HAND SANITIZER- alcohol gel
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

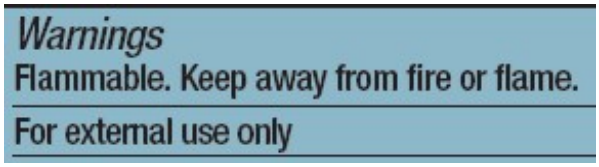
Purpose

Hand sanitizer to help decrease bacteria on the skin.

Warnings

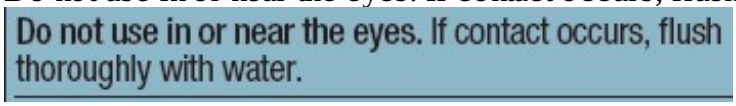
Flammable. Keep away from fire or flame.

For external use only

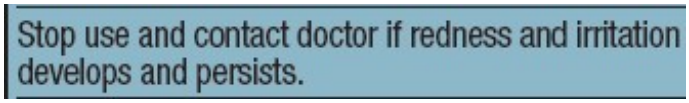


Do not use

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.

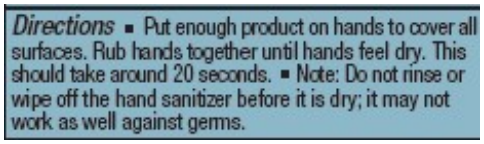


Keep out of reach of children. If swallowed, get medical help or contact the Poison Control Center right away.

Directions

Put enough product on hands to cover all surfaces. Rub hands together until hands feel dry. This should take around 20 seconds. Note: Do not rinse or wipe off the hand sanitizer before it is dry; it may not

work as well against germs.

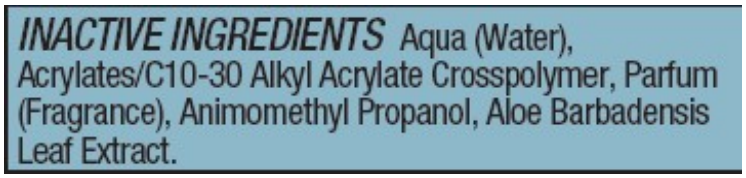


Other information

Store below 110°F (43°C)

Inactive ingredients

Aqua (Water), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Parfum (Fragrance), Animomethyl Propanol, Aloe Barbadensis Leaf Extract.



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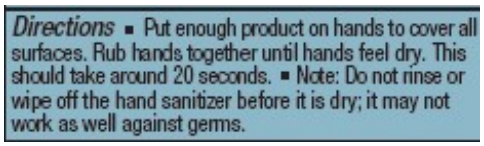
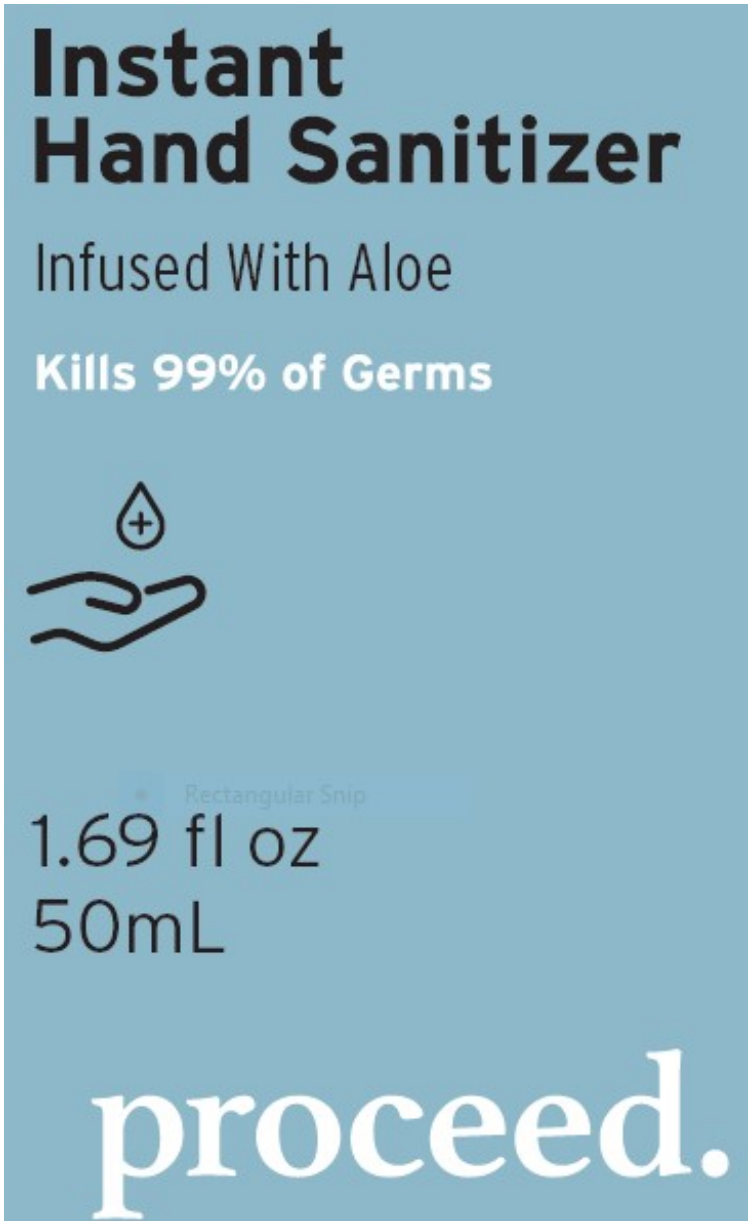


Package Label - Principal Display Panel

Instant Hand Sanitizer. 50mL



HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80380-071
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**
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	0.6 mL in 100 mL

AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.15 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.1 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80380-071-01	70 mL in 1 BOTTLE, DISPENSING; 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(80380-071)

Revised: 10/2020 Shedrain Corporation