HAND SANITIZER- isopropyl alcohol gel
PHARMEDICA USA 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 Lotion Product

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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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

60 ml NDC: 75383-999-01

JOURN

ALSO

Daily moisturizer, also sanitizes.

Inspired by you.

The world has changed, but you have not. Day in and day out, you make sure everything you do is in good hands.

We just want to make sure those hands are good.

BLOSSOM

with

SHEA BUTTER

HIBISCUS

JOJOBA

ourjourn.com

Drug Facts

Active ingredients	**Purpose**
Isopropyl Alcohol 75 % v/v	Antimicrobial

Uses
Hand sanitizing to help reduce bacteria that potentially causes disease. Recommended for repeated use.

Warnings
Flammable. Keep away from heat or flame. For external use only.

Do not use
In children less than 2 months of age or on open skin wounds.

When using this product keep out of eyes, ears, and mouth. In case of eye contact, rinse thoroughly with water.

Stop use and see a doctor if irritation or redness develops. 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 - **(800) 222-1222**.

Directions
- Place enough product on hands to thoroughly cover all surfaces. Rub hands together briskly until dry.
- Children under the age of 6 should be supervised when using this product.

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

Inactive ingredients
Glycerin, Carbomer, Hydrogen Peroxide, Aqua, Hibiscus Rosa-Sinensis (Hibiscus) Flower Extract, Aloe Barbadensis (Aloe Vera) Leaf Juice, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea) Butter, Cholecalciferol (Vitamin D), Glyceryl Stearate, Polysorbate 80, Tocopherol, Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer, PEG-12 Dimethicone, Ethyl Alcohol.

Moisturizes your hands, while eliminating 99.9% of germs and bacteria.

60 ml | 2 fl oz.

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75383-101
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
DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER (UNII: O4I3UFO6ZF)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
PEG-15 GLYCERYL STEARATE (UNII: 91245SPD5K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HIBISCUS ROSA-SINENSIS FLOWER (UNII: VB092Y7Z8T)	
ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
2-(DIETHYLAMINO)ETHANOL (UNII: S6DL4M053U)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75383-101-99	60 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	
2	NDC:75383-101-98	100 mL in 1 TUBE; Type 0: Not a Combination Product	12/01/2020	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/01/2020	

Labeler - PHARMEDICA USA LLC (076399908)

Establishment

Name	Address	ID/FEI	Business Operations
PHARMEDICA USA LLC		076399908	manufacture(75383-101)

Revised: 1/2022 PHARMEDICA USA LLC