BLUZEN HAND SANITIZER- ethyl alcohol gel Remcoda, 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.

BLUZEN HAND SANITIZER GEL

Drug Facts

Active ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses ■ hand sanitizer to help reduce bacteria on skin.

Warnings

Flammable, keep away from fire/flame.

For external use only.

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water.

do not inhale or ingest.

Stop use and ask a doctor if irritation and redness develop

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

Directions

- place enough product in your palm to thoroughly cover your hands
 rub hands together briskly until dry
- supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store below 110°F (43°C)

Inactive ingredients

water, aloe barbadensis leaf juice, glycerin, carbomer, mentha piperita (peppermint) oil, triethanolamine

Questions? 1-800-777-1603

MOISTURIZING FORMULA WITH ALOE VERA

MINT

KILLS 99.9% OF GERMS

MADE IN THE USA

SULFATE FREE * PARABEN FREE

VEGAN, CRUELTY FREE

SHOPBLUZEN.COM

Distributed by: Remcoda, LLC, New York, NY, 10018

Packaging



BLUZEN HAND SANITIZER

Active Ingredient/Active Moiety

ethyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79200-102	
Route of Administration	TOPICAL			

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)		
PEPPERMINT O IL (UNII: AV092KU4JH)		
TROLAMINE (UNII: 903K93S3TK)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79200-102- 16	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/01/2020		

Labeler - Remcoda, Llc (117130169)

Revised: 7/2020 Remcoda, Llc