HAND SANITIZER- alcohol gel
SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD

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.

XEPA Hand Sanitizer

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.

Directions

- Place enough product on hands to cover all surface. Rub hands together until dry.
- For Children under 6 years of age, use with supervision

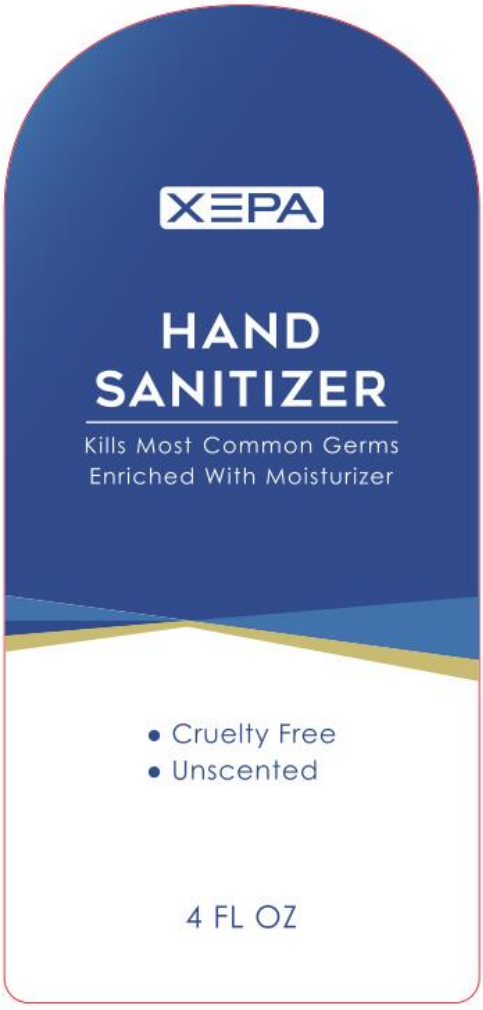
Other information

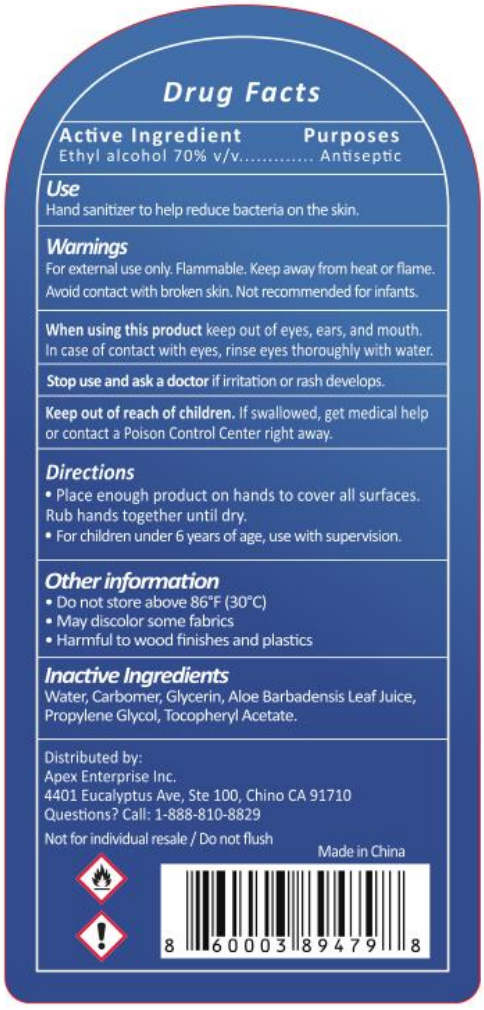
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water,Carbomer,Glycerin, Aloe Barbadnsis Leaf Juice, Propylene Glycol, Tocopheryl Acetate

Package Label - Principal Display Panel





HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74913-173
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**
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	2 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	26.6 mL in 100 mL

CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74913-173-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/08/2020	

Labeler - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)

Registrant - SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD (546345856)

Establishment

Name	Address	ID/FEI	Business Operations
SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD		546345856	manufacture(74913-173)

Revised: 8/2020 SHANTOU S.E.Z BAOJIE INDUSTRY CO., LTD