

BODY MERRY SPF 15 SUNSCREEN CREAM- octinoxate, zinc oxide lotion

Body Merry, LLC

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.

Body Merry SPF 50 Sunscreen Cream

Active Ingredients

Octinoxate 7.5%

Zinc Oxide 9.5%

Purpose

Sunscreen

Warnings

- For external use only.
- Do not use on broken or damaged skin
- When using this product, keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash or irritation occurs or lasts.
- If swallowed, seek medical help or contact a poison control center right away.
- Keep out of reach of children.

Directions

Apply every morning as a daily moisturizer. Apply generously and evenly 15 minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating. Children under six months of age: consult a doctor before use.

Other Information

Protect the product in this container from excessive heat.

Uses:

Helps prevent sunburn. Higher SPF gives more sunburn protection. If used as directed with other sun protection measures (see Sun Alert) decreases the risk of skin cancer and early skin aging caused by the sun.

Sun Alert: 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 value of 15 or higher and other sun protection measures such as limited time in the sun, especially from 10 a.m. to 2 p.m. Wear long pants, hats, sunglasses, and long-sleeve shirts.

Inactive Ingredients:

Water, Cocos Nucifera (Coconut) Oil, Carthamus Tinctorius (Safflower) Seed Oil, Cetyl Alcohol, Caprylic/Capric Triglyceride, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Titanium Dioxide, Polyglyceryl-3 Beeswax, Polyglyceryl-6 Distearate, Jojoba Esters, Polyhydroxystearic Acid,

Carbomer, *CO Glycerin, Sodium Hydroxide, Thymus Vulgaris (Thyme) Leaf Extract, Rosa Canina Fruit Extract, Gardenia Florida Fruit Extract, Fucus Vesiculosus Extract, *CO Carum Petroselinum (Parsley) Extract, *CO Centella Asiatica Leaf Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Daucus Carota Sativa (Carrot) Root Extract, *CO Euphrasia Officinalis Extract, Benzyl Alcohol, Disodium EDTA, Dehydroacetic Acid

Warning

Keep out of reach of children.



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73428-1002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.095 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

WATER (UNII: 059QF0KO0R)

COCONUT OIL (UNII: Q9L0O73W7L)

SAFFLOWER OIL (UNII: 65UEH262IS)

CETYL ALCOHOL (UNII: 936JST6JCN)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73428-1002-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	11/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/14/2019	

Labeler - Body Merry, LLC (085595190)

Registrant - Body Merry, LLC (085595190)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(73428-1002)

Revised: 11/2019

Body Merry, LLC