

**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.*

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**Hand Sanitizer 1L**

**Active Ingredient(s)**

Ethyl 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.

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.

**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

33.8 FL OZ (1L)

1000 mL NDC: 76911-002-05



# HAND SANITIZER



Expiration Date : MM/DD/YYYY  
NDC : 76911-002-05

DRUG FACTS	
ACTIVE INGREDIENT ETHYL ALCOHOL 70 % v/v .....	PURPOSE ANTISEPTIC
USES 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.	
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).	

Manufactured by Griffith Foods S.A. de C.V.  
Av. Industriales del Poniente 537, Col. Pío XII,  
Santa Catarina, N.L., México, C.P. 66362  
Made in Mexico

## 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: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76911-002-05	1000 mL in 1 POUCH; Type 0: Not a Combination Product	05/20/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

**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	relabel(76911-002) , manufacture(76911-002)

## Establishment

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

Revised: 5/2020

Griffith Foods, S.A. de C.V.