

HAND DEFENDER- alcohol liquid
Gm Integraciones y Soluciones en Control, 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.

Active Ingredient

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

Inactive ingredients

Glycerin and purified water

Product Label

**Hand
Defender**

**Alcohol
Antiseptic 70%**

Hand Sanitizer Liquid

**Topical Solution
Non-sterile Solution**



1L (33.8 FL OZ)

DRUG FACTS

Active ingredient[s]	<i>Purpose</i>
Alcohol 70% v/v.....Antiseptic
Use[s]	
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<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 	
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Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients: Glycerin and Purified Water	

MADE IN MEXICO

GEL ANTIBACTERIAL MÉXICO
Blvd Manuel Ávila Camacho 80, El Parque,
C.P.53398 Naucalpan de Juárez, Méx
Tel. (011) 52 55 4161 6888 Ext. 1300
ventas@gelantibacterialmexico.com
gelantibacterialmexico.com

Expiration
dating period

Batch number



HAND DEFENDER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77377-002
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)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77377-002-01	1 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
2	NDC:77377-002-02	2 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
3	NDC:77377-002-03	10 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	

4	NDC:77377-002-04	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
5	NDC:77377-002-05	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
6	NDC:77377-002-06	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
7	NDC:77377-002-07	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
8	NDC:77377-002-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
9	NDC:77377-002-09	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
10	NDC:77377-002-10	540 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
11	NDC:77377-002-11	700 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
12	NDC:77377-002-12	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
13	NDC:77377-002-13	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
14	NDC:77377-002-14	1900 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
15	NDC:77377-002-15	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
16	NDC:77377-002-16	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
17	NDC:77377-002-17	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
18	NDC:77377-002-18	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
19	NDC:77377-002-19	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
20	NDC:77377-002-20	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
21	NDC:77377-002-21	200000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
22	NDC:77377-002-22	220000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
23	NDC:77377-002-23	1000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/01/2020	

Labeler - Gm Integraciones y Soluciones en Control, S.A. de C.V. (812758685)

Establishment

Name	Address	ID/FEI	Business Operations
Gm Integraciones y Soluciones en Control, S.A. de C.V.		812758685	manufacture(77377-002)