

ANTIBACTERIAL HAND SANITIZER- antibacterial hand sanitizer gel
Shanghai Rays hinc ENVI-TECH Developing CO., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Antibacterial Hand Sanitizer

Active Ingredients

Glutaraldehyde 0.3%, AES 7.0%, APG 1.0%, AEO-9 0.5%, CAB 3.8%

Purpose

Antibacterial

Uses

For hand sanitizing to reduce bacteria on the skin.

Warnings

For external use only-hands. Flammable. Keep away from heat and flame.

Do not use

in children less than 2 months of age on open skin wounds

Directions

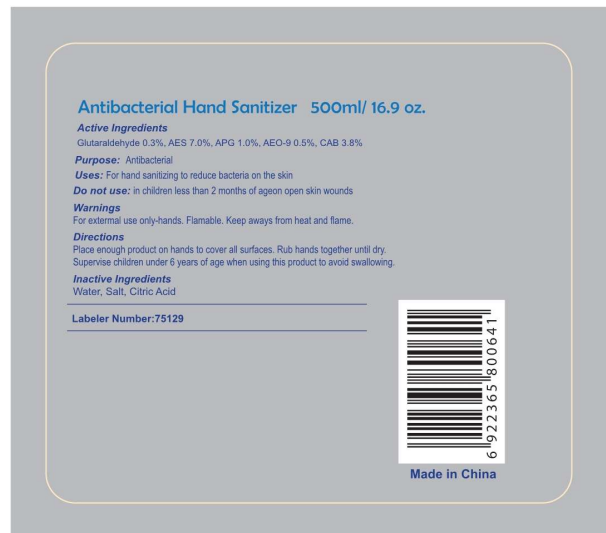
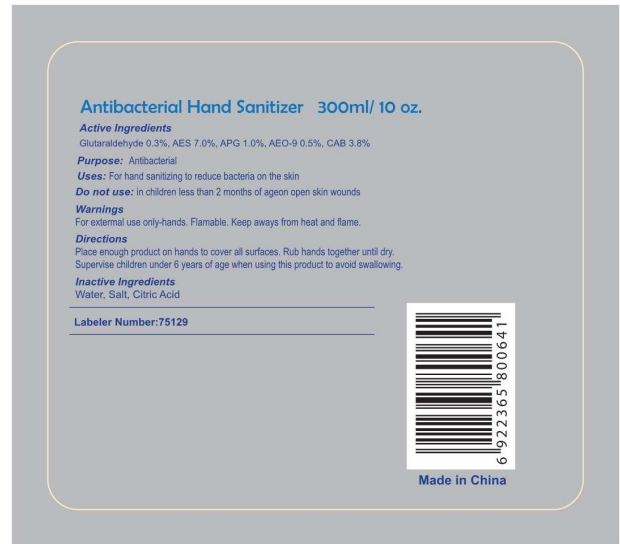
Place enough product on hands to cover all surfaces. Rub hands together until dry.
Supervise children under 6 years of age when using this product to avoid swallowing.

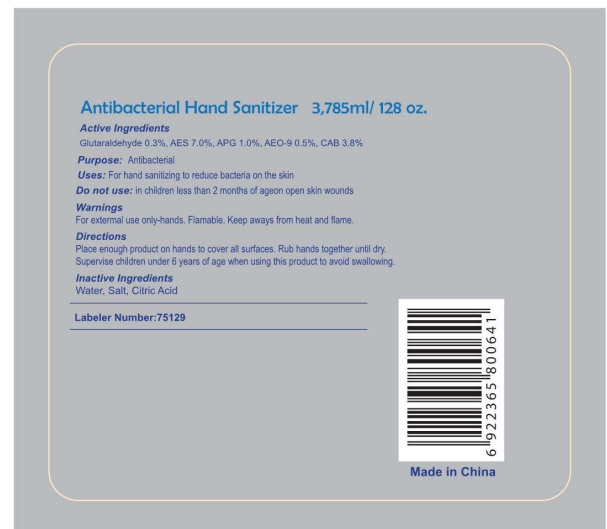
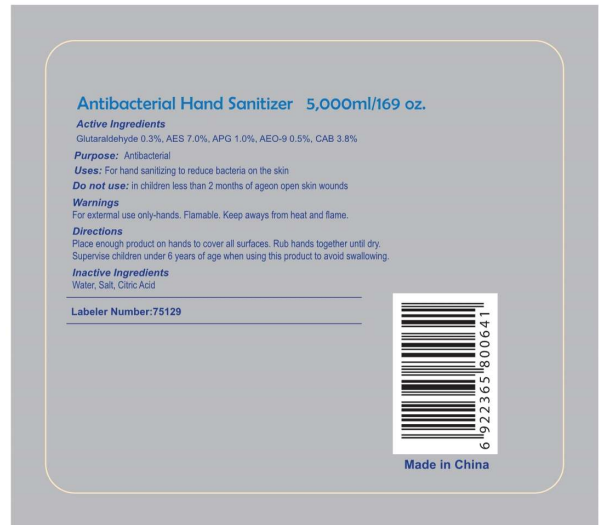
Other information

Inactive Ingredients

Water, Salt, Citric Acid

Package Label - Principal Display Panel





ANTIBACTERIAL HAND SANITIZER

antibacterial hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75129-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLUTARAL (UNII: T3C89M417N) (GLUTARAL - UNII:T3C89M417N)	GLUTARAL	0.3 g in 100 mL

CARBONIC ANHYDRASE 1 (UNII: 31F7ZV0E20) (CARBONIC ANHYDRASE 1 - UNII:31F7ZV0E20)

CARBONIC ANHYDRASE 1

3.8 g
in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75129-002-01	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020	
2	NDC:75129-002-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020	
3	NDC:75129-002-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020	
4	NDC:75129-002-04	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/18/2020	

Labeler - Shanghai Rayshine ENVI-TECH Developing CO., Ltd. (420836386)

Registrant - Shanghai Rayshine ENVI-TECH Developing CO., Ltd. (420836386)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Rayshine ENVI-TECH Developing CO., Ltd.		420836386	manufacture(75129-002)

Revised: 4/2020

Shanghai Rayshine ENVI-TECH Developing CO., Ltd.