HAND SANITIZER GREEN- alcohol gel
HAND SANITIZER- alcohol gel
HAND SANITIZER BLUE- alcohol gel
Grupo Delveg, S.A. de C.V.

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.

Gomina Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help to decrease bacteria on the skin that could cause disease. Recommended for repeted use.

Warnings

For external use only: hands. Flammable. Keep away from fire or flame.

Keep out of eyes, in case of contact, flush thoroughly with water. Avoid contact with broken skin. Do not inhale nor ingest.

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

Keep out of reach of children if swallowed, get medical help or contact a Poisson Control Center immediately.

Directions

- Put enough product in hands to cover them, rub them together briskly until dry.
- Children under 6 years old need adult supervision to use this product.

Other information

- Store in a cool, dry place at a temperature from 32°F to 95°F.

Inactive ingredients

carbomer, demineralized water, glycerin, Microcare®CB (benzyl alcohol and a mixture of methylchloroisothiazolinone and methylisothiazolinone) and triethanolamine. May contain FD&C Blue No. 1, FD&C Blue No. 2, FD&C Yellow No. 5 (tartrazine) and/or FD&C Yellow No. 6.

Questions? +52 444 823 5650

Label NDC 79008-001

1000 mL NDC: 79008-001-01

Label NDC: 79008-001-02

220 mL NDC: 79008-001-02

Label NDC 79008-001-03

1000 mL NDC: 79008-001-03

Bottle w/dispenser

Label NDC 79008-002-01

1000 mL NDC: 79008-002-01

Label NDC: 79008-002-02

220 mL NDC: 79008-002-02

Label NDC 79008-002-03

1000 mL NDC: 79008-002-03

Bottle w/dispenser

Label NDC 79008-003-01

1000 mL NDC: 79008-003-01

Label NDC: 79008-003-02

220 mL NDC: 79008-003-02

Label NDC 79008-003-03

1000 mL NDC: 79008-003-03

Bottle w/dispenser

HAND SANITIZER GREEN

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79008-002
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**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	

Product Characteristics			
Color	green	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79008-002-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2020	
2	NDC:79008-002-02	220 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2020	
3	NDC:79008-002-03	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/27/2020	

HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79008-001
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**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79008-001-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79008-001-02	220 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79008-001-03	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/27/2020	

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 BLUE

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79008-003
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	

Product Characteristics			
Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79008-003-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2020	
2	NDC:79008-003-02	220 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/27/2020	
3	NDC:79008-003-03	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/27/2020	

Labeler - Grupo Delveg, S.A. de C.V. (816144521)

Registrant - Grupo Delveg, S.A. de C.V. (816144521)

Establishment

Name	Address	ID/FEI	Business Operations
Grupo Delveg, S.A. de C.V.		816144521	manufacture(79008-001, 79008-002, 79008-003) , pack(79008-001, 79008-002, 79008-003) , label(79008-001, 79008-002, 79008-003)

Revised: 10/2020 Grupo Delveg, S.A. de C.V.