# NEOVA DNA DAMAGE CONTROL - SILC SHEER BROAD SPECTRUM SPF 40- octinoxate, titanium dioxide, zinc oxide emulsion PhotoMedex, 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.

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### Neova DNA Damage Control - Silc Sheer SPF 40 - Drug Facts

# **Active Ingredients**

Octinoxate 3.0%, Titanium Dioxide 3.0%, Zinc Oxide 9.0%

## Purpose

Sunscreen

#### Uses

- Helps prevent sunburn
- If used as directed and with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin again 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:

- 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 of 15 or higher
  and other sun protection measures including:

#### **Inactive Ingredients**

<sup>°</sup>After 80 minutes of swimming or sweating.

<sup>°</sup>Immediately after towel drying.

<sup>°</sup>At least every two hours.

 $<sup>^{\</sup>circ}$ Limit time in the sun, especially from 10 a.m. - 2 p.m.

<sup>°</sup>Wear long-sleeve shirts, pants, hats, and sunglasses.

Alumina, Butylene Glycol, Citric Acid, Cyclopentasiloxane, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Ergothioneine, HDI/Trimethylol Hexyllactone Crosspolymer, Iodopropynl Butylcarbamate, Iron Oxides, Lauryl PEG-9 Polymethylsiloxyethyl Dimethicone, Lecithin, Methicone, Micrococcus Lysate, Plankton Extract, Purified Water, Silica, Sodium Chloride, Sodium Hydroxide, Triethoxycaprylylsilane.

#### Other Information

Protect this product from excessive heat and direct sun.

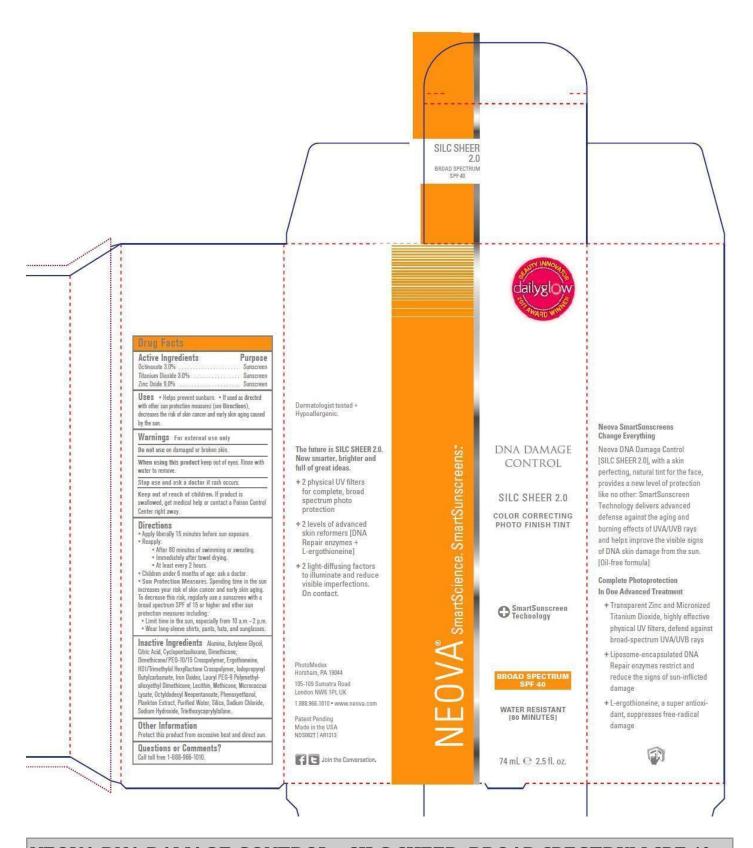
#### **Questions or Comments?**

Call toll free 1-888-966-1010.

Neova DNA Damage Control Silc Sheer SPF 40 2.5 fl. oz. (74 mL) label and box

DNADamageControl2-5ozSilcSheerLabel.jpg SILC SHEER 2.0 BROAD SPECTRUM SPF 40 SmartSunscreen Technology . Triggers a repair that helps defend against the visible consequences of photodamage. · Delivers high performance protection against the aging + burning effects of UVA/UVB rays. DNA DAMAGE CONTROL If used as directed with other sun protection measures, decreases the risk of skin cancer SILC SHEER 2.0 and early skin aging caused by the sun Directions: Apply every morning to face and neck. Apply liberally 15 minutes before PHOTO FINISH TINT sun exposure. Reapply: After 80 minutes of swimming or sweating; immediately after towel drying, at least every 2 hours WARNINGS: For external use only. SmartSunscreen Avoid contact with eyes. Do not use on damaged Technology or broken skin. Discontinue use if rash occurs. If rash persists, consult a doctor. Keep out of reach of children. Active Ingredients: Octinoxate 3.0%, Titanium Dioxide 3.0%, Zinc Oxide 9.0% BROAD SPECTRUM Key Performance Ingredients: DNA Repair SPF 40 Enzymes: Photolysomes, Endosomes; Antioxidant: L-ergothioneine. WATER RESISTANT PhotoMedex, Horsham, PA 190446 105-109 Sumatra Road, London NW6 1PL UK [80 MINUTES] 1.888.966,1010 \* www.negva.com Patent Pending 74 mL @ 2.5 fl. oz. NDS002T | AR1213

DNADamageControl2-5ozSilcSheerBox.jpg



# NEOVA DNA DAMAGE CONTROL - SILC SHEER BROAD SPECTRUM SPF 40

octinoxate, titanium dioxide, zinc oxide emulsion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62362-169	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 mL	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	3 g in 100 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALUMINUM O XIDE (UNII: LMI26 O 69 33)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
ERGO THIO NEINE (UNII: BDZ3DQM98W)		
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)		
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)		
EGG PHO SPHO LIPIDS (UNII: 1Z74184RGV)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)		

Packaging			
# Item Co	de Package Description	Marketing Start Date	Marketing End Date
1 NDC:62362-169	01 1 in 1 BOX		
1 NDC:62362-169	74 mL in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	10/08/2012		

# Labeler - PhotoMedex, Inc. (054503875)

Establishment				
Name	Address	ID/FEI	Business Operations	
Photo Medex, Inc.		054503875	manufacture(62362-169)	

Revised: 1/2014 PhotoMedex, Inc.