HAND SANITIZER- alcohol gel Billion Internet Group SA de CV

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) (70%, 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. glycerin
- c. triethanolamine
- d. Carbomer
- e. purified water USP

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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Decrease bacteria on skin

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hours.

When using this product, avoid contact with eyes.In case of contact flush eyes with water.

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

Stop use and ask a doctor if redness or irritation develops and persists for more than 72 hours.

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

Directions

 Directions: Wet hands thoroughly with product, rub, and allow to dry. Children under 6 years of age, use only under adult supervision.

Other information

• Do not store above 105°F (43°C). May discolor some fabrics and surfaces.

Inactive ingredients

WATER (AQUA), CARBOMER, TRIETHANOLAMINE, GLYCERIN.

Package Label - Principal Display Panel

5000 mL NDC: 76708-111-05





4000 mL NDC: 76708-113-04



bacterias* sobre las manos, frote y distribuya uniformemente. Deje secar a temperatura ambiente. Directions: Place enough product in your palms, rub hands thoroughly. Allow to dry. Advertencia: Para uso externo. Evite contacto con los ojos, si esto ocurre enjuague con abundante agua. Mantener fuera del alcance de los niños. Warning: For external use only. Avoid contact with eyes, if this happens, rinse thoroughly with water. Keep out of reach of children. *Frotando las manos por lo menos 30seg. Bajo la norma NMX-K-631-NORMEX-2008 Manufactured for/Hecho en México para: Billion Internet Group SA de CV Horacio 632, Polanco V Sección, Miguel Hidalgo, CDMX, 11560, México. www.RoyalAlbert.com.mx

> 76708-113-04 135.26 fl oz (4L)

20000 mL NDC: 76708-114-20

Drug Facts

Active Ingredient..... Ethyl Alcohol 70% v/v..... .Purpose ..Antimicrobial

Uses • Decreases bacteria on skin.

Warnings For external use only. Hammable. Keep away from heat or flame. When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours.

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

Directions • Wet hands thoroughly with product and allow to dry. Children under 6 years of age, use only under adult supervision.

Other Information • Do not store above 105° F (43°C). May discolor some fabrics and surfaces.

Inactive ingredients

AQUA, ISOPROPYL ALCOHOL, CARBOMER, TRIETHANOLAMINE, **GLYCERIN**



76708-114-20

676.28 fl oz (20L)

250 mL NDC: 76708-112-25

Drug Facts Active Ingredient..... Ethyl Alcohol 70% v/v..... .Purpose ..Antimicrobial Uses • Decreases bacteria on skin. Warnings For external use only. Flammable. Keep away from heat or flame. When using this product, avoid contact with eyes. In case of contact flush eyes with water. Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Directions • Wet hands thoroughly with product and allow to dry. Children under 6 years of age, use only under adult supervision. Other Information • Do not store above 105° F (43°C). May discolor some fabrics and surfaces. **Inactive ingredients** AQUA, ISOPROPYL ALCOHOL, CARBOMER, TRIETHANOLAMINE, **GLYCERIN**



GEL ANTIBACTERIAL DÉSINFECTANT POUR LES MAINS

Ingredients/Ingredientes: Alcohol, Water (Aqua), Carbomer, Triethanolamine, Polypropylene, Glycerin. Modo de Uso: Aplique el gel para manos contra bacterias* sobre las manos, frote y distribuya uniformemente. Deje secar a temperatura ambiente. Directions: Place enough product in your palms, rub hands thoroughly. Allow to dry. Advertencia: Para uso externo. Evite contacto con los ojos, si esto ocurre enjuague con abundante agua. Mantener fuera del alcance de los niños. Warning: For external use only. Avoid contact with eyes, if this happens, rinse thoroughly with water. Keep out of reach of children. *Frotando las manos por lo menos 30seg. Bajo la norma NMX-K-631-NORMEX-2008 Manufactured for/Hecho en México para: Billion Internet Group SA de CV Horacio 632, Polanco V Sección, Miguel Hidalgo, CDMX, 11560, México. www.RoyalAlbert.com.mx

> 76708-112-25 8.45 fl oz (250mL)



HAND SANITIZER

KILLS 99.99% OF GERMS*

www.deltamedsupply.com 8 FL OZ (236ml)

Drug Facts

Active Ingredient..... Ethyl Alcohol 70% v/v..... .Purpose

Uses - Decreases bacteria on skin.

Warnings For external use only. Flammable. Keep away from heat or flame.

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develops & persists for more than 72 hours.

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

Directions • Wet hands thoroughly with product and allow to dry. Children under 6 years of age, use only under adult

Other Information • Do not store above 105° F (43°C). May discolor some fabrics and surfaces.

Inactive ingredients

AQUA, ISOPROPYL ALCOHOL, CARBOMER, TRIETHANOLAMINE, **GLYCERIN**

Drug Facts

Active Ingredient Ethyl Alcohol 70% v/v ..

Uses: Decreases bacteria on skin

- For external use only. Flammable. Keep away from heat or
- When using this product, avoid contact with eyes. In case of contact, flush eyes with water.
- Stop use and ask a doctor if redness or irritation
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away Directions: Wet hands thoroughly with product, rub,

and allow to dry. Children under 6 years of age, use only under adult supervision.

Other Information: Do not store above 105°F (43°C) May discolor some fabrics and surfaces.

Inactive Ingredients

WATER (AQUA), CARBOMER, TRIETHANOLAMINE, GLYCERIN.

Made in Mexico Distributed by: DeltaMed Supply, LLC 111 Oakhurst Drive, Clinton, MS, 39056

NDC: 76708-222-08



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76708-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	175 mL in 250 mL	

Inactive Ingredients		
Ingredient Name	Strength	
TROLAMINE (UNII: 9O3K93S3TK)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		

Product Characteristics			
Color white Score		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging						
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NI	OC:76708-112-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76708-114	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	14000 mL in 20000 mL

Inactive Ingredients				
Ingredient Name	Strength			
TROLAMINE (UNII: 9O3K93S3TK)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)				

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:76708-114-20	20000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

Marketing Infor			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76708-111
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
l	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	3500 mL in 5000 mL	

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)

Product Characteristics

ColorwhiteScoreShapeSizeFlavorImprint Code

Contains

Packaging

l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
П	1 NDC:76708-111-05	5000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76708-113

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	2800 mL in 4000 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Product	Chara	cteristics

1 Todact Characteristics			
Color	white	Score	
Shape		Size	

Flavor	Imprint Code	
Contains		

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76708-113-04	4000 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76708-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	165.2 mL in 236 mL

Inactive Ingredients	
Ingredient Name	Strength
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76708-222-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

Labeler - Billion Internet Group SA de CV (812836549)

Revised: 5/2020 Billion Internet Group SA de CV