# HEALTHY HANDS LIQUID- alcohol liquid EATON CHEMICAL, 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.

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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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away.

#### 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

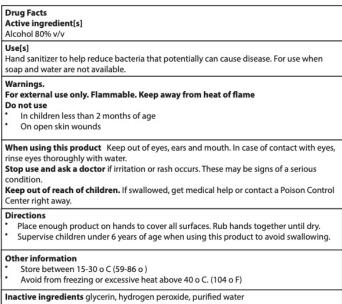
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

#### Package Label - Principal Display Panel





1 Tote, 945 L

#### **HEALTHY HANDS LIQUID**

alcohol liquid

**Product Information** 

LB099

Product Type			HUMAN OTC DRUG	Ite m C	ode (Source	e) N	IDC:77075-099	
Route of Admin	istration	1	TOPICAL					
Active Ingred	lient/A	rtive Moi	etv					
Active Ingredient/Active Moiety Ingredient Name					Basis	of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			0 M)	ALCOHO	0	80 mL in 100 mL		
Inactive Ingr	edients							
Ingredient Name						Strength		
GLYCERIN (UNII: PDC6A3C0OX)						1.45 mL in 100 mL		
GLYCERIN (UNI	: PDC6A3	COOX)				1.45 mL in 100	mL	
GLYCERIN (UNI HYDROGEN PER			0 AN9 V)			1.45 mL in 100 0.125 mL in 100		
	RO XIDE (	UNII: BBX06	50 AN9 V)					
HYDROGEN PER WATER (UNII: 05	RO XIDE (	UNII: BBX06	50 AN9 V)					
HYDROGEN PER WATER (UNII: 05 Packaging	RO XIDE (	UNII: BBX06		14-12		0.125 mL in 10	0 mL	
HYDRO GEN PER WATER (UNII: 05	RO XIDE (	UNII: BBX06	0 AN9 V) Package Descrip	tion			0 mL g Marketing End	
HYDROGEN PER WATER (UNII: 05 Packaging	<b>RO XIDE</b> () 9 Q F0 KO 9 450 0 0	UNII: BBX06 0R)	<b>Package Descrip</b> ITAINER, FLEXIBLE INT		LK; Type 0:	0.125 mL in 10 Marketin	0 mL g Marketing End	
HYDROGEN PER WATER (UNII: 05 Packaging # Item Code	<b>RO XIDE</b> () 9 Q F0 KO 9 450 0 0	UNII: BBX06 0R) mL in 1 CON	<b>Package Descrip</b> ITAINER, FLEXIBLE INT		LK; Type 0:	0.125 mL in 10 Marketin Start Dat	0 mL g Marketing End	
HYDROGEN PER WATER (UNII: 05 Packaging # Item Code 1 NDC:77075- 099-06	945000 Not a Cc	UNII: BBX06 0R) mL in 1 CON mbination Pi	<b>Package Descrip</b> ITAINER, FLEXIBLE INT		LK; Type 0:	0.125 mL in 10 Marketin Start Dat	0 mL g Marketing End	
HYDROGEN PER WATER (UNII: 05 Packaging # Item Code	о хире ( 9 Q F0 KO 9 450 00 Not a Cc Infori	UNII: BBX06 0R) mL in 1 CON mbination Pr mation	<b>Package Descrip</b> ITAINER, FLEXIBLE INT	ERMEDIATE BU		0.125 mL in 10 Marketin Start Dat	0 mL g Marketing End	
HYDROGEN PER WATER (UNII: 05 Packaging # Item Code 1 NDC:77075- 099-06 NDC:77075-	945000 Not a Co	UNII: BBX06 0R) mL in 1 CON mbination Pr mation	<b>Package Descrip</b> ITAINER, FLEXIBLE INT roduct	ERMEDIATE BU		0.125 mL in 10 Marketin Start Dat 03/30/2020	0 mL 1g Marketing End te Date	

## Labeler - EATON CHEMICAL, INC. (056388804)

### Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
R. N. EATON & COMPANY, INC.		056388804	manufacture(77075-099)

Revised: 5/2020

#### EATON CHEMICAL, INC.