ALOE HAND SANITIZER- alcohol gel
TONYMOLY 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.

ACTIVE INGREDIENT

ALCOHOL 62% w/w

INACTIVE INGREDIENT

Water, Glycerin, Carbomer, Triethanolamine, Fragrance, Linalool, Hexyl Cinnamal, Aloe Vera Gel, Witch Hazel Extract, Butylphenyl Methylpropional, Trehalose Hydrate, Sodium Hyaluronate

PURPOSE

Antimicrobial

WARNINGS

For external use only. Flammable. Keep away from heat or flame

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Do not use
• in children less than 2 months of age
• on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

KEEP OUT OF REACH OF CHILDREN

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

Uses

Hand gel that kills germs that can potentially cause disease.

Directions

Dispense an appropriate product onto the palm of hands. Rub hands together until dry.

Other Information

Store between 15-30C (59-86F)
Avoid freezing and excessive heat above 40C (104F)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ALOE HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59078-810
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WITCH HAZEL (UNII: 101I4J0U34)	
Butylphenyl Methylpropional (UNII: T7540GJV69)	
Trehalose (UNII: B8WCK70T7I)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59078-810-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2021	

Labeler - TONYMOLY CO., LTD. (688216798)

Registrant - TONYMOLY CO., LTD. (688216798)

Establishment

Name	Address	ID/FEI	Business Operations
MEGACOS MANUFACTURING Co., Ltd.		694745986	manufacture(59078-810)

Revised: 3/2021 TONYMOLY CO., LTD.