

HAND SANITIZER- alcohol hand sanitizer gel

Henry Rose 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.

Drug Facts

Active Ingredient(s)

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.

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

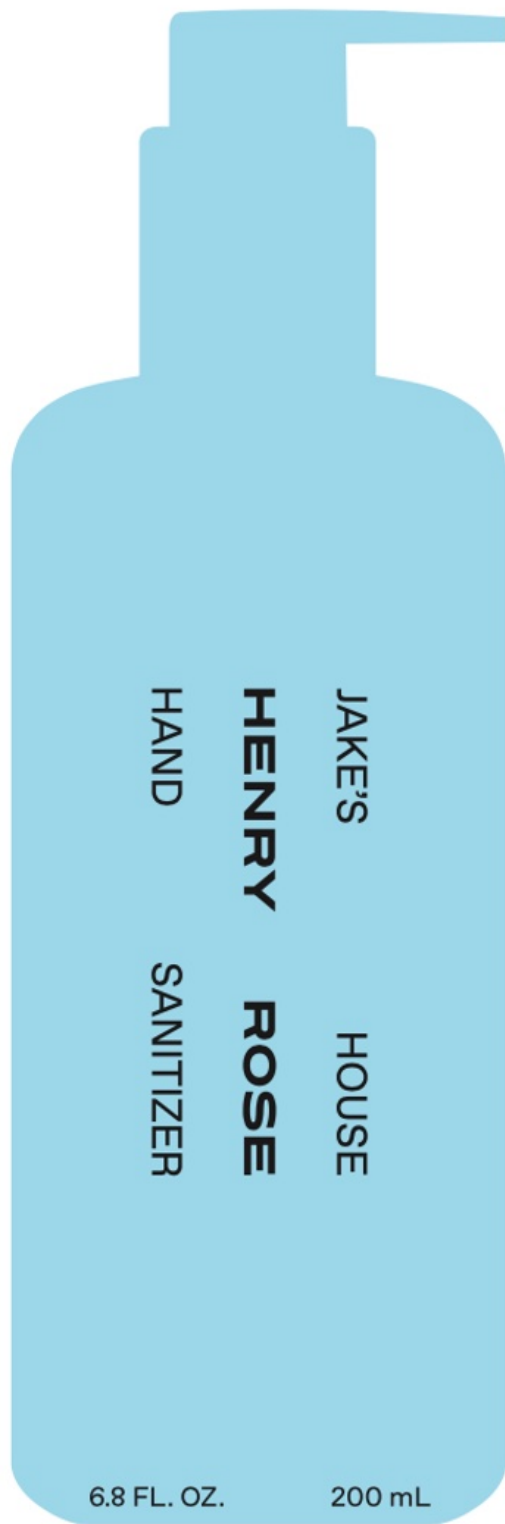
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

WATER (AQUA), GLYCERIN, FRAGRANCE, CARBOMER, ALOE BARBADENSIS LEAF JUICE, SODIUM HYDROXIDE, LINALOOL

Package Label - Principal Display Panel

200 mL NDC: 80006-070-02



KILLS 99.99% OF COMMON GERMS*
 GEL FORMULATED WITH
 SOOTHING ALOE.

Drug Facts	
Active Ingredients	Purpose
Ethyl Alcohol 70% V/V.....	Antiseptic
Uses Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> • For external use only. • Flammable. Keep away from heat or flame. 	
When using this product keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water. Avoid contact with broken skin. Do not inhale or ingest.	
Stop use and ask doctor if irritation or rash appears or lasts. 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	
<ul style="list-style-type: none"> • Put enough product in your palm to cover hands. Rub hands together until dry. • Children under 6 years of age should be supervised when using this product to avoid swallowing. 	
Other Information	
<ul style="list-style-type: none"> • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F) • May discolor some fabrics. Harmful to wood finishes and plastics. 	
Inactive Ingredients	
Water (Aqua), Fragrance, Glycerin, Carbomer, Aloe barbadensis leaf juice, Sodium hydroxide	

*Kills most common germs, based on testing performed using ASTM E2315 Standard.

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HAND SANITIZER

alcohol hand sanitizer gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80006-070

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
WATER (UNII: 059QF0K00R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80006-070-02	200 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	03/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/15/2020	

Labeler - Henry Rose LLC (117413381)

Revised: 3/2021

Henry Rose LLC