

**XTRACARE WITH COOLING ACTION OATMEAL SKIN RELIEF CALMIN-  
dimethicone lotion  
Rejoice International**

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**XtraCare with cooling action Oatmeal Skin Relief Calmin**

***Active Ingredient***

***Purpose***

Dimethicone 1/3% ..... Skin Protectant

XtraCare (with cooling action) Oatmeal Skin Relief Calming Lotion

dimethicone skin protectant

with natural colloidal oatmeal

provides immediate and lasting moisture relief for itchy, extra dry skin

12 fl oz (354 mL)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

☐ **Use** Help prevent and temporarily protects chafed, chapped, or cracked skin.

☐ **Warnings For external use only.**

**When using this product** avoid contact with eyes. In case of eye contact, 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** apply liberally as often as needed.

☐ **Other Information** store at room temperature.

DISTRIBUTED BY:

REJOICE INTERNATIONAL INC.

48325 BINGHAMPTON DR.,

NORTHVILLE, MI 48168 USA

MADE IN CHINA

☐ ***Inactive Ingredients***

water, paraffinum liquidum, isopropyl myristate, glycerin, glyceryl stearate, propylene glycol, PEG-100 stearate, polyacrylamide, cetyl alcohol, avena sativa kernel extract, fragrance, DMDM hydantoin, stearyl alcohol, c13-14 isoparaffin, laureth-7, disodium EDTA, menthol, aloe barbadensis leaf juice, methylparaben, propylparaben.



with cooling action  
**Oatmeal**

**Skin Relief  
Calming Lotion**

dimethicone skin protectant

with natural  
colloidal oatmeal

provides immediate  
and lasting moisture  
relief for itchy, extra  
dry skin

NET WT 8 OZ (227g)

with cooling action

# Oatmeal

**Skin Relief Calming Lotion**

**Drug Facts**

Active Ingredient	Purpose
Dimethicone 1.3%.....	Skin protectant

**Use** Help prevent and temporarily protects chafed, chapped, or cracked skin.

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**Directions** apply liberally as often as needed.

**Other information** Store at room temperature.

**Questions/Comments?** 1-855-345-5575

**Inactive ingredients** Water, Petrolatum, Mineral Oil, Glycerin, Glyceryl Stearate, Propylene Glycol, PEG-100 Stearate, Polyacrylamide, Cetyl Alcohol, Avena Sativa (Oatmeal) Kernel Extract, Fragrance, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Menthol, Aloe Barbadensis Leaf Juice, Methylparaben, Propylparaben.



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NOTRHVILLE, MI 48168, USA  
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**XTRACARE WITH COOLING ACTION OATMEAL SKIN RELIEF CALMIN**  
dimethicone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57337-055
<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	3 g in 227 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>POLYACRYLAMIDE (1500 MW)</b> (UNII: 5D6TC4BRWW)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>OAT</b> (UNII: Z6J799EAJK)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-055-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	11/26/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	11/26/2013	

**Labeler** - Rejoice International (078741245)

## Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-055)

Revised: 2/2024

Rejoice International