

HAND SANITIZING WIPES- alcohol cloth

Sweet River Trading 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 75% 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 years 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.

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.

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

80 wipes NDC: 79145-001-01

Please see the attached image, HandSanitizerWipePackage80Count.jpg

Drug Facts (continued)**INDICATIONS:** Medicated wipes to kill harmful bacteria and germs.**DIRECTIONS:** Open the lid, lift the adhesive and remove the wipe. Gently wipe to clean. Close lid after use to keep the product from drying out.**STORAGE AND HANDLING INSTRUCTIONS:**

Store in a cool dry place away from heat, direct sunlight, or flames. Wipes are insoluble in water. Do not flush down the toilet.

FOR EMERGENCIES CALL CHEMTREC: 1-800-424-9300 (24-Hour)**PART #: SANT7858**
P100101-001A**Manufactured For:**
Sweet River Trading Company1821 Industrial Drive
Stockton, CA - 95206
800-967-8851
Info@SweetRiverTC.com
www.SweetRiverTradingCompany.comLot number: 102
Expiration date: 06/10/2021**HAND SANITIZING WIPES**
KILLS 99.9% OF GERMS**HAND SANITIZING WIPES****75% ALCOHOL****KILLS 99.9% OF GERMS****80**
COUNT**HAND SANITIZING WIPES****KILLS 99.9% OF GERMS****Drug Facts****ACTIVE INGREDIENTS:** Ethanol 75%**INACTIVE INGREDIENTS:** Water 23.5%, 2-phenoxyethanol 0.5%, Didecyl dimethyl ammonium chloride 0.25%, Benzalkonium Chloride 0.2%, Ethylhexylglycerin 0.1%, Propylene glycol 0.1%, Glycerin 0.1%.**USE:** To help reduce bacteria that can potentially cause disease. For use when soap and water are not available. For skin, around wounds, keyboards, phones, office supplies, portable supplies, tableware etc.**WARNINGS:** Flammable. Keep away from fire or flame. For external use only. Avoid contact with eyes and damaged skin. In case of contact with eyes, rinse thoroughly. If a rash develops, discontinue use and consult a doctor.**KEEP OUT OF REACH OF CHILDREN:** Do not use on children under 2 years of age. If swallowed, get immediate medical help or contact a Poison Control Center right away.**HAND SANITIZING WIPES**

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 145-00 1(NDC:78 150-00 1)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79 145-00 1-02	80 in 1 BAG	06/19/2020	
1		4.2 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/19/2020	

Labeler - Sweet River Trading Company, LLC (117555520)

Registrant - Zhejiang Yiwu Caijie Daily Necessities Factory (554524322)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Yiwu Caijie Daily Necessities Factory		554534322	manufacture(79 145-00 1) , relabel(79 145-00 1)

Revised: 7/2020

Sweet River Trading Company, LLC