

UNICHEM- ethyl alcohol 70% safe on skin spray
Universal Chemical Products, Corp.

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.

Ethyl Alcohol 70% Safe on Skin

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Helps prevent the risk of infection in minor cuts, scrapes and burns.

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.

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

Directions

- Clean affected area

- 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

Glutaraldehyde, purified water USP, Isopropyl Alcohol, Glycerine

Package Label - Principal Display Panel



70% Ethyl Alcohol

DRUG FACTS

ACTIVE INGREDIENT
Ethyl Alcohol 70% Antiseptic

USE(S) - Helps prevent the risk of infection in minor cuts, scrapes and burns. Do not use in children less than 2 months - on open skin wounds. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control.

WARNINGS
For external use only. **(Flammable, keep away from heat or flame)**

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

DIRECTIONS - Clean the affected area. - Apply 1 to 3 times daily
OTHER INFORMATION - Store between 15-30°C (59-86°F), avoid freezing and excessive heat above 40°C.

INACTIVE INGREDIENTS - Purified Water, Isopropyl Alcohol, Glutaraldehyde, Glycerine

Packed by:

UNIVERSAL CHEMICALS PRODUCTS, CORP.
PO BOX 540 LOITZA, PR 00772
787.876.1717



0 98968 40011 6

70% Ethyl Alcohol

Antiseptic

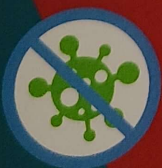
Safe on Skin

Net Content:
32 FL OZ (946.4mL)



Uses:

- Sanitize surfaces
- Hygienic purposes
- First aid antiseptic
- Safe on skin
- Evaporates away leaving no residues



#StaysSafe

UNICHEM

ethyl alcohol 70% safe on skin spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82150-870
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.25 mL in 100 mL
GLUTARALDEHYDE (UNII: T3C89M417N)	0.03 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.75 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	0.75 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82150-870-32	946.4 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/24/2020	

Labeler - Universal Chemical Products, Corp. (963557095)

Registrant - Universal Chemical Products, Corp. (963557095)

Establishment

Name	Address	ID/FEI	Business Operations
Universal Chemical Products, Corp.		963557095	manufacture(82150-870)