

## Product Information

# Lonzagard<sup>®</sup>

Benzethonium Chloride USP for Personal Care Applications.

### NEW PRESERVATIVE FOR LEAVE-ON PRODUCTS IN EUROPE

Quaternary ammonium-based antimicrobial compound.

Offer a high efficacy, mildness and safety.

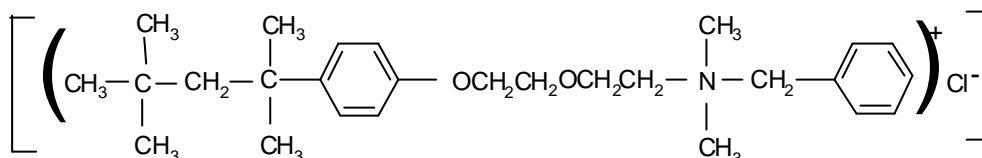
Widely acceptable worldwide as a fast-acting preservative and as an active antimicrobial ingredient.

Quality standard meets with USP and EP 97.

#### 1. Active matter

Diisobutylphenoxyethoxyethyl-dimethylbenzyl ammonium chloride

INCI-name: Benzethonium chloride



|     |             |           |
|-----|-------------|-----------|
| 1.1 | CAS No.:    | 121-54-0  |
| 1.2 | EINECS No.: | 204-479-9 |
| 1.3 | UN No.:     | 1759      |

#### 2. Specifications

|      |  |                |
|------|--|----------------|
| 2.1  | Assay                                      | 97.0 - 103.0 % |
| 2.2  | Loss on drying (DR-43)                     | 5.0 % max.     |
| 2.3  | Melting point, initial                     | 158.0 °C min.  |
| 2.4  | Melting point, final                       | 163.0 °C max.  |
| 2.5  | Residue on ignition                        | 0.1 % max.     |
| 2.6  | Chlorine, anhydrous basis                  | 7.70 - 8.00 %  |
| 2.7  | Clarity, 10% solids in water, transmission | 85.0 % min.    |
| 2.8  | Colour (APHA, 10% aqu. sol.)               | 40.0 max.      |
| 2.9  | Amine HCl                                  | 0.2 % max.     |
| 2.10 | Screen test, retained on 20 mesh           | 2.0 % max.     |
| 2.11 | Water content at time of manufacture       | 0.5 % max.     |
| 2.12 | pH, 1 % solids in water                    | 5.0 - 6.5      |

#### 3. Properties

|     |                          |  |
|-----|--------------------------|--|
| 3.1 | Appearance               | white to off-white powder  |
| 3.2 | Odour                    | odourless  |
| 3.3 | Bulk density             | 0.44 g/ml  |
| 3.4 | Average Molecular weight | 448.09   |
| 3.5 | Ionogenicity             | cationic   |
| 3.6 | Solubility               | freely soluble in water, lower alcohols, ketones and glycols   |
| 3.7 | Compatibility            | compatible with nonionic surface active agents and most polar solvents<br>Incompatible with soap or anionic surface active agents. |

## 4. Registrations

- 4.1 Europe As an active : notified by LONZA under the Biocidal product directive ; Product type 1  
As a preservative in personal care:

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Listed as a preservative for cosmetics on the EEC positive list.  
Benzethonium chloride is included as reference number 53 in Part 1 of Annex VI to Directive 76/768/EEC as a preservative which may be employed in rinse-off and leave-on cosmetic products up to a concentration of 0,1 %.

- 4.2 USA Benzethonium chloride is currently acceptable under 11 FDA monographs or tentative final monographs(TFM) as an active ingredient:  
59 FR 31402 TFM for Health Care Antiseptic Drug Products  
59 FR 6084 TFM for Oral antiseptic Drug Products  
59 FR 5226 Vaginal Drug Products for OTC Human use  
59 FR 54458 Skin Protectant Drug Product for OTC Human Use  
59 FR 49890 Topical Antifungal Drug Products for OTC Human Use  
59 FR 63554 Dandruff and Psoriasis Drug Product for OTC Human Use  
59 FR 33644 TFM for First Aid Antiseptic Drug Products  
55 FR 25204 Skin protectant- Diaper Rash Products  
55 FR 25240 Topical Antifungal –Diaper Rash Products  
55 FR 25246 Topical Antifungal –Diaper Rash Products  
50 FR 2190 Hair Grower and Hair Loss Prevention Drug Products for OTC

As a preservative for Personal care:

Approved by key North American regulatory authorities including the Cosmetic, Toiletry and Fragrance Association in the United States and the Canadian Cosmetic, Toiletry and Fragrance Association.

Approved for both rinse-off and leave-on applications at 0.5% max.  
0.02% allowed in eye area.

- 4.3 Brazil As a preservative for Personal care:  
Approved at 0.1 % max. for rinse-off products

- 4.4 Japan As a preservative for Personal care:  
Approved for use in personal care and cosmetic products under the Japanese Ministry of Health and Welfare for both rinse-off (0.5% max. ) and leave-on products (0.2% max.).

## 5. Antimicrobial efficacy

Benzethonium chloride, the active in Lonzagard, disrupts the membrane by solubilizing the lipids.

### 5.1 BACTERIA

The bactericidal activity of Lonzagard has been demonstrated in presence of gram negative and gram positive strains.

Time-kill results (log kill for 60 seconds contact time) are available upon request.

### 5.2 FUNGI & YEAST

The fungicidal activity of Lonzagard has been demonstrated in presence of:  
Saccharomyces cerevisiae

Pityrosporum ovale  
Trichophyton mentagrophytes  
Monilia albicans  
Aspergillus niger

**6. Use areas**

Lonzagard can be used as an active in Personal Care Hand Soaps, wipes, Non-alcohol hand sanitizers and other antibacterial personal care products.  
Lonzagard can be used as a preservative in rinse off and leave-on products and particularly in cationic and non-ionic systems.

**7. Recommendations to formulate**

Check the compatibility with anionic systems since Lonzagard is a cationic biocide.  
Lonzagard is soluble in water, lower alcohols and glycols. It can be used effectively over a wide pH range and can be added at both room and elevated temperatures at any step of the production.

**8. Analytical procedures**

Available upon request.

**9. Storage**

Product is supplied in fiber drums holding 50 kg net.  
It can be stored in the sealed original drum over a period of minimum three years.

**10. Regulatory information**

refer to MSDS

**11. Toxicological information**

refer to MSDS

**12. Ecological and ecotoxicological information**

refer to MSDS

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