

MADA 70% ALCOHOL- alcohol gel

Mada Medical Products, 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.

Drug Facts

Active ingredient

Alcohol Denat. 72% v/v

Purpose

Antibacterial Agent

Uses

Hand sanitizer to help reduce bacteria on the skin that could cause disease.

Warnings

For external use only.

FLAMMABLE Keep away from heat or flame.

Avoid contact with eyes.

If eye contact occurs, flush with water.

Stop use if, in rare instances, redness or irritation develop.

If condition persists for more than 72 hours, consult a physician.

Keep out of reach of children.

If swallowed, contact a physician or poison control center.

Directions

Apply a small amount to palm.

Briefly rub, covering hands with product until dry.

Inactive ingredients

Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Isopropyl Alcohol, Carbomer, Triisopropanolamine

PRODUCT CODE

705555

STORE BETWEEN

33 TO 110F

MADA GEL 70% ALCOHOL

QUANTITY AND SIZE

55 Gallon Drum

BATCH NUMBER

EXP:

MANUFACTURED FOR:

MADA MEDICAL
 625 WASHINGTON AVE.
 CARLSTADT, NJ 07072
 MADE IN USA
 Rev:01/18

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Drug Facts	
Active Ingredient	Purpose
Alcohol 72% v/v	Antibacterial Agent
<p>Directions: Apply to skin to help reduce bacteria on the skin that could cause disease.</p>	
<p>Warnings: For external use only. FLAMMABLE. Keep away from heat or flames. Avoid contact with eyes. If eye contact occurs, flush with water. Stop use if, or use ceases, redness or irritation develop. If condition persists for more than 72 hours, consult a physician. Stay out of reach of children. If swallowed, contact a physician or poison control center.</p>	
<p>Directions: Apply small amount to skin. Gently rub, covering hands with product until dry.</p>	
<p>Contains: Active Ingredients: Water, Glycerin, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Isopropyl Alcohol, Carbomer, Triisopropanolamine.</p>	

MADA 70% ALCOHOL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11928-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TRISOPROSPANOLAMINE (UNII: W9EN9DLM98)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11928-005-55	208 L in 1 DRUM; Type 0: Not a Combination Product	10/12/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/12/2017	

Labeler - Mada Medical Products, Inc. (048411862)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company		004236139	manufacture(11928-005)

Revised: 1/2018

Mada Medical Products, Inc.