

ANTIBACTERIAL HAND SANITIZER- ethyl alcohol liquid

Royal Deluxe Accessories 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.

Antibacterial Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- To help reduce bacteria on the skin.

Warnings

For external use only. •Flammable. Keep away from fire or flame.

When using this product • avoid contact with eyes. If contact occurs, rinse with water.

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

Keep out of reach of children. • In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- put enough product in your palm to cover hands and rub hands together until dry. • for children under 6, use only under adult supervision.
- not recommended for infants.

Other information:

- store at a temperature below 110°F.(43°C).
- may discolor some fabrics.

Inactive ingredients□:

Water (Aqua), Glycerin, Propylene Glycol, Carbomer, Fragrance, Triethanolamine, Aloe Barbadosis Leaf Extract, Tocopheryl Acetate (Vitamin E), FD&C Yellow No.5 (Tartrazine), FD&C Blue No.1.

KILLS GERMS WITHOUT WATER

Effective at eliminating over 99.99% of many common harmful germs and bacteria.

Distributed by:Royal Deluxe Accessories,LLC

Made in China / Fabrique'en Chine / Hecho en China

Packaging



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ITEM#3400

MFD:04.2020
EXP:04.2022

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MFD:04.2020
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ITEM#AM500

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ANTIBACTERIAL HAND SANITIZER

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77043-166
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
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77043-166-02	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

2	NDC:77043-166-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333A	04/30/2020	

Labeler - Royal Deluxe Accessories Llc (831333054)

Revised: 4/2020

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