

CITRI-SANI70 SANITIZER- alcohol gel

Stewart Industries

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.

HandSani70

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) (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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Carbomer
- f. Fragrance

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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
- do not use in or near eyes

Keep out of the 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

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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

Purified water, hydrogen peroxide, Carbomer, fragrance and Glycerin

Package Label - Principal Display Panel



Drug Facts	
Active Ingredients: Denatured Ethanol 70%.....	Purpose Antiseptic, Hand Sanitizer
Uses - 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 and flame.	
Do Not Use - • in children less than 2 months of age • on open skin wounds • do not use in or near eyes	
When using this product - Keep out of the 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.	
Inactive Ingredients - Purified water, hydrogen peroxide, carbomer, fragrance and glycerin.	
Other information - Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics	

Distributed by: STEWART Medical Supply
150 McQuiston Dr.- Battle Creek, MI 49037 | 269.660.9290



Made in the USA

118mL NDC: 80392-001-04

or

236 mL NDC:80392-001-08

or

354 mL NDC: 80392-001-12

or

3785 mL NDC:80392-001-01

CITRI-SANI70 SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80392-001
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
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	4 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80392-001-01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80392-001-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80392-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80392-001-12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Stewart Industries (002034663)

Registrant - Stewart Industries (002034663)

Establishment

Name	Address	ID/FEI	Business Operations
Stewart Industries		002034663	manufacture(80392-001)