

SANICLEAN- hand wipe liquid
XS Supply 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.

SANICLEAN Hand Wipe

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. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part
- b. Sterile distilled water or boiled cold water/RO 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)

Isopropyl Alcohol 70% 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

RO water

Package Label - Principal Display Panel

DIRECTION FOR USE:

- Peel label and release wet tissue from opening.
- Thread the middle tissue through the opening lid.
- Close cap pulling tissue until it tears off.
- Close lid immediately after use to preserve moisture of wipes.

WIPE HANDS BEFORE AND AFTER:

- RESHROOM
- EATING DRINKING
- CONTACT WITH OTHERS
- CLOSING KISSING TOUCHING

SANI-CLEA
ALCOHOL WIPES

- Cleans and sanitizes hands
- Kills 99.99% of germs
- Safe to use before eating and drinking

70% Isopropyl Alcohol

100 | Sheets
13 x 18 cm

Ingredients: Aqua, Isopropyl Alcohol

NDC 80015-717-01

SANICLEAN			
hand wipe liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80015-717
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	30 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80015-717-01	100 mL in 1 CANISTER; Type 0: Not a Combination Product	08/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/24/2020	

Labeler - XS Supply LLC (080284229)

Revised: 8/2020

XS Supply LLC