RINSE-FREE HAND SANITIZER- rinse-free hand sanitizer gel Ningbo Haishu Huasen Houseware 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.

Rinse-free Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 75%

Purpose

Antiseptic

Use

To decrease bacteria on the skin that could cause diseasee.

Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from heat and flame.

Discontinue if skin becomes irritated and ask a doctor.

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

Do not use

Do not inhale or ingest..

Do not store above 105°F.

Keep out of eyes. In case of contact with eyes, flush thoroughly with water.

Do not inhale or ingest.

Avoid contact with broken skin.

/

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

Directions

Wet hands thoroughly with product and rub until dry without wiping.

For children under 6, use only under adult supervisiono.

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, glycerin, propylene glycol, carbomer, sodium hydroxide

Package Label - Principal Display Panel



Drug Facts Active Ingredient Ethyl Alcohol 75% Purpose Antiseptic

Uses

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

Warnings

For external use only.

Made in China

Drug Facts(continued)

Directions

- Wet hands thoroughly with product and rub until dry without wiping.
- For children under 6,use only under adult supervision.
- · Not recommended for infants.

When using this product

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

Other Information

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

Drug Facts(continued)

Warnings

- For external use only.
- Flammable.Keep away from heat and flame.
- Discontinue if skin becomes irritated and ask a doctor.
- . Keep out of reach of children.
- . In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Inactive Ingredients

Water, glycerin, propylene glycol,carbomer,sodium hydroxide



Drug Facts

Active Ingredient Ethyl Alcohol 75%

Purpose Antisentic

RINSE-FREE HAND SANITIZER

rinse-free hand sanitizer gel

Product Information

HUMAN OTC DRUG NDC:78345-006 Product Type Item Code (Source)

TOPICAL, CUTANEOUS **Route of Administration**

Active Ingredient/Active Moiety

- 1	8		
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	68 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER 1342 (UNII: 809 Y72KV36)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
TROLAMINE (UNII: 903K93S3TK)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:78345-006-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020		
	2 NDC:78345-006-02	500 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 - Ningbo Haishu Huasen Houseware Co.,Ltd (554532212)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ningbo Haishu Huasen Houseware Co.,Ltd		554532212	manufacture(78345-006)	

Revised: 5/2020 Ningbo Haishu Huasen Houseware Co.,Ltd