

FALCON HAND SANITIZING GEL- alcohol solution

Falcon Industrial, Inc.

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.

This is a hand rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.00% v/v).
- c. Carbomer (0.75% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Aminoethyl Propanol (1.00% v/v)

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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

Package Label - Principal Display Panel

3.785 L (3785 mL) NDC: 78166-700-01

**Falcon Hand
Sanitizing Gel**
Alcohol Antiseptic 70%
Topical Solution

Hand Sanitizer
Non-sterile Solution

3.785 L (3785 mL)

NDC: 78166-700-01

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Use • Hand sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings

Flammable. Keep away from fire, or flame.

For external use only

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 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 • Apply. Put enough product on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds.

• Supervise children under 6 years of age when using this product to avoid swallowing.

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

Inactive ingredients • Deionized Water, Glycerin, Carbomer, Aminoethyl Propanol.

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78 166-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78 166-700-01	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Falcon Industrial, Inc. (612813498)

Establishment

Name	Address	ID/FEI	Business Operations
Falcon Industrial, Inc.		612813498	manufacture(78166-700)

Revised: 7/2020

Falcon Industrial, Inc.