

FOAMING HAND SANITIZER- alcohol liquid
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.

62% Ethanol Foaming HS

This is a foaming hand sanitizer manufactured according to FDA Guidance.

Active Ingredient(s)

Alcohol 62% 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, Bis-PEG-10 Dimethicone, purified water USP

Package Label - Principal Display Panel

3789 mL NDC: 79363-601-28

NDC: 79363-601-28



Help keep yourself protected
against viruses and bacteria

Crafted in Mundelein, IL
Distributed by Eclipse MFG



Foaming
Hand Sanitizer

62%
Alcohol

128 FL OZ - 1 Gallon (3.79 L)

Proudly made
in America

Drug Facts	Purpose
Active ingredient(s) Ethanol 62% w/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. 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 <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: Water (Aqua), Glycerol, Bis-PEG-10 Dimethicone	
Questions? 1-800-424-6900	

FOAMING HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79363-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	54.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.7188 g in 100 g
BIS-PEG-10 DIMETHICONE/DIMER DILINOLEATE COPOLYMER (UNII: CF5W1YCX11)	1.007 g in 100 g
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79363-601-28	3296 g in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/30/2020	

Labeler - REALCHEM MANUFACTURING (120491681)**Establishment**

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117584702	manufacture(79363-601) , pack(79363-601) , repack(79363-601)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117742005	manufacture(79363-601) , pack(79363-601) , repack(79363-601)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		117828480	manufacture(79363-601) , pack(79363-601) , repack(79363-601)

Establishment

Name	Address	ID/FEI	Business Operations
REALCHEM MANUFACTURING		120491681	manufacture(79363-601) , pack(79363-601) , repack(79363-601)

Revised: 1/2021

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