

SALON TECHNOLOGIES INTERNATIONAL SANITIZING HAND 80% - alcohol liquid

Salon Technologies International, 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.

Salon Technologies International Sanitizing Hand Spray 80 %

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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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 INGREDIENTS

Alcohol 80% v/v

Purpose

Antiseptic, Hand Sanitizer

USES:

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

- With children less than 2 months of age
- On open skin wounds
- Near eyes

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.

OTHER INFORMATION:

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

INACTIVE INGREDIENTS:

Purified water USP, Glycerin, Hydrogen Peroxide, Denatonium Benzoate

Package Label - Principal Display Panel

NET: 2 FL OZ (60 ml)

NDC: 76804-001-01



DRUG FACTS:	
ACTIVE INGREDIENTS	Purpose
Alcohol 80% v/v.....	Antiseptic
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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 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	
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alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76804-001(NDC:74481-001)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)				
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76804-001-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/27/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/27/2020		

Labeler - Salon Technologies International, Inc (877118302)

Establishment

Name	Address	ID/FEI	Business Operations
Salon Technologies International, Inc		877118302	repack(76804-001)

Revised: 5/2020

Salon Technologies International, Inc