

HAND SANITIZER- ethyl alcohol gel
HIGH 5 HANDS LLC

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 75%

Purpose
Antiseptic

USES

Decreases bacteria on hands.

WARNINGS

For external use only. Flammable. Keep away

from fire or flame. Avoid contact with broken skin.

Do not use in or near the eyes. In case of contact, flush thoroughly with water.

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

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

DIRECTIONS

Wet hands thoroughly with product and allow to dry without wiping. Children under 6 years of age should be supervised. Not recommended for infants.

OTHER INFORMATION

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


INACTIVE INGREDIENTS

Acrylate/C10-30 Alkyl Acrylate crosspolymer, Aloe Barbadensis Leaf Juice, Aminomethyl propanol, Denatonium benzoate, Fragrance (Parfum), Glycerin, Maltodextrin, Propylene Glycol, Tocopheryl Acetate, Water (Aqua)



DRUG FACTS	
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Distributed by **High 5 Hands, LLC**
Bryn Mawr, PA 19101 www.high5hands.com
Made in China



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78869-338
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
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	

CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78869-338-01	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/10/2020	

Labeler - HIGH 5 HANDS LLC (117533415)

Registrant - Nantong Health & Beyond Hygienic Products Inc. (421280161)

Revised: 6/2020

HIGH5 HANDS LLC