</b><br>Do not use on damage or broken skin.  |   |
| When using this product keep out of eyes - Rinse with water to remove  |   |
| Stop use and ask doctor if rash occurs   |   |
| Keep Out of reach of children. If product is swallowed, get immediate medical help or contact a Poison Control Center right away.  |   |
| <b>Directions</b><br>• apply liberally 15 minutes before sun exposure<br>• reapply: after 80 minutes of swimming or sweating, immediately after towel drying<br>At least every 2 hours. Children under 6 months: Ask a doctor  |   |
| <b>Sun Protection Measures:</b> Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures. Limit time in the sun especially from 10am to 2pm. |   |
| <b>Inactive Ingredients:</b> Water, Acrylates/C10-30 Alkyl Acrylate Copolymer, Stearic Acid, Glycerin Monostearate, Bis-Octyldodecyl Dimer Dilinoleate/Propanediol Copolymer, Sorbeth-2-Hexaoleate, Phenoxyethanol, Ethylhexylglycerin, Triethanolamine Disodium EDTA                              |   |
| <b>Other Information</b><br>• Protect product from excessive heat and direct sun   |   |
| <b>Questions:</b> 1-800-535-5053   |   |

Made in USA Manufactured in an FDA registered facility.  
 Distributed by: Markelino Tampa, FL Ph. (877) 773-9800 asf/92243

## 2000DL-CL30

promo spf30 lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58418-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength        |
|---|-------------------|-----------------|
| <b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | Octocrylene       | 2.34 g in 30 mL |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 0.9 g in 30 mL  |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)                                    |          |
| <b>SORBETH-12 HEXAOLEATE</b> (UNII: F3ECF77W74)   |          |
| <b>BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER</b> (UNII: TY3J98ZR7R)      |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |          |
| <b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L) |          |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)  |          |
| <b>TROLAMINE</b> (UNII: 9O3K93S3TK)   |          |

**GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4)

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### 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.