HAND SANITIZER- isopropyl alcohol spray UBQ Industries, LLC

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.

Hand Sanitizer Spray - Scented - Citrus Eucalyptus

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, orange essential oil, cinnamon essential oil, camphor essential oil, eucalyptus essential oil, bitter almond essential oil

Package Label - Principal Display Panel

236 ml NDC: 80668-868-01

SoClean.

75% Isopropyl Alcohol Hand Sanitizer Spray

Meets CDC recommendations for hand-washing in the absence of water.

Citrus + Eucalyptus

Responsibly sourced.

USA Recyclable bottle.

ONE 8 OZ (236ml) BOTTLE

SoClean.

SoClean.com

Citrus + Eucalyptus Hand Sanitizer Spray

75% Isopropyl Alcohol

Drug Facts

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Purposeantiseptic

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C001166 Rev B PN0014-8CCE NDC 80668-868-01 Exp 03/2023 Lot 80062621

HAND SANITIZER

isopropyl alcohol spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80668-868

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

Manufactured for: SoClean Inc. 12 Vose Farm Road, Peterborough, NH 03458, USA

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)			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80668- 868-01	236 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/05/2021	

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

Labeler - UBQ Industries, LLC (069021187)

Establishment				
Name	Address	ID/FEI	Business Operations	
UBQ Industries, LLC		069021187	manufacture(80668-868)	

Revised: 4/2021 UBQ Industries, LLC