NEOVA DNA DAMAGE CONTROL - ACTIVE SPF 45- 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.

Neova DNA Damage Control - Active SPF 45 - Drug Facts

Active Ingredients

Zinc Oxide 8.0%, Octinoxate 7.5%, Octisalate 3.0%

Purpose

Zinc Oxide - sunscreen, Octinoxate - sunscreen, Octisalate - sunscreen

Uses

• Helps prevent sunburn. • Higher SPF gives more sunburn protection. • Retains SPF after 80 minutes of activity in the water or perspiring.

Warnings
For external use only

When using this product

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

Rash or irritation develops and lasts.

Keep out of reach of children

If swallowed, contact a Poison Control Center immediately or get medical help right away.

Directions

Apply liberally before sun exposure.
• Reapply as needed or after towel drying, swimming or perspiring. • Children under 6 months of age: ask a doctor.

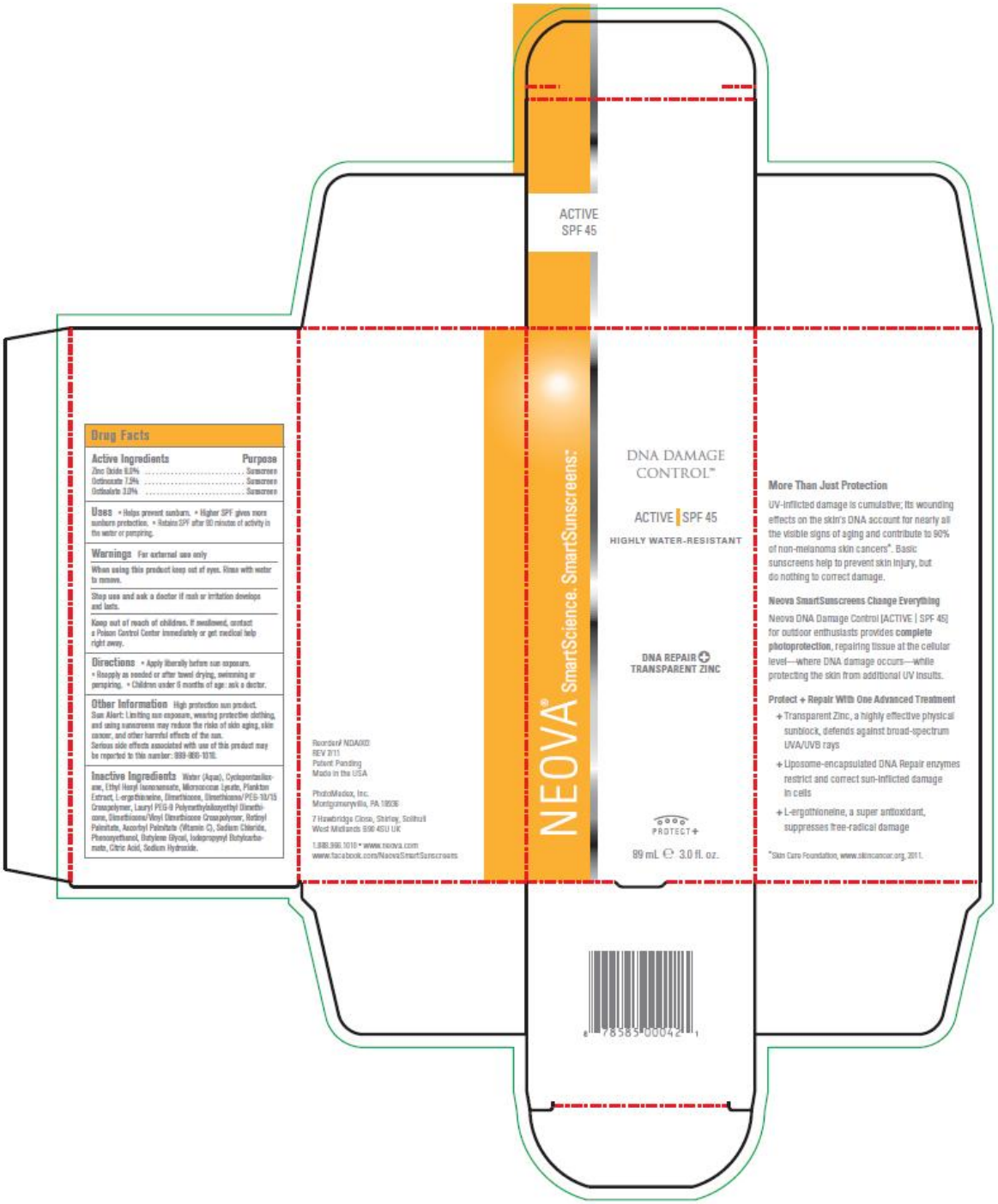
Other Information

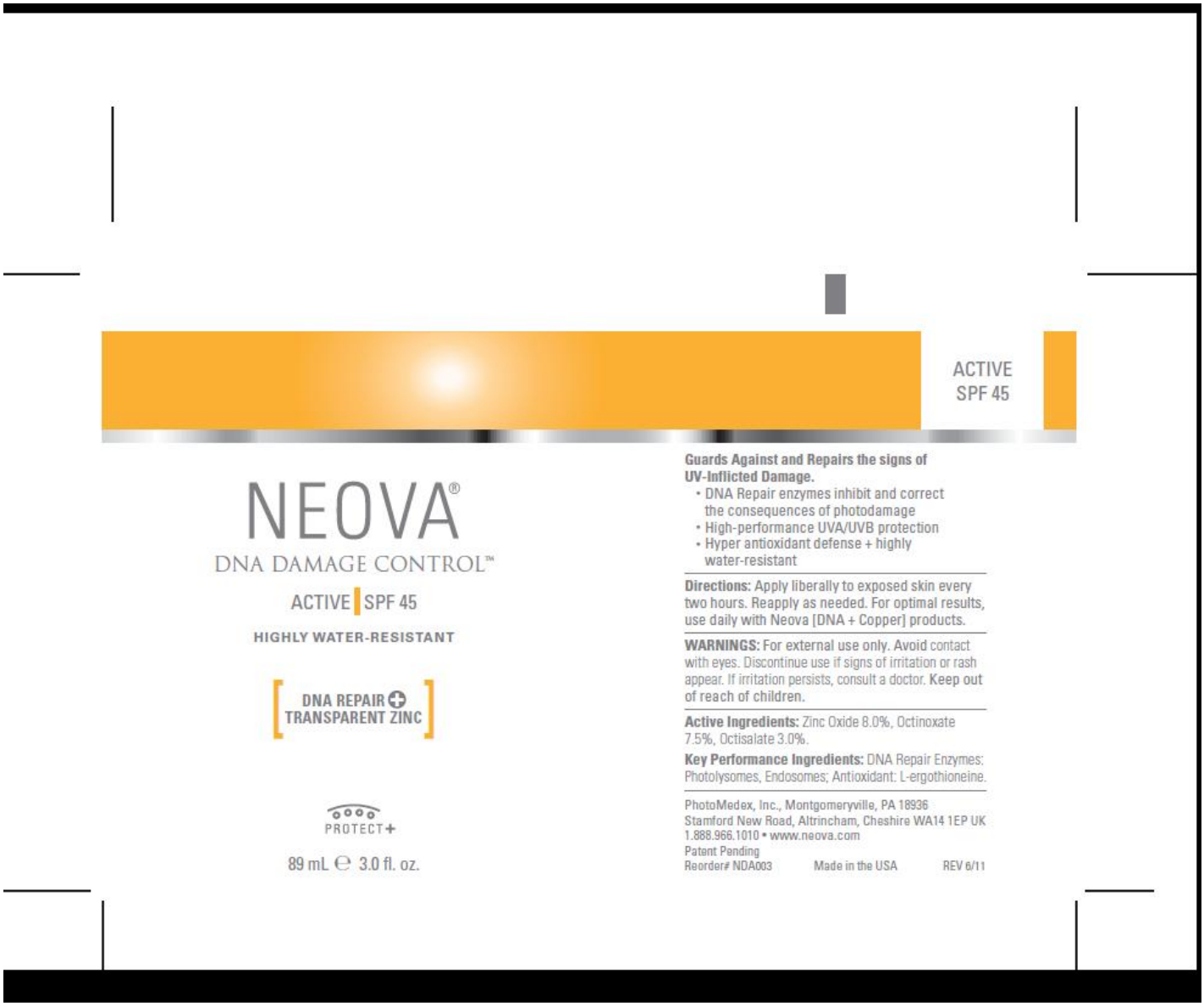
High protection sun product. Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun. Serious side effects associated with use of this product may be reported to this number: 888-966-1010.

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.

Image of Box and Label





NEOVA DNA DAMAGE CONTROL - ACTIVE SPF 45

zinc oxide, octinoxate, octisalate emulsion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62362-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	8 mL in 100 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 mL in 100 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	3 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

Water (UNII: 059QF0KO0R)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Ethylhexyl Isononanoate (UNII: I6KB4GE3K4)	
Micrococcus Luteus (UNII: LV6L29Z6AX)	
Ergothioneine (UNII: BDZ3DQM98W)	
Dimethicone (UNII: 92RU3N3Y1O)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Sodium Chloride (UNII: 451W47IQ8X)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	
Citric Acid (UNII: 2968PHW8QP)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-129-01	1 in 1 BOX		
1	NDC:62362-129-89	89 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/05/2012	

Labeler - PhotoMedex, Inc. (054503875)

Establishment

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

Revised: 1/2012 PhotoMedex, Inc.