CRAZY AARONS HAND SANITIZER 68% ALCOHOL- alcohol hand sanitizer gel
Crazy Aaron Enterprises, Inc.

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.

Crazy Aarons Sea Ya Later Hand Sanitizer

Drug Facts

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Active Ingredient

Ethanol 68% v/v

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only.

Flammable - Keep away from fire or flame.

When using this product

keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation or rash occurs. These may be signs of a serious condition..

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

- on open skin wounds
- on children less than 2 months of age

Directions

• Place enough product on hands to cover all surfaces. Rub hands together briskly until dry.

• Supervise children under 6 years of age when using this product to avoid swallowing

Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive Ingredients

Ammonium Polyacryloyldimethyl Taurate, Blue 1, Calcium Sodium Borosilicate, FD&C Yellow 5 Aluminum Lake, Fragrance, Glycerin, Mica, Propylene Glycol, Silica, Tin Oxide, Titanium Dioxide, Water

CRAZY AARONS HAND SANITIZER 68% ALCOHOL

alcohol hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80032-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
BOROSILICATE GLASS (UNII: BOJ6T9AR90)	
MICA (UNII: V8A1AW0880)	
DIBUTYLTIN OXIDE (UNII: T435H74FO0)	

COBALT TITANIUM OXIDE (UNII: CN422GY0TE)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
3-(NONYLOXY)1,2-PROPANEDIOL (UNII: 73E9M7IT67)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80032-300-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/20/2020	

Labeler - Crazy Aaron Enterprises, Inc. (092666531)

Registrant - Crazy Aaron Enterprises, Inc. (092666531)

Establishment

Name	Address	ID/FEI	Business Operations
B & J Group		064604222	manufacture(80032-300)

Establishment

Name	Address	ID/FEI	Business Operations
Action-Pak, Inc.		117537305	relabel(80032-300) , repack(80032-300)

Revised: 9/2020 Crazy Aaron Enterprises, Inc.