

HAND SANITIZER- alcohol gel
REALCHEM MANUFACTURING

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.

70% EtOH Gel w/Vit E Scented

This is a hand sanitizer scented gel with added Vitamin E manufactured according to the FDA Guidance.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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 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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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, RapidGel EZ100, Tocopheryl Acetate, purified water USP

Package Label - Principal Display Panel

237 mL NDC: 79363-703-08

NDC 79363-703-08



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> ■ For external use only ■ Flammable keep away from heat or flame 	
When using this product ■ Do not use on children less than 2 months of age ■ Do not use on open skin wounds ■ When using this product keep out of eyes, ears, and mouth.	
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Keep out of reach of children.	
If swallowed: Immediately call a Poison Control Center or a doctor/physician. Rinse mouth.	
Directions	
<ul style="list-style-type: none"> ■ Place enough product on hands to cover all surfaces. ■ Rub hands together until dry. 	
Other information	
<ul style="list-style-type: none"> ■ Store between 15°-30° C (59°-86°F) ■ Avoiding freezing and excessive heat above 40° C (104°F) 	
Inactive Ingredients: Glycerol, Water (Aqua), PEG 6; AMP-Acrylates/Vinyl, Fragrance, Denatonium Benzoate, Vitamin E	

RC xxxxx

Simpli Safe



Gel- Hand Sanitizer With Vitamin E



Cucumber Aloe

Help keep yourself protected against viruses and bacteria

Enhanced with Vitamin E and extra moisturizer; leaves your hands feeling clean, soft, and refreshed, with a light scent after each use

Crafted in Mundelein, IL
Distributed by Eclipse MFG



8 oz (237mL)



NDC 79363-703-08



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
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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: Immediately call a Poison Control Center or a doctor/physician. Rinse mouth.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. 	
Other information	
<ul style="list-style-type: none"> Store between 15°-30° C (59°-86°F) Avoiding freezing and excessive heat above 40° C (104°F) 	
Inactive Ingredients: Glycerol, Water (Aqua), PEG 6; AMP-Acrylates/Vinyl, Fragrance, Denatonium Benzoate, Vitamin E	

RC xxxxx

Simpli Safe



Gel- Hand Sanitizer With Vitamin E Ginger Citrus

8 oz (237mL)

Help keep yourself protected against viruses and bacteria

Enhanced with Vitamin E and extra moisturizer; leaves your hands feeling clean, soft, and refreshed, with a light scent after each use

Crafted in Mundelein, IL Distributed by Eclipse MFG



NDC 79363-703-08



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
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Keep out of reach of children.	
If swallowed: Immediately call a Poison Control Center or a doctor/physician. Rinse mouth.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces. Rub hands together until dry. 	
Other information	
<ul style="list-style-type: none"> Store between 15°-30° C (59°-86°F) Avoiding freezing and excessive heat above 40° C (104°F) 	
Inactive Ingredients: Glycerol, Water (Aqua), PEG 6; AMP-Acrylates/Vinyl, Fragrance, Denatonium Benzoate, Vitamin E	

RC xxxxx

Simpli Safe



Gel- Hand Sanitizer With Vitamin E Lavender

8 oz (237mL)

Help keep yourself protected against viruses and bacteria

Enhanced with Vitamin E and extra moisturizer; leaves your hands feeling clean, soft, and refreshed, with a light scent after each use

Crafted in Mundelein, IL Distributed by Eclipse MFG



NDC 79363-703-08



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
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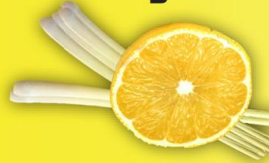
RC xxxxx



Safe Simpli



Gel- Hand Sanitizer With Vitamin E Lemongrass



Help keep yourself protected against viruses and bacteria

Enhanced with Vitamin E and extra moisturizer; leaves your hands feeling clean, soft, and refreshed, with a light scent after each use

Crafted in Mundelein, IL
Distributed by Eclipse MFG



8 oz (237mL)



NDC 79363-703-08



Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
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Other information	
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Inactive Ingredients: Glycerol, Water (Aqua), PEG 6; AMP-Acrylates/Vinyl, Fragrance, Denatonium Benzoate, Vitamin E	

RC xxxxx



Safe Simpli



Gel- Hand Sanitizer With Vitamin E Lime & Sea Salt



Help keep yourself protected against viruses and bacteria

Enhanced with Vitamin E and extra moisturizer; leaves your hands feeling clean, soft, and refreshed, with a light scent after each use

Crafted in Mundelein, IL
Distributed by Eclipse MFG



8 oz (237mL)



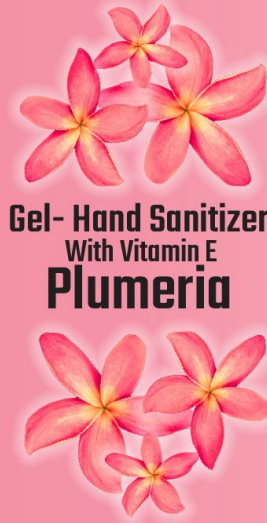
NDC 79363-703-08



Drug Facts	
Active Ingredient[s] Ethyl Alcohol 70% v/v	Purpose Antiseptic
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RC xxxxx

Simpli Safe



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Crafted in Mundelein, IL
Distributed by Eclipse MFG



8 oz (237mL)

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79363-703
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
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	1 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.03 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79363-703-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/11/2020	

Labeler - REALCHEM MANUFACTURING (120491681)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117584702	pack(79363-703) , manufacture(79363-703) , repack(79363-703)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117742005	manufacture(79363-703) , pack(79363-703) , repack(79363-703)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117828480	manufacture(79363-703) , pack(79363-703) , repack(79363-703)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		120491681	manufacture(79363-703) , pack(79363-703) , repack(79363-703)

Revised: 1/2021

REALCHEM MANUFACTURING