HAND SANITIZER- alcohol solution J&J CHEMICAL CO

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 (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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 80% 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.

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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

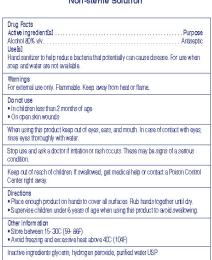
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel





MADE IN THE USA · SDS AVAILABLE www.jjchem.com





Flammable Liquid and vapor, Causes eye irritation, Ethyl Alcohol 80%

Keep out of reach of children.

Head label before use.

Keep container tightly closed.

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, If present and easy to do so. Continue rinsing. If eye irritation persists: Get medical advice/attention.

In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

Storage: Store in a well ventilated place. Keep cool.

J & J Chemical Co. 1450 Athens Road, Crawford, GA 30630 Telephone (706) 743-1900 Emergency Contact (Available 24/7): 1-800-535-5053

NET CONTENTS: 208,000 ml NDC: 75562-111-55

J&J Chemical EUROPE GmbH German y europe@jjchem.com



208000 mL NDC: 75562-111-55

HAND SANITIZER

alcohol solution

Product Information

Route of Administration

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75562-111

GA • UT • AZ 1-800-345-3303 • 706-743-1900

order@iichem.com

TOPICAL

Active Ingradient/Active Mojety

Active Ingredient/Active Molety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:75562-111-55	208000 mL in 1 DRUM; Type 0: Not a Combination Product	04/20/2020	
ľ	2 NDC:75562-111-01	3800 mL in 1 JUG; Type 0: Not a Combination Product	05/11/2020	

Alcohol Antiseptic 80% Topical Solution Non-sterile Solution

Act Alco Use Har	g Facts Purpose the ingredient(s) Purpose chol 60% y/v Antisepti 1931 1931 do amitzer to help reduce bacteria that potentially can cause disease. For use when p and water are not available.
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Non-sterile Solution





International Distribution J&J Chemical EUROPE GmbH Germany europe@jjchem.com

WARNING

Flammable Liquid and vapor, Causes eye irritation, Ethyl Alcohol 80%

Keep out of reach of children.

Read label before use. Keep container tightly closed.
Keep away from heat/sparks/open flames/hot surfaces. No smoking.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists: Get medical advice/attention.

In case of fire: Use dry sand, dry chemical or alcohol-resistant foam

Storage: Store in a well ventilated place. Keep cool.

J & J Chemical Co. 1450 Athens Road, Crawford, GA 30630 Telephone (706) 743-1900 Emergency Contact (Available 24/7): 1-800-535-5053

NET CONTENTS: 1 gallon (3.8 L)

NDC: 75562-111-01



Marketing Information

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

0	8			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/20/2020		

Labeler - J&J CHEMICAL CO (083106757)

Registrant - J&J CHEMICAL CO (083106757)

Establishment				
Name	Address	ID/FEI	Business Operations	
J&J CHEMICAL CO		083106757	manufacture (75562-111)	

Revised: 5/2020 J&J CHEMICAL CO