

SAFETY MAX- disinfectant gel gel
SafetyMax Corporation

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.

SafetyMax Sanitizer Gel

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

To decrease bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

Flammable. Keep away from heat or flame.

For external use only-Hands.

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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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 whipping.
- For children under 6 years use only under adult supervision.
- Not recommended for infants.

Other information

- Store below 106 F (41 C)
- May discolor certain fabrics or surfaces.

Inactive ingredients

Water, glycerin, carbomer, sodium hydroxide, Ethylhexyl glycerin, Aloe barbadensis leaf extract

Package Label - Principal Display Panel

BETTER FOR DAILY USE



HAND SANITIZER GEL



75% Ethyl Alcohol

Net: 16.9 fl. oz. e 500ml

Drug Facts	
Active Ingredient Purpose Ethyl Alcohol 75% v/v.....	Antiseptic
Uses 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 do not use in or near the eyes. In case of contact, 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 • Put enough product on your palm to cover hands and rub hands together briskly until dry. • Children under 6 years of age should be supervised when using products.	
Other information • Avoid freezing and excessive heat above 40C (104F) • May discolor certain fabrics or surfaces	
Inactive ingredients aloe barbadensis leaf extract, benzyl benzoate, carbomer, citral, ethylhexylglycerin, geraniol, glycerin, limonene, linalool, sodium hydroxide, water.	

Distributed by:
SAFETYMAX CORPORATION
San Francisco, CA 94124
www.safetymax.com
MADE IN CHINA

500 mL NDC: 78503-111-03

SAFETY MAX

disinfectant gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78503-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GERANIOL (UNII: L837108USY)	
CITRAL (UNII: T7EU009VPP)	
LINALOOL, (+)- (UNII: F4VNO44C09)	
GLYCERIN (UNII: PDC6A3C00X)	
CARBOMER 934 (UNII: Z135WT9208)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BENZYL BENZOATE (UNII: N863NB338G)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78503-111-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78503-111-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:78503-111-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
4	NDC:78503-111-04	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - SafetyMax Corporation (792731853)

Establishment

Name	Address	ID/FEI	Business Operations
Fujian Jinghua Blotechnology Co., Ltd.		416242797	manufacture(78503-111)

Revised: 7/2020

SafetyMax Corporation