# 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

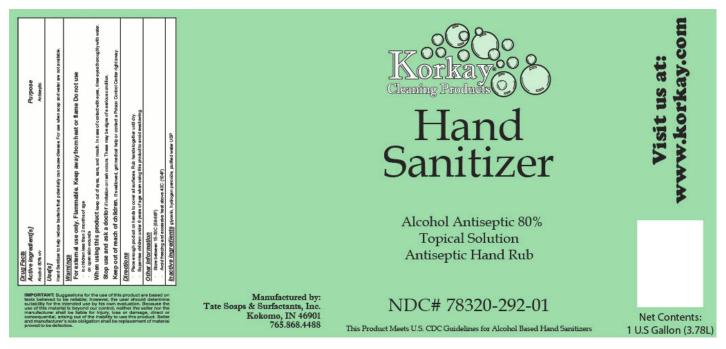
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

3785 mL NDC: 78320-292-01



#### 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 **Basis of Strength Ingredient Name** 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 PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL				
WATER (UNII: 059QF0KO0R)					

I	Packaging					
#	t 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		1329 16 8 39	manufacture(78320-292)			

Revised: 1/2021 Tate Soaps & Surfactants Inc