

DERMA-GLOVE - ethanol, triclosan gel
RWM TECHNOLOGIES

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.

DERMA-GLOVE HAND SANITIZER GEL

DERMA-GLOVE(R) no rinse hand sanitizer gel

Active Ingredient

Ethanol 60%.....Antimicrobial

Triclosan 0.3%.....Antiseptic

Antiseptic/Antimicrobial hand sanitizer gel

- Hand sanitizer to help reduce bacteria on the skin that could cause disease
- Recommended for repeated use

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use in or near eyes. In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if skin irritation or redness develops and persists for more than 72 hours.

Keep out of the Reach of Children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Place enough product in your palm to thoroughly cover your hands
- Rub hands together briskly until dry
- Rinse with water after use
- Children under 6 years of age should be supervised when using this product

- Do not store above 110° F (43° C)
- For additional information, see Material Safety Data Sheet (MSDS).

Deionized Water, Glycereth-18 Ethylhexanoate, Glycereth-18, Polyoxyethylene (20) Sorbitan Monooleate, 2-Amino-2-methyl-1-propanol, Acrylate crosspolymer, Polyquaternium-69, Citric Acid and Sodium Citrate

Questions or Comments?

Call 1-888-300-1225 Monday through Friday 8:00 AM to 5:00 PM



derma-glove® hand sanitizer gel

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DRUG FACTS	
Active Ingredients	Purpose
Ethanol 60% Triclosan 0.3%	Antimicrobial Antiseptic
Uses	
<ul style="list-style-type: none"> Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use. 	
Warnings	
Flammable. Keep away from fire or flame.	
For external use only.	
When using this product do not use in or near eyes. In case of eye contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if skin irritation or redness develops and persists 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	
<ul style="list-style-type: none"> Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Rinse with water after use. Children under 6 years of age should be supervised when using this product. 	
Other information	
<ul style="list-style-type: none"> Do not store above 110°F (43°C). For additional information, see Material Safety Data Sheet (MSDS). 	
Inactive ingredients Deionized Water, Glyceth-18 Ethylhexanoate, Glyceth-18, Polyoxyethylene (20) Sorbitan Monooleate, 2-Amino-2-methyl-1-propanol, Acrylate crosspolymer, Polyquaternium-69, Citric Acid and Sodium Citrate	
Questions or comments?	
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COMPOSITION

Active Ingredients:	Product Name: Ethanol SDA-40B-190 Proof Irgasan DP 300 USP	INCI Name: Ethanol Triclosan	Wt % 58 0.3
Inactive Ingredients:	Product Name: Deionized Water Hest G-18-0 Polysorbate 80 AMP-95 Ultrez 21 Aquatyle 300 Tinosan SDC	INCI Name: Deionized Water Glyceth-18 Ethylhexanoate, Glyceth-18 Polyoxyethylene (20) Sorbitan Monooleate 2-Amino-2-methyl-1-propanol Acrylate Crosspolymer Polyquaternium-69 Citric Acid and Sodium Citrate	

LABEL

DERMA-GLOVE

ethanol, triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24673-248
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ethanol (UNII: 3K9958 V90 M) (Ethanol - UNII:3K9958 V90 M)	Ethanol	0.58 g in 1 g
Triclosan (UNII: 4NM5039 Y5X) (Triclosan - UNII:4NM5039 Y5X)	Triclosan	0.03 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24673-248-01	55.2 g in 1 BOTTLE, PUMP		
2	NDC:24673-248-02	110.4 g in 1 BOTTLE, PUMP		
3	NDC:24673-248-03	220.8 g in 1 BOTTLE, PUMP		
4	NDC:24673-248-04	3532.8 g in 1 BOTTLE, PUMP		
5	NDC:24673-248-05	17664 g in 1 DRUM		
6	NDC:24673-248-06	194304 g in 1 DRUM		
7	NDC:24673-248-07	883200 g in 1 DRUM		
8	NDC:24673-248-08	1236480 g in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	02/03/2010	

Labeler - RWM TECHNOLOGIES (003215779)

Revised: 6/2010

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