

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.

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 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

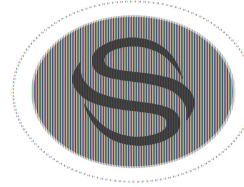
Inactive ingredients

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

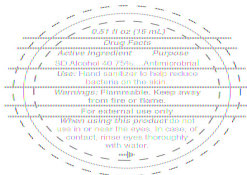
Package Label - Principal Display Panel

Blue

C: 100%
M: 94%
Y: 0%
K: 1%



D=31mm



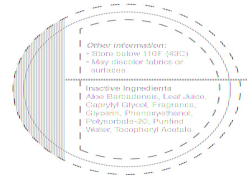
H=50mm

TOP PLY



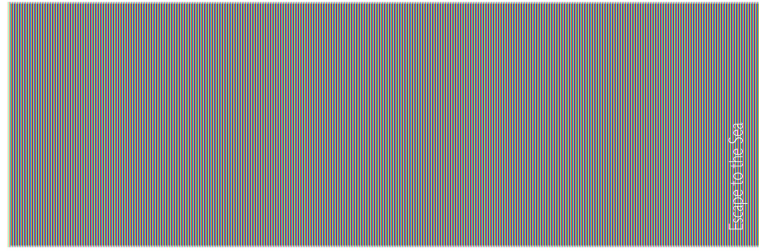
INSIDE PLY

H=72mm



BOTTOM PLY

Sticker located on bottom of tube



H=:

w=116.18mm



H=:

w=116.18mm

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 |
|---|----------|
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| PHENOXYETHANOL (UNII: H1E492ZZ3T) | |
| WATER (UNII: 059QF0KO0R) | |
| 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:58133-959-15 | 15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 05/03/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 05/03/2023 | |

Labeler - Cosmetic Specialty Labs, Inc. (032973000)

Establishment

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

Revised: 5/2023

Cosmetic Specialty Labs, Inc.