# SNEAKY CLEAN GEL- sneaky clean gel gel Sneaky Clean

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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#### **Sneaky Clean Gel**

This is a hand sanitizer manufactured according to the part333A of the OTC monograph.

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)

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v) in an aqueos solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydroxypropyl Cellulose.
- d. Sterile distilled water or boiled cold water.

#### Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

#### 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**

glycerin, hydroxypropyl cellulose, fragrance, purified water USP

### **Package Label - Principal Display Panel**



78% Ethyl Alcohol 1 gallon / 3.78 L Alcohol Antiseptic 70% Topical Solution Gel Antiseptic Hand Rub | Non-Sterile Solution 1 gallon / 3.78 L

**Drug Facts** 

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#### **SNEAKY CLEAN GEL**

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HUMAN OTC DRUG Product Type Item Code (Source) NDC:75725-533

TOPICAL **Route of Administration** 

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

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mactive ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	0.7 mL in 100 mL			

Packaging					
#	Item Code		Package Description	Marketing Start Date	Marketing End Date
1 NDC:75725-533-		3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		06/05/2020	
Marketing Information					
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketin		Marketing End Date			

06/03/2020

## Labeler - Sneaky Clean (117494659)

OTC monograph not final part333A

Establishment				
Name	Address	ID/FEI	Business Operations	
JDSO Inc		081122737	manufacture(75725-533)	

Revised: 6/2020 Sneaky Clean