

HAND SANITIZER- hand sanitizer gel

Fortress Expert 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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Helps reduce bacteria that potentially can cause disease

Helps prevent Cross contamination by hand contact

Recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from fire heat, or flame

Do not use near eyes

Incase of eye contact flush with water for 15 minutes

If irritation persists stop use of product and get medical attention

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.

Keep out of reach of children.

In case of accidental ingestion seek medical attention or contact a poison control center immediately

Directions

Wet hands thoroughly with product and rub completely covering hands

Allow to dry without wiping

Children under the age of 6 should use with adult supervision

Not recommended for infants

Other information

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carbomer, Fragrance (Parfum), Triethanolamine, Triisopropanolamine

Package Label - Principal Display Panel

REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 0.51 FL.OZ. / 15 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

SDB-RHS-301

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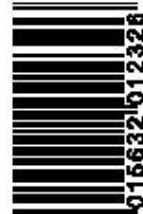
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Pomona, CA 91768

Made in China



5-015632-012328

REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 32.3 FLOZ. / 950 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 1.7 FL.OZ. / 50 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 2 FLOZ. / 59 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 1 FLOZ. / 30 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfum), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 1 FLOZ. / 30 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 11.22 FL.OZ. / 330 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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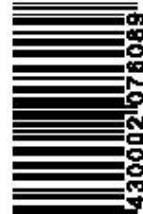
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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 16.32 FL.OZ. / 480 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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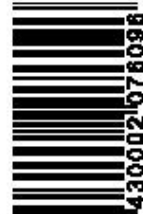
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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 16.32 FL.OZ. / 480 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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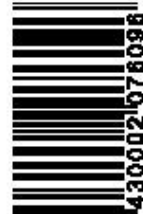
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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 8.5 FL.OZ. / 250 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfum), Triethanolamine, Triisopropanolamine

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REZITINAS®

HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 5.1 FL.OZ. / 150 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfum), Triethanolamine, Triisopropanolamine

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Made in China



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HAND SANITIZER

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 32.0 FL. OZ. / 944 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....

Uses

- Helps reduce bacteria that potential
- Helps prevent cross contamination
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat
- Do not use near eyes
- In case of eye contact flush with water
- If irritation persists stop use of product

Keep out of reach of children.

- In case of accidental ingestion seek contact a poison control center immediately

Directions

- Wet hands thoroughly with product covering hands
- Allow to dry without wiping
- Children under the age of 6 should be supervised
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carbopol, Triethanolamine, Trisopropanolamine

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REZITINAS®

**HAND
SANITIZER**

**KILLS 99.99%
OF GERMS**

**Moisturizing Gel
Leaves Hands Soft**

NET WT. 17 FLOZ. / 500 ML

Drug Facts

Active Ingredient

Ethyl Alcohol 70%.....Antiseptic

Uses

- Helps reduce bacteria that potentially can cause disease
- Helps prevent cross contamination by hand contact
- Recommended for repeated use

Warnings

For external use only

- Flammable, keep away from fire, heat, or flame
- Do not use near eyes
- In case of eye contact flush with water for 15 minutes
- If irritation persists stop use of product and get medical attention

Keep out of reach of children.

- In case of accidental ingestion seek medical attention or contact a poison control center immediately.

Directions

- Wet hands thoroughly with product and rub completely covering hands
- Allow to dry without wiping
- Children under the age of 8 should use with adult supervision
- Not recommended for infants

Inactive Ingredients

Water, PEG-40 Hydrogenated Castor Oil, Carboner, Fragrance (Parfem), Triethanolamine, Triisopropanolamine

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HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73549-001
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
TRISOPROPANOLAMINE (UNII: W9EN9DLM98)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73549-001-01	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
2	NDC:73549-001-02	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
3	NDC:73549-001-03	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
4	NDC:73549-001-04	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
5	NDC:73549-001-05	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
6	NDC:73549-001-06	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
7	NDC:73549-001-07	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
8	NDC:73549-001-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
9	NDC:73549-001-09	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
10	NDC:73549-001-10	330 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
11	NDC:73549-001-11	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
12	NDC:73549-001-12	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
13	NDC:73549-001-13	944 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	
14	NDC:73549-001-14	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/10/2020	

Labeler - Fortress Expert Co., Ltd (543358697)

Establishment

Name	Address	ID/FEI	Business Operations
Fortress Expert Co., Ltd		543358697	manufacture(73549-001)