

**HAND AND SKIN SHIELD- dimethicone gel**  
**DCG Vision Marketing & Sales International Ltd.**

*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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**DCG - HAND AND SKIN SHIELD (69570-102)**

**ACTIVE INGREDIENT(S)**

MINERAL OIL 50%

**PURPOSE**

SKIN PROTECTANT

**USES**

Helps prevent and temporarily protects chafed, chapped or cracked skin. Helps prevent and protect from the drying effects of chemicals, wind and cold weather.

Keep out of reach of children.

**WARNINGS**

For external use only. If swallowed, do NOT induce vomiting. Rinse mouth with water. If symptoms develop seek medical attention. • When using this product, do not get into eyes. If in contact with eyes flush with water. Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

**DIRECTIONS**

• Clean and dry hands and skin. Apply True Effects Hand & Skin Shield™ to the palm of hand and rub thoroughly into hands and skin, making sure front and back of hands including cuticles are completely covered. Allow to dry for 3-5 minutes or until completely absorbed into skin. • After coming into contact with dangerous chemicals, wash hands thoroughly and reapply.

**Other:**

STORE IN A COOL PLACE AWAY FROM DIRECT SUNLIGHT

**Inactive Ingredients:**

Aqua/Water, Stearic Acid, Propylene Glycol, Glyceryl Stearate, Isopropyl Palmitate,

Ricinus Communis (Castor) Seed Oil, Cyclopentasiloxane, Phenoxyethanol, Sodium Hydroxide, Dimethiconol, Ethylhexylglycerin, Xanthan Gum, Disodium EDTA, Simmondsia Chinensis (Jojoba) Seed Oil, Acrylates Copolymer, Aloe Barbadensis Leaf Extract.

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Dimethicone (Dimethiconol) 1%	Skin protectant
<b>Uses:</b> Helps prevent and temporarily protects chafed, chapped or cracked skin. Helps prevent and protect from the drying effects of chemicals, wind and cold weather.	
<b>Warning:</b> For external use only. If swallowed, DO NOT induce vomiting. Rinse mouth with water. If symptoms develop seek medical attention. • When using this product, do not get into eyes. If in contact with eyes flush with water. Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days	
<b>Keep out of reach of children.</b>	
<b>Directions:</b> • Clean and dry hands and skin. Apply True Effects Hand & Skin Shield™ to the palm of hand and rub thoroughly into hands and skin, making sure front and back of hands including cuticles are completely covered. Allow to dry for 3-5 minutes or until completely absorbed into skin. • After coming into contact with dangerous chemicals, wash hands thoroughly and reapply.	
<b>Other:</b> STORE IN A COOL PLACE AWAY FROM DIRECT SUNLIGHT	
<b>Inactive Ingredients</b> Acrylates Copolymer, Aloe Barbadensis Leaf Extract, Aqua/Water, Cyclopentasiloxane, Disodium EDTA, Ethylhexylglycerin, Glycerol Stearate, Isopropyl Palmitate, Mineral Oil, Phenoxyethanol, Propylene Glycol, Ricinus Communis (Castor) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Stearic Acid, Xanthan Gum.	

MADE IN CANADA  
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**WORLD'S MOST SERIOUS BARRIER CREAM**

True Effects Hand & Skin Shield™ is the **WORLD'S MOST SERIOUS SKIN BARRIER CREAM**, which provides fast, safe, effective, and long lasting skin protection, anytime you need it.

True Effects Hand & Skin Shield™ is proven to form a safe invisible barrier to protect hands and skin against damaging chemicals and natural agents that come into direct contact with skin on a daily basis. True Effects Hand and Skin Shield is excellent for use when working in WET environments.

True Effects Hand & Skin Shield™ is non-toxic, non-greasy, non-sticky and will not wipe off skin once applied. Lasts for 4 hours plus even after repeated washings with soap and water or hand sanitizers.

True Effects Hand & Skin Shield™ protects against most chemicals such as: paints, fiberglass, dilute alkalis and acids, industrial detergents and cleaning agents, tar, grease, inks, dyes, oils, caustic grime, glues and adhesives.

- ✓ Protects against many skin irritants
- ✓ Protects for 4 hours plus
- ✓ Moisturizes the skin with Aloe Vera
- ✓ Allows skin to breathe and heal naturally

<b>DRUG FACTS</b>	
<b>ACTIVE INGREDIENTS:</b>	<b>PURPOSE:</b>
Dimethicone (Dimethiconol) 1%	Skin protectant
<b>USES:</b> Helps prevent and temporarily protects chafed, chapped or cracked skin. Helps prevent and protect from the drying effects of chemicals, wind and cold weather.	
<b>WARNINGS:</b> For external use only. If swallowed, DO NOT induce vomiting. Rinse mouth with water. If symptoms develop seek medical attention. When using this product, do not get into eyes. If in contact with eyes, flush with water. Stop use and ask a doctor if condition worsens or if symptoms last more than 7 days or clear up and occur again within a few days.	
<b>KEEP OUT OF REACH OF CHILDREN</b>	
<b>DIRECTIONS:</b> Clean and dry hands and skin. Apply True Effects™ Hand & Skin Shield™ to the palm of hand and rub thoroughly into hands and skin, making sure front and back of hands including cuticles are completely covered. Allow to dry for 3-5 minutes or until completely absorbed into skin. Severely cracked skin may sting once cream is applied. This is normal. If excessive stinging or rash occurs or worsens, discontinue use.	
<b>STORE IN A COOL PLACE AWAY FROM DIRECT SUNLIGHT</b>	
<b>INACTIVE INGREDIENTS:</b> Deionized Aqua/Water, Stearic Acid, Propylene Glycol, Glycerol Stearate, Isopropyl Palmitate, Ricinus Communis (Castor) Seed Oil, Cyclopentasiloxane, Phenoxyethanol, Ethylhexylglycerin, Sodium Hydroxide, Mineral Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Xanthan Gum, Disodium EDTA, Acrylates Copolymer, Aloe Barbadensis Leaf Extract.	
<b>WARNING:</b> This product is intended to act as a secondary form of skin protection and is not intended to replace gloves. After coming into contact with dangerous chemicals, wash hands thoroughly and reapply.	

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**SAFE FOR ALL TYPES OF SKIN**

**WORLD'S MOST SERIOUS SKIN BARRIER CREAM**

**17 FL. OZ**

**GUARANTEED TESTED**

- WORKS LIKE AN INVISIBLE GLOVE
- HELPS GUARD AGAINST HUNDREDS OF SKIN IRRITANTS & PLANT OILS LIKE POISON IVY/OAK
- MOISTURIZES & HYDRATES SKIN
- EASILY WASH OFF DIRT, GREASE & GRIME
- INSTANT RELIEF OF DRY, CHAPPED, CRACKED & DAMAGED SKIN
- HYPOALLERGENIC & DERMATOLOGICALLY TESTED
- NON-TOXIC, NON-GREASY & ODORLESS
- 4 HOURS+ PROTECTION

**BEFORE**      **AFTER**

True Effects™ Hand & Skin Shield™ is proven to quickly protect skin by forming a safe, effective and invisible barrier against most chemicals and natural agents, lasting up to 4 hours plus.

True Effects™ Hand & Skin Shield™ is non-greasy and helps guard against damage caused by constant exposure to moisture from repeated hand washing and cleaning in wet environments. It revitalizes and conditions dry, cracked hands and skin, even after repeated washings.

Helps Guard Against: most chemicals such as dilute alkalis and acids, industrial detergents, tar, grease, inks, caustic grime and plant oils such as poison ivy/oak.

How To Use: clean and dry hands. Apply product to palm of hand and rub into skin making sure front and back of areas including cuticles, are completely covered. Wait 3-5 minutes or until completely absorbed.

## HAND AND SKIN SHIELD

dimethicone gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69570-102
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 mL
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	0.2 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>JOJOBA OIL</b> (UNII: 724GKU717M)
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)
<b>CASTOR OIL</b> (UNII: D5340Y219G)
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69570-102-11	502 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2015	
2	NDC:69570-102-12	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/08/2015	
3	NDC:69570-102-13	100 mL in 1 TUBE; Type 0: Not a Combination Product	10/11/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/08/2015	

**Labeler** - DCG Vision Marketing & Sales International Ltd. (252375576)

Revised: 11/2021

DCG Vision Marketing & Sales International Ltd.