

Lonzagard® Benzethonium Chloride USP

Efficacious Antibacterial



INCI: Benzethonium Chloride

Key Product Benefits

- Strong antibacterial
- Not sensitizing
- Water soluble
- Light in color
- Odorless
- Can be used in a variety of personal care applications
- Has a wide range of global regulatory acceptance

Recommended Use Level

0.1–0.5%

Description

Lonzagard® Benzethonium Chloride USP is a reliable and trusted cationic antimicrobial that can also be used as a personal care preservative. Lonzagard® Benzethonium Chloride USP offers greater efficacy, mildness, and safety versus competitive chemistries as an active antimicrobial ingredient, coupled with global-acceptance as a fast-acting preservative.

Compositional Breakdown

Chemical Compound Breakdown	CAS No.	EINECS No.
Benzethonium Chloride	121-54-0	204-479-9

Chemical Compound Breakdown	%
Benzethonium Chloride	>99%

Applications

- Baby care
- Baby wipes
- Body wash
- Conditioner
- Cream
- Deo/ Anti-perspirant
- Eye creams/gels
- Eye shadow
- Face lotion
- Face wipes
- Facial cream
- Feminine hygiene
- Foundation
- Hand soap (non anti-bac)
- Lipstick/gloss
- Lotion
- Make up remover
- Mascara
- Oil in Water
- Oral care (as preservative, not the active)
- Powder
- Shampoo
- Suncare
- Toner
- Water in Oil

Efficacy

MICs were conducted on Lonzagard® Benzethonium Chloride USP for both bactericidal and bacteriostatic activity with results following.

MICs

Organism	MIC (ppm)
<i>Streptococcus pyogenes</i> C-203	20
<i>Streptococcus viridans</i>	3
<i>Escherichia coli</i>	63
<i>Salmonella gallinarum</i>	31
<i>Salmonella choleraesuis</i>	31
<i>Salmonella typhimurium</i>	5
<i>Salmonella schottmulleri</i>	31
<i>Pseudomonas aeruginosa</i> PRD-10	125
<i>Lactobacillus casei</i>	10
<i>Shigella sonnei</i>	31
<i>Klebsiella pneumoniae</i>	5
<i>Saccharomyces cerevisiae</i>	10
<i>Pityrosporum ovale</i>	1
<i>Trichophyton mentagrophytes</i>	25
<i>Monilia albicans</i>	1
<i>Aspergillus niger</i>	1250
<i>Aspergillus oryzae</i>	0.625
<i>Penicillium notatum</i>	1
<i>Penicillium luteum</i>	1

Microbiological Challenge Studies

A study was run on a formula using a 0.5% concentration of Lonzagard® Benzethonium Chloride USP. The protocol used was a PCPC challenge test. All samples were inoculated at the beginning of the study, sampled at 24 hours, 7, 14, 21 and 28 days. The samples were diluted in neutralizer and plated quantitatively for viable organisms at all sampling times. After 28 days, all samples were re-inoculated and subjected to a second challenge.

Lotion

pH: 5–5.5

Phase (A)	%	Phase (B)	%
Water	qs	Hydroxyethylcellulose	1.5
Urea	5.00	—	—
Sorbitan Monostearate	2.00	—	—
Caprylic/ Capric Triglyceride	20.00	—	—
PEG 1750 Monostearate	1.50	—	—
Glyceryl Monostearate	2.00	—	—
Decaglycerol Decaoleate	5.00	—	—

Test Organism	Unpreserved Control			Test – Lonzagard® Benzethonium Chloride USP (0.5%)				
	Initial Challenge		Re challenge	Initial Challenge		Re challenge		
	24 Hrs	1 Week	28 Days	28 Days	24 Hrs	1 Week	28 Days	28 Days
<i>S. aureus</i>	2.0 x 10 ⁶	1.4 x 10 ⁶	1.0 x 10 ²	8.3 x 10 ²	<10	<10	<10	<10
<i>K. pneumoniae</i> + <i>E. gergoviae</i>	1.1 x 10 ⁵	3.0 x 10 ⁴	<10	<10	<10	<10	<10	<10
<i>P. aeruginosa</i> + <i>B. cepacia</i>	1.0 x 10 ⁵	1.5 x 10 ³	<10	3.0 x 10 ⁵	<10	<10	<10	<10
<i>C. albicans</i>	6.9 x 10 ⁴	3.0 x 10 ¹	<10	<10	<10	<10	<10	<10
Mixed Molds	5.8 x 10 ⁴	3.2 x 10 ⁴	1.5 x 10 ⁴	2.5 x 10 ⁴	1.0 x 10 ²	1.0 x 10 ¹	<10	1.0 x 10 ¹

Global Regulatory

Europe

- Benzethonium chloride is approved, Annex V to Regulation EC/1223/2009
- Max concentration of 0.1 %; not permitted for oral care

Japan

- Japan = 0.5 % for rinse-off; 0.2 % for leave-on
- Not permitted for contact with mucous membranes (eye, oral care, vaginal, etc.)

US

- U.S. (CIR opinion)
 - 0.5 % for skin applications
 - 0.02 % for eye area

Formulation Recommendations

- Soluble in water, lower alcohols and glycols
- Compatible with a wide variety of formulations as well as most types of cationic and non-ionic systems
- It can be used effectively over a particularly wide pH range
- Can be added at both room and elevated temperatures in any phase of production

Typical Properties

Appearance	Free-flowing powder
Color	White
Odor	Odorless

USA

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