

HAND SANITIZER- alcohol liquid
Nancy's Passions LLC

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.

80% Alcohol Hand Sanitizer Spray Topical Antiseptic Non-Sterile

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 Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

- 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 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.

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Directions

- 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.

Other information

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

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Outer (Principle Front Panel of Pouch)



This pouch has the spray bottle top + bottom inside the pouch. The pouch is my external packaging.

Manufactured by Nancy's Passions LLC
FEI # 301-738-3474 California, 92704 US

50 mL NDC: 80078-001-03

Topical Spray Solution
Alcohol Antiseptic
Hand Sanitizer

80% Alcohol

Non-sterile

The image shows the front panel of the pouch. It is manufactured in California by me. The rear has the drug facts and pertinent information. Inside the pouch, there is the product that also has the appropriate label and all info (front and back). I am using a pouch as a security feature.

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80078-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.013 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRUS AURANTIUM FRUIT OIL (UNII: 59JDQ5VT0T)	0.005 mL in 100 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.02 mL in 100 mL
SPEARMINT OIL (UNII: C3M81465G5)	0.01 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	8.431 mL in 100 mL
2-AMINO-1,3-PROPANEDIOL (UNII: IC94L30J8M)	2.418 mL in 100 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.0278 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.581 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	28.5158 mL in 100 mL
RHODIOLA ROSEA ROOT (UNII: 3S5ITS5ULN)	0.013 mL in 100 mL
VACCINIUM ANGUSTIFOLIUM WHOLE (UNII: R3538BZ1BW)	0.013 mL in 100 mL
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	0.022 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	3.2833 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.332 mL in 100 mL
SAGE OIL (UNII: U27K0H1H2O)	0.02 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.066 mL in 100 mL
PANTHENOL (UNII: WV9CM0O67Z)	0.8165 mL in 100 mL
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.022 mL in 100 mL
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	0.022 mL in 100 mL
COCO GLUCOSIDE (UNII: ICS790225B)	0.017 mL in 100 mL
SODIUM HYDROXYMETHYLGLYCINATE (UNII: DIG6BWZ9XT)	0.004 mL in 100 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.173 mL in 100 mL
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	0.0545 mL in 100 mL
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	0.0545 mL in 100 mL
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)	0.035 mL in 100 mL
BETAINE (UNII: 3SCV180C9W)	0.026 mL in 100 mL

WITCH HAZEL (UNII: 10114J0U34)	0.01 mL in 100 mL
CEDRUS ATLANTICA BARK OIL (UNII: ZX5QRE4U60)	0.1 mL in 100 mL
VANILLA PLANIFOLIA OIL (UNII: 0A3F415158)	0.06 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80078-001-03	1 in 1 POUCH	12/10/2020	
1		50 mL in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package		

Outer Pouch Front Panel



This pouch has the spray bottle top + bottom inside the pouch. The pouch is my external packaging.

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/26/2020	

Labeler - Nancy's Passions LLC (080236251)

Registrant - Nancy's Passions LLC (080236251)

Establishment

Name	Address	ID/FEI	Business Operations
Nancy's Passions LLC		080236251	manufacture(80078-001)

Revised: 11/2020

Nancy's Passions LLC