

HPY 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 Instant Hand Sanitizer

Active Ingredient(s)

ethanol 50% - 60% w/w.

phenoxyethanol 0.8% - 1% 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.

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 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 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 as the main active component. The ethanol content is 50% - 60% (w / w), phenoxyethanol content is 0.8% - 1%(w / w). Can kill 99.9% of bacteria (E.coli, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans, Shigella dysentery, and Streptococcus hemolyticus b).

[Scope of Use] It is suitable for use by medical staff in intensive care unit, emergency room, ward and outpatient department and by other personnel in need of rapid hand disinfection. 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.cn/ www.huiallergy.com

[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: 80222-002-01

HPY INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80222-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	60 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T) (PHENOXYETHANOL - UNII:HIE492ZZ3T)	PHENOXYETHANOL	1 mg in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80222-002-01	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
2	NDC:80222-002-02	100 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
3	NDC:80222-002-03	500 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/20/2020	
4	NDC:80222-002-04	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/20/2020	
5	NDC:80222-002-05	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(80222-002) , label(80222-002)

Revised: 8/2020

HPY BIOTECH CO.,LTD.