

## **KORKAY HAND SANITIZER GEL 80% TOPICAL- alcohol gel**

**Tate Soaps & Surfactants 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.*

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### **Korkay Hand Sanitizer Gel 80% Topical Solution**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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)**

Alcohol 80% 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, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

3785 mL NDC: 78320-292-01

**Drug Facts**

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Alcohol 80% w/v

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**IMPORTANT:** Suggestions for the use of this product are based on tests believed to be reliable; however, the user should determine suitability for the intended use by his own evaluation. Because the use of this material is beyond our control, neither the seller nor the manufacturer shall be liable for injury, loss or damage, direct or consequential, arising out of the inability to use this product. Seller and manufacturer's sole obligation shall be replacement of material proved to be defective.

**Manufactured by:**  
Tate Soaps & Surfactants, Inc.  
Kokomo, IN 46901  
765.868.4488

**NDC# 78320-292-01**  
  
This Product Meets U.S. CDC Guidelines for Alcohol Based Hand Sanitizers

**Visit us at:**  
**www.korkay.com**

**Net Contents:**  
1 U.S. Gallon (3.78L)

## KORKAY HAND SANITIZER GEL 80% TOPICAL

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78320-292
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78320-292-01	1 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/22/2020	
2	NDC:78320-292-03	6 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/22/2020	
3	NDC:78320-292-55	250035 mL in 1 DRUM; Type 0: Not a Combination Product	01/04/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

**Labeler** - Tate Soaps & Surfactants Inc (132916839)

## Establishment

Name	Address	ID/FEI	Business Operations
Tate Soaps & Surfactants Inc		132916839	manufacture(78320-292)

Revised: 1/2021

Tate Soaps & Surfactants Inc