OROGIN ESSENTIAL EUCALYPTIC FRESH- alcohol solution Global Impact Innovation LLC

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 80% 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.

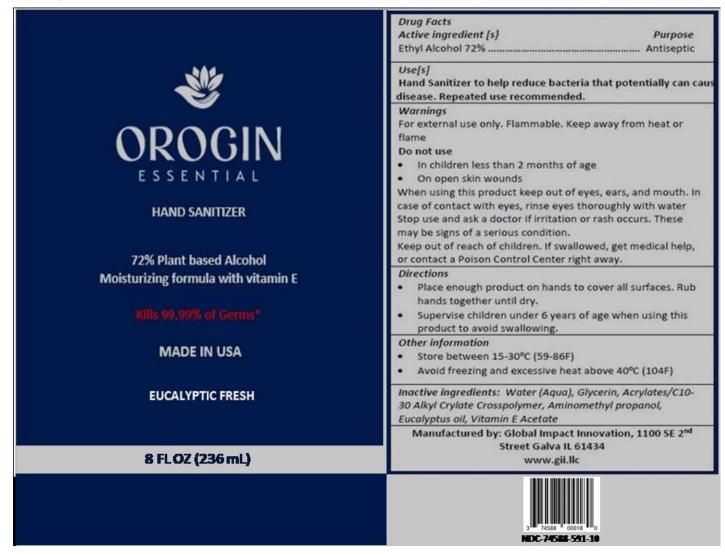
Other information

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

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Cryalate Crosspolymer, Aminomethylpropanol, Vitamin E Acetate, Eucalyptus Oil

Package Label - Principal Display Panel



236 mL NDC: 74588-591-10

	Drug Facts Active ingredient [s] Purpose Ethyl Alcohol 72%		
*	Use[s] Hand Sanitizer to help reduce bacteria that potentially can caus disease. Repeated use recommended.		
OROGIN ESSENTIAL HAND SANITIZER	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		
72% Plant based Alcohol	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.		
Moisturizing formula with vitamin E Kills 99.99% of Germs®	 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. 		
MADE IN USA	Other information Store between 15-30°C (59-86F) Avoid freezing and excessive heat above 40°C (104F) 		
EUCALYPTIC FRESH	Inactive ingredients: Water (Aqua), Glycerin, Acrylates/C10- 30 Alkyl Crylate Crosspolymer, Aminomethyl propanol, Eucalyptus oil, Vitamin E Acetate		
16 FL OZ (473 mL)	Manufactured by: Global Impact Innovation, 1100 SE 2 nd Street Galva IL 61434 www.gii.llc		
	3 74558 ¹ 00017 1 NDC-74582-591-11		

473 mL NDC: 74588-591-11

	Drug Facts Active ingredient [s] Purpose Ethyl Alcohol 72% Antiseptic
**	Use[s] Hand Sanitizer to help reduce bacteria that potentially can caus disease. Repeated use recommended.
ESSENTIAL HAND SANITIZER	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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MADE IN USA	Other information Store between 15-30°C (59-86F) Avoid freezing and excessive heat above 40°C (104F)
EUCALYPTIC FRESH	Inactive ingredients: Water (Aqua), Glycerin, Acrylates/C10- 30 Alkyl Crylate Crosspolymer, Aminomethyl propanol, Eucalyptus oil, Vitamin E Acetate
32 FL OZ (945 mL)	Manufactured by: Global Impact Innovation, 1100 SE 2 nd Street Galva IL 61434 www.gii.llc
	3 74588 00009 8 NEC 74588 -591-12

945 mL NDC: 74588-591-12

	Drug Facts Active ingredient [s] Purpose Ethyl Alcohol 72% Antiseptic
*	Use[s] Hand Sanitizer to help reduce bacteria that potentially can caus disease. Repeated use recommended.
OROGIN	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
HAND SANITIZER 72% Plant based Alcohol	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.
Moisturizing formula with vitamin E Kills 99.99% of Germs®	 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.
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EUCALYPTIC FRESH	Inactive ingredients: Water (Aqua), Glycerin, Acrylates/C10- 30 Alkyl Crylate Crosspolymer, Aminomethyl propanol, Eucalyptus oil, Vitamin E Acetate
1 Gal (3.78 L)	Manufactured by: Global Impact Innovation, 1100 SE 2 nd Street Galva IL 61434 www.gii.llc
	3 74588 00005 0 HDC-74588-591-04

3.78 L NDC: 74588-591-04

OROGIN ESSENTIAI	L EUCALYPTIC FRES	H				
Product Information						
Product T ype	HUMAN OTC DRUG	Ite	m Code (Sourco	e)	NDC:74588-591	
Route of Administration	TOPICAL					
Active Ingredient/Active I	Moiety					
Ingre	dient Name		Basis of Stre	ngth	Strength	
ALCOHOL (UNII: 3K9958V90M)	(ALCOHOL - UNII:3K9958V90M)		ALCOHOL		170.3436 mL in 236.588 mL	
Inactive Ingredients						
	Ingredient Name				Strength	
GLYCERIN (UNII: PDC6A3C0OX)			3.	3.4305 mL in 236.588 mL		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			0.	0.1183 mL in 236.588 mL		
WATER (UNII: 059QF0KO0R)			55	5.2945 i	nL in 236.588 mL	

EUCALYPTOL (UNII: RV6J6604TK)	0.349 mL in 236.588 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.3312 mL in 236.588 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	6.7213 mL in 236.588 mL

1 10		236.588 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2020	
2 ND				
	C:74588-591-11	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2020	
B ND 12	C:74588-591-	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2020	
4 ND 04	C:74588-591-	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 5/31/20 20	

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/31/2020	-

Labeler - Global Impact Innovation LLC (117465830)

Revised: 6/2020

Global Impact Innovation LLC