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 eves

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. 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

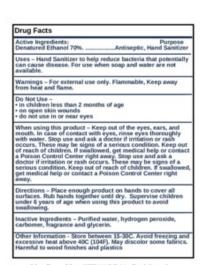
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Purified water, hydrogen peroxide, Carbomer, fragrance and Glycerin

Package Label - Principal Display Panel





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



118mL NDC: 80392-001-04

or

236 mL NDC:80392-001-08

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354 mL NDC: 80392-001-12

or

3785 mL NDC:80392-001-01

CITRI-SANI70 SANITIZER

alcohol gel

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Product	Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80392-001
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Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

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		
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	1 mL in 100 mL		

]	Packaging			
1	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)	

Revised: 8/2020 Stewart Industries