

**128OZ 3785ML 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.*

-----

**128oz 3785ml 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**

H Y P E L A B S

Hand Sanitizer Spray

Surface Disinfectant

80% Ethyl Alcohol

128 oz. (3785ml)

Shake well before use

MADE IN NY

MADE IN THE USA

Ingredients:  
80% Ethyl Alcohol

Manufactured By:  
SunBeam Laboratories  
888-259-5710

**Drug Facts**

**Active ingredient[s]**

Alcohol 80%v/v.....Antiseptic

**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



STOP  
CORONA



Hand Sanitizer Spray

Ingredients:  
80% Ethyl Alcohol

80% Denatured Ethyl Alcohol

Shake well before use



128 oz. (3785 ml)

Manufactured By:  
SunBeam Laboratories  
888-259-5710

3785 mL NDC: 75321-0128-2



Hand Sanitizer Spray  
 Surface Disinfectant  
 80% Ethyl Alcohol

Shake well before use



128 oz. (3785ml)

Ingredients:  
 80% Ethyl Alcohol

Manufactured By:  
 SunBeam Laboratories  
 888-259-5710

3785 mL NDC: 75321-0128-3

**128OZ 3785ML HAND SANI HYPE-LABS**

alcohol spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75321-0128
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3028 mL in 3785 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	757 mL in 3785 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75321-0128-1	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75321-0128-2	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75321-0128-3	3785 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(75321-0128)

Revised: 4/2020

SunBeam Laboratories LLC