

SANITIZE PLUS- alcohol gel
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

Carbopol, Glycerin, Purified Water USP, Triethanolamine

Product Label



Alcohol Antiseptic 70%
Topical Solution

Hand Sanitizer
Non-Sterile Solution

250ML (8.4 FL OZ)

www.sanitizeplusonline.com

DRUG FACTS

Active Ingredient(s): Alcohol 70% v/v..... **Purpose:** Antiseptic

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MADE IN MEXICO
Distributed by Fiat Investments
4900 N. 10th St. Suite C4
McAllen, TX 78504
P. 956 633 1403
sales@sanitizeplusonline.com
DUNS: 812758685

Expiration Dating Period:

Batch Number:



SANITIZE PLUS

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77377-003
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77377-003-01	1 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
2	NDC:77377-003-02	2 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
3	NDC:77377-003-03	10 mL in 1 POUCH; Type 0: Not a Combination Product	07/01/2020	
4	NDC:77377-003-04	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
5	NDC:77377-003-05	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
6	NDC:77377-003-06	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
7	NDC:77377-003-07	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
8	NDC:77377-003-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
9	NDC:77377-003-09	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
10	NDC:77377-003-10	540 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
11	NDC:77377-003-11	700 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
12	NDC:77377-003-12	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
13	NDC:77377-003-13	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
14	NDC:77377-003-14	1900 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
15	NDC:77377-003-15	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
16	NDC:77377-003-16	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
17	NDC:77377-003-17	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
18	NDC:77377-003-18	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
19	NDC:77377-003-19	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
20	NDC:77377-003-20	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
21	NDC:77377-003-21	200000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
22	NDC:77377-003-22	220000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2020	
23	NDC:77377-003-23	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(77377-003)

Revised: 7/2020

Gm Integraciones y Soluciones en Control, S.A. de C.V.