

HAND SANITIZER- alcohol gel
Global Exports U.S.A., Inc.

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 do not use in or near the eyes. In case of contact, 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

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using products.

Other information

- Store below 110°F(43°C)
- Avoid freezing and excessive heat above 104°F(40°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

Aloe Vera, Carbomer Interpolymer (type B), Glycerin, Lemon oil, Triethanolamine, Water (Aqua)

Package Label - Principal Display Panel



HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77050-016
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
Lemon Oil (UNII: I9GRO824LL)			

Glycerin (UNII: PDC6A3C00X)	
Trolamine (UNII: 9O3K93S3TK)	
Water (UNII: 059QF0KO0R)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Carbomer Interpolymer Type B (Allyl Pentaerythritol Crosslinked) (UNII: 132584PQMO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77050-016-01	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/04/2020	
2	NDC:77050-016-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
3	NDC:77050-016-03	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
4	NDC:77050-016-04	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	
5	NDC:77050-016-05	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	
6	NDC:77050-016-06	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
7	NDC:77050-016-07	1893 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	
8	NDC:77050-016-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
9	NDC:77050-016-09	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	
10	NDC:77050-016-10	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/01/2020	
11	NDC:77050-016-11	18927 mL in 1 CONTAINER; 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 Drug	505G(a)(3)	06/04/2020	

Labeler - Global Exports U.S.A., Inc. (607803517)

Establishment

Name	Address	ID/FEI	Business Operations
Global Exports U.S.A., Inc.		607803517	PACK(77050-016) , LABEL(77050-016)