

**HAND SANITIZER- ethyl alcohol gel**  
**SHANDISHI Biological Technology 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.*

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**77753-004 □Hand Sanitizer 70% Alcohol**

**DRUG FACTS**

**Active ingredient**

Ethyl Alcohol 70% v/v

**Purpose**

Antiseptic

**Uses**

For Hand Sanitizing

**Warnings**

Warnings: For external use only-hands.

Flammable: Keep away from heat and flame.

When using this product Keep out of 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 skin irritation develops.

**Keep out of reach of children.**

Keep out of reach of children

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

**Directions**

Wet hands thoroughly with product and allow to dry without wiping●For children under 6 use only under adult Supervision.●Not recommended for infants.

**Other information**

1 Do not store above 105°F

1 May discolor some fabrics

**Inactive ingredients**

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Package Labeling

<b>Drug Facts</b>	Hand Sanitizer
<b>Active ingredients</b> .....	<b>Purpose</b>
Ethyl Alcohol 70% v/v	Antiseptic
<b>Uses:</b> For Hand Sanitizing	
<b>Warnings:</b> For external use only-hands.	
Flammable: Keep away from heat and flame.	
When using this product Keep out of 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 skin irritation develops.	
Keep out of reach of children If swallowed, get medical help or call a Poison Control Center right away.	
<b>Directions:</b> Wet hands thoroughly with product and allow to dry without wiping • For children under 6 use only under adult supervision. • Not recommended for infants.	
<b>Other information:</b> Do not store above 105°F. • May discolor some fabrics. • Harmful to wood finishes and plastics.	
<b>Inactive ingredients:</b> Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.	
Distributed by: Newacme LLC Commerce, CA, 90040	2808 Vail Ave MADE IN CHINA
	
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**HAND SANITIZER**

ethyl alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77753-004
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:77753-004-01	12 in 1 BOX	05/20/2020	
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:77753-004-02	12 in 1 BOX	05/09/2020	
2		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:77753-004-03	12 in 1 BOX	05/20/2020	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:77753-004-04	12 in 1 BOX	05/09/2020	
4		53 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:77753-004-05	12 in 1 BAG	05/20/2020	
5		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:77753-004-06	8 in 1 BOX	05/20/2020	
6		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:77753-004-07	8 in 1 BOX	05/09/2020	
7		236 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:77753-004-08	8 in 1 BOX	05/20/2020	
8		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:77753-004-09	4 in 1 BOX	05/20/2020	
9		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:77753-004-10	4 in 1 BOX	05/20/2020	
10		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:77753-004-11	12 in 1 BOX	05/20/2020	
11		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:77753-004-12	4 in 1 BOX	05/20/2020	

12		1000 mL in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:77753-004-13	4 in 1 BOX	05/20/2020	
13		2000 mL in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:77753-004-14	4 in 1 BOX	05/20/2020	
14		3780 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	05/08/2020	

**Labeler** - SHANDISHI Biological Technology Co., Ltd. (411868994)

### Establishment

Name	Address	ID/FEI	Business Operations
SHANDISHI Biological Technology Co., Ltd.		411868994	manufacture(77753-004)

Revised: 6/2020

SHANDISHI Biological Technology Co., Ltd.