FASTENAL CLEAN CHOICE- fastenal clean choice gel Streamline Polymers 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.

Fastenal Clean Choice

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product.

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (0.63% v/v).
- c. Carbomer 940 (6.27% v/v)
- d. PEG-8 Dimethicone (0.45% v/v)
- e. Trolamine (0.22% v/v)
- f. East Indian Lemon Grass Oil (0.14% v/v)
- g. Purified Water

The firm does not add other active or inactive ingredients.

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

Carbomer 940, Fragrance, Glycerin, Peg-8 Dimethicone, Trolamine, Water

Package Label - Principal Display Panel



Drug Facts

Active Ingredient & Purpose

Ethyl Alcohol 70% v/v Antiseptic

Use[s]
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GEL HAND

*KILLS 99.99% OF ALL GERMS

MADE WITH LEMON SCENTED ESSENTIAL OIL

1 gal (3785ml) | 70% Alcohol



Drug Facts [Cont.]
Directions
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Distributed by Fasternel Company and its Subsid Windows, MN 85997 #2016 fasternel.com

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2 L NDC: 74793-0010-5









FASTENAL CLEAN CHOICE

fastenal clean choice gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74793-0010
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)	0.63 mL in 100 mL		
EAST INDIAN LEMONGRASS OIL (UNII: UPOM8M3VZW)	0.14 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	6.27 mL in 100 mL		
TROLAMINE (UNII: 903K93S3TK)	0.22 mL in 100 mL		

WATER (UNII: 059QF0KO0R)	22.29 mL in 100 mL
PEG-8 DIMETHICONE (UNII: GIA7T7640D)	0.45 mL in 100 mL

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74793- 0010-1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	
2	NDC:74793- 0010-2	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	
3	NDC:74793- 0010-3	251 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	
4	NDC:74793- 0010-4	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	
5	NDC:74793- 0010-5	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/16/2020	

Labeler - Streamline Polymers LLC (117054225)

Revised: 1/2022 Streamline Polymers LLC