HAND SANITIZER- alcohol gel GRIFFITH FOODS, 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.

HAND SANITIZER

Active Ingredient(s)

Alcohol 70% 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 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Water, glycerin, carbomer, triethanolamine, isopropyl myristate, tocopheryl acetate (Vitamin E).

Package Label - Principal Display Panel

492 mL NDC: 76911-002-01



918 mL NDC: 76911-002-02



3450 mL 3.45L NDC:76911-002-03





HAND SANITIZER

alcohol gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76911-002 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
TROLAMINE (UNII: 9O3K93S3TK)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
WATER (UNII: 059QF0KO0R)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76911-002- 01	492 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2020		
2	NDC:76911-002- 02	918 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2020		
3	NDC:76911-002- 03	3450 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2020		
4	NDC:76911-002- 04	1900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/15/2020		

Labeler - GRIFFITH FOODS, S.A. DE C.V. (951577057)

Registrant - GRIFFITH FOODS, S.A. DE C.V. (951577057)

Establishment				
Name	Address	ID/FEI	Business Operations	
GRIFFITH FOODS, S.A. DE C.V.		810552984	manufacture(76911-002), repack(76911-002)	

Establishment			
Name	Address	ID/FEI	Business Operations
GRIFFITH FOODS, S.A. DE C.V.		951577057	manufacture(76911-002), repack(76911-002)

Revised: 5/2020 GRIFFITHFOODS, S.A. DE C.V.