

ENVIROPURE- benzalkonium chloride liquid
Cemi International, 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.

ENVIROPURE ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antiseptic

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

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help 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

Other information

- store between 15-30°C (59-86°F)

- avoid freezing and excessive heat above 40°C (104°F)
- do not use if the cap is broken

Inactive ingredients urea, water

Questions? 973-575-6591

You may also report serious side effects to this phone number. Mon-Fri 9:00 AM- 5:00 PM

alcohol-free

triclosan-free & fragrance-free

BAC-D

BACTERIAL DEFENSE



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West Caldwell, NJ 07006

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WindmillVitamins.com

Packaging

<p style="text-align: center;">ENVIROPURE™</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>ANTISEPTIC HAND SANITIZER</p> </div> <p style="text-align: center;">alcohol-free triclosan-free & fragrance-free BENZALKONIUM CHLORIDE 0.13%</p> <div style="text-align: center;">  </div> <p style="text-align: center;">128 fl. oz. (1 gal) (3.78 L)</p>	<table border="1"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td>Active ingredient</td> <td>Purpose</td> </tr> <tr> <td>Benzalkonium chloride 0.13%</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Uses</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • hand sanitizer to decrease bacteria on the skin • recommended for repeated use • for use when soap and water are not available </td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">Flammable, keep away from fire/ flame For external use only</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds </td> </tr> <tr> <td colspan="2">When using this product - do not get into eyes. In case of contact, rinse eyes thoroughly with water</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • irritation and redness develop • condition persists for more than 72 hours </td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • 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 </td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F) • do not use if the cap is broken </td> </tr> <tr> <td colspan="2">Inactive ingredients urea, water</td> </tr> <tr> <td colspan="2">Questions? 973-575-6591</td> </tr> <tr> <td colspan="2">You may also report serious side effects to this phone number. Mon-Fri 9:00 AM- 5:00 PM</td> </tr> </table>	Drug Facts		Active ingredient	Purpose	Benzalkonium chloride 0.13%	Antiseptic	Uses		<ul style="list-style-type: none"> • 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		Do not use		<ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 		When using this product - do not get into eyes. In case of contact, rinse eyes thoroughly with water		Stop use and ask a doctor if		<ul style="list-style-type: none"> • irritation and redness develop • condition persists for more than 72 hours 		Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.		Directions		<ul style="list-style-type: none"> • 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 		Other information		<ul style="list-style-type: none"> • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F) • do not use if the cap is broken 		Inactive ingredients urea, water		Questions? 973-575-6591		You may also report serious side effects to this phone number. Mon-Fri 9:00 AM- 5:00 PM		<p style="writing-mode: vertical-rl; transform: rotate(180deg);"> ©Copyright Windmill Health Products® All Rights Reserved. Distributed by: Windmill Health Products® 10 Henderson Drive West Caldwell, NJ 07006 Made in the U.S.A. </p> <p style="text-align: right;">Item# N11895</p> <div style="text-align: right;">  <p>0 35046 11895 2</p> </div>
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ENVIROPURE
benzalkonium chloride liquid
Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73741-102	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	1.3 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
UREA (UNII: 8W8T17847W)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73741-102-28	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/06/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/06/2020		

Labeler - Cemi International, Inc (015038336)

Establishment

Name	Address	ID/FEI	Business Operations
Cemi International, Inc		015038336	manufacture(73741-102)

Revised: 4/2020

Cemi International, Inc