

HAND SANITIZER- alcohol gel
GFA Production (Xiamen) 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.

Hand Sanitizer

Drug Facts

Active ingredient

Ethyl alcohol 62 v/v

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use.

Warnings

Flammable. Keep away from fire or flame

For external use only.

Do not use

- in the eyes.

Stop use and ask a doctor if

- irritation or redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands thoroughly with product and allow to dry without wiping.

Other information

- Store between 15-25°C (59 ° to 77°F)

Inactive Ingredients

Carbomer, propylene glycol, purified water, titanium dioxide

□*Package Labeling:*

Warnings

Intended for use exclusively by adults, and use only as directed. Excessive use may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

Directions for safe use

For hand washing to decrease bacteria on the skin that may cause disease.

Manufacturer:

GFA Production Xiamen Co., Ltd

No. 20 Huli Industrial Park
Meixi Road, Tong'an, Xiamen
Fujian, China 361100



Genuine First Aid



Hand Sanitizer



Wash away bacteria



Refreshing texture



Protect family health



No-wash quick-drying

Net Wt. 7.05 oz (200ml)

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TO REPORT A SERIOUS ADVERSE EVENT, CONTACT (800) 258-4696



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:508 14-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50814-050-02	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/01/2020	

Labeler - GFA Production (Xiamen) Co., Ltd. (421256261)

Establishment

Name	Address	ID/FEI	Business Operations
GFA Production (Xiamen) Co., Ltd.		421256261	manufacture(50814-050)

Revised: 4/2020

GFA Production (Xiamen) Co., Ltd.