

**NILAQUA ANTISEPTIC HAND SANITIZER FOAM- benzalkonium chloride liquid  
WATERLESS LIMITED**

*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.*

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**Nilaqua® ANTISEPTIC HAND SANITIZER**

***Drug Facts***

***Active ingredient***

Benzalkonium chloride 0.8% w/v

***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***

**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)

***Inactive ingredients***

amines, c10-16-alkyldimethyl, n-oxides, didecyl dimethyl ammonium chloride, sodium ethylhexyl sulfate, water

**Questions? ☎+1-855-578-0021**

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

Kind to Hands

**Nil aqua<sup>®</sup> Antiseptic Hand Sanitizer**

Is an alcohol free, antiseptic hand sanitiser that is kind and gentle to the skin.

- **Fragrance Free**
- **Fast Drying Formula**
- **Kind & Gentle to Skin**
- **Vegan Friendly**
- **Alcohol & PHMB Free**

Approved:

BS EN 1276, 1500, 1650

13623, 13704, 13727, 14348,

12791, 14476 2013 +A2:2019

[alcoholfreesanitiser.com](http://alcoholfreesanitiser.com).√

Recycle

Manufactured by: Waterless

Hope Mill, Stroud,

Glos, UK, GL5 2SQ

**Made in the UK**

**Packaging**

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12791, 14476 2013 + A2: 2019



**ANTISEPTIC HAND SANITIZER**

Kind to Hands  
Alcohol Free

alcoholfreesanitiser.com

Lot.No:  
Expiry:



6.76 fl oz (200 mL)

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Manufactured by:

**Waterless**  
Hope Mill, Stroud,  
Glos, UK, GL5 2SQ



**Made in the UK**

**NILAQUA ANTISEPTIC HAND SANITIZER FOAM**

benzalkonium chloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80349-102
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.8 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
(C10-C16)ALKYLDIMETHYLAMINE OXIDE (UNII: LF6BKC321J)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)	

**SODIUM ETHASULFATE (UNII: 12838560LI)**

**WATER (UNII: 059QF0KO0R)**

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80349-102-01	55 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/08/2020	
2	NDC:80349-102-02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/08/2020	
3	NDC:80349-102-03	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/08/2020	
4	NDC:80349-102-04	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/08/2020	
5	NDC:80349-102-05	800 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/08/2020	
6	NDC:80349-102-06	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/08/2020	
7	NDC:80349-102-07	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/08/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/08/2020	

**Labeler - WATERLESS LIMITED (211503494)**

### Establishment

Name	Address	ID/FEI	Business Operations
WATERLESS LIMITED		211503494	manufacture(80349-102)

Revised: 11/2020

WATERLESS LIMITED