

PAPILION HYGIENIC DISINFECTANT ANTIBACTERIAL- alcohol liquid AR KAGIT SAN. ve TIC. LTD. STI.

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) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, 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 (0.5% v/v).
- c. Aloe Vera Leaf (0.1% v/v).
- d. Sterile distilled 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: Antibacterial

Purpose

Antibacterial, Papilion Hygienic Disinfectant Antibacterial Sprey

Uses

Use disinfectant spray to help reduce bacteria on the skin that could cause disease.

Warnings

For external use only. Flammable. Keep away from fire or flame.

When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Stop use and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Put enough product in your palm to cover hands and rub hands together until dry.
- Children under 6 years should be supervised when using this product.

Other information

- Store below 106 F (41 C).
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water (Aqua), Glycerin, Propylene Glycol, Aloe Barbadensis Extract.

Package Label - Principal Display Panel

120 mL NDC: 79262-160-01



PAPILION HYGIENIC DISINFECTANT ANTIBACTERIAL

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79262-160
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
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.25 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79262-160-01	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/21/2021	

Labeler - AR KAGIT SAN. ve TIC. LTD. STI. (356385935)

Revised: 2/2021

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