

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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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

Alcohol Antiseptic 80% Topical Solution Non-sterile Solution		WARNING 								
Drug Facts Active ingredient(s) Purpose Alcohol 80% w/v Antiseptic Use(s) 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. 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		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 for extinction. Storage: Store in a well ventilated place. Keep cool. J & J Chemical Co. 1450 Athens Road, Crawford, GA 30630 Telephone (706) 749-1900 Emergency Contact (Available 24/7): 1-800-535-5053								
MADE IN THE USA • SDS AVAILABLE www.jjchem.com	USA Manufacturing Facilities J&J CHEMICAL CO GA • UT • AZ 1-800-345-8308 • 706-743-1900 order@jjchem.com	International Distribution J&J Chemical EUROPE GmbH Germany europa@jjchem.com								
	NET CONTENTS: 208,000 ml NDC: 75562-111-55	HMIS Ratings <table border="1"><tr><td>Health</td><td>2</td></tr><tr><td>Flammability</td><td>3</td></tr><tr><td>Physical Hazard</td><td>0</td></tr><tr><td>Personal Protection</td><td>B</td></tr></table>	Health	2	Flammability	3	Physical Hazard	0	Personal Protection	B
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208000 mL NDC: 75562-111-55

HAND SANITIZER			
alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75562-111
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

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	
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

Drug Facts
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Alcohol Antiseptic 80%
Topical Solution
Non-sterile Solution

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order@jjchem.com

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 for extinction.

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

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Telephone (706) 743-1900
Emergency Contact (Available 24/7): 1-800-535-5053

HMIS Ratings

Health	2	Corrosive, Irritant, Flammable, Toxic
Physical hazard	3	Flammable liquid, Flammable solid
Personal hazard	0	None
Personal protection	E	Eye Protection, Hand Protection, Skin Protection, Respiratory Protection

NET CONTENTS: 1 gallon (3.8 L)
NDC: 75562-111-01

Marketing Information

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