

AKTIVE SANITIZING WIPES- alcohol cloth
Hall Global 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.

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. Ethyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water\
- e. Fragrance

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)

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Use wipes on hands, skin, or surfaces to decrease bacteria, recommended for repeated use.

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

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 immediately

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

Wet hands thoroughly with product, and allow to dry. Discard wipe in trash receptacle after use. Do not flush. Children under 6 years of age should be supervised when using this product.

Other information

- Store between 60-90 F (15-30C)
- Avoid freezing and excessive heat above 104 F(40C). May discolor some fabrics. Harmful to wood finishes and plastics.

Inactive ingredients

glycerin, hydrogen peroxide, purified water, fragrance

Package Label - Principal Display Panel



Sanitizing Wipes

Anytime. Anywhere. Stay Clean.

Directions for use: Lift the resealable lid and remove one towelette to sanitize skin. Suitable for use on non-sensitive skin. Avoid using on or around the eyes, open wounds, or other sensitive areas. Close packet securely to avoid drying out.

*As seen in laboratory settings, actual use may vary.



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Sanitizing Wipes

EFFECTIVE AT ELIMINATING 99.99% OF COMMON GERMS AND BACTERIA IN AS LITTLE AS 15 SECONDS.

75
WIPES

75 Wipes
12 FL OZ (350g)

Drug Facts

Active Ingredients: Ethyl Alcohol 75% **Purpose(s):** Antiseptic, Hand Sanitizer

Uses: Use wipes on hands, skin, or surfaces to decrease bacteria, recommended for repeated use.

Warnings: For external use only. Flammable, keep away from heat and flame.

Do Not Use: On children less than 2 months of age or 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 occurs. There may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions: Wet hands thoroughly with product, and allow to dry. Discard wipe in trash receptacle after use. Do not flush. Children under 6 years of age should be supervised when using this product.

Inactive Ingredients: Purified water, hydrogen peroxide, fragrance, and glycerin.

Other Information: Store between 60-90°F (15-30°C). Avoid freezing and excessive heat above 104°F (40°C). May discolor some fabrics. Harmful to wood finishes and plastics.



PLEASE RECYCLE

Manufactured in the USA
by Active Health
2231 Linwood Ave
Naples, FL 34112
1-800-287-1513
ActiveHealth.com

AKTIVE SANITIZING WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81156-001
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 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	1 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81156-001-75	375 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:81156-001-16	800 mL in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Hall Global LLC (117729725)

Registrant - Hall Global LLC (117729725)

Establishment

Name	Address	ID/FEI	Business Operations
Hall Global LLC		117729725	manufacture(81156-001)

Revised: 11/2020

Hall Global LLC