CURATIVE BIOCENTRIC ANTISEPTIC HAND SANITIZER- alcohol gel Circular Centric, 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.

Curative Biocentric Antiseptic Hand Sanitizer

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 (percentage in final product formulation):

Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

- a. Glycerol (2.00% v/v).
- b. Carbomer Homopolymer Type C (0.25% v/v).
- c. Sterile distilled water or boiled cold water
- d. Fragrance Lavender (parfum)
- e. FD&C Blue No. 1 and FD&C Red No. 33

The firm does not add other active or inactive ingredients than stated above. Different or additional ingredients may impact the quality and potency of the product.

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 fire 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, carbomer, fragrance (parfum), dye, purified water (aqua) USP

Package Label - Principal Display Panel

4" Drug Facts Purpos FOR PROMO 6 Uses · hand sanitizer to decrease bacteria on the skin recommended for repeated use + for use when soap and water are not available Warnings • Flammable, keep away from fire/flame For external use only BIOCENTRIC Do not use • on children less than 2 months of age • on open skin wounds **ANTISEPTIC** When using this product • do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water SCAN Stop use and ask a doctor if • irritation or redness develop • condition persists for more than 72 hours HAND SANITIZER Keep out of reach of children. If swallowed, get medical help TOPICAL GEL or contact a Poison Control Center right away. Directions - wet hands thoroughly with product and allow to dry without wiping - supervise children under 6 years of age when using this product to avoid swallowing www.CircularCentric.com Other Information • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F) www.Curative.us Inactive ingredients Water (Aqua), glycerin, carbomer, fragrance (parfum), dye 20Z Distributed by: Circular Centric, Inc. (60mL) You may also report serious side effects to this phone number: 949-504-5353 • Mon-Fri 9:00 AM - 5:00 PM 12080 Magnolia Ave, Riverside, CA /

60 mL NDC: 77094-400-02



236 mL NDC: 77094-400-08

7.75"



0.125" corner ra

500 mL NDC: 77094-400-16



3785 mL NDC: 77094-400-01

CURATIVE BIOCENTRIC ANTISEPTIC HAND SANITIZER

alcohol gel

Product Information	roduct Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77094-444		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958	V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.00001 mL in 100 mL	
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	0.00001 mL in 100 mL	

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77094-444- 02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/24/2020		
2	NDC:77094-444- 08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/24/2020		
3	NDC:77094-444- 16	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/24/2020		
4	NDC:77094-444- 01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/24/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/24/2020	

Labeler - Circular Centric, Inc. (117507693)

Registrant - Circular Centric, Inc. (117507693)

Revised: 7/2020 Circular Centric, Inc.