

HAND SANITIZER- 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.

77753-003 □Hand Sanitizer Alcohol Spray

Active Ingredient

Ethyl Alcohol 75%

Purpose

Antiseptic

Use

For handwashing to decrease bacteria on the skin.

Flammable, Keep away from fire or flame.

For external use only

When using this product avoid contact with eyes. If contact occurs rinse eyes thoroughly with water.

Stop use and ask a doctor if skin irritation or rash develops and continues 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

- Place enough product in your palm to thoroughly cover your hands.
- Children under 6 years of age should be supervised when using this product.
- Rub hands together briskly until dry.
- Not recommended for infants.

Inactive ingredients

Aloe vera leaf juice, Glycerin, Fragrance(parfum) ,Water

Drug Facts

Hand Sanitizer

0.67fl oz(20mL)

Active ingredient

Ethyl Alcohol 75% v/v.....

Purpose

Antiseptic

Uses

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, Keep away fromn fire or flame.

For external use only

When using this product avoid contact with eyes. If contact occurs rinse eyes thoroughly with water.

Stop use and ask a doctor if skin irritation or rash develops and continues for more than 72 hours.

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

Directions

• Place enough product in your palm to thoroughly cover your hands. • Children under 6 years of age should be supervised when using this product. • Rub hands together briskly until dry. • Not recommended for infants.

Other Information

Do not store above 105°F. • Discolor some fabrics. • Hamful to wood finishes and plastics.

Inactive ingredients

Aloe vera leaf juice, Glycerin, Fragrance(parfum) ,Water

Distributed by Newacme LLC.

Designed in Germany

2808 Vail Ave Commerce, CA, 90040

Made in China

HAND SANITIZER

ethyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77753-003
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77753-003-01	12 in 1 BOX	05/29/2020	
1		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:77753-003-02	12 in 1 BOX	05/29/2020	
2		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:77753-003-03	12 in 1 BOX	05/29/2020	
3		20 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:77753-003-04	2 in 1 BOX	05/29/2020	
4		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:77753-003-05	12 in 1 BOX	05/29/2020	
5		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:77753-003-06	8 in 1 BOX	05/29/2020	
6		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:77753-003-07	8 in 1 BOX	05/29/2020	
7		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:77753-003-08	8 in 1 BOX	05/29/2020	
8		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:77753-003-09	4 in 1 BOX	05/29/2020	
9		500 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:77753-003-10	4 in 1 BOX	05/29/2020	
10		1000 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 mono graph not final	part333E	05/29/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
SHANDISHI Biological Technology Co., Ltd.		411868994	manufacture(77753-003)

Revised: 5/2020

SHANDISHI Biological Technology Co., Ltd.