

PANACEA LIFE SCIENCES HAND SANITIZER SPRITZ- alcohol liquid

Panacea Life Sciences

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.

Panacea Life Sciences Hand Sanitizer Spritz

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) (62%, 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.

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)

Alcohol 62% 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.

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 USP, 2-propanol, 1,2,3-Propanetriol, hydrogen peroxide

Package Label - Principal Display Panel for 100 ml, 175 ml, 236 ml and 1893 ml package sizes

Drug Facts	
Active ingredient Purpose Ethyl Alcohol 62%.....Antibacterial	
Uses For handwashing to decrease bacteria on the skin.	
Warnings Flammable. Keep away from fire or flame. For external use only.	
When using this product ▪ Do not use in eyes. In case of contact with eyes, rinse with water.	
Stop use and ask a doctor if irritation and redness develop and persist.	
Keep out of reach of children. If swallowed, get medical help promptly.	
Directions ▪ Wet hands thoroughly with product and allow to dry without wiping.	
Other information Store in a well-ventilated place. Keep cool.	HAND SANITIZER <i>SPRITZ</i>
Inactive ingredients Water, 2-propanol, 1,2,3- Propanetriol, Hydrogen peroxide.	

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64 FL OZ (1893 mL)

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 62%.....	Antibacterial

Uses For handwashing to decrease bacteria on the skin.

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

When using this product
▪ Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if irritation and redness develop and persist.

Keep out of reach of children. If swallowed, get medical help promptly.

Directions ▪ Wet hands thoroughly with product and allow to dry without wiping.

Other information Store in a well-ventilated place. Keep cool.

Inactive ingredients Water, 2-propanol, 1,2,3-Propanetriol, Hydrogen peroxide.



HAND SANITIZER SPRITZ

8 FL OZ (236 mL)

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 62%.....	Antibacterial

Uses For handwashing to decrease bacteria on the skin.

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

When using this product
▪ Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if irritation and redness develop and persist.

Keep out of reach of children. If swallowed, get medical help promptly.

Directions ▪ Wet hands thoroughly with product and allow to dry without wiping.

Other information Store in a well-ventilated place. Keep cool.

Inactive ingredients Water, 2-propanol, 1,2,3-Propanetriol, Hydrogen peroxide.



HAND SANITIZER SPRITZ

5.9 FL OZ (175 mL)



Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 62%.....	Antibacterial

Uses For handwashing to decrease bacteria on the skin.

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

When using this product
▪ Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if irritation and redness develop and persist.

Keep out of reach of children. If swallowed, get medical help promptly.

Directions ▪ Wet hands thoroughly with product and allow to dry without wiping.

Other information Store in a well-ventilated place. Keep cool.

Inactive ingredients Water, 2-propanol, 1,2,3-Propanetriol, Hydrogen peroxide.



HAND SANITIZER SPRITZ

3.3 FL OZ (100 mL)



PANACEA LIFE SCIENCES HAND SANITIZER SPRITZ

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74456-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 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: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74456-002-01	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/13/2020	
2	NDC:74456-002-02	175 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/13/2020	
3	NDC:74456-002-03	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/13/2020	
4	NDC:74456-002-04	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

Labeler - Panacea Life Sciences (081187647)

Registrant - Panacea Life Sciences (081187647)

Establishment

Name	Address	ID/FEI	Business Operations
Panacea Life Sciences		081187647	manufacture(74456-002)

