

HAND SANITIZER - ISOPROPYL ALCOHOL ANTISEPTIC 75 PERCENT - isopropyl alcohol gel

MAREK HEWRYK LLC

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 - ISOPROPYL ALCOHOL ANTISEPTIC 75%

ACTIVE INGREDIENT

ISOPROPYL ALCOHOL 75% W/V

PURPOSE

ANTISEPTIC

USE(S)

HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.

DO NOT USE

- IN CHILDREN LESS THAN 2 MONTHS OF AGE
- ON OPEN SKIN WOUNDS

WHEN USING THIS PRODUCT KEEP OUT OF EYES, EARS, AND MOUTH. IN CASE OF CONTACT WITH EYES, RINSE EYES THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH OCCURS. THESE MAY BE SIGNS OF A SERIOUS CONDITION.

KEEP OUT OF REACH OF CHILDREN.

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

DIRECTIONS

- PLACE ENOUGH PRODUCT ON HANDS TO COVER ALL SURFACES. RUB HANDS TOGETHER UNTIL DRY.
- SUPERVISE CHILDREN UNDER 6 YEARS OF AGE WHEN USING THIS PRODUCT TO AVOID SWALLOWING.

OTHER INFORMATION

- STORE BETWEEN 15-30 C (59-86F)
- AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)

INACTIVE INGREDIENTS

GLYCERIN, HYDROGEN PEROXIDE, PURIFIED WATER USP, ALOE BARBADENSIS (ALOE VERA) LEAF JUICE, CARBOMER, TOCOPHERYL ACETATE (VIT. E), ANTHEMIS NOBILIS (CHAMOMILE) EXTRACT, TILIA CORDATA (LINDEN) EXTRACT, FRAGRANCE (PARFUM)

Advanced HAND SANITIZER

Non-sterile Solution

Isopropyl Alcohol Antiseptic 75%

Topical Solution

- Kills 99.9% of Germs
- Fast, Effective & Moisturizing



DRUG FACTS

Active ingredient

Isopropyl Alcohol 75% w/v

Purpose

Antiseptic

Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings: For external use only. Flammable. Keep away from heat or flame **Do not use** • in children less than 2 months of age • on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. **Stop use and ask a doctor** if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.

Other information • Store between 15-30C (59-86F)
• Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients: glycerin, hydrogen peroxide, purified water USP, aloe barbadensis (aloe vera) leaf juice, carbomer, tocopheryl acetate (vit. E), anthemis nobilis (chamomile) extract, tilia cordata (linden) extract, fragrance (parfum)

Manufactured by Marek Hewryk LLC,
Fort Lauderdale, FL 33314, USA
Made in USA



HAND SANITIZER - ISOPROPYL ALCOHOL ANTISEPTIC 75 PERCENT

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75161-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL	75 mL

UNII:ND2M416302)		ALCOHOL	in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0K00R)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)				
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75161-101-11	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	05/04/2020		

Labeler - MAREK HEWRYK LLC (033217270)

Establishment			
Name	Address	ID/FEI	Business Operations
MAREK HEWRYK LLC		033217270	manufacture(75161-101)

Revised: 5/2020

MAREK HEWRYK LLC