INSTANT HAND SANITIZER - ethyl alcohol gel AMERICAN SALES COMPANY

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

ETHYL ALCOHOL 62%

USES

TO HELP REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

• AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THOROUGHLY WITH WATER.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

• IRRITATION OR RASH DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- APPLY A SMALL AMOUNT IN YOUR PALM AND RUB HANDS TOGETHER BRISKLY UNTIL DRY.
- CHILDREN UNDER 6 SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.

OTHER INFORMATION

DO NOT STORE ABOVE $110^{\rm O}$ C (43 $^{\rm O}$ C). MAY DISCOLOR CERTAIN FABRICS OR SURFACES.

PURPOSE

ANTISEPTIC

INACTIVE INGREDIENTS

WATER, GLYCERIN, ISOPROPYL MYRISTATE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, AMINOMETHYL PROPANOL, CARBOMER, FRAGRANCE.







KILLS 99.99% OF GERMS*

15 FL OZ (443 mL)



Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 62%	Antiseptic

Uses - To help reduce bacteria on the skin

Warnings

For external use only. Flammable. Keep away from fire or heat source. When using this product = avoid contact with eyes. If contact occurs,

rinse thoroughly with water.

Stop using this product and ask a doctor if = irritation or redness develops and lasts.

Keep out of reach of children. = In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions = Wet hands thoroughly and rub together until dry

Other information = Store at room temperature below 110°F (43°C). Inactive ingredients = Water, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Aminomethyl Propanol, Carbomer,

Fragrance (Parfum). *Effective at eliminating over 99.99% of many common harmful germs

and bacteria in as little as 30 seconds. DISTRIBUTED BY FOODHOLD U.S.A., LLC

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INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source)

TOPICAL

NDC:41520-225

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
.ALPHATO COPHERO L ACETATE, D- (UNII: A7E6112E4N)				

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

CARBOMER 934 (UNII: Z135WT9208)

Packaging

1 ucinig mg				
I	# Item Code	Package Description	Marketing Start Date	Marketing End Date
I	1 NDC:41520-225-15	443 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	0 2/0 1/20 13	

Labeler - AMERICAN SALES COMPANY (809183973)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(41520-225)	

Revised: 2/2013 AMERICAN SALES COMPANY