

HAND SANITIZER- 2OZ HYPE-LAB- 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.

2oz 59ml 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

The image shows a rectangular package label for PRISM HEMP Hand Sanitizer Spray. The label has a white background with a blue border. At the top center is the PRISM HEMP logo, which consists of a stylized green leaf with a red triangle on the left and a blue triangle on the right, and the word "PRISM" in large bold letters above "HEMP" in smaller spaced-out letters. Below the logo, the text "Hand Sanitizer Spray" and "Surface Disinfectant" are written in a large, bold, black font. Underneath that, "80% Ethyl Alcohol" is written in a slightly smaller bold black font. At the bottom center, "2 oz. (59ml)" is written in a bold black font. On the left side of the label, there are two circular "MADE IN" logos: one for "MADE IN NY" and one for "MADE IN THE USA" with an American flag. Below these logos is a standard barcode. On the right side of the label, the text "Ingredients: 80% Ethyl Alcohol" is written in a smaller black font. Below that, "Manufactured By: SunBeam Laboratories 888-259-5710" is written in a green font.

Shake well before use

MADE IN NY

MADE IN THE USA

PRISM
H E M P

Hand Sanitizer Spray
Surface Disinfectant
80% Ethyl Alcohol

2 oz. (59ml)

Ingredients:
80% Ethyl Alcohol

Manufactured By:
SunBeam Laboratories
888-259-5710

59 mL NDC: 75321-0002-3



STOP
CORONA



Hand Sanitizer Spray

Ingredients:
80% Ethyl Alcohol

80% Denatured Ethyl Alcohol

Shake well before use



2 oz. (59ml)

Manufactured By:
SunBeam Laboratories
888-259-5710

59 mL NDC: 75321-0002-2

H Y P E L A B S

Hand Sanitizer Spray

Surface Disinfectant

80% Ethyl Alcohol

Ingredients:
80% Ethyl Alcohol

Shake well before use



2 oz. (59ml)

Manufactured By:
SunBeam Laboratories
888-259-5710

Drug Facts	
Active ingredient[s] Alcohol 80%v/v.....	Purpose Antiseptic
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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients purified water USP	

59 mL NDC: 75321-0002-1

HAND SANITIZER- 2OZ HYPE-LAB				
alcohol spray				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75321-0002	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	47 mL in 59 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)		12 mL in 59 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-0002-1	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75321-0002-2	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75321-0002-3	59 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(75321-0002)

Revised: 4/2020

SunBeam Laboratories LLC