

ALOE VERA HAND SANITIZER- isopropyl alcohol lotion

Classic Coatings Systems

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

Classic Hand Sanitizer is a no-rinse hand sanitizer and contains emollients to moisturize and soothe the skin. Formulated to be fragrance-free, dye-free and acceptable for use in sensitive environments such as hospitals, food processors, and other service establishments. Classic Hand Sanitizer contains at least 75% of isopropyl alcohol and meets Food & Drug Administration guidelines.

WARNING: FOR EXTERNAL USE ONLY. FLAMMABLE LIQUID AND VAPOR. KEEP AWAY FROM FIRE, OPEN FLAME, HOT SURFACES, SMOKING, HEAT & SPARKS. KEEP CONTAINER TIGHTLY CLOSED.

KEEP OUT OF REACH OF CHILDREN: IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

AVOID EYE CONTACT: IN CASE OF CONTACT, FLUSH THOROUGHLY WITH WATER. DO NOT INHALE OR INGEST. AVOID CONTACT WITH BROKEN SKIN. DISCONTINUE USE IF IRRITATION OR REDNESS DEVELOPS. IF CONDITION PERSISTS FOR MORE THAN 72 HOURS CONSULT A DOCTOR.



HAND SANITIZER
ALOE VERA
Kills 99.9%
of harmful germs and bacteria



75%IPA
6 fl oz - (177ml)
Active Ingredients:
Isopropyl Alcohol 75%
Inactive Ingredients: Aloe Vera, Water, Glycerin & Carbomer

DIRECTIONS: Place solution on hands and rub into skin until dry.

APPLY TO HANDS



RUB HANDS TOGETHER UNTIL DRY



DO NOT USE FOR CHILDREN UNDER 2 YEARS OLD. FOR CHILDREN UNDER 6, USE ONLY UNDER ADULT SUPERVISION. STORE AT A TEMPERATURE BELOW 100F (37C)

Manufactured by
Classic Coatings Systems
Corona, Ca.
Tech Support:
(714) 720-8954

B#201404

HEALTH HAZARD	0	HEALTH HAZARD RATING
FLAMMABILITY	3	LEAST.....0
PHYSICAL HAZARD	0	SLIGHT.....1
		MEDIUM.....2
		SEVERE.....3
		EXTREME.....4

177mL NDC: 75816-375-06

ALOE VERA HAND SANITIZER

isopropyl alcohol lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75816-375
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75816-375-05	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/20/2020	
2	NDC:75816-375-27	1040988 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/20/2020	
3	NDC:75816-375-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	04/20/2020	
4	NDC:75816-375-06	177 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	
5	NDC:75816-375-32	946 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/20/2020	
6	NDC:75816-375-55	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

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

Labeler - Classic Coatings Systems (133106232)

Establishment

Name	Address	ID/FEI	Business Operations
Classic Coatings Systems		133106232	manufacture(75816-375)