

HAND SANITIZER- alcohol liquid

Savvy Wellness

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.

Savvy Wellness Germs-Awa Plus Hand Sanitizing Gel

This is a gel hand sanitizer manufactured using only United States Pharmacopoeia (USP) grade ingredients in the preparation of the product.

Active Ingredient(s)

Alcohol 80% v/v.

Purpose

Antiseptic

Use

Hand rub 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 and on open skin wound.

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.

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

Purified water USP, PEG 300, aloe vera, hydroxyethyl cellulose, sodium hydroxide, tocopheral acetate, cassia bark oil, lavender oil, tea tree oil, lemon peel oil.

Package Label - Principal Display Panel



Drug Facts		NDC 79027-001-01
<u>Active Ingredient(s)</u>	<u>Purpose</u>	
Alcohol 80% v/v	Antiseptic	
<p>Use(s) Hand rub 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 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 or rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <p>Other Information Store between 15-30C(59-86F). Avoid freezing and excessive heat above 40C(104F).</p> <p>Inactive Ingredients purified water USP, PEG-300, aloe vera, hydroxyethyl cellulose, tocopherol acetate, cassia bark oil, sodium hydroxide, tea tree oil, lemon peel oil, lavender oil.</p> <p style="text-align: center;">Distributed by PalletBackers LLC Canoga Park, CA 91303 www.germsawayplus.com</p>		
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1.25 mL NDC:

79027-001-01

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79027-001
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
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.03 mL in 100 mL
WATER (UNII: 059QF0K00R)	15.98 mL in 100 mL
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	1.06 mL in 100 mL
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	1.46 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	1.46 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79027-001-01	1.25 mL in 1 POUCH; Type 0: Not a Combination Product	06/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/29/2020	

Labeler - Savvy Wellness (094766868)

Establishment

Name	Address	ID/FEI	Business Operations
MaxPax LLC		017038858	pack(79027-001)

Establishment

Name	Address	ID/FEI	Business Operations
Flavorcraft LLC		621632921	manufacture(79027-001)

Revised: 6/2020

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