

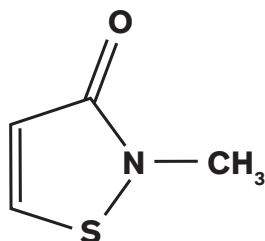
## General

A Sustainable, Broad Spectrum Bactericide for the Preservation of Rinse-Off Haircare and Rinse-Off Skin-Care Products.

LANXESS's unique knowledge of isothiazolinone chemistry and the personal care industry has resulted in the development of Neolone® 950 Preservative. This broad spectrum bactericide is a sustainable solution for a range of personal care rinse-off formulations.

The active ingredient of Neolone® 950 Preservative is an isothiazolinone identified by the INCI name Methylisothiazolinone.

## Structure



Methylisothiazolinone C<sub>4</sub>H<sub>5</sub>NOS  
CAS No.: 2682-20-4

## Formulation/stability

Neolone® 950 Preservative is a precise formulation of 9.5% active ingredient in water. Every batch of Neolone® 950 Preservative is manufactured to exact specifications, and a certificate of analysis can be provided with each order. This stable formulation has a three-year product shelf life.

## Physical properties

The following are typical properties of Neolone® 950 preservative; **they are not to be considered product specifications.**

|                  |  |
|------------------|--|
| Appearance       | Clear liquid   |
| Color            | APHA < 100   |
| pH               | 3–6  |
| Specific gravity | 1.02   |
| Solubility       | Totally miscible in water, lower alcohols and glycols, low solubility in hydrocarbons. |

## Applications

- Shampoos, including zinc pyrithione-containing shampoos
- Conditioners
- Body wash/shower gels
- Liquid hand soaps
- Cosmetic ingredients such as surfactants, rheology modifiers, silicone emulsions, opacifiers, etc.

## We supply more than a preservative

In the current regulatory climate, where more and more data are required by regulatory authorities, it is important not only to choose a high purity and consistent quality preservative, but also the right supplier who is able to give you the technical, regulatory and commercial support that you need. LANXESS has more than 30 years of experience with isothiazolinone chemistry and over 100 patents. To support the use of our products, we maintain the following information on Neolone® 950 Preservative:

- Complete regulatory dossiers
- Extensive toxicological databases

- Environmental fate database that is continually updated
- Safe handling expertise that can help you in your manufacturing facilities
- Technical expertise with isothiazolinone chemistry
- Public relations/media expertise and support

### Features and benefits

- Global Approvals for use as a preservative in rinse-off personal care products\*
- Broad spectrum bactericide
- Effective and compatible with a variety of bactericides, fungicides and boosters
- Easy to dose and highly water soluble
- Effective at low use levels
- Excellent stability in use over a wide range of pH (2 to 12) and temperatures
- Compatible with a wide range of personal care products and ingredients
- Safe to use at recommended use levels
- Excellent environmental profile: rapidly degrades, does not bioaccumulate and is nonpersistent in the environment
- Does not release formaldehyde

### Current regulatory status

Neolone® 950 Preservative for Global Formulations Extensive databases and global expertise provided LANXESS with a solid foundation for obtaining registration and global approval for Neolone® 950 Preservative.

### Recommended use rates

The recommended use level for Neolone® 950 Preservative is 0.05%–0.1% (48–95 ppm of active ingredient) of Neolone® 950 Preservative as supplied.

Neolone® 950 Preservative should be added as the last ingredient and at the lowest temperature ( $\leq 45^{\circ}\text{C}$ ) possible. Neolone® 950 Preservative may tolerate exposure to higher temperatures ( $70^{\circ}\text{C}$ ), however the stability of the active ingredients should be confirmed. Since the process conditions and components of personal care formulations vary considerably and may have impact on the efficacy of preservatives, we urge each manufacturer to verify the efficacy and stability of Neolone® 950 Preservative in use.

### Microbiological properties/activity

Neolone® 950 Preservative exhibits outstanding anti-microbial activity, inhibiting a wide variety of Gram-positive and Gram-negative bacteria. The following table gives the minimum inhibitory concentration (MIC) in ppm active ingredient methylisothiazolinone, which inhibited the growth of various microorganisms in broth tests. The figure below shows comparative MIC ranges against bacteria for methylisothiazolinone and other personal care preservatives.

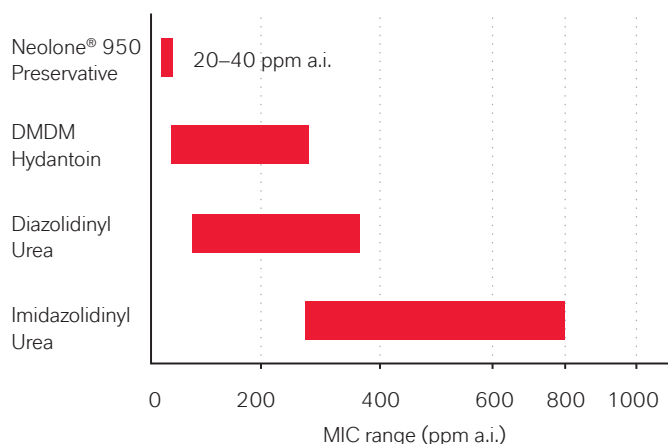
**Table 1: Minimum inhibitory concentrations (MIC) of Neolone® 950 Preservative**

| Organism                      | ATCC No.    | MIC<br>(ppm active ingredient) |
|-------------------------------|-------------|--------------------------------|
| <b>Bacteria</b>               |             |                                |
| <i>Enterobacter aerogenes</i> | 15038       | 30                             |
| <i>Pseudomonas aeruginosa</i> | 15442       | 40                             |
| <i>Burkholderia cepacia</i>   | 17765       | 20                             |
| <i>Pseudomonas oleovorans</i> | 8062        | 30                             |
| <i>Pseudomonas putida</i>     | 795         | 20                             |
| <i>Staphylococcus aureus</i>  | 6538        | 40                             |
| <i>Serratia marcescens</i>    | Lab isolate | 30                             |

\* Minimal inhibitory concentrations test parameters: nutrient broth, 30°C/pH 7, 24 hour contact

\*Customers should verify the appropriate legislation by jurisdiction.

**Figure 1: Minimum inhibitory concentration (MIC) ranges of Neolone® 950 Preservative compared to other preservatives**



The data demonstrate that Neolone® 950 Preservative inhibits a wide variety of bacteria at low active ingredient levels. Overall, the MIC values for Neolone® 950 Preservative are lower compared to other bacterial preservatives. MIC values are an indicator of intrinsic antimicrobial activity and should not be taken as recommended use concentrations in personal care products.

#### Neolone® 950 preservative performance in rinse-off applications

Neolone® 950 Preservative microbiological performance was assessed with LANXESS's 3-cycle challenge test which uses separate pools of bacteria and fungi. LANXESS's method is a modification of the Personal Care Product Council (PCPC) preservative efficacy test.

**Table 2 - Bacteria**

| Product                       | Neolone® 950 Preservative (% Product) | Bacteria – Estimated CFU/g after day: |           |           |
|-------------------------------|---------------------------------------|---------------------------------------|-----------|-----------|
|                               |                                       | 7                                     | 14        | 21        |
| Shampoo, pH 6.1               | 0 (Unpreserved)                       | $>10^6$                               | $>10^7$   | $>10^6$   |
|                               | 0.05                                  | $<10$                                 | $<10$     | $<10$     |
|                               | 0.10                                  | $<10$                                 | $<10$     | $<10$     |
| Body Wash, pH 6.8             | 0 (Unpreserved)                       | 10                                    | $>10^3$   | $>10^3$   |
|                               | 0.05                                  | $<10$                                 | 30        | 20        |
|                               | 0.10                                  | $<10$                                 | $<10$     | 10        |
|                               |                                       | <b>7</b>                              | <b>14</b> | <b>21</b> |
| Hair Conditioner              | 0 (Unpreserved)                       | $>10^3$                               | $>10^3$   | $>10^3$   |
|                               | 0.05                                  | $<10$                                 | $<10$     | $<10$     |
|                               | 0.08                                  | $<10$                                 | $<10$     | $<10$     |
| Sodium Lauryl Sulfate, pH 8.9 | 0 (Unpreserved)                       | $>10^7$                               | $>10^7$   | $>10^7$   |
|                               | 0.05                                  | $<10$                                 | $<10$     | $<10$     |
|                               | 0.10                                  | $<10$                                 | $<10$     | $<10$     |

### Chemical stability

Neolone® 950 Preservative shows excellent stability in personal care formulations and with cosmetic raw materials. Neolone® 950 Preservative is stable over a wide range of pH and temperature conditions and is compatible with a variety of surfactants and proteins. The data on the right demonstrates these formulation advantages.

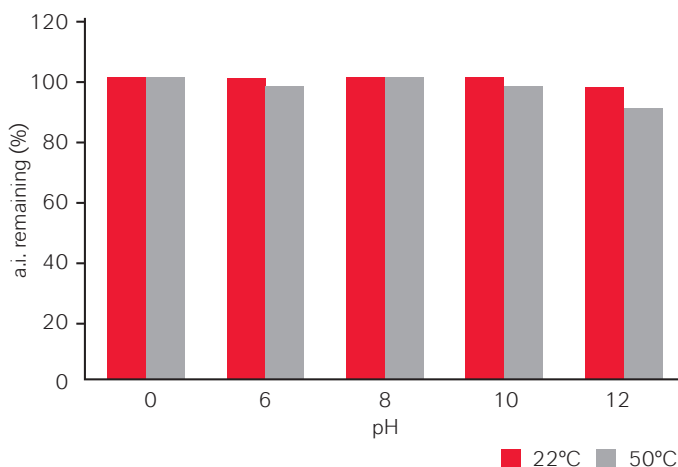
**Table 3: Neolone® 950 Preservative Stability in Surfactants**

| Matrix                          | % Active Ingredient Remaining at 4 Weeks |                  |      |
|---------------------------------|--|------------------|------|
|                                 | 25°C                                     | 42°C             | 50°C |
| Sodium Lauryl Ether Sulfate     | 100                                      | 100              | 100  |
| Sodium Lauryl Sulfate           | 100                                      | 100              | 100  |
| Cocamidopropyl Betaine          | 100                                      | 85               | 66   |
| Sodium C14-16 Olefin Sulfonate  | 100                                      | 93               | 79   |
| Ammonium Lauryl Sulfate         | 100                                      | 98               | 100  |
| Sodium Dodecylbenzene Sulfonate | 100                                      | 100              | N/A  |
| Sodium Lauroyl Sarcosinate      | 84                                       | 52 weeks at 25°C |      |

**Table 4: Neolone® 950 Preservative Stability in Proteins**

| Matrix                       | % Active Ingredient Remaining at 12 Weeks |  |
|------------------------------|---|--|
|                              | 35°C                                      |  |
| 2% Keratin                   | 86  |  |
| 1% Collagen                  | 91  |  |
| 8% Elastin                   | 94  |  |
| 2% Hydrolyzed Animal Protein | 93  |  |

**Figure 2: Effect of pH and Temperature in Buffered Water Methylisothiazolinone Stability After 3 Weeks**



### Analytical procedures

High Performance Liquid Chromatography (HPLC) HPLC analysis is the preferred method for determining use levels of methylisothiazolinone, the active ingredient in Neolone® 950 Preservative. This method can be used to determine Neolone® 950 Preservative active ingredient levels in many personal care products. If you require detailed information on HPLC methods, please contact your local LANXESS representative.

### Handling, Storage & Disposal

Store products in tightly closed original containers at temperatures recommended on the product label.

Dispose in accordance with all local, state (provincial) and federal regulations. Empty containers may contain hazardous residues. This material and its container must be disposed in a safe and legal manner.

It is the user's responsibility to verify that treatment and disposal procedures comply with local, state (provincial) and federal regulations. Contact your LANXESS representative for more information.

### Health and Safety Information:

Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling the LANXESS products mentioned in this publication. For materials mentioned which are not LANXESS products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be followed. Before working with any of these products, you must read and become familiar with the available information on their hazards, proper use and handling. This cannot be overemphasized. Information is available in several forms, e.g., material safety data sheets, product information and product labels. Consult your LANXESS representative in Germany or contact the Regulatory Affairs and Product Safety Department of LANXESS Deutschland GmbH, or, for business in the USA, the LANXESS Corporation Product Safety and Regulatory Affairs Department in Pittsburgh, PA, USA.

### Regulatory Compliance Information:

Some of the end uses of the products described in this publication must comply with applicable regulations, such as the FDA, BfR, NSF, USDA, and CPSC. If you have any questions on the regulatory status of these products, for business in the USA, contact the LANXESS Corporation Regulatory Affairs and Product Safety Department in Pittsburgh, PA, USA or for business outside US the Regulatory Affairs and Product Safety Department of LANXESS Deutschland GmbH in Germany.

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