

ANTIBACTERIAL- alcohol gel
Continental Manufacturing Chemist, 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.

Antibacterial

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Use(s)

To decrease bacteria on skin

Warnings

For external use only

Flammable! Keep away from fire or flame. Do not use in eye; if this happens rinse thoroughly with water.

Do not use

Ask a doctor before use if

Ask a doctor or pharmacist before use if

When using this product

Stop use and ask a doctor if

irritation or redness develops and persists more than 72 hours

Pregnancy/Breastfeeding

Keep out of reach of children

If ingested get medical help or contact a Poison Control Center right away

Directions

Wet hands thoroughly with product and allow to dry without wiping. Children under six should be supervised while using this product.

Other information

Storage

Do not store above 105F (40C)

Inactive ingredients

Amino Methyl Propanol, Carbomer, FD&C Blue #1, Fragrance, Propylene Glycol, Purified Water

Questions

Principal Display Panel

D-009 ANTIBACTERIAL GEL

DRUG FACTS

ACTIVE INGREDIENT: Ethyl Alcohol 62%

PURPOSE: Antiseptic

USES: To decrease bacteria on skin

WARNINGS: FOR EXTERNAL USE ONLY
Flammable! Keep away from fire or flame
Do not use in eyes; if this happens rinse thoroughly with water. Stop use ask a doctor if irritation or redness develops and persists more than 72 hours

KEEP OUT OF REACH OF CHILDREN
If ingested get medical help or contact a Poison Control Center right away

DIRECTIONS:
Wet hands thoroughly with product and allow to dry without wiping. Children under six should be supervised while using this product.

INACTIVE INGREDIENTS: Amino Methyl Propanol, Carbomer, FD&C Blue #1, Fragrance, Glycerine, Propylene Glycol, Purified Water

Do not store above 105F (40C)

D-009 ANTIBACTERIAL GEL
LOT # XXXXX
RETEST DATE: XX/XX/XXXX

GROSS WT: _____

TARE WT: _____

NET WT: _____

MANUFACTURED BY:
CONTINENTAL MANUFACTURING CHEMIST, INC.
MADRID, IA 50156

DEDICATED TOTE
RINSE WITH WATER AND RETURN TO MANUFACTURER

Antibacterial Gel Labels

ANTIBACTERIAL			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49794-009
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	620 g in 1.0 kg		
Inactive Ingredients				
Ingredient Name	Strength			
2-ETHYLAMINOETHANOL (UNII: 1G0G2TK41H)				
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0K00R)				
Product Characteristics				
Color	BLUE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49794-009-99	1000 kg in 1 CONTAINER		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333A	09/01/2011		

Labeler - Continental Manufacturing Chemist, Inc. (005278007)

Revised: 12/2011

Continental Manufacturing Chemist, Inc.