

2000DL-CL30V- spf30 bs vanilla 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.

vanilla scented SPF30 BROAD SPECTRUM LOTION
FORMULA #2000-DL-CL30V
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

Sun Protection For All Ages

IceCream[®]
SUNSCREEN



SPF
30
STAY COOL
AND PROTECTED

Vanilla

UVA/UVB Protection
Broad Spectrum Sunscreen SPF 30
Water and Sweat Resistant 80 Minutes
6 oz. 177 ml

Reef-Friendly
Sulfate-Free
Animal Cruelty Free

Drug Facts

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Avobenzene 3%	Sunscreen
Octocrylene 8%	Sunscreen

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- Reapply:
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 - immediately after towel drying
 - at least every 2 hours
- Children under 6 months: Ask a doctor

Inactive Ingredients: Water, Glyceryl Stearate, Bis-Octyldodecyl Dimer Dilinoleate/Propanediol Copolymer, Sorbeth 2 Hexaoleate, Stearic Acid, Palmitic Acid, Phenoxyethanol, Triethanolamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ethylhexylglycerin, Disodium EDTA, Lauric Acid, Myristic Acid, Vanilla Fragrance.

Other Information: Protect product from excessive heat and direct sun.

Questions: 1-877-773-9800

Manufactured in an FDA registered facility.

Made in USA

Manufactured for and distributed by:
Rim Enterprises, LLC
Boca Raton, Florida
icecreamsunscreen.com



2000DL-CL30V

spf30 bs vanilla lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58418-003
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: 9O3K93S3TK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	

Product Characteristics

Color	white (white to off-white)	Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58418-003-06	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 not final	part352	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.		091986179	manufacture(58418-003)

Revised: 8/2023

Tropical Enterprises International, Inc.