

BODY- lotion lotion
Derma Glove

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.

Ethanol 62% v/v

Antimicrobial

For external use only. Flammable. Keep away from children.

Do not use in or near eyes. In case of eye contact, rinse thoroughly with water.

If redness or irritation develop and persist for more than 72 hours.

If swallowed, get medical help or contact a Poison Control Center right away.

Apply lotion directly onto body and rub with hands until dry. Product may be used on all skin surfaces. Children under 6 years of age should be supervised when using this product.

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Do not store above 110oF (43oC). For additional information, see Safety Data Sheet (SDS).

Water (aqua), glycereth-18 (and) glycereth-18 ethylhexanoate, PEG 1450, PEG-10 dimethicone, cocamide MEA, ethylene glycol distearate, acrylate crosspolymer, fragrance (parfum), 2-amino-2-methyl-1-propanol, FD&C Blue #1.

Call 1-888-300-1225, Monday through Friday 8:00AM to 5:00PM EST/EDT.

Drug Facts	
Active Ingredient	Purpose
Ethanol 62% v/v.....	Antimicrobial
Uses · Body sanitizer to help reduce bacteria on the skin. · Recommended for repeat use.	
Warnings · For external use only. · Flammable. Keep away from fire and flame.	
When using this product · Do not use in or near eyes. · In case of eye contact, rinse thoroughly with water.	
Stop use and see a doctor · If redness or irritation develop and persist for more than 72 hours.	
Keep out of reach of children · If swallowed, get medical help or contact a Poison Control Center right away.	
Directions · Apply lotion directly onto body and rub with hands until dry. · Product may be used on all skin surfaces. · Children under 6 years of age should be supervised when using this product.	
Other information · Do not store above 110°F (43°C). · For additional information, see Safety Data Sheet (SDS).	
Inactive ingredients · Water (aqua), glycereth-18 (and) glycereth-18 ethylhexanoate, PEG 1450, PEG-10 dimethicone, cocamide MEA, ethylene glycol distearate, acrylate crosspolymer, fragrance (parfum), 2-amino-2-methyl-1-propanol, FD&C Blue #1	
Questions or comments? · Call 1-888-300-1225, Monday through Friday 8:00AM to 5:00PM EST/EDT.	

lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70741-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	30 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70741-005-02	40 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/07/2016	

Labeler - Derma Glove (962709569)

Registrant - Derma Glove (962709569)

Establishment

Name	Address	ID/FEI	Business Operations
Mid Lab Incorporated		047371463	manufacture(70741-005)

Revised: 9/2016

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