

**SPA MYSTIQUE SKIN RELIEF OATMEAL DAILY MOISTURIZING- dimethicone lotion**  
**Volume Distributors, 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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**SPA MYSTIQUE SKIN RELIEF OATMEAL DAILY MOISTURIZING LOTION**

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**Active Ingredient**

Dimethicone.....1.3%

**Purpose**

Skin protectant

**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.

**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.

**Inactive ingredients**

Water, Paraffinum Liquidum, Isopropyl Myristate, Glycerin, Glyceryl Stearate, Propylene Glycol, PEG-100 Stearate, Polyacrylamide, Cetyl Alcohol, Fragrance, DMDM Hydantoin, Stearyl Alcohol, C13-14 Isoparaffin, Laureth-7, Disodium EDTA, Methylparaben, Propylparaben, Avena Sativa Kernel Extract.

SPA MYSTIQUE Skin Relief Oatmeal Daily Moisturizing Lotion dimethicone skin protectant with

soothing oat essence To protect and Relieve Dry Skin 8 fl. oz (235 mL) MADE IN CHINA Spa  
Mystique Vernon, CA 90058 USA Spa Mystique is a trademark of Volume Brands International Visit  
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**SPA MYSTIQUE SKIN RELIEF OATMEAL DAILY MOISTURIZING LOTION 8OZ/235ml  
(50523-100-08)**



# SPA MYSTIQUE SKIN RELIEF OATMEAL DAILY MOISTURIZING

dimethicone lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50523-100
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	13 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW) (UNII: 0L414VCS5Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OAT (UNII: Z6J799EAJK)	
MINERAL OIL (UNII: T5L8T28FGP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50523-100-08	1 in 1 CARTON		
1		235 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/20/2012	

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## Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co.,Ltd.		529047265	manufacture(50523-100)

Revised: 8/2014

Volume Distributors, Inc.