

**DERMASIL- dimethicone lotion**  
**Rise International Group LLC**

*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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Dermasil® Labs has developed Dermasil® OTC pharmaceutical skincare, a powerful dry skin treatment and skin protectant. This lotion contains four systems to control and provide long-lasting relief from severe dry skin:

- Occlusives** to block moisture loss from the skin's surface
- Humectant** to bind water in the skin's outermost layers
- Skin Lipids** to enhance the skin's natural ability to retain moisture
- EFA's** an important component of the skin's moisture barrier

**Indications:**

Suitable for severe dry skin, and control of symptoms such as chapping, cracking, flaking, roughness, redness, soreness, and the itching associated with dry skin.

**Drug Facts**

**Active Ingredient**

Dimethicone 1%

**Purpose**

Skin protectant

**Uses**

- Temporarily protects and helps relieve chapped or cracked skin.
- Helps protect from the drying effects of wind and cold weather.

**Warnings**

- For external use only.
- Do not get into eyes.
  
- 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.
  
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply as needed

**Inactive Ingredients**

Water (Aqua), Petrolatum, Mineral Oil (Paraffinum Liquidum), Glycerin, Stearic Acid, Glycol Stearate,

Glyceryl Stearate, PEG-40 Stearate, Cetyl Alcohol, Sodium Hydroxide, Phenoxyethanol, Methylisothiazolinone, Iodopropynyl Butylcarbamate, Magnesium Aluminum Silicate, Helianthus Annuus (Sunflower) Seed Oil, Cetyl Acetate, Acetylated Lanolin Alcohol, Carbomer, Disodium EDTA, Geranium Maculatum Oil, Lecithin, Borago Officinalis Seed Oil, Cholesterol, Ascorbyl Palmitate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Ethylene Brassylate, Santalum Album (Sandalwood) Oil, Rosa Damascena Extract, Vanilla Planifolia Fruit Extract.

**Questions/Comments? 1-800-282-1813**

**△Cruelty-Free. No Animal Testing.**

**Please Recycle This Bottle.**

www.riseintlgroup.com

**RISE INTERNATIONAL GROUP LLC**

Lodi, NJ 07644. Made in China

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**Principal Display Panel - Bottle Label Dermasil 8oz**

**Dermasil®**

**LABS**

**Pharmaceutical Research**

Controls Even Severe Dry Skin

Skin Lipid & EFA Treatment

Hypo-Allergenic

**Dermasil®**

**Dry Skin Treatment**

**ORIGINAL LOTION**

8 FL.OZ. (1/2 PINT, 237 ml)



Pharmaceutical Research

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**INACTIVE INGREDIENTS:** WATER (AQUA) , GLYCERIN, PETROLATUM, MINERAL OIL (PARAFFINUM LIQUIDUM) , STEARIC ACID, GLYCOL STEARATE, GLYCERYL STEARATE, PEG-40 STEARATE, CETYL ALCOHOL, CETYL ACETATE, SODIUM HYDROXIDE, PHENOXYETHANOL, CARBOMER, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, DISODIUM EDTA, ACETYLATED LANOLIN ALCOHOL, GERANIUM MACULATUM OIL, METHYLISOTHIAZOLINONE, IODOPROPYNYL BUTYL CARBAMATE, MAGNESIUM ALUMINUM SILICATE, LECITHIN, BORAGO OFFICINALIS SEED OIL, CHOLESTEROL, ASCORBYL PALMITATE, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, ETHYLENE BRASSYLATE, SANTALUM ALBUM (SANDALWOOD) OIL, ROSA DAMASCENA EXTRACT, VANILLA PLANIFOLIA FRUIT EXTRACT. Questions/Comments? 1-800-282-1813



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## DERMASIL

dimethicone lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67143-2101
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
dimethicone (UNII: 92RU3N3Y1O) (dimethicone - UNII:92RU3N3Y1O)	dimethicone	0.01 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength

<b>WATER</b> (UNII: 059QF0KO0R)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>GLYCOL STEARATE</b> (UNII: 0324G66D0E)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>MAGNESIUM</b> (UNII: I38ZP9992A)
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)
<b>CETYL OLEATE</b> (UNII: 78K2L26L8N)
<b>LANOLIN</b> (UNII: 7EV65EAW6H)
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>GERANIUM MACULATUM ROOT</b> (UNII: 93IXI5B6OJ)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>BORAGE OIL</b> (UNII: F8XAG1755S)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)
<b>SANDALWOOD OIL</b> (UNII: X7X01WMQ5F)
<b>ROSA DAMASCENA FLOWER</b> (UNII: JWB78P295A)
<b>VANILLA</b> (UNII: Q74T35078H)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67143-210-1-3	237 mL in 1 BOTTLE		
2	NDC:67143-210-1-2	237 mL in 1 TUBE		
3	NDC:67143-210-1-5	214 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/15/2009	

**Labeler** - Rise International Group LLC (011184988)

### Establishment

Name	Address	ID/FEI	Business Operations
Kingkey Daily Chemical Co., Ltd.		545349263	MANUFACTURE(67143-2101)

