

**INSTANT HAND SANITIZER- alcohol gel**  
**SBU GROUP L.P.DBA APOLLO DISTRIBUTORS**

*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.*

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**Instant Hand Sanitizer**

***Drug Facts***

***Active ingredients***

Ethyl / Alcohol 75% v/v

***Purpose***

Antiseptic

***Uses***

- Hand sanitizer to help decrease bacterial on the skin, when water, soap & towel are not available.
- Recommended for repeated use.

***Warnings***

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

Do not apply around eyes.

**Do not use**

Do not use in ears & mouth.

**When using 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 persists for more than 72 hours.

**Keep out of reach of children.**

Children must be supervised in use of htis product.

***Directions***

- Place enough product into your palms and thoroughly spread on both hands.
- Rub into skin until dry.

***Other information***

- Store below 110 °F (43 °C).
- May discolor certain fabrics or surfaces.

***Inactive ingredients***

Glycerin, Acrylates/C 10-30 Alkyl Acrylate Crosspolymer Fragrance Aminomethyl Propanol, Propylene Glycol, Tocopherol, Disodium EDTA, Aloe Barbadensis Leaf Juice Powder, Lactic Acid, Citric acid.

Package Labeling

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Fragrance  
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Propylene Glycol,  
Tocopherol, Disodium EDTA  
Aloe Barbadensis,  
Leaf Juice Powder,  
Lactic Acid, Citric Acid.

Apollo Distributors  
10510 Rockley Road  
Houston, Texas 77099

855423200100  
Made in P.R.C.

**INSTANT HAND SANITIZER**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78303-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ETHYLENE GLYCOL (UNII: FC72KVT52F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78303-003-00	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/15/2020	

**Labeler** - SBU GROUP L.P.DBA APOLLO DISTRIBUTORS (841530095)

## Establishment

Name	Address	ID/FEI	Business Operations
Aogrand International Trade Corporation		421353092	manufacture(78303-003)

## Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU XUELEI COSMETIC CO LTD		526885026	manufacture(78303-003)

Revised: 7/2020

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