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.

77753-002 Hand Sanitizer

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

Drug Facts

Hand Sanitizer

Active ingredients ..... **Purpose**

Ethyl Alcohol 70% v/v — Antiseptic

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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: Do not store above 105°F. • May discolor some fabrics.• Harmful to wood finishes and plastics.

Inactive ingredients:
Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Distributed by: Newacme LLC 2808 Vail Ave
Commerce, CA, 90040 MADE IN CHINA

08429381028915

HAND SANITIZER ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77753-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77753-002-01	12 in 1 BOX	05/20/2020	
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:77753-002-02	12 in 1 BOX	05/09/2020	
2		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:77753-002-03	12 in 1 BOX	05/20/2020	
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:77753-002-04	12 in 1 BOX	05/09/2020	
4		53 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:77753-002-05	12 in 1 CARTON	05/20/2020	
5		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:77753-002-06	8 in 1 BOX	05/20/2020	
6		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:77753-002-07	8 in 1 BOX	05/09/2020	
7		236 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:77753-002-08	8 in 1 BOX	05/20/2020	
8		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:77753-002-09	4 in 1 BOX	05/20/2020	
9		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:77753-002-10	4 in 1 BOX	05/20/2020	
10		500 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(77753-002)

Revised: 5/2020 SHANDISHI Biological Technology Co., Ltd.