

HAND SANITIZER- hand sanitizer gel
NINGBO JIANGBEI OCEAN STAR TRADING 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.

47993-258

Active ingredients

Ethyl Alcohol 62%

Antiseptic

Uses

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

Warnings:

For external use only

Flammable

When using this product.

- Keep out of eyes. In case of contact with eyes
- Avoid contact with broken skin.
- Do not inhale or ingest.

Stop use and ask a doctor if

- Irritation or redness develops.
- Condition persists for more than 72 hours.

Directions:

- Wet hands thoroughly with product and allow to dry without wiping.
- For children under 6
- Not recommended for infants.

For children under 6

Other information

- Do not store above 105
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive Ingredients:

Water,Carbomer 940,Triethanolamine,Glycerin,Aloe Barbadensis leaf juice

Drug Facts

Hand Sanitizer **237 ml / 8 oz**

Active ingredient	Purpose
Ethyl Alcohol 62%	Antiseptic

Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

Warnings

For external use only: hands

Flammable, keep away from fire or flame.

When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin. ■ do not inhale or ingest.

Stop use and ask a doctor if ■ irritation or redness develops ■ condition persists for more than 72 hours

Directions ■ wet hands thoroughly with product and allow to dry without wiping ■ for children under 6, use only under adult supervision ■ not recommended for infants

Other information ■ do not store above 105°F ■ may discolor some fabrics ■ harmful to wood finishes and plastics

Inactive Ingredients Water, Carbomer 940, Triethanolamine, Glycerin, Aloe Barbadensis leaf juice

Best Used by:
Batch Code:
Made in China

Drug Facts

Hand Sanitizer **500 ml / 16.9 oz**

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses ■ to decrease bacteria on the skin that could cause disease ■ recommended for repeated use

Warnings

For external use only: hands

Flammable, keep away from fire or flame.

When using this product ■ keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ avoid contact with broken skin. ■ do not inhale or ingest.

Stop use and ask a doctor if ■ irritation or redness develops ■ condition persists for more than 72 hours

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Inactive Ingredients Water, Carbomer 940, Triethanolamine, Glycerin, Aloe Barbadensis leaf juice

Best Used by:
Batch Code:
Made in China

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47993-258
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 g in 112 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47993-258-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020	
2	NDC:47993-258-02	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	05/13/2020	

Labeler - NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD (529334491)

Registrant - NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD (529334491)

Establishment

Name	Address	ID/FEI	Business Operations
NINGBO OCEANSTAR CHEMICAL PRODUCTS CO.,LTD		544493972	manufacture(47993-258)

Revised: 5/2020

NINGBO JIANGBEI OCEAN STAR TRADING CO.,LTD