

**NEOVA DNA DAMAGE CONTROL - EVERYDAY SPF 43- zinc oxide, octinoxate, octisalate 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 - Everyday SPF 43 - 2mL sample package insert**

**Directions for use:**

Apply every morning to face, neck, décolletage and hands. 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 :**

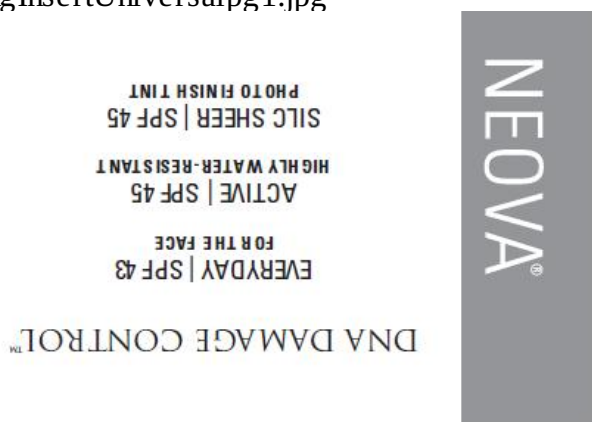
Zinc Oxide 7.5%, Octinoxate 7.5%, Octisalate 2.5%.

**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.

**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](http://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.

PkgInsertUniversalpg2.jpg

## 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.<sup>1</sup> 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.<sup>5</sup>

**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.<sup>5</sup>

**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.<sup>7</sup>

**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.<sup>2</sup>

**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.<sup>3</sup>

**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.<sup>4</sup>

**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.<sup>8</sup>

**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.<sup>9</sup>

**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.

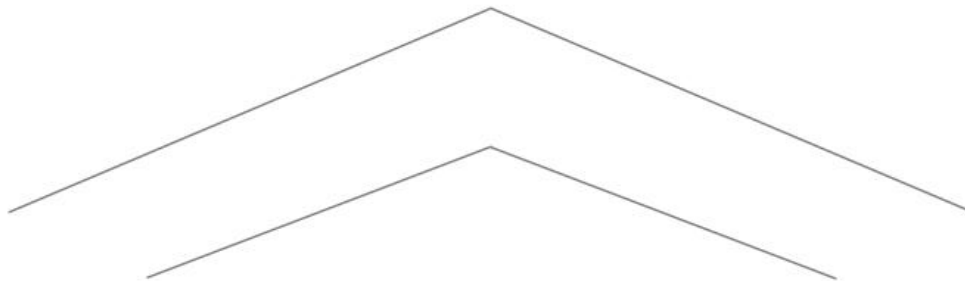
cone, Isopropyl Palmitate, Helianthus Annuus (Sunflower) Seed Oil, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Micrococcus Lysate, Plankton Extract, Xanthophyll, Rosmarinus Officinalis (Rosemary) Leaf Extract, Squalane, Lecithin, Silica, Hydrated Silica, Microcrystalline Wax, Cetyl Dimethicone,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

AmpuleEday.jpg



DNA Damage Control™  
EVERYDAY | SPF 43

PouchEday.jpg



**+**  
**ZINC**

'A 18936

4SU UK

1. OZ.



# NEOVA®

## SmartScience. SmartSunscreens.™

DNA Damage Control [Everyday | SPF 43] 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
- Hyper antioxidant defense + oil-free hydration

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

**DNA REPAIR  
TRANSPARENT**

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# NDE002S  
REV 6/11

2 mL e 0.07 fl

DNA DAMAGE CONTROL™  
EVERYDAY | SPF 43  
FOR THE FACE

### NEOVA DNA DAMAGE CONTROL - EVERYDAY SPF 43

zinc oxide, octinoxate, octisalate emulsion

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62362-139
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.5 mL in 100 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 mL in 100 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.5 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Isopropyl Palmitate</b> (UNII: 8CRQ2TH63M)	
<b>Octyl Stearate</b> (UNII: 772Y4UFC8B)	
<b>Ethylhexyl Isononanoate</b> (UNII: I6KB4GE3K4)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>Cetearyl Glucoside</b> (UNII: 09FUA47KNA)	
<b>Ergothioneine</b> (UNII: BDZ3DQM98W)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Glycereth-26</b> (UNII: NNE56F2N14)	
<b>Hyaluronate Sodium</b> (UNII: YSE9PPT4TH)	
<b>Panthenol</b> (UNII: WV9CM0O67Z)	
<b>Allantoin</b> (UNII: 344S277G0Z)	
<b>Alpha-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Ascorbyl Palmitate</b> (UNII: QN83US2B0N)	
<b>Oleth-3 Phosphate</b> (UNII: 8Q0Z18J1VL)	
<b>Polyisobutylene (1300 MW)</b> (UNII: 241BN7J12Y)	
<b>Egg Phospholipids</b> (UNII: 1Z74184RGV)	
<b>Butylene Glycol</b> (UNII: 3XUS85K0RA)	
<b>Citric Acid</b> (UNII: 2968PHW8QP)	
<b>Iodopropynyl Butylcarbamate</b> (UNII: 603P14DHEB)	
<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-139-03	1 in 1 POUCH		
1	NDC:62362-139-02	2 mL in 1 PACKAGE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/06/2012	

**Labeler** - PhotoMedex, Inc. (054503875)

**Establishment**

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

Revised: 1/2012

PhotoMedex, Inc.