

HAND SANITIZER- alcohol spray
Shedrain Corporation

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.

Active Ingredient(s)

Ethanol 70%. Purpose: Antimicrobial

<i>ACTIVE INGREDIENT</i>	<i>PURPOSE</i>
Ethanol 70%.....	Antimicrobial

Purpose

Hand sanitizer to help decrease bacteria on the skin.

USE ▪ Hand sanitizer to help decrease bacteria on the skin

Use

Spray enough product on hands to cover all surfaces. Rub hands together until hands feel dry.

DIRECTIONS ▪ Spray enough product on hands to cover all surfaces. Rub hands together until hands feel dry.

Warnings

Flammable. Keep away from fire or flame For external use only. Highly flammable liquids and vapors.

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

Hand Sanitizer
Hazard statement: Highly flammable liquids and vapors

DANGER

Do not use

Do not use in or near the eyes. If contact occurs, flush thoroughly with water.

Do not use in or near the eyes. If contact occurs, flush thoroughly with water.

Stop use and contact doctor if redness and irritation develops and persists.

Stop use and contact doctor if redness and irritation develops and persists.

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

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

Other information

Store below 110°F (43°C)

OTHER INFORMATION
Store below 110°F (43°C)

Inactive ingredients

Aqua (Water), Glycerin, Parfum (Fragrance), Aloe Barbadensis Leaf Extract.

INACTIVE INGREDIENTS Aqua (Water),
Glycerin, Parfum (Fragrance), Aloe
Barbadensis Leaf Extract.

Spray enough product on hands to cover all surfaces. Rub hands together until hands feel dry.

DIRECTIONS ▪ Spray enough product
on hands to cover all surfaces. Rub
hands together until hands feel dry.

Package Label - Principal Display Panel

Pocket hand sanitizer

Pocket Hand Sanitizer

Infused With Aloe

Kills 99.9% of Germs



0.7 fl oz
20mL

Rectangular Snap

proceed.

HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80380-070
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: PDC6A3C0OX)	3 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80380-070-01	70 mL in 1 CASE; Type 0: Not a Combination Product	10/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/23/2020	

Labeler - Shedrain Corporation (009025552)

Establishment

Name	Address	ID/FEI	Business Operations
XIAMEN ROSEMARY BIOTECHNOLOGY CO.,LTD		543263460	manufacture(80380-070)

Revised: 10/2020

Shedrain Corporation