

HAND SANITIZER 70 PERCENT- ethyl alcohol gel
Emilia Cosmetics Ltd

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.

HAND SANITIZER

ACTIVE INGREDIENT

ETHYL ALCOHOL 70% V/V

PURPOSE

ANTIMICROBIAL

USES

HAND SANITIZER TO HELP REDUCE BACTERIA ON THE SKIN

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE, KEEP AWAY FROM OPEN FIRE OR FLAME.

WHEN USING THIS PRODUCT DO NOT USE NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH AND LASTS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- PUT ENOUGH PRODUCT IN YOUR PALM TO COVER HANDS AND RUB HANDS BRISKLY TOGETHER UNTIL DRY.
- CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT.
- NOT RECOMMENDED FOR INFANTS.

OTHER INFORMATION

- STORE BELOW 110°F (43°C)
- MAY DISCOLOR CERTAIN FABRICS OR SURFACE.

INACTIVE INGREDIENTS

WATER, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, ETHYLHEXYLGLYCERIN, PANTHENOL (PRO-VITAMIN B5), FRAGRANCE.



SANI-X

HAND SANITIZER

CONTAINS 70% V/V ALCOHOL

2 mL / 0.068 fl oz

Drug Facts

Active ingredient

Ethyl Alcohol 70% v/v

Purpose

Antimicrobial

Use hand sanitizer to help reduce bacteria on the skin**Warnings****For external use only****Flammable, keep away from open fire or flame.**

When using this product do not use in or near the eyes.

In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears

and lasts. Keep out of reach of children. If swallowed,

get medical help or contact a Poison Control Center

right away.

Directions****** put enough product in your palm to cover hands and

rub hands together briskly until dry * children under 6

years of age should be supervised when using this

product * not recommended for infants.

Other information * store below 110° F (43°C)

* may discolor certain fabrics or surface.

Inactive ingredients water, glycerin, carbomer,
aminomethyl propanol, ethylhexylglycerin, panthenol
(pro-vitamin B5), fragrance.**Manufactured by:**

Emilia Cosmetics LTD. | Manufactured in Israel

Distributed by eXpackUSA inc , New Jersey , 07647, USA

HAND SANITIZER 70 PERCENT

ethyl alcohol gel

Product Information**Product Type**

HUMAN OTC DRUG

Item Code (Source)

NDC:43219-104

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PANTHENOL (UNII: WV9CM0O67Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43219-104-02	2 mL in 1 POUCH; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/06/2020	

Labeler - Emilia Cosmetics Ltd (600076624)

Revised: 5/2020

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