

**NAPLES COMPANY - SUNSCREEN BROAD SPECTRUM SPF 30 TINTED MINERAL FACE- titanium dioxide and zinc oxide cream**  
**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.*

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**Naples Soap Company - Sunscreen Broad Spectrum SPF 30 Tinted Mineral Face Cream**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide (7.75%)	Sunscreen
Zinc Oxide (10.0%)	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 (Aqua), Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/ Caprate, Aluminum Stearate, Carthamus Tinctorius Oleosomes, Polyhydroxystearic Acid, Aloe (Aloe Barbadensis) Leaf Juice, Knotweed (Polygonum Aviculare) Extract, Tocopheryl Acetate, Perilla (Perilla Frutescens) Extract, Grape (Vitis Vinifera) Fruit Cell Extract, Garden Cress (Lepidium Sativum) Sprout Extract, Squalane, Cetearyl Alcohol, Isononyl Isononanoate, Coco-Glucoside, Pentylene Glycol, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Jojoba (Simmondsia Chinensis) Seed Oil, Stearic Acid, Sucrose Stearate, Phenethyl Alcohol, Tetrahexyldecyl Ascorbate, Glyceryl Caprylate, Ethylene/Propylene/Styrene Copolymer, Sorbitan Oleate, Polyglyceryl-2 Caprate, Propanediol, Alumina, Arachidyl Alcohol, Iron Oxides (CI 77492, CI 77491, CI 77499)

## **Other Information**

Protect this product from excessive heat and direct sunlight

## **Questions or Comments?**

Questions? 1-888-256-8265 or visit [www.naplessoap.com](http://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 30

30

Tinted Mineral  
Face Cream

2 fl oz (60mL)

TINTED



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<b>Active Ingredients</b> Titanium Dioxide (7.75%) Zinc Oxide (10.0%)	<b>Purpose</b> Sunscreen 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</b> 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.	
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## NAPLES COMPANY - SUNSCREEN BROAD SPECTRUM SPF 30 TINTED MINERAL FACE

titanium dioxide and zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66163-0602
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	7.75 g in 100 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	10 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)	

<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)
<b>CARTHAMUS TINCTORIUS SEED OLEOSOMES</b> (UNII: 9S60Q72309)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>POLYGONUM AVICULARE TOP</b> (UNII: ZCD6009IUF)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>GARDEN CRESS SPROUT</b> (UNII: PWQ18YNR62)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35J00J)
<b>JOJOBA OIL</b> (UNII: 724GKU717M)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>SUCROSE STEARATE</b> (UNII: 274KW0050M)
<b>PHENYLETHYL ALCOHOL</b> (UNII: ML9LGA7468)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)
<b>POLYGLYCERYL-2 CAPRATE</b> (UNII: JX7WXJ41DH)
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-0602-1	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)