HAND SANITIZER- alcohol gel Commercial Beverage Concepts, 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.

Gel Hand Sanitizer 70%, 237mL

DRUG FACTS

ACTIVE INGREDIENT [S]

ALCOHOL 70% v/v

PURPOSE

ANTISEPTIC

USE[S]

Health care personnel hand rub to help reduce baceria that potentionally can cause disease.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME.

DO NOT USE

- In 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.
- Suprevise children under 6 years of age when using this product to avoid swallowing.

OTHER INFORMATION

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

INACTIVE INGREDIENTS

PEG-6 & AMP, Glycerin, Acrylates / Vinyl Isodecanoate Crosspolymer, Tocopheryl Acetate,

Package Labeling:







80z | 237ml

DRUG FACTS ACTIVE INGREDIENT[S] | ALCOHOL 70% V/V PURPOSE | ANTISEPTIC

Health care personnel hand rub to help reduce bacteria that potentionally can cause disease.

VARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM HEAT OR FLAME. DO NOT USE

- In 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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C 104F INACTIVE INGREDIENTS Water, PEG-6 & AMP, Glycerin,

Acrylates / Vinyl Isodecanoate Crosspolymer; Tocopheryl Acetate, Isopropyl Myristate, Fragrance (Parfum).

Manufactured by: Commercial Beverage Concepts, LLC 2408 Karbach St., Houston, Texas 77092



HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75594-870	
Route of Administration	TOPICAL			

	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
POLYETHYLENE GLYCOL 300 (UNII: 5655G9 Y8 AQ)				
ADENO SINE PHO SPHATE (UNII: 415SHH325A)				
GLYCERIN (UNII: PDC6A3C0OX)				
ACRYLATES/VINYL ISODECANO ATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8 MDB 79 NA)				
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:75594-870-32	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020					
Marketing Information								
	Marketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
O'	ΓC monograph not fi	nal part333E	06/01/2020					

Labeler - Commercial Beverage Concepts, LLC (080925174)

Revised: 6/2020 Commercial Beverage Concepts, LLC