HAND SANITIZER- alcohol liquid
True Value Company, 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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away.

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

000 mL NDC: 00

HAND SANITIZER

Desinfectante para manos

NON-STERILE SOLUTION

Solución no estéril

80%

Alcohol Antiseptic

Alcohol antiséptico

TOPICAL SOLUTION

Solución tópica

6892296 80ETH 1 GALLON (3.78L)

Drug Facts

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Información del producto

Ingrediente[s] activo[s]	Propósito
Alcohol 80% por volumen	Antiséptico

Uso[s] Desinfectante para las manos que ayuda a reducir las bacterias que potencialmente pueden causar enfermedades. Para usar cuando no hay agua y jabón disponibles.

Advertencias **Solamente para uso externo. Inflamable. Manténgalo alejado del calor o llamas.**

No lo use • en niños menores de 2 meses de edad • en heridas abiertas de la piel

Cuando use este producto no permita que entre en los ojos, los oídos y la boca. En caso de contacto con los ojos, enjuague completamente los ojos con agua.

Detenga el uso y pregunte a un médico si ocurre irritación o erupción en la piel. Estas pueden indicar una condición grave.

Manténgalo fuera del alcance de los niños. En caso de ingestión, obtenga atención médica o comuníquese inmediatamente con un centro de control de veneno.

Instrucciones • Aplique suficiente producto en las manos para cubrirlas completamente. Frote ambas manos entre sí hasta que estén secas. • Supervise a los niños menores de 6 años de edad cuando use este producto para evitar que lo ingieran.

Información adicional • Almacénelo entre 15 y 30 °C (59 y 86 °F) • Evite el congelamiento y el calor excesivo mayor a 40 °C (104 °F)

Ingredientes inactivos glicerina, peróxido de hidrógeno, agua purificada USP (farmacopea de EE. UU.)

TV GPMC, L.L.C.
201 JANDUS RD, CARY, IL 60013
1-800-323-7545
Manufactured in the United States of America

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HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73998-003
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:73998-003-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/27/2020	
2	NDC:73998-003-02	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/27/2020	

Labeler - True Value Company, LLC (006929681)

Establishment

Name	Address	ID/FEI	Business Operations
TV GPMC, L.L.C.		943795539	manufacture(73998-003)

Revised: 8/2020 True Value Company, LLC