# HOME HAND SANITIZER- alcohol gel UNIWARE HOUSEWARE CORP.

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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## **Active Ingredient**

Alcohol 70% v/v.

## Purpose

Antimicrobial

#### Uses

Hand Sanitizer to help reduce bacteria on the skin.

## **Warnings**

Flammable. Keep away from fire or flame.

For external use only.

**When using this product** avoid contact with face, eyes and broken skin. In case of contact, rinse thoroughly with water.

**Stop use and ask a doctor if** irritation or redness appears and lasts.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Put enough product in your palm to cover hands and rub hands until dry.
- Children under 6 years of age should be supervised when using the product.

#### Other information

- Store below 110° F (43° C).
- May discolor certain fabrics or surfaces.

### **Inactive ingredients**

Water (Aqua), Isopropyl Alcohol, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 2-amino-2-methyl-1-propanol.

## Package Label - Principal Display Panel





FRONT BACK

#### HOME HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78712-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
AMINO METHYLPRO PANO L (UNII: LU49 E6626Q)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78712-001- 01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
2	NDC:78712-001- 02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
3	NDC:78712-001- 03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
4	NDC:78712-001- 04	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
5	NDC:78712-001- 05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
6	NDC:78712-001- 06	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
7	NDC:78712-001- 07	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
8	NDC:78712-001- 08	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
9	NDC:78712-001- 09	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/22/2020		

## Labeler - UNIWARE HOUSEWARE CORP. (931896372)

Revised: 6/2020 UNIWARE HOUSEWARE CORP.