

HAND SANITIZER- alcohol gel
RealChem Manufacturing Inc.

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 Unscented Gel HS with Aloe & Vit E

This is a 70% ethanol unscented gel hand sanitizer with added aloe and vitamin E, manufactured according to FDA guidance. T

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.

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

- 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 EZ1, purified water USP

Package Label - Principal Display Panel

118 mL NDC: 79363-706-04

NDC # 79363-706-04



407 South 17th St.,
Clear Lake, IA 50428
www.nexchem.com

Drug Facts	
Active Ingredient[s] Ethyl Alcohol 70% v/v.....	PurposeAntiseptic
Use[s] Hand Sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.	
Warnings ■ 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. 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: Immediately call a Poison Control Center or a doctor/physician. Rinse mouth.	
Directions ■ Place enough product on hands to cover all surfaces. ■ Rub hands together until dry.	
Other information ■ 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, Denatonium Benzoate, Tocopheryl Acetate, Aloe Barbadensis (Pure Inner Leaf Juice)	

Distributed by:
AZTEC SUPPLY CORP.
5024 West 67th Street
Bedford Park, IL 60638
PH: 708-594-6080
email:aztecsox@outlook.com
www.aztecsupplycorp.com

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79363-706
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
GLYCERIN (UNII: PDC6A3C0OX)	0.516 mL in 100 mL
WATER (UNII: 059QF0K00R)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	0.886 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79363-706-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/06/2021	

Labeler - RealChem Manufacturing Inc. (120491681)**Establishment**

Name	Address	ID/FEI	Business Operations
RealChem Manufacturing Inc		117742005	manufacture(79363-706) , pack(79363-706) , repack(79363-706)

Establishment

Name	Address	ID/FEI	Business Operations
RealChem Manufacturing Inc		117828480	manufacture(79363-706) , pack(79363-706) , repack(79363-706)

Establishment

Name	Address	ID/FEI	Business Operations
RealChem Manufacturing Inc		120491681	manufacture(79363-706) , pack(79363-706) , repack(79363-706)

Revised: 2/2021

RealChem Manufacturing Inc.