GO CLEAN HAND SANITIZER- alcohol gel
U.S. Oil Chem, 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.

Zen Hand Sanitizer

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Sterile Water
c. Hydroxypropyl Cellulose

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Go Clean 70% Gel Hand Sanitizer Topical Solution

Purpose

Antiseptic, Hand Sanitizer

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 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.

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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

purified water USP, POLYACRYLATE CROSSPOLYMER-6

Package Label - Principal Display Panel

GoClean

HAND SANITIZER

Gel Hand Sanitizer

ADVANCED CLEANSING FORMULA

Unscented

MADE IN THE U.S.A.

1 GAL (128 FL OZ)

Drug Facts

Active ingredient[s] ***Purpose***

Alcohol 70% v/v..... Antiseptic

Use[s]

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Inactive ingredients Sterile water, Polyacrylate Crosspolymer-6, glycerin

DISTRIBUTED BY:
US OIL CHEM LLC
COLUMBIA, MO
65203

GO CLEAN HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74833-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2789 mL in 3785 mL

Inactive Ingredients	
Ingredient Name	**Strength**
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74833-610-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
2	NDC:74833-610-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
3	NDC:74833-610-04	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2020	
4	NDC:74833-610-05	475 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	
5	NDC:74833-610-06	950 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	
6	NDC:74833-610-08	3786 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	
7	NDC:74833-610-07	1893 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/12/2020	

Labeler - U.S. Oil Chem, LLC (080356315)

Revised: 10/2020 U.S. Oil Chem, LLC