

MOISTUREWORX- petrolatum spray
DermWorx Incorporated

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.

MoistureWorx™ Skin Protection Spray
(30% White Petrolatum)

Active ingredient

White Petrolatum, USP 30%

Inactive Ingredients

cholesterol, diazolidinyl urea, glyceryl distearate, methylparaben, propylene glycol, propylparaben, polysorbate 80, sodium laureth sulfate, steareth-10, water.

Use:

- Helps prevent and protect chapped skin.
- Helps prevent and protect from the drying effects of wind and cold weather.

Directions:

Apply as needed.

Warnings: For external use only.

When using, do not get into eyes.

Do not use on:

- deep or puncture wounds
- animal bites
- serious burns

See a doctor if condition lasts more than 7 days.

Keep out of reach of children.

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

Ask a doctor or pharmacist before use

if you are using other topical medications at the same time.

Stop use

if excessive irritation of the skin develops.

Patient Information

MOISTUREWORX™

(White Petrolatum, USP - 30%) Spray

Active Ingredient:

White Petrolatum, USP 30%

Inactive Ingredients:

cholesterol, diazolidinyl urea, glyceryl distearate, methylparaben, propylene glycol, propylparaben, polysorbate 80, sodium laureth sulfate, steareth-10, water.

Use:

- Helps prevent and protect chapped or cracked skin.
- Helps prevent and protect from the drying effects of wind and cold weather.
- Helps prevent loss of moisture, keeping the skin smooth.

Clinical Pharmacology:

The outer layer of skin consists of dead skin cells which protect the delicate living cells of the deeper layers beneath. This outer layer needs to stay moisturized in order to protect the deeper layers of skin. To keep the moisture (water) from leaving the outer layer, your skin produces natural oils. These oils also help keep irritants from the deeper layers of skin.

Regular washing with soap, or exposure to chemicals, can remove these natural oils. When the natural oil is stripped from the outer layer, moisture quickly leaves the surface resulting in dry, irritated, and itchy skin. Worse, the deeper layers of skin are now left exposed to harsh damaging irritants such as detergents, powder, etc. This results in more dry, irritated, and itchy skin that ultimately becomes chapped, cracked and damaged.

Everyday skin lotions only attempt to replace natural oils with artificial ones. This is a temporary relief but does little to heal the skin. Regular use of these lotions can actually cause the skin to produce less natural oils. Instead of attempting to replace these natural oils, MoistureWorx™, when applied to the skin, forms a moisture-barrier with the outer layer of dead skin cells. Thus, MoistureWorx™ helps reduce the natural oil and moisture loss, allowing the skin to heal itself. MoistureWorx™ helps the outer layer of skin keep its natural oils and moisturizers that protect the deeper layers of skin, leaving skin soft and supple. MoistureWorx™ keeps the outer layer of skin functioning so it can breathe and perspire naturally.

The active ingredient in MoistureWorx™ is white petrolatum, one of the most common dermal barrier ingredients. Most white petrolatum-based products currently marketed by cosmetic and pharmaceutical companies are in a cream, lotion or ointment form. However, these products are thick, oily and aesthetically unpleasant. The occlusive nature and moisturizing properties are desirable, but the heavy, characteristic feel of white petrolatum is not.

The use of white petrolatum as an emollient has been well accepted for dry skin conditions, especially with flaking skin such as sunburn and chapping. It has been shown that when white petrolatum is applied to sunburned skin, evaporation is curtailed - it acts as a barrier to loss of moisture from the epidermis.

White petrolatum has a long history of consumer use, efficacy and safety. As a result, significant evidence of efficacy and safety exists from the universal use of white petrolatum over many decades for a wide variety of topical indications. Studies have shown that when large amounts of white petrolatum are ingested, the product is essentially nontoxic. It has even been approved as a direct food additive. Further, it has been established that white petrolatum is not absorbed through intact or injured

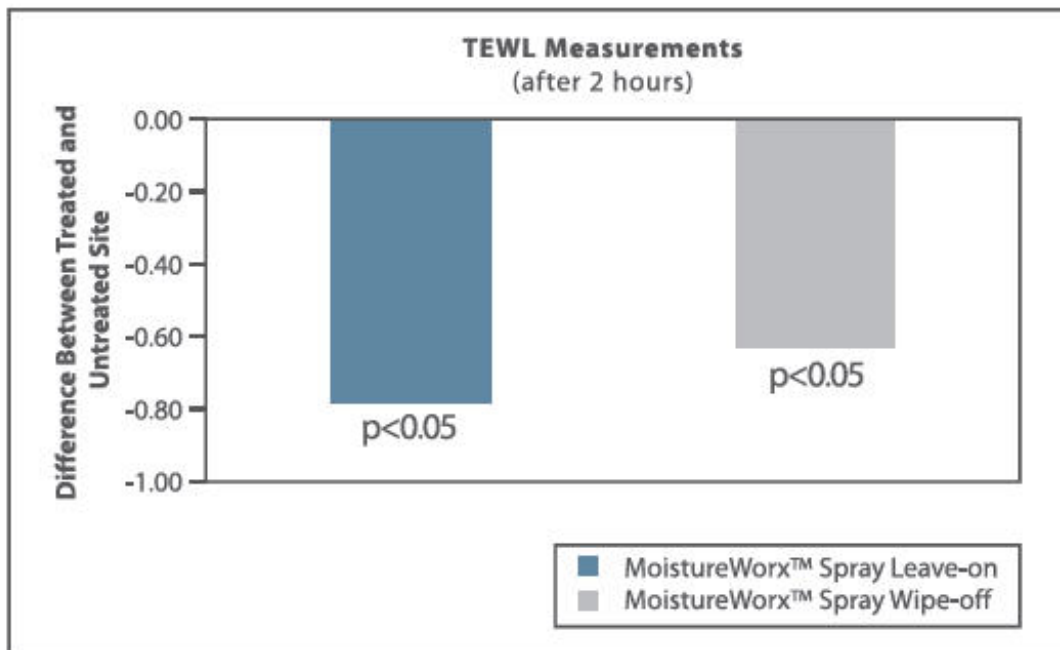
skin and is neither sensitizing nor irritating.

As a result, clinical and marketing experience has confirmed that white petrolatum is safe when used as a skin protectorant. It has an extremely low risk in actual consumer use situations. Moreover, petroleum provides a favorable public health benefit, requires no specific dosage limitation, and requires few specific warnings and no general warnings (e.g. pregnancy or overdose).

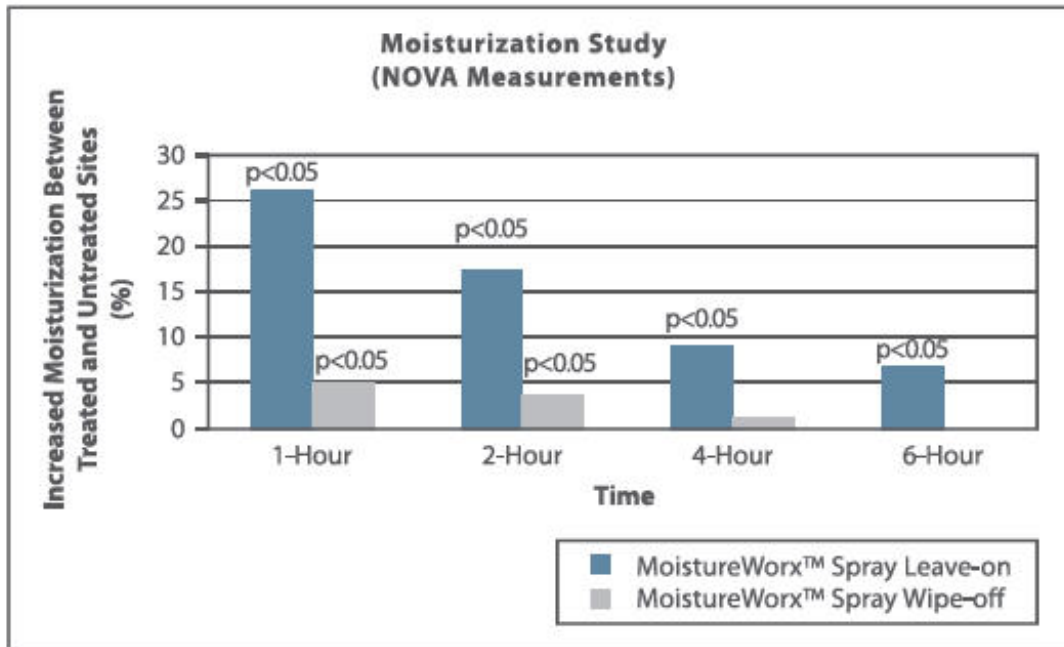
The ease of application and delivery of white petrolatum over a relatively large surface area was a key consideration in developing MoistureWorx™. DermWorx has incorporated a novel microencapsulation technique (Novasome®) in the formulation that will significantly increase the aqueous solubility of white petrolatum. This technology utilizes proprietary organized lipid structures and lipid vesicle encapsulation technologies and provides for a nanoparticle in an aqueous transport system. Using this technology, high concentrations of thick solids such as white petrolatum can be transformed into water-based sprayable products.

To evaluate the moisturization efficacy of MoistureWorx™, a clinical study was performed in thirty-three (33) subjects ranging in age from 21 to 60 years with mild to moderate dry skin. MoistureWorx™ was applied two different ways, as a “leave-on” and as a “wipe-off” product.

Moisturization efficacy was determined via a measurement of the skin moisture content (DPM).

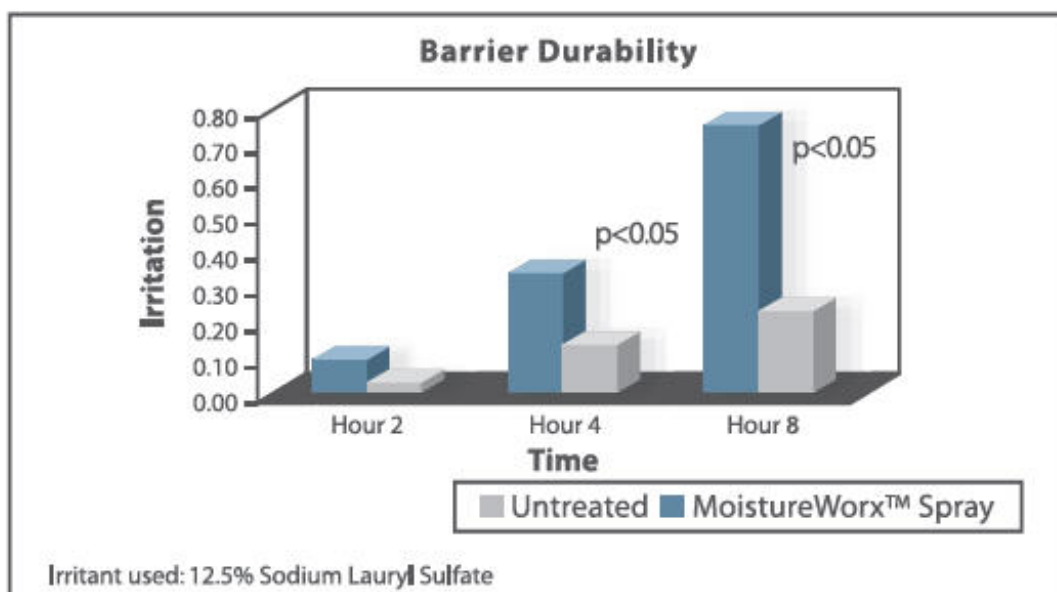


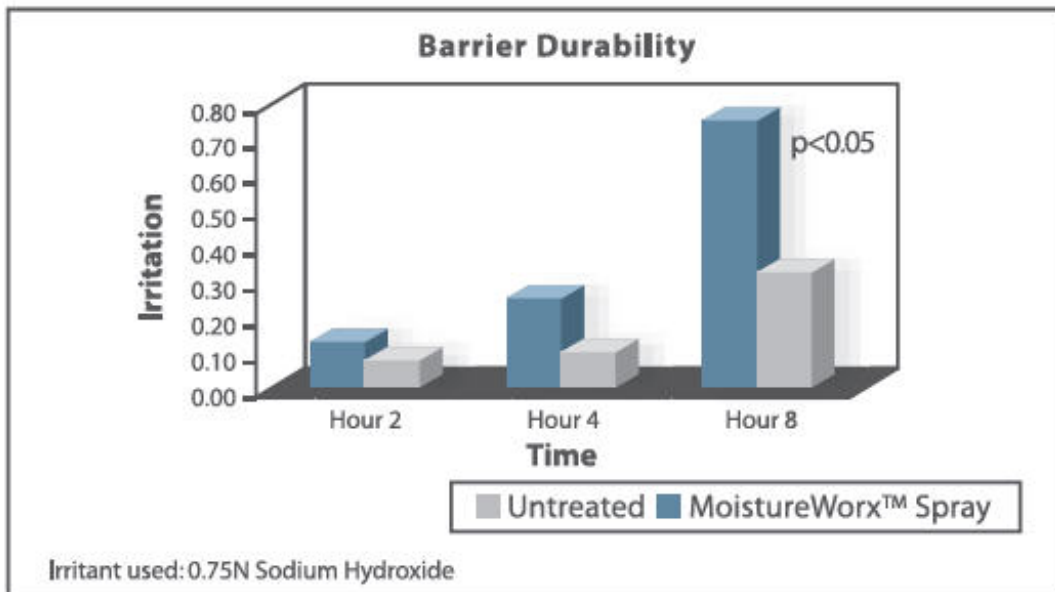
Trans-epidermal water loss (TEWL) was also determined.



The results show that MoistureWorx™ used either as a “leave-on” or as a “wipe-off” product, was effective in moisturizing the skin. In addition, the rate of moisture loss through the skin was significantly reduced.

The barrier durability of MoistureWorx™ in protecting the skin from irritation resulting from exposure to known irritants was also evaluated. Twenty-nine (29) subjects completed the study. Sodium lauryl sulfate at concentrations of 7.5%, 10.0% and 12.5% and sodium hydroxide at a concentration of 0.75N were applied to a small patch (8 mm in diameter) and the patches were applied to sites, treated and untreated, on each subject's back. The patches were removed at 2, 4 and 8 hours after application and the sites evaluated for dermal irritation due to the irritants.





The results show that MoistureWorx™ protected the skin exposed to the irritants after eight hours vs. unprotected skin.

Warnings:

For external use only.

When using this product:

- do not get into eyes.

Do not use on:

- deep or puncture wounds
- animal bites
- serious burns

See a doctor if condition lasts more than 7 days.

Directions:

Apply as needed not less than every four hours.

How Supplied:

4 fl. oz spray bottle

NDC: 28109-020-01

Distributed by:

DermWorx, Inc.

Hollywood, FL 33022

E-mail: info@dermworx.com

www.dermworx.com

Principal Display Panel - Bottle Label

NDC 28109-020-01

MoistureWorx™

SKIN PROTECTION SPRAY

30% White Petrolatum, USP

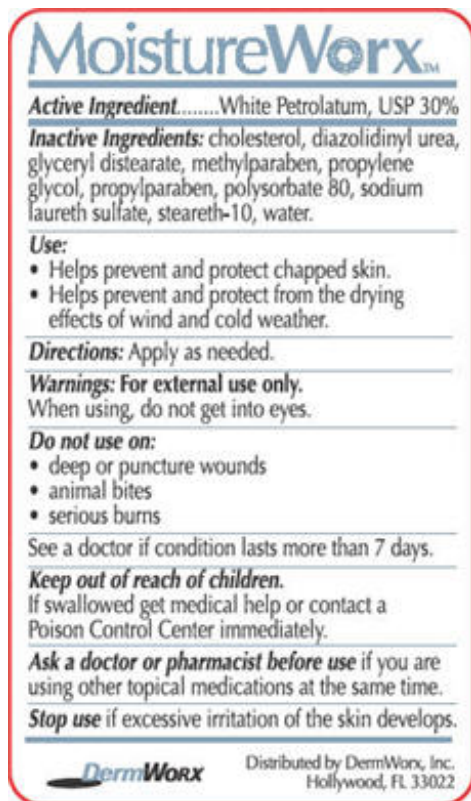
Clinically proven and patented formulation, utilizing nanotechnology, that moisturizes and protects the skin

Hypoallergenic • Noncomedogenic • Fragrance Free

Gently cleanses and moisturizes skin while delivering targeted, encapsulated white petrolatum into the skin's crack and fissures

4 fl. oz. (120 mL)





Bottle Label

Principal Display Panel - Outer Carton Label

MoistureWorx™

SKIN PROTECTION SPRAY

30% White Petrolatum, USP

Clinically proven and patented formulation, utilizing nanotechnology, that moisturizes and protects the skin

Hypoallergenic • Noncomedogenic • Fragrance Free

28109-020-06

MoistureWorx™

SKIN PROTECTION SPRAY

30% White Petrolatum, USP

Unit Contains 6 4fl oz (120mL) Bottles

Distributed by DermWorx, Inc. • Hollywood, FL 33022



Outer Carton Label

| MOISTUREWORX | | | | |
|--|-------------------|---------------------|----------------------|--------------------|
| petrolatum spray | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:28 109-020 | |
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | Basis of Strength | Strength | | |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 36 mL in 120 mL | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:28 109-020-06 | 6 in 1 CARTON | | |

| | | | | |
|---|------------------|--------------------|--|--|
| 1 | NDC:28109-020-01 | 1 in 1 CARTON | | |
| 1 | | 120 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 05/27/2008 | |

Labeler - DermWorx Incorporated (015678067)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---------------------|
| IGI Laboratories, Inc. | | 011036910 | MANUFACTURE |

Revised: 2/2010

DermWorx Incorporated