

HAND SANITIZER- alcohol spray
Scentsational Soaps & Candles, 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.

Alcohol 70% v/v. Purpose: Antiseptic

Antiseptic, Hand Sanitizer

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

For external use only. Flammable. Keep away from heat or flame.

* 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 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. This may be a sign of a serious condition.

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

* 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.

* Store between 15-30C (59-86F)

* Avoid freezing and excessive heat above 40C (104F)

Purified Water USP. Glycerin, Aloe barbadensis Leaf Juice, Fragrance, Hydrogen Peroxide

Drug Facts

Active ingredient(s) *Ethanol Alcohol 70% v/v*.....**Purpose** *Antiseptic*

Uses
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Warnings
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Directions:
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Other information:
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■ Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients Distilled Purified Water USP, Glycerin, Aloe barbadensis Leaf Juice, Fragrance, Hydrogen Peroxide

Distributed by: Scentsational Soaps and Candles, Inc.
730 Commerce Dr. Venice, FL 34292



Hand Sanitizer

Non-Sterile Solution

ALCOHOL ANTISEPTIC 70%
TOPICAL SOLUTION

3.4 FL. OZ. (100.55 mL)

100.55 mL NDC: 75078-004-01

HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75078-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	26.425 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75078-004-01	100.55 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/21/2020	

Labeler - Scentsational Soaps & Candles, Inc. (360738236)

Establishment

Name	Address	ID/FEI	Business Operations
Scentsational Soaps & Candles, Inc.		360738236	manufacture(75078-004)

Revised: 10/2020

Scentsational Soaps & Candles, Inc.