

HAND SANITIZER- ethyl alcohol gel
Jinhua Jiangxin Crafts Co., Ltd.

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.

78877-001 70% Alcohol Hand Sanitizer

Active Ingredient

Ethanol 70.0%

Purpose

Antiseptic

Use

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use.

For external use only; hands

Flammable, keep away from fire or flame.

When using this product ● keep out eyes. In case of contact with eyes, flush thoroughly with water ● avoid contact with broken skin

● do not inhale or ingest.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Directions spray hands thoroughly with product and allow to dry without wiping ● for children under 6, use only under adult supervision ● not recommended for infants.

Inactive ingredients

Water, Carbomer, Glycerin, Triethanolamine



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78877-001
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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78877-001-01	2 in 1 CARTON	06/09/2020	
1		48 in 1 BOX		
1		20 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:78877-001-02	120 in 1 CARTON	06/09/2020	
2		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:78877-001-03	48 in 1 CARTON	06/09/2020	
3		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:78877-001-04	4 in 1 CARTON	06/09/2020	

4		24 in 1 BOX		
4		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:78877-001-05	48 in 1 CARTON	06/09/2020	
5		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:78877-001-06	24 in 1 CARTON	06/09/2020	
6		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:78877-001-07	24 in 1 CARTON	06/09/2020	
7		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:78877-001-08	24 in 1 CARTON	06/09/2020	
8		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:78877-001-09	12 in 1 CARTON	06/09/2020	
9		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:78877-001-10	6 in 1 CARTON	06/09/2020	
10		1000 mL in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:78877-001-11	6 in 1 CARTON	06/09/2020	
11		48 in 1 BOX		
11		20 mL in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:78877-001-12	3 in 1 CARTON	06/09/2020	
12		100 in 1 BOX		
12		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:78877-001-13	3 in 1 CARTON	06/09/2020	
13		50 in 1 BOX		
13		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:78877-001-14	3 in 1 CARTON	06/09/2020	
14		50 in 1 BOX		
14		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:78877-001-15	2 in 1 CARTON	06/09/2020	
15		50 in 1 BOX		
15		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/09/2020	

Labeler - Jinhua Jiangxin Crafts Co., Ltd. (554536959)

Establishment

Name	Address	ID/FEI	Business Operations
Jinhua Jiangxin Crafts Co., Ltd.		554536959	manufacture(78877-001)