HAND SANITIZER GEL- ethyl alcohol gel
Cerberus Craft Distillery 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.

Hand Sanitizer gel 80%

HAND SANITIZER

Product NDC 74592-003

Drug Facts

Active Ingredient[s] Purpose
Ethyl Alcohol 80% v/v.....Antiseptic

Use[s]
Hand Sanitizer to help reduce bacteria that potentially can cause disease cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame.

Do not use
- on children less than 2 months of age
- on open skin wounds

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.

Directions
- Place enough product on hands to cover all surfaces, rub hands together 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
Acrylates Copolymer, Glycerin, Aminomethyl Propanol, Hydrogen Peroxide, Purified Water

128 oz 3785 mL

Hand Sanitizer Gel (Unscented)

Alcohol Antisceptic 80%

HANDCRAFTED FLORIDA MADE LOCALLY

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Gel Hand Sanitizer
Non-Sterile Solution

Product NDC 74592

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HAND SANITIZER GEL

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74592-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.6 mL in 1 g
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 1 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 1 g
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	5 mL in 1 g

Product Characteristics			
Color	white (Clear)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74592-003-16	16 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	
2	NDC:74592-003-34	3.4 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	
3	NDC:74592-003-02	2 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	
4	NDC:74592-003-04	4 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	
5	NDC:74592-003-69	6.9 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2020	

Labeler - Cerberus Craft Distillery LLC (059557965)

Establishment

Name	Address	ID/FEI	Business Operations
Cerberus Craft Distillery LLC		059557965	label(74592-003) , manufacture(74592-003)

Revised: 11/2020 Cerberus Craft Distillery LLC