

SANITI- alcohol gel
TFS SERVICES, 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.

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

3,780 mL NDC: 77723-200-01

Saniti

MOISTURIZING

HAND SANITIZER

HELPS KILL GERMS

Meets World Health Organization Standards

1 Gallons (3,780 mL)



Saniti

MOISTURIZING
HAND SANITIZER

HELPS KILL GERMS

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Uses	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warning	
For external use only. Flammable. Keep away from fire, heat or flame.	
Do Not Use	
* On 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. This may be a sign of a serious condition.	
Keep out of reach from children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions for Use	
* Place enough product on hand to cover all surfaces. Rub hands together until dry. * Supervise children 6 years of age and under when using this product to avoid swallowing.	
Other Information	
* Store between 15C-30C (59F-86F). * Avoid freezing and excessive heat above 40C (104F).	
Inactive Ingredients	
Glycerin, hydrogen peroxide, purified water USP.	
Questions?	
Call: 1-855-891-3835	



Saniti

MOISTURIZING

HAND SANITIZER

HELPS KILL GERMS

Meets World Health Organization Standards

5 Gallons (18,900 mL)



Saniti

MOISTURIZING

HAND SANITIZER

HELPS KILL GERMS

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Uses	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warning	
For external use only. Flammable. Keep away from fire, heat or flame.	
Do Not Use	
<ul style="list-style-type: none"> * On 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. This may be a sign of a serious condition.	
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Directions for Use	
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Other Information	
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Inactive Ingredients	
Glycerin, hydrogen peroxide, purified water USP.	
Questions?	
Call: 1-855-891-3835	



Saniti

MOISTURIZING

HAND SANITIZER

HELPS KILL GERMS

Meets World Health Organization Standards

55 Gallons (208,000 mL)



Saniti

MOISTURIZING
HAND SANITIZER

HELPS KILL GERMS

Drug Facts	
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Alcohol 80% v/v.....	Antiseptic
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Warning	
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Do Not Use	
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Other Information	
* Store between 15C-30C (59F-86F). * Avoid freezing and excessive heat above 40C (104F).	
Inactive Ingredients	
Glycerin, hydrogen peroxide, purified water USP.	
Questions?	
Call: 1-855-891-3835	



Saniti

MOISTURIZING

HAND SANITIZER

HELPS KILL GERMS

Meets World Health Organization Standards

330 Gallons (1,248,000 mL)



Saniti

MOISTURIZING
HAND SANITIZER

HELPS KILL GERMS

Drug Facts	
Active Ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Uses	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warning	
For external use only. Flammable. Keep away from fire, heat or flame.	
Do Not Use	
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Inactive Ingredients	
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Questions? Call: 1-855-891-3835	



alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77723-200
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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77723-200-01	3780 mL in 1 JUG; Type 0: Not a Combination Product	05/28/2020	
2	NDC:77723-200-02	18900 mL in 1 PAIL; Type 0: Not a Combination Product	05/28/2020	
3	NDC:77723-200-03	208000 mL in 1 DRUM; Type 0: Not a Combination Product	05/28/2020	
4	NDC:77723-200-04	1248000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/28/2020	

Labeler - TFS SERVICES, LLC (117518663)

Establishment

Name	Address	ID/FEI	Business Operations
TFS SERVICES, LLC		117518663	manufacture(77723-200)