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)



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Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:78869-008			
Route of Administration	TOPICAL						
A. (* T							
Active Ingredient/Active Moiety							
Ingred		Basis of Strengt	h	Strength			
ALCOHOL (UNII: 3K9958V90M) (ALC		ALCOHOL 75 ml		nL in 100 mL			
Inactive Ingredients							
	Ingredient Name				Strength		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)						
PROPYLENE GLYCOL (UNII: 6DC9Q	l67V3)						

WATER (UNII: 059QF	0KO0R)		
ALOE VERA LEAF (U	JNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PD	C6A3C0OX)		
CARBOMER INTERP	OLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
ALPHATOCOPHER	COL ACETATE (UNII: 9E8X80D2L0)		
AMINO METHYLPRO	PANOL (UNII: LU49E6626Q)		
DENATO NIUM BENZ	OATE (UNII: 4YK5Z54AT2)		
Packaging # Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:78869-008- 01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Inf	ormation		
Marketing Catego	ry Application Number or Monograph Citatio	n Marketing Start Date	Marketing End Date
OTC monograph not f	nal part333E	06/10/2020	

Labeler - HIGH 5 HANDS LLC (117533415)

Revised: 6/2020

HIGH 5 HANDS LLC