HPY MOISTURIZING INSTANT HAND SANITIZER- alcohol gel
HPY BIOTECH 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.

HPY Moisturizing Instant Hand Sanitizer

Active Ingredient(s)

ethanol 30% - 40% w/w.

benzalkonium chloride 0.08% - 0.12% w/w

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.

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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.

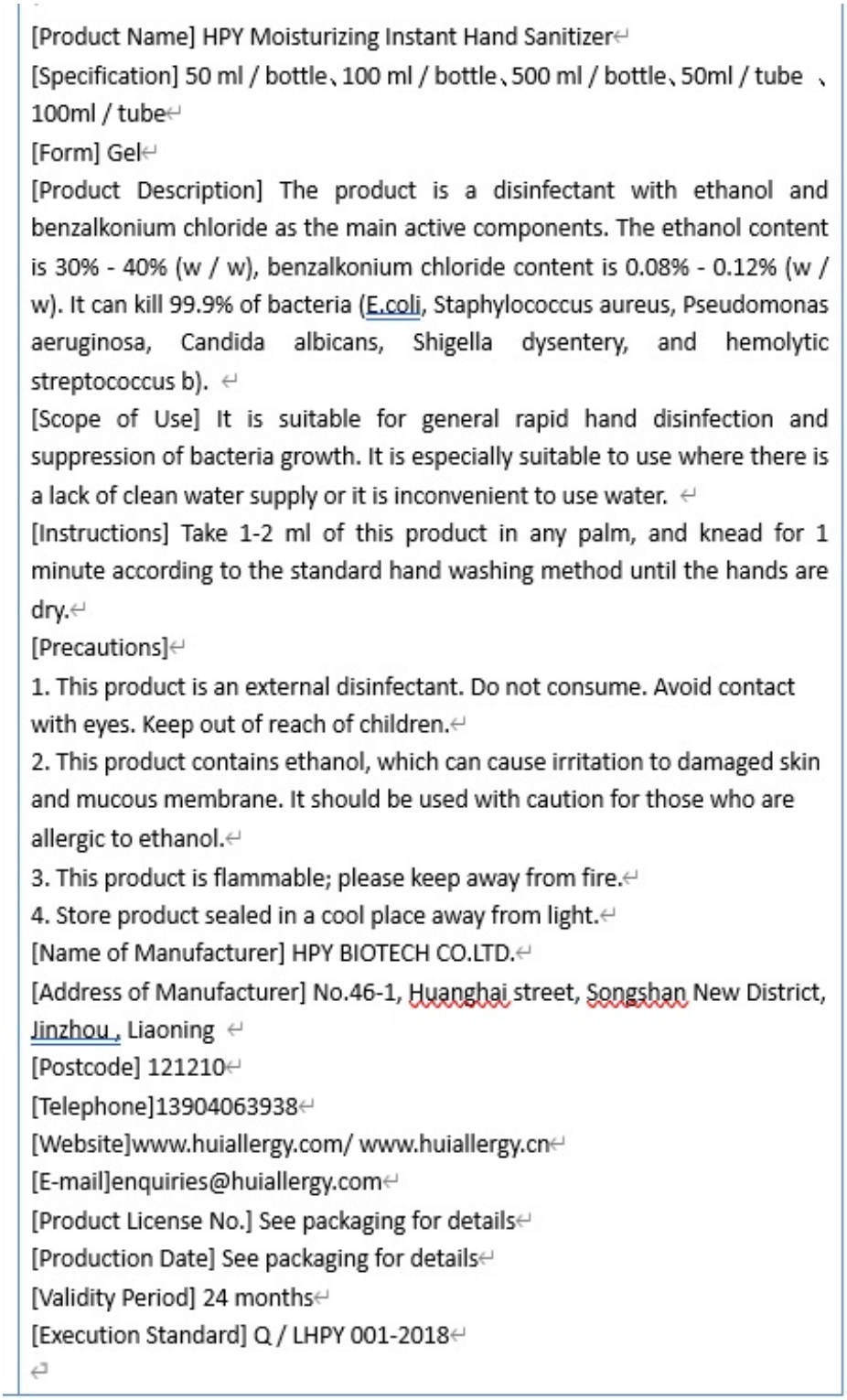
Other information

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

Inactive ingredients

glycerin, purified water USP

Package Label - Principal Display Panel


[Product Name] HPY Moisturizing Instant Hand Sanitizer
[Specification] 50 ml / bottle、100 ml / bottle、500 ml / bottle、50ml / tube 、100ml / tube
[Form] Gel
[Product Description] The product is a disinfectant with ethanol and benzalkonium chloride as the main active components. The ethanol content is 30% - 40% (w / w), benzalkonium chloride content is 0.08% - 0.12% (w / w). It can kill 99.9% of bacteria (E.coli, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Shigella dysentery, and hemolytic streptococcus b).
[Scope of Use] It is suitable for general rapid hand disinfection and suppression of bacteria growth. It is especially suitable to use where there is a lack of clean water supply or it is inconvenient to use water.
[Instructions] Take 1-2 ml of this product in any palm, and knead for 1 minute according to the standard hand washing method until the hands are dry.
[Precautions]
1. This product is an external disinfectant. Do not consume. Avoid contact with eyes. Keep out of reach of children.
2. This product contains ethanol, which can cause irritation to damaged skin and mucous membrane. It should be used with caution for those who are allergic to ethanol.
3. This product is flammable; please keep away from fire.
4. Store product sealed in a cool place away from light.
[Name of Manufacturer] HPY BIOTECH CO.LTD.
[Address of Manufacturer] No.46-1, Huanghai street, Songshan New District, Jinzhou , Liaoning
[Postcode] 121210
[Telephone]13904063938
[Website]www.huiallergy.com/ www.huiallergy.cn
[E-mail]enquiries@huiallergy.com
[Product License No.] See packaging for details
[Production Date] See packaging for details
[Validity Period] 24 months
[Execution Standard] Q / LHPY 001-2018

50 mL NDC: 80222-001-01

HPY MOISTURIZING INSTANT HAND SANITIZER alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80222-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 mg in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	35 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80222-001-01	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
2	NDC:80222-001-02	100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
3	NDC:80222-001-03	500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
4	NDC:80222-001-04	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020	
5	NDC:80222-001-05	100 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/20/2020	

Labeler - HPY BIOTECH CO.,LTD. (413571769)

Registrant - HPY BIOTECH CO.,LTD. (413571769)

Establishment

Name	Address	ID/FEI	Business Operations
HPY BIOTECH CO.,LTD.		413571769	manufacture(80222-001) , label(80222-001)

Revised: 8/2020 HPY BIOTECH CO.,LTD.