

**MINUS-SOL FACIAL SUN PROTECTION SUNSCREEN BROAD SPECTRUM SPF 30 PLUS WHITE - octinoxate, titanium dioxide, zinc oxide cream**

**Aledian Corporation**

*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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**Minus-Sol Facial Sun Protection Sunscreen Broad Spectrum SPF 30 Plus White**

**Drug Facts**

**Active ingredients**

Octyl Methoxycinnamate 4%  
Titanium Dioxide 5%  
Zinc Oxide 5%

**Purpose**

Sunscreen

**Use**

- 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 Poison Control Center right away.

**Directions:**

For sunscreen use

- Apply liberally 15 minutes before sun exposure
- Children under 6 months of age: Ask a doctor

- **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 value 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
- Reapply
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

#### **Other information**

- Protect the product in this container from excessive heat and direct sun

#### **Inactive ingredients**

ALUMINA, C9-15 FLUCROALCOHOL PHOSPHATES, CETYL PPG/PPG-10/1 DIMETHICONE, CHITOSAN, CYCLOPENTASILOXANE, DISOPROPYLOMER DUNCLEATE, DIMETHOCONEVINYL DIMETHICONE CROSSPOLYMER, HEXYL LAURATE, IRON OXIDE BLACK, IRON OXIDE RED, IRON OXIDE YELLOW METHYLPARABEN, FRAGRANCE, POLYGLYCERY-4 ISOSTEARATE, PROPYLPARABEN, PHEXACECENE COPOLYMER.

#### **Minus-sol**

Formulated with the newest technological advancement; this ultra-fine, light, silky smooth, very water resistant facial cream provides long-lasting double UV protection. It is an oil free formulation that contains an inactive ingredient (Enhanced Chitosan) which results in a smooth silky feeling.

Distributed by:  
Aledian Corporation  
Miami Beach, FL 33140 USA

Made in Thailand

To report a serious adverse event  
Contact:  
1.866.Minus.Sol

[www.MinusSol.com](http://www.MinusSol.com)

SPF 30+ Minus-Sol  
Facial Sun Protection Sunscreen Broad Spectrum SPF 30+  
Silky Smooth Cream Oil Free  
Water Resistant (80 Minutes)  
Dermatologically Tested  
White  
Net Wt. 1.76 oz (50g)

#### **Product Labels**



**Minus-Sol<sup>TM</sup>**

**Facial Sun Protection  
Sunscreen  
Broad Spectrum SPF 30+**

**Silky Smooth Cream  
Oil Free  
Water Resistant (80 Minutes)  
Dermatologically Tested**

**White**

Net Wt. 1.76 oz (50g)

**Minus-Sol**

**Active ingredients**

Octyl Methoxycinnamate 4%, Titanium Dioxide 2%, Zinc Oxide 5%

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**This Unit Not Labeled For Retail Sale  
This unit is packaged in an outer container. Please  
see outer container for drug facts information.**

			<p><b>Minus-Sol<sup>®</sup></b></p> <p>Formulated with the newest technological advancement; this ultra-fine, light, silky smooth, very water resistant facial cream provides long-lasting double UV protection. It is an oil free formulation that contains an inactive ingredient (Enhanced Chitosan) which results in a smooth silky feeling.</p>						
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octinoxate, titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68411-4057
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYGLYCERYL-4 ISO STEARATE</b> (UNII: 820DPX33S7)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68411-4057-3	1 g in 1 TUBE		
2	NDC:68411-4057-1	25 g in 1 TUBE		
3	NDC:68411-4057-2	50 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/22/2012	

**Labeler** - Aledian Corporation (140038410)

**Registrant** - Aledian Corporation (140038410)

### Establishment

Name	Address	ID/FEI	Business Operations
Pan Rajdhevee Group Public Company Limited		671668125	manufacture(68411-4057)

Revised: 3/2013

Aledian Corporation