

NAHMIAS ET FILS DISTILLERY HAND SANITIZER- nahmias et fils hand sanitizer liquid
Nahmias et Fils Distillery

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) (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


NAHMIA S ET FILS
 SINCE 1900

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

473 ML

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> • 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.	
Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Purpose

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Alcohol 80% v/v.....	Antiseptic

Antiseptic, Hand Sanitizer

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Package Label - Principal Display Panel



**Alcohol Antiseptic 80%
Topical Solution**

**Hand Sanitizer
Non-sterile Solution**

473 ML

mL NDC: 00000-000-00

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NAHMIAS ET FILS DISTILLERY HAND SANITIZER			
nahmias et fils hand sanitizer liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74255-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	378 mL in 473 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.59125 mL in 473 mL
WATER (UNII: 059QF0KO0R)	87.5 mL in 473 mL
GLYCEROL FORMAL (UNII: 3L7GR2604E)	6.8585 mL in 473 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74255-0001-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/02/2020	

Labeler - Nahmias et Fils Distillery (085541817)**Establishment**

Name	Address	ID/FEI	Business Operations
Nahmias et Fils Distillery		085541817	manufacture(74255-0001)

Revised: 4/2020

Nahmias et Fils Distillery