

NEOVA DNA DAMAGE CONTROL - SILC SHEER SPF 45 - octinoxate, titanium dioxide 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.

Neova DNA Damage Control - Silc Sheer SPF 45 - 2mL sample package insert

Directions for use:

Apply evenly to face. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied

in a 2.5 fl. oz. / 74 mL bottle.

Active Ingredients:

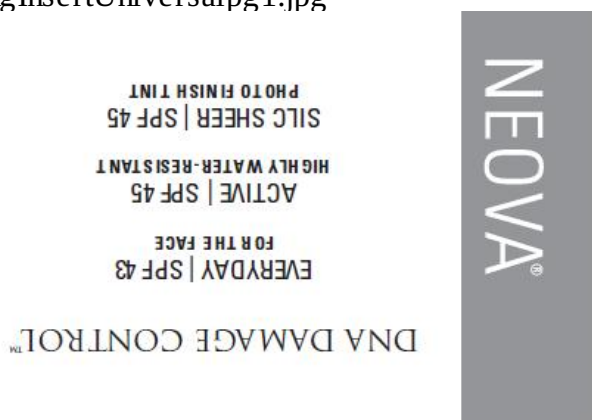
Titanium Dioxide 3.5%, Octinoxate 6.5%.

Inactive Ingredients:

Camellia Sinensis Leaf Extract,
Aloe Barbadensis Extract, Octyl Stearate, Cyclomethicone,
Isopropyl Palmitate, Helianthus Annuus (Sunflower)
Seed Oil, Lauryl PEG-9 Polydimethylsiloxyethyl
Dimethicone, Micrococcus Lysate, Plankton Extract,
Xanthophyll, Rosmarinus Officinalis (Rosemary) Leaf
Extract, Squalane, Lecithin, Silica, Hydrated Silica,
Microcrystalline Wax, Cetyl Dimethicone, Hydrogenated
Castor Oil, Sodium Chloride, Phenoxyethanol, Iodopropynyl
Butylcarbamate, Melanin, Caramel, Iron Oxides,
CI 77499, CI 77491, CI 77492.

Image of package insert, package, and pouch

PkgInsertUniversalpg1.jpg



PhotoMedex, Inc.
Montgomeryville, PA 18936
Made in the USA
Patent Pending

1.888.966.1010
www.neova.com

EVERYDAY | SPF 43 Reorder# NDE002
ACTIVE | SPF 45 Reorder# NDA003
SILC SHEER | SPF 45 Reorder# NDS002

6/11

- 1 Skin Care Foundation, www.skincancer.org, 2011.
- 2, 5, 8 Yarosh DB, Kibetel J, O'Connor A, et al. *DNA Repair Liposomes in Animagenesis*. *J Environ Pathol Toxicol Oncol*. 1997;16:287-292.
- 3, 6, 9 Stege, H., L. Roza, A.A. Vink, M. Grewe, T. Ruzicka, S. Grether-Beck and J. Krutmann. *Enzyme Plus Light Therapy to Repair DNA Damage in Ultraviolet-B-Irradiated Human Skin*. *Proc. Natl. Acad. Sci. USA*, February 15, 2000, Vol. 97, No. 4.
- 4, 7 Obayashi, K., K. Kurihara, Y. Okano, H. Masaki and D.B. Yarosh. *L-Ergothioneine Scavenges Superoxide and Singlet Oxygen and Suppresses TNF and MMP-1 Expression in UV-Irradiated Human Dermal Fibroblasts*. *J. Cosmet. Sci.* 56:17-27, 2005.

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More Than Just Protection

UV-inflicted damage is cumulative; its wounding effects on the skin's DNA account for nearly all the visible signs of aging and contribute to 90% of non-melanoma skin cancers.¹ Basic sunscreens help to prevent skin injury, but do nothing to correct damage.

Neova® SmartSunscreens™ Change Everything

Neova DNA Damage Control sunscreens provide **complete photoprotection**, repairing tissue at the cellular level—where DNA damage occurs—while protecting the skin from additional UV insults.

DNA DAMAGE CONTROL EVERYDAY | SPF 43

Description

An elegant, lightweight moisturizing physical sunscreen designed especially for daily photoprotection of the face, neck, décolletage and back of hands.

- Offers superior protection + repair in one advanced treatment
- Defends against broad-spectrum UVA/UVB rays
- Restricts and corrects sun-inflicted DNA damage in cells
- Provides hyper antioxidant defense
- Delivers oil-free hydration

Active Ingredients

Zinc Oxide, 7.5%. Micronized zinc oxide applies light and transparent to the skin, offering highly effective, broad spectrum UVA/UVB protection.

Octinoxate, 7.5%, Octisalate, 2.5%. Provides broad

Octinoxate, 7.5%, Octisalate, 3.0%. Provides broad spectrum UVA/UVB protection.

Key Performance Ingredients

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.⁵

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.⁵

L-ergothioneine. A powerful antioxidant that also blocks the activation of the two enzymes, elastase and matrix metalloproteinases (MMPs), which degrade collagen and elastin and destroy the skin's supporting structure, leading to wrinkle formation.⁷

Ascorbyl Palmitate (Vitamin C). An effective free radical-scavenging antioxidant which promotes skin health and vitality. It is also required for the manufacture of collagen, a protein that forms the basis of connective tissue—the most abundant tissue in the body.

Indications: DNA Damage Control [ACTIVE | SPF 45] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended for active lifestyles. Suitable for all skin types, even the most sensitive.

Directions for Use: Apply liberally to exposed skin every

spectrum UVA/UVB protection.

Key Performance Ingredients

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.²

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.³

L-ergothioneine. A powerful antioxidant that also blocks the activation of the two enzymes, elastase and matrix metalloproteinases (MMPs), which degrade collagen and elastin and destroy the skin's supporting structure, leading to wrinkle formation.⁴

Sodium Hyaluronate. A powerful humectant that deeply hydrates and binds up to 1,000 times its own weight in moisture, providing an immediate moisturizing boost.

Tocopheryl Acetate (Vitamin E). A natural antioxidant and moisturizer, reducing transdermal water loss and helping to maintain connective tissue. It is effective as a natural defense against harmful UV rays, preventing hyper-pigmentation and sun damage.

Ascorbyl Palmitate (Vitamin C). An effective free radical-scavenging antioxidant which promotes skin health and vitality. It is also required for the manufacture of collagen, a protein that forms the basis of connective tissue—the most abundant tissue in the body.

Indications: DNA Damage Control [EVERYDAY | SPF 43] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended daily, for all skin types, even the most sensitive.

Directions for Use: Apply every morning to face, neck and décolletage. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied in a 2.5 fl. oz. / 74 mL tube.

Active Ingredients: Zinc Oxide 7.5%, Octinoxate 7.5%, Octisalate 2.5%.

Inactive Ingredients: Water (Aqua), Isopropyl Palmitate, Octyl Stearate, Ethyl Hexyl Isononanoate, Cyclopentasiloxane, Cetearyl Glucoside, Micrococcus Lysate, Plankton Extract, L-ergothioneine, Dimethicone, Glycereth-26, Sodium Hyaluronate, Panthenol, Allantoin, Tocopheryl Acetate, Ascorbyl Palmitate (Vitamin C), Oleth-3 Phosphate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, PEG-7 Trimethylolpropane Coconut Ether, Lecithin, Polyether-1, Phenoxyethanol, Butylene Glycol, Citric Acid, Iodopropynyl Butylcarbamate, Triethoxycaprylylsilane.

DNA DAMAGE CONTROL

ACTIVE | SPF 45

Description

A rapidly-absorbing, highly water-resistant physical sunscreen for the face and body, ideal for everyday use and ultra-active wear.

- Offers superior protection + repair in one advanced treatment

two hours. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied in a 3.0 fl. oz. / 89 mL tube.

Active Ingredients: Zinc Oxide 8.0%, Octinoxate 7.5%, Octisalate 3.0%.

Inactive Ingredients: Water (Aqua), Cyclopentasiloxane, Ethyl Hexyl Isononanoate, Micrococcus Lysate, Plankton Extract, L-ergothioneine, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Lauryl PEG-9 Polymethylsiloxyethyl Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Retinyl Palmitate, Ascorbyl Palmitate (Vitamin C), Sodium Chloride, Phenoxyethanol, Butylene Glycol, Iodopropynyl Butylcarbamate, Citric Acid, Sodium Hydroxide.

DNA DAMAGE CONTROL

SILC SHEER | SPF 45

Description

A micronized physical sunscreen, with the cosmetic benefit of a skin-perfecting sheer tint for the face, that evens out skin tone. Perfect alone or as an under-makeup primer.

- Offers superior protection + repair in one advanced treatment
- Defends against broad-spectrum UVA/UVB rays
- Restricts and corrects sun-inflicted DNA damage in cells
- Residue-free, tinted matte finish
- Oil-free

Active Ingredients

Titanium Dioxide 3.5%. A highly effective physical sunscreen that defends against broad-spectrum UVA/UVB exposure.

Octinoxate 6.5%. Filters UVB rays.

Key Performance Ingredients

Endosomes. A liposome encapsulated extract from the marine microbe, *Micrococcus lysate*. Extremely UV-resistant, the extract contains the enzyme UV-endonuclease which intensifies the skin's ability to repair sun-inflicted DNA damage, speeding recovery reaction, and reducing the appearance of post-sunburn peeling.⁸

Photolysomes. A liposome encapsulated DNA repair enzyme, Photolyase derived from plankton, is hyper-efficient in its defense against high doses of solar UV and unique in its ability to undo DNA damage in cells and prevent cell death caused by UV.⁹

Antioxidant Complex. Green tea, Rosemary extracts and Lutein defend against free-radical damage.

Natural Aloe Vera Extract. Soothes skin while helping to hydrate and heal.

Indications: DNA Damage Control [SILC SHEER | SPF 45] is for guarding against broad spectrum UV rays and repairing the signs of photodamage.

Recommended daily, for all skin types, even the most sensitive.

Directions for Use: Apply evenly to face. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

Supplied in a 2.5 fl. oz. / 74 mL bottle.

Active Ingredients: Titanium Dioxide 3.5%, Octinoxate 6.5%.

Inactive Ingredients: Camellia Sinensis Leaf Extract, Aloe Barbadosis Extract, Octyl Stearate, Cyclomethi-

- Defends against broad-spectrum UVA/UVB rays
- Restricts and corrects sun-inflicted DNA damage in cells
- Provides hyper antioxidant defense
- Very water-resistant and sweat-resistant
- Oil-free

Active Ingredients

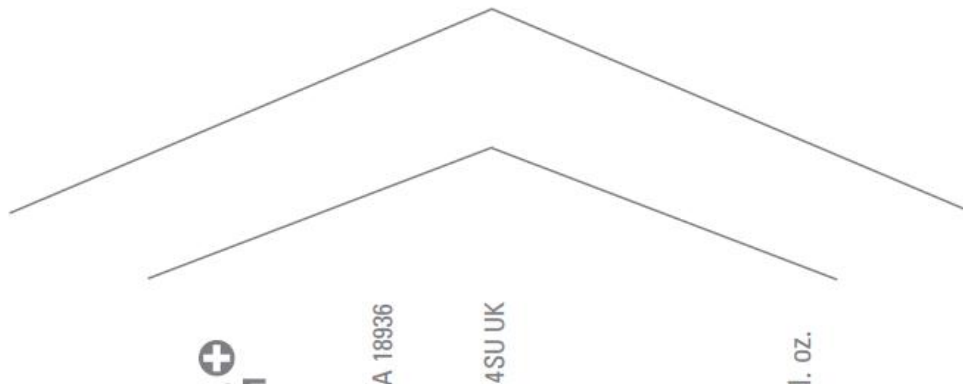
Zinc Oxide, 8.0%. Micronized zinc oxide applies light and transparent to the skin, offering highly effective, broad spectrum UVA/UVB protection.

cone, Isopropyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Micrococcus Lysate, Plankton Extract, Xanthophyll, Rosmarinus Officinalis (Rosemary) Leaf Extract, Squalane, Lecithin, Silica, Hydrated Silica, Microcrystalline Wax, Cetyl Dimethicone, Hydrogenated Castor Oil, Sodium Chloride, Phenoxyethanol, Iodopropynyl Butylcarbamate, Melanin, Caramel, Iron Oxides, CI 77499, CI 77491, CI 77492.

AmpuleSHEER.jpg

DNA Damage Control™
SILC SHEER | SPF 45

PouchSHEER.jpg



NEOVA®

SmartScience. SmartSunscreens.™

DNA Damage Control [SILC SHEER | SPF 45], with a sheer, natural tint for the face, provides **complete photoprotection**, repairing tissue at the cellular level—where DNA damage occurs—while protecting the skin from additional UV insults.

- DNA Repair enzymes inhibit and correct the consequences of photodamage
- High-performance UVA/UVB protection
- Powerful antioxidant complex + skin-perfecting sheer tint

Directions: Apply every morning to face and neck. Reapply as needed. For optimal results, use daily with Neova [DNA + Copper] products.

DNA DAMAGE CONTROL™
SILC SHEER | SPF 45
PHOTO FINISH TINT

DNA REPAIR TITANIUM

PhotoMedex, Inc.
Montgomeryville, PA
7 Hawbridge Close
Shirley, Solihull
West Midlands B90
1.888.966.1010
www.neova.com
Patent Pending
Made in the USA
Reorder# NDS002S
REV 5/11

2 mL e 0.07 fl

NEOVA DNA DAMAGE CONTROL - SILC SHEER SPF 45

octinoxate, titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62362-149
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	6.5 mL in 100 mL
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	3.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Aloe Vera Leaf (UNII: ZY8 1Z83H0 X)	
Octyl Stearate (UNII: 772Y4UFC8B)	
Cyclomethicone (UNII: NMQ347994Z)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Sunflower Oil (UNII: 3W1JG795YI)	
Lutein (UNII: X72A60C9MT)	
Rosemary (UNII: IJ67X351P9)	
Squalane (UNII: GW89575KF9)	
Egg Phospholipids (UNII: 1Z74184RGV)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Microcrystalline Wax (UNII: XOF597Q3KY)	
Hydrogenated Castor Oil (UNII: ZF94AP8MEY)	
Sodium Chloride (UNII: 451W47IQ8 X)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	
Caramel (UNII: T9D99G2B1R)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-149-03	1 in 1 POUCH		
1	NDC:62362-149-02	2 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/09/2012	

Establishment

Name	Address	ID/FEI	Business Operations
PhotoMedex, Inc.		054503875	manufacture

Revised: 1/2012

PhotoMedex, Inc.