

DERMASIL DRYSKIN- dimethicone lotion
Kingkey MBC Life Technology Group Co., 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.

ACTIVE INGREDIENT

Dimethicone 1%

PURPOSE

Skin protectant

Use

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 to Hands and Body every day.

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 BUTYLCARBAMATE, 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.

Package Label - Principal Display Panel

Dermasil®

LABS

Pharmaceutical Research

Controls Even Severe Dry Skin

Skin Lipid & EFA Treatment

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. Apply lotion to body daily.

Drug Facts	
Active Ingredient	Purpose
Dimethicone 1%.....	Skin protectant
Uses	
<ul style="list-style-type: none"> ■ Temporarily protects and helps relieve chapped or cracked skin. ■ Helps protect from the drying effects of wind and cold weather. 	
Warnings	
<ul style="list-style-type: none"> ■ 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 to Hands and Body every day.	

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 BUTYLCARBAMATE, 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.

Try our **PARABEN-FREE** Day/Night Face Cream!



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Pharmaceutical Research

Controls Even Severe Dry Skin
Skin Lipid & EFA Treatment
Hypo-Allergenic

Dermasil®
Dry Skin Treatment
ORIGINAL LOTION

8 FL OZ (236 ml)

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ORIGINAL LOTION
8 FL OZ (236 ml)

NDC: 73928-100-01

DERMASIL DRYSKIN

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73928-100
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-40 MONOSTEARATE (UNII: ECU18C66Q7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL OLEATE (UNII: 78K2L26L8N)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
GERANIUM MACULATUM ROOT OIL (UNII: H2E371EDYX)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
BORAGE OIL (UNII: F8XAG1755S)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALMOND OIL (UNII: 66YXD4DKO9)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
SANDALWOOD OIL (UNII: X7X01WMQ5F)	
ROSA DAMASCENA FLOWER (UNII: JWB78P295A)	
VANILLA (UNII: Q74T35078H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73928-100-01	236 mL in 1 TUBE; Type 0: Not a Combination Product	07/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/14/2023	

Labeler - Kingkey MBC Life Technology Group Co., Ltd. (545349263)**Establishment**

Name	Address	ID/FEI	Business Operations
Kingkey MBC Life Technology Group Co., Ltd.		545349263	manufacture(73928-100)

Revised: 7/2023

Kingkey MBC Life Technology Group Co., Ltd.