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.

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 Barbadenis Leaf Juice.
c. Caprylyl Glycol.
d. Glycerin.
e. Phenoxyethanol.
f. Polysorate-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 thoroughtly 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 biskly 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

NDC:58133-959-63

HAND SANITIZER

alcohol aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58133-959
Route of Administration	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
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
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:58133-959-63	178 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/30/2021	

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.