XTRACARE SKIN RELIEF OATMEAL DAILY MOISTURIZING- dimethicone lotion China Ningbo Shangge Cosmetic Technology Corp.

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 Skin Relief Oatmeal Daily Moisturizing

Active Ingredient Purpose

Dimethicone 1/3% Skin Protectant

XtraCare Skin Relief Oatmeal Daily Moisturizing Lotion

dimethicone skin protectant

with soothing oat essence

To Protect & Relieve Dry Skin

12 fl oz (354 mL)

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

□*Use*□ help prevent and temporarily protets 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, methylparaben, propylparaben.



XTRACARE SKIN RELIEF OATMEAL DAILY MOISTURIZING

dimethicone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	3 g in 227 g

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
MINERAL O IL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PEG-100 STEARATE (UNII: YD01N1999R)				
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
OAT (UNII: Z6J799EAJK)				
DMDM HYDANTO IN (UNII: BYR0 546 TOW)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
LAURETH-7 (UNII: Z95S6G8201)				
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:58503-054-01	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 final	part347	11/26/2013			

$\pmb{Labeler} \textbf{-} \textbf{China Ningbo Shangge Cosmetic Technology Corp. (529287434)}$

Establishment				
Name	Address	ID/FEI	Business Operations	
China Ningbo Shangge Cosmetic Technology Corp		529287434	manufacture(58503-054)	