HAND SANITIZER ALCOHOL CLEANER- ethyl alcohol spray 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.

77753-001 [Hand Sanitizer Alcohol Spray Cleaner

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Use

Hand and surface sanitizing.

■For external use only
Flammable. Keep away from fire or flame
When using this product
n Keep out of eyes. In case of contact with eyes
flush thoroughly with water
■Avoid contact with open skin

1 Do not inhale or ingest Stop use and ask a doctor If skin iritation or redness develops

Keep out of reach of children
If swallowed, get medical help or contact a Poison Control Center right away

Directions

Wet hands thoroughly with product and allow to dry without wiping Children under 6 years of age use only under adult supervision.

Not recommended for infants

Inactive ingredients

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

Drug Facts

Hand Sanitizer & Alcohol Spray Cleaner

Active ingredients.....

..Purpose

Ethyl Alcohol 75% v/v

Antiseptic

Uses: Hand and surface sanitizing.

Warnings: For external use only.

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.

Directions: Wet hand or surface 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, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Distributed by: Newacme LLC Commerce, CA, 90040

2808 Vail Ave

MADE IN CHINA



HAND SANITIZER ALCOHOL CLEANER

ethyl alcohol spray

Product Information

HUMAN OTC DRUG NDC:77753-001 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Maiety

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

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

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:77753-001-01	12 in 1 BOX	05/20/2020			
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:77753-001-02	12 in 1 BOX	05/20/2020			
2		15 mL in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:77753-001-03	12 in 1 BOX	05/20/2020			
3		30 mL in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:77753-001-04	12 in 1 BOX	05/20/2020			
4		53 mL in 1 BOTTLE; Type 0: Not a Combination Product				
5	NDC:77753-001-05	12 in 1 BOX	05/20/2020			
5		60 mL in 1 BOTTLE; Type 0: Not a Combination Product				
6	NDC:77753-001-06	8 in 1 BOX	05/20/2020			
6		120 mL in 1 BOTTLE; Type 0: Not a Combination Product				
7	NDC:77753-001-07	8 in 1 BOX	05/20/2020			
7		236 mL in 1 BOTTLE; Type 0: Not a Combination Product				
8	NDC:77753-001-08	8 in 1 BOX	05/20/2020			
8		250 mL in 1 BOTTLE; Type 0: Not a Combination Product				
9	NDC:77753-001-09	4 in 1 BOX	05/20/2020			
9		473 mL in 1 BOTTLE; Type 0: Not a Combination Product				
10	NDC:77753-001-10	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	05/20/2020			

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

Establishment					
Name	Address	ID/FEI	Business Operations		
SHANDISHI Biological Technology Co., Ltd.		411868994	manufacture(77753-001)		