

**NAPLES COMPANY - SUNSCREEN BROAD SPECTRUM SPF 25 LIGHTWEIGHT
FACE- octinoxate and zinc oxide lotion
Cosmetic Solutions 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.

Naples Soap Company - Sunscreen Broad Spectrum SPF 25 Lightweight Face Cream

Drug Facts

Active Ingredients	Purpose
Octinoxate (7.0%)	Sunscreen
Zinc Oxide (6.0%)	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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply to all skin exposed to the sun
- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 2 hours 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 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-sleeved shirts, pants, hats and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

Water, Isocetyl Stearate, Cetyl Dimethicone, Styrene/Acrylates Copolymer, Sorbitol, Ethyl Macadamiate, Cetearyl Alcohol, Dimethicone, Acrylates/Dimethicone Copolymer, Phenoxyethanol, Glyceryl Stearate, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-100 Stearate, Cetareth-20, Ethylhexyl Salicylate, VP/Eicosene Copolymer, Xanthan Gum, Polymethyl Methacrylate, Caprylyl Glycol, Coconut (Cocos Nucifera) Oil, Ethylhexylglycerin, Vaccinium Vitis-Idaea Fruit Extract, Cork Oak (Quercus Suber) Bark Extract, Triethoxycaprylylsilane, Tea Plant (Camellia Sinensis) Leaf Extract, Disodium EDTA, Tocopheryl Acetate, Oak (Quercus) Root Extract, Gotu Kola (Centella Asiatica) Extract, Knotweed (Polygonum Aviculare) Extract, Citric Acid, Gluconolactone, Isomalt, Calcium Gluconate, Lecithin, Grape (Vitis Vinifera) Fruit Cell Extract, Sodium Benzoate, Garden Cress (Lepidium Sativum) Sprout Extract

Other Information

Protect this product from excessive heat and direct sunlight

Questions or Comments?

Questions? 1-888-256-8265 or visit www.naplessoap.com

Distributed by: Naples Soap Company • Naples, FL 33913

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

NAPLES
SOAP COMPANY

NATURALLY BETTER
SKIN CARE

SUNSCREEN

Broad Spectrum SPF 25

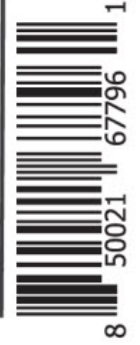
25

Lightweight
Face Cream

2 fl oz (60mL)



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NAPLES COMPANY - SUNSCREEN BROAD SPECTRUM SPF 25 LIGHTWEIGHT FACE

octinoxate and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-2603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isocetyl Stearate (UNII: 3RJ7186O9W)	
Sorbitol (UNII: 506T60A25R)	
Ethyl Macadamiate (UNII: ANA2NCS6V1)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Dimethicone (UNII: 92RU3N3Y1O)	

Phenoxyethanol (UNII: HIE492ZZ3T)
Glyceryl Monostearate (UNII: 230OU9XXE4)
Glycerin (UNII: PDC6A3C0OX)
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPAS at 1.5%) (UNII: 86FQE96TZ4)
PEG-100 Stearate (UNII: YD01N1999R)
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWJY)
Octisalate (UNII: 4X49Y0596W)
Xanthan Gum (UNII: TTV12P4NEE)
Poly(Methyl Methacrylate; 450000 MW) (UNII: Z47NNT4J11)
Caprylyl Glycol (UNII: 00YIU5438U)
Ethylhexylglycerin (UNII: 147D247K3P)
Lingonberry (UNII: 0UNK9RZQ7X)
Quercus Suber Bark (UNII: 8R5219271Q)
Triethoxycaprylylsilane (UNII: LDC331P08E)
Green Tea Leaf (UNII: WZZU1RY8B0)
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)
Centella Asiatica Whole (UNII: 7M867G6T1U)
Polygonum Aviculare Top (UNII: ZCD6009IUF)
Citric Acid Monohydrate (UNII: 2968PHW8QP)
Gluconolactone (UNII: WQ29KQ9POT)
Isomalt (UNII: S870P55O2W)
Calcium Gluconate (UNII: SQE6VB453K)
Sodium Benzoate (UNII: OJ245FE5EU)
Garden Cress Sprout (UNII: PWQ18YNR62)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-2603-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	07/01/2022	

Labeler - Cosmetic Solutions LLC (807907928)