

**HAND SANITIZER- alcohol aerosol, spray**  
**Cosmetic Specialty Labs, Inc.**

*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.*

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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) (75%, 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. Aloe Barbadensis Leaf Juice.
- c. Caprylyl Glycol.
- d. Glycerin.
- e. Phenoxyethanol.
- f. Polysorbate-20.
- g. Purified Water.
- h. Tocopheryl Acetate.

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**

SD Alcohol 40 75%

Antimicrobial

**Use**

Hand Sanitizer to help reduce bacteria on the skin.

**Warnings**

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

**When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

**Stop use and ask a doctor if** irritation or rash appears and lasts.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Center right away.

**Directions**

- Use enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

**Other information**

- Store below 110F (43C)
- May discolor fabrics or surfaces

**Inactive ingredients**

Aloe Barbadensis Leaf Juice, Caprylyl Glycol, Fragrance, Glycerin, Phenoxyethanol, Polysorbate-20, Purified Water, Tocopheryl Acetate.

**Package Label - Principal Display Panel**

15 mL NDC:58133-959-16

## HAND SANITIZER

alcohol aerosol, spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58133-959
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0K00R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58133-959-16	15 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/05/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/05/2021	

**Labeler** - Cosmetic Specialty Labs, Inc. (032973000)

### Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Specialty Labs, Inc.		032973000	manufacture(58133-959) , label(58133-959) , pack(58133-959) , analysis(58133-959)

Revised: 8/2021

Cosmetic Specialty Labs, Inc.