

**HOOK YA SPF 50 SPORT SUNSCREEN- titanium dioxide, zinc oxide lotion
Prime Enterprises, 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.

Hook Ya Sport Mineral Sunscreen Lotion SPF 50

Active Ingredients

Titanium Dioxide 4%

Zinc Oxide 4%

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

For external use only

Do not use

on damaged or broken skin

When using this product

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash occurs

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

apply liberally 15 minutes before sun exposure

reapply

after 80 minutes of swimming or sweating

immediately after towel drying

at least every two hours

Sun Protection Measures. 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 including:

limit time in the sun, especially from 10 a.m. - 2 p.m.

wear long-sleeve shirts, pants, hats and sunglasses

children under 6 months: ask a doctor

Inactive Ingredients

Acrylates/C12-22 Alkyl Methacrylate Copolymer, Allantoin, Alumina, Aluminum Starch Octenylsuccinate, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Ethylhexylglycerin, Glycerin, Hexyl Laurate, Isotridecyl Isononanoate, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Sodium Chloride, Stearic Acid, Tocopheryl Acetate, Trimethylsiloxysilicate, Water

Other Information

protect this product from excessive heat and direct sun

Questions or Comments?

Call 1-877-667-9490

Hook Ya Sport Mineral Sunscreen Lotion SPF 50

HOOK YA

SPORT MINERAL SUNSCREEN LOTION



50
SPF

**REEF SAFE
BAIT SAFE
BOAT SAFE**

Comfortable and Ultra Light Finish
Developed by an Outdoorsman
Fragrance Free & Non-Greasy
Water Resistant 80 Minutes
Broad Spectrum SPF 50



3 Fl. Oz. (89 mL)

Distributed by HookYa, LLC • HookYaProducts.com • Saint Augustine, FL 32084

Drug Facts	
Active Ingredients	Purpose
Titanium Dioxide 4%	Sunscreen
Zinc Oxide 4%	
Uses	
<ul style="list-style-type: none"> 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	
For external use only	
Do not use on damaged or broken skin	
When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours Sun Protection Measures. 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 including: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. – 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses children under 6 months: Ask a doctor 	
Inactive ingredients	
Acrylates/C12-22 Alkyl Methacrylate Copolymer, Allantoin, Alumina, Aluminum Starch Octenylsuccinate, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Ethylhexylglycerin, Glycerin, Hexyl Laurate, Isotridecyl Isononanoate, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Sodium Chloride, Stearic Acid, Tocopheryl Acetate, Trimethylsiloxyethylsilicate, Water	
Other information	
protect this product from excessive heat and direct sun	
Questions or comments?	
Call 1-877-887-8456	



Made in USA from U.S. and imported ingredients

HOOK YA SPF 50 SPORT SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0585
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	43.6 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	43.6 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOTRIDECYL ISONONANOATE (UNII: WEF51750MT)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Product Characteristics

Color	white (White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0585-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/09/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/09/2022	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprise, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0585) , manufacture(58443-0585) , analysis(58443-0585) , pack(58443-0585)

Revised: 11/2022

Prime Enterprises, Inc.