HAND SANITIZER- ethyl alcohol gel Three Square Market, Inc

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

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

For hand washing to decrease bacteria on the skin.

Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

Avoid contact with broken skin.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help.

Directions

Not recommended for infants.

Wet hands thoroughly with product and allow to dry without wiping.

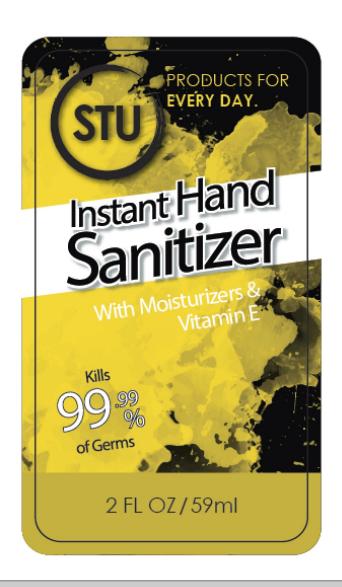
Children under 6 years of age should be supervised when using this product.

Other Information

Do not store above 110°F. May discolor some fabrics.

Inactive Ingredients

Water, Aloe Barbadensis Leaf Juice, Maltodextrin, Glycerin, Propylene Glycol, Acrylates/C10-30 Alkyl Acrylate crosspolymer, Triethanoamine, Fragrance, Tocopheryl Acetate.



Drug Facts

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Made in China

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78602-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	62 mL in 100 mL

inactive Ingredients			
Ingredient Name	Strength		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)			
WATER (UNII: 059QF0KO0R)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
GLYCERIN (UNII: PDC6A3C0OX)			

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) TROLAMINE (UNII: 9O3K93S3TK)

Packaging					
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 I	NDC:78602-002-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/03/2020	

Labeler - Three Square Market, Inc (117117771)

Revised: 6/2020 Three Square Market, Inc