

HAND SANITIZER- ethyl alcohol liquid

J.R. Watkins, 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

This is a hand sanitizer manufactured according to CFR 21 part 333A.

- a. Alcohol (ethanol) (USP grade) (62%, weight/weight (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Water
- c. Glycerin
- d. Distilled water
- e. Ethylhexylglycerin
- f. Aloe Barbadensis Leaf Juice

The firm does not add other active or inactive ingredients.

Active Ingredient(s)

Alcohol 62% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

To reduce bacteria on the skin.

Recommended for repeated use.

Warnings

For external use only.

Flammable: Keep away from heat or flame

When using this product

When using this product do not use in or near the eyes, if contact occurs, rinse thoroughly with water

Stop use and ask a doctor if

Stop use and ask a doctor if irritation or redness develop, condition persists for more than 72 hours

Keep out of reach of children

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

Directions

- Wet hands thoroughly and allow to dry without wiping.

- Children under 6, use adult supervision.

Other information

Store Below 110°F (43°C)

Inactive ingredients

Water, Glycerin, Ethylhexylglycerin, Aloe Barbadensis Leaf Juice



HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72342-090
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
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ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72342-090-18	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - J.R. Watkins, LLC (081071049)

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J.R. Watkins, LLC