64OZ HAND SANI HYPE-LABS- alcohol spray SunBeam Laboratories 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.

64oz 1893ml Hand Sanitizer

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) (80%, 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. 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 80% 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.

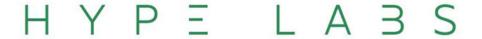
Other information

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

Inactive ingredients

purified water USP

Package Label - Principal Display Panel



Hand Sanitizer Spray

Shake well before use



Surface Disinfectant 80% Ethyl Alcohol

64 oz. (1893ml)

Ingredients: 80% Ethyl Alcohol

Manufactured By: SunBeam Laboratories 888-259-5710

Drug Facts

Active ingredient[s] Purpose

Use[s]

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.

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







Hand Sanitizer Spray

Ingredients: 80% Ethyl Alcohol

Shake well before use 80% Denatured Ethyl Alcohol



64 oz. (1893 ml)

Manufactured By: SunBeam Laboratories 888-259-5710

1893 mL NDC: 75321-0064-2



Shake well before use



Hand Sanitizer Spray
Surface Disinfectant
80% Ethyl Alcohol

Ingredients: 80% Ethyl Alcohol

Manufactured By: SunBeam Laboratories 888-259-5710

64 oz. (1893ml)

1893 mL NDC: 75321-0064-3

64OZ HAND SANI HYPE-LABS

alcohol spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75321-0064	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1514 mL in 1893 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	379 mL in 1893 mL		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-0064- 1	1893 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75321-0064- 2	1893 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75321-0064-3	1893 mL in 1 BOTTLE, SPRAY; 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 - SunBeam Laboratories LLC (105139335)

Establishment				
Name	Address	ID/FEI	Business Operations	
SunBeam Laboratories LLC		105139335	manufacture(75321-0064)	

Revised: 4/2020 SunBeam Laboratories LLC