

**XTRACARE OATMEAL DAILY MOISTURIZING 8 OZ- 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.*

-----  
**XtraCare Oatmeal Daily Moisturizing Lotion 8 oz**

**Active ingredient**

Dimethicone 1.3%

**Purpose**

Skin Protectant

**Uses**

- 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**

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 immediately.

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

**Other information** Store at room temperature.

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.

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



**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>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.	

333367 2103



8 4 9 6 0 7 0 6 9 0 2 3

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

MANUFACTURED FOR:  
REJOICE INTERNATIONAL CORP.  
21800 HAGGERTY RD.  
NORTHVILLE, MI 48167 U.S.A.  
MADE IN CHINA

## XTRACARE OATMEAL DAILY MOISTURIZING 8 OZ

dimethicone lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57337-138
<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	1.3 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	

<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>OAT</b> (UNII: Z6J799EAKJ)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>POLYACRYLAMIDE (10000 MW)</b> (UNII: E2KR9C9V2I)
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)
<b>LAURETH-7</b> (UNII: Z95S6G8201)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-138-01	227 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/19/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/19/2021	

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

### Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Technology Co., Ltd.		529287434	manufacture(57337-138)

Revised: 4/2021

Rejoice International Inc.