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.

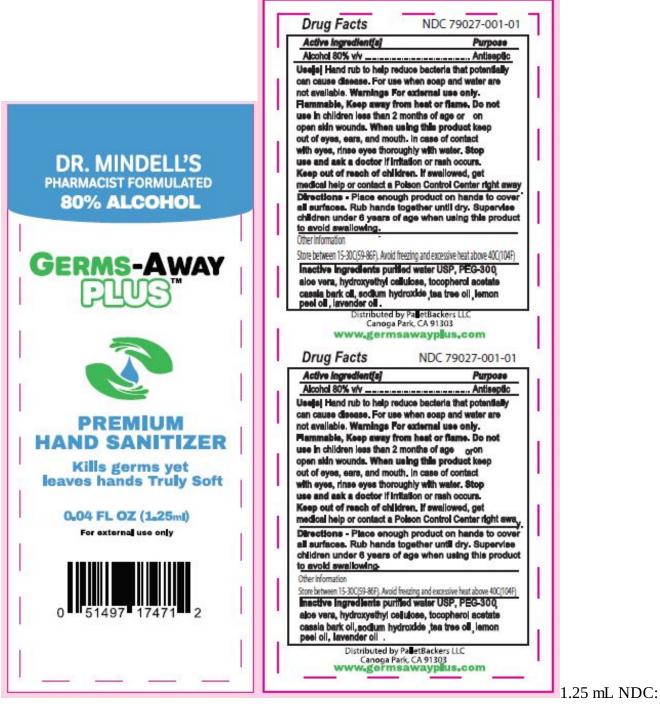
Other information

- 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



79027-001-01

 HAND SANITIZER

 alcohol liquid

 Product Information

 Product Type
 HUMAN OTC DRUG

 Route of Administration
 TOPICAL

Active Ingredient/A	Active Moiety			
Ingredient Name		Basis of Streng	th Strength	
ALCOHOL (UNII: 3K995	8V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL	
Inactive Ingredient	S			
		Strength		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			0.01mL in 100 mL	
SODIUM HYDRO XIDE (UNII: 55X04QC32I)			0.03 mL in 100 mL	
WATER (UNII: 059QF0K	15	15.98 mL in 100 mL		
HYDRO XYETHYL CELL	1.	1.06 mL in 100 mL		
POLYETHYLENE GLYC	OL 300 (UNII: 5655G9 Y8 AQ)	1.46 mL in 100 mL		
ALOE VERA LEAF (UNII	: ZY8 1Z8 3H0 X)	1.46 mL in 100 mL		
Packaging				
# Item Code	Package Description	Marketing Start Dat	e Marketing End Date	
1 NDC:79027-001-01 1.2	25 mL in 1 POUCH; Type 0: Not a Combination Product	06/29/2020		
Marketing Infor	mation			
Marketing Category	Application Number or Monograph Citation	Marketing Start Dat	e 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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