

HELPMATE HAND SANITIZER- alcohol denat. liquid
Xiamen Wally Bath Manufacture 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.

Active Ingredient(s)

Alcohol denat.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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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, PEG-40 Hydrogenated Castor Oil, Carbomer, Aminomethyl propanol, Aloe Barbadensis Leaf Extract

Package Label - Principal Display Panel

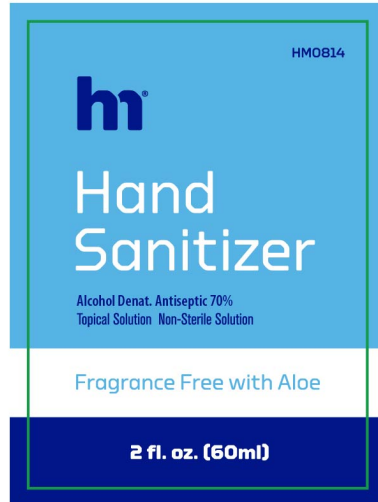
60ml package ndc: 78868-005-01

60ml hand sanitizer
 20pc 入一个PDQ
 4 * 6排列

60ml hand sanitizer



瓶子的盖子透明
 Hand Sanitizer 要求有aloe Vera,
 不要香味,
 不要颜色

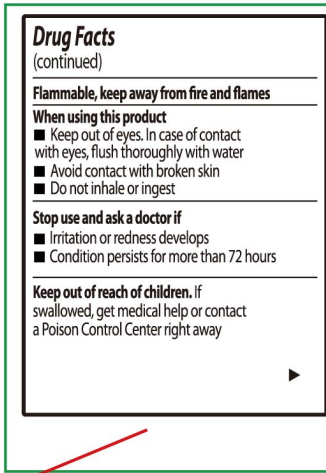
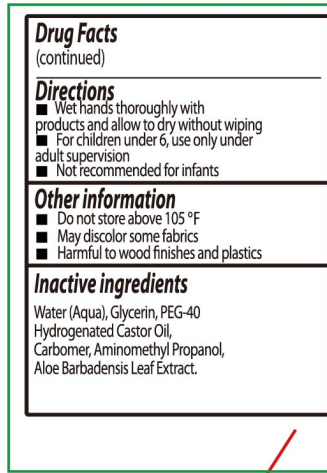


B面反面

B面

A面反面

A面



刷胶

30ml package ndc: 78868-005-02

30ML

30ml hand sanitizer
50pc 入桶



瓶子的盖子透明
Hand Sanitizer 要求有aloe Vera,
不要香味,
不要颜色

亮膜, 纸标 背标亮膜, 透明标

25*43MM

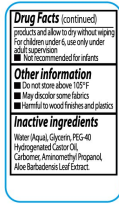


after

B面反面



B面



A面反面



A面



PVC 桶条码

JAR UPC

70*25MM

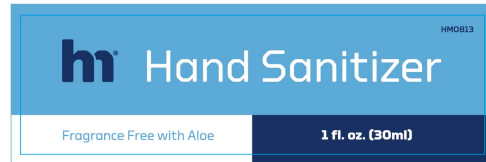
亮膜, 纸标



正面标签亮膜, 纸标

FRONT STICKER

100*30MM



左右标签亮膜, 纸标

LEFT & RIGHT SIDE STICKER

130*130MM



HELPMATE HAND SANITIZER

alcohol denat. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78868-006
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
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
POLYOXYL 40 CASTOR OIL (UNII: 4ERD2076EF)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78868-006-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78868-006-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Xiamen Wally Bath Manufacture Co., Ltd (548232606)

Establishment

Name	Address	ID/FEI	Business Operations
Xiamen Wally Bath Manufacture Co., Ltd		548232606	manufacture(78868-006)

Revised: 1/2023

Xiamen Wally Bath Manufacture Co., Ltd