

**OATMEAL SKIN RELIEF CALMING . 8OZ- dimethicone lotion**

**Rejoice International Inc.**

*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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**Oatmeal daily moisturizing lotion (8 oz.)**

***Active Ingredient***

Dimethicone 1.3%

***Purpose***

Skin protectant

☐**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.

Do not use on

Deep or puncture wounds

Animal bites

Serious burns

Stop use and ask a doctor if conditions 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.

☐***Inactive Ingredients***

Water, Petrolatum, Cetyl Alcohol, Glyceryl Stearate, Propylene Glycol, Glycerin, Stearyl Alcohol, PEG-100 Stearate, Polyacrylamide, DMDM Hydrantoin, Isopropyl Myristate, Fragrance, C13-14 Isoparaffin, Laureth-7, Avena Sativa (Oat) Kernel Extract, Disodium EDTA, Methylparaben, Propylparaben

**XtraCare<sup>®</sup>**

with cooling action

# Oatmeal

**Skin Relief  
Calming Lotion**

dimethicone skin protectant



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

**NET WT 8 OZ (227 g)**

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Dimethicone 1.3%	Skin protectant
<b>Use</b> Help prevent and temporarily protects chafed, chapped, or cracked skin.	
<b>Warnings</b> For external use only.	
<b>When using this product</b> avoid contact with eyes. In case of eye contact, flush with water.	
<b>Do not use on</b> ● deep or puncture wounds ● animal bites ● serious burns	
<b>Stop use and ask a doctor if</b> 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> If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions</b> apply liberally as often as needed.	
<b>Other information</b> Store at room temperature.	
<b>Questions/Comments?</b> 1-855-345-5575	
<b>Inactive ingredients</b> Water, Petrolatum, Cetyl Alcohol, Glyceryl Stearate, Propylene Glycol, Glycerin, Stearyl Alcohol, PEG-100 Stearate, Polyacrylamide, DMDM Hydantoin, Isopropyl Myristate, Fragrance, C13-14 Isoparaffin, Laureth-7, Avena Sativa (Oat) Kernel Extract, Disodium EDTA, Methylparaben, Propylparaben.	



DISTRIBUTED BY:  
REJOICE INTERNATIONAL INC.  
NORTHVILLE, MI 48168, USA  
MADE IN CHINA

## OATMEAL SKIN RELIEF CALMING . 8OZ

dimethicone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57337-100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	3 g in 227 g

### Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAURETH-7 (UNII: Z95S6G8201)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	

<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>CETYL STEARATE</b> (UNII: 06R15UQA7L)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4HIY)	
<b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)	
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-100-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/07/2019	

**Labeler** - Rejoice International Inc. (078741245)

### Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-100)

Revised: 3/2019

Rejoice International Inc.