

HAND SANITIZER- ethyl alcohol gel
Sante Manufacturing 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.

Spa Soap Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl alcohol 62%.

Purpose

Antiseptic

For handwashing to decrease bacteria on the skin.

Warnings

Flammable, keep away from fire or flame. For external use only.

When using this product Avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor If redness or irritation develop and persist 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

Spread on both hands, rub in, let dry.

Inactive Ingredients: Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice (Aloe Vera) Tocopheryl Acetate (Vitamin E)

Packaging



NDC #####-###-##

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 62% w/w.....	Antibacterial

Use hand sanitizer to help reduce bacteria on the skin

Warnings
 Flammable. Keep away from fire or flame.

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

Stop use and ask a doctor if irritation or redness develops.

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

Directions ■ apply palmful to hands ■ rub hands together vigorously until dry ■ supervise children in the use of this product.

Other information ■ store below 110°F (43°C) ■ may discolor certain fabrics or surfaces.

Inactive ingredients
 Water, Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance, Propylene Glycol, Isopropyl Myristate, Aloe Barbadensis Leaf Juice (Aloe Vera), Tocopheryl Acetate (Vitamin E).

Distributed by
 Sante Manufacturing Inc.
 Mississauga, ON L4T 1L2

Manufactured In China

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HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71020-101
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
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ALOE (UNII: V5VD430YW9)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71020-101-60	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/17/2020	

Labeler - Sante Manufacturing Inc (242048747)

Revised: 6/2020

Sante Manufacturing Inc