

ULTRA GUARD- hand sanitizer liquid
Midwest extraction services 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.

Hand Sanitizer

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



ULTRA GUARD

**PREMIUM
HAND SANITIZER**

UNSCENTED FOR PROFESSIONALS

1 Gallon

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Flammable. Keep away from heat or flame	
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MADE IN USA



Manufactured Exclusively for:
Ultra Guard,
Waseca, MN 56093
507-214-3550

3785 mL NDC: 77085-100-01

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION

ULTRA GUARD

PREMIUM
HAND SANITIZER
NON-STERILE SOLUTION

16 oz

HAND SANITIZER ALCOHOL 80%

Drug Facts				
<table border="0"> <tr> <td><i>Active Ingredient</i></td> <td><i>Purpose</i></td> </tr> <tr> <td>Alcohol 80% v/v.....</td> <td>Antiseptic</td> </tr> </table>	<i>Active Ingredient</i>	<i>Purpose</i>	Alcohol 80% v/v.....	Antiseptic
<i>Active Ingredient</i>	<i>Purpose</i>			
Alcohol 80% v/v.....	Antiseptic			
<i>Uses</i> to decrease bacteria on the skin that could cause disease. For use when soap and water are not available				
<i>Warnings</i> for external use only: hands				
Flammable keep away from heat or flame				
When using this product keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.				
Stop use and ask a doctor if irritation and redness develop or if condition persists for more than 72 hours.				
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center.				
Directions: Wet hands thoroughly with product and allow to dry without wiping. Adult supervision for children under 6. Not recommended for infants less than 2 months of age				
Other Information: Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F)				
<i>Inactive Ingredients</i> glycerin, hydrogen peroxide, purified water usp				

Manufactured
Exclusively for:
Midwest Ethanol
Waseca, MN 56093
507-214-3550



473mL NDC: 77085-100-02

ULTRA GUARD

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77085-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3028.32 mL in 3785.41 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.73 mL in 3785.41 mL
GLYCERIN (UNII: PDC6A3C0OX)	54.88 mL in 3785.41 mL
WATER (UNII: 059QF0K00R)	693.67 mL in 3785.41 mL

Product Characteristics

Color		Score	
Shape		Size	

Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77085-100-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/15/2020	
2	NDC:77085-100-02	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/15/2020	

**Alcohol Antiseptic 80%
Topical Solution**

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507-214-3550

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/15/2020	

Labeler - Midwest extraction services llc (101993370)

