

INSTANT HAND SANITIZER- alcohol gel

Products Chemical Company

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 sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer 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 (isopropyl) (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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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.

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 20-25C (68-77F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

water, carbopol, propylene glycol, triethanolamine.

Package Label - Prin



Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 70%.....	Antimicrobial
Uses	
■ For handwashing to decrease bacteria on the skin	
■ Recommended for repeated use	
Warnings For external use only	
Flammable, keep away from fire or flame	
Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.	
Directions ■ wet hands thoroughly with product.	
■ briskly rub hands together until dry.	
■ supervise children in the use of this product.	
Other Information ■ may discolor certain fabrics	
■ store at 20 degrees to 25 degrees C	
Inactive Ingredients water, carbopol, propylene glycol, triethanolamine..	

948mL NDC: 77269-300-01

INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77269-300
---------------------	----------------	---------------------------	---------------

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 903K93S3TK)	0.07 mL in 100 mL
WATER (UNII: 059QF0KO0R)	31.5 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77269-300-01	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - Products Chemical Company (117062156)

Establishment

Name	Address	ID/FEI	Business Operations
Products Chemical Company		117062156	manufacture(77269-300)

Revised: 1/2021

Products Chemical Company