

# Bronopol

**B**

## 1 Nonproprietary Names

BP: Bronopol

## 2 Synonyms

2-Bromo-2-nitro-1,3-propanediol;  $\beta$ -bromo- $\beta$ -nitrotrimethylene-glycol; *Myacide*.

## 3 Chemical Name and CAS Registry Number

2-Bromo-2-nitropropane-1,3-diol [52-51-7]

## 4 Empirical Formula and Molecular Weight

$C_3H_6BrNO_4$  200.00

## 5 Structural Formula



## 6 Functional Category

Antimicrobial preservative.

## 7 Applications in Pharmaceutical Formulation or Technology

Bronopol 0.01–0.1% w/v is used as an antimicrobial preservative either alone or in combination with other preservatives in topical pharmaceutical formulations, cosmetics, and toiletries; the usual concentration is 0.02% w/v.

## 8 Description

Bronopol is a white or almost white crystalline powder; odorless or with a faint characteristic odor.

## 9 Pharmacopeial Specifications

See Table I.

**Table I:** Pharmacopeial specifications for bronopol.

Test	BP 2017
Identification	+
Characters	+
Acidity or alkalinity (1% w/v solution)	5.0–7.0
Related substances	+
Sulfated ash	$\leq 0.1\%$
Water	$\leq 0.5\%$
Assay (anhydrous basis)	99.0–101.0%

## 10 Typical Properties

**Antimicrobial activity** Bronopol is active against both Gram-positive and Gram-negative bacteria including *Pseudomonas aeruginosa*, with typical minimum inhibitory concentrations (MICs) between 10–50  $\mu\text{g/mL}$ ;<sup>(1–8)</sup> see also Table II. At room temperature, a 0.08% w/v aqueous solution may reduce the viability of culture collection strains of *Escherichia coli* and *Pseudomonas aeruginosa* by 100-fold or more in 15 minutes. Antimicrobial activity is not markedly influenced by pH in the

range 5.0–8.0, nor by common anionic and nonionic surfactants, lecithin, or proteins.<sup>(2,5,6)</sup> Bronopol is less active against yeasts and molds, with typical MICs of 50–400  $\mu\text{g/mL}$  or more, and has little or no useful activity against bacterial spores. See also Section 12.

**Table II:** Minimum inhibitory concentrations (MICs) of bronopol.<sup>(2,9)</sup>

Microorganism	MIC ( $\mu\text{g/mL}$ )
<i>Aspergillus niger</i>	3200
<i>Bacillus subtilis</i>	12.5
<i>Burkholderia (Pseudomonas) cepacia</i>	25
<i>Candida albicans</i>	1600
<i>Escherichia coli</i>	12.5–50
<i>Klebsiella aerogenes</i>	25
<i>Legionella pneumophila</i>	50
<i>Penicillium roqueforti</i>	400
<i>Penicillium funiculosum</i>	1600
<i>Pityrosporum ovale</i>	125
<i>Proteus mirabilis</i>	25–50
<i>Proteus vulgaris</i>	12.5–50
<i>Pseudomonas aeruginosa</i>	12.5–50
<i>Saccharomyces cerevisiae</i>	3200
<i>Salmonella gallinarum</i>	25
<i>Staphylococcus aureus</i>	12.5–50
<i>Staphylococcus epidermidis</i>	50
<i>Streptococcus faecalis</i>	50
<i>Trichophyton mentagrophytes</i>	200
<i>Trichoderma viride</i>	6400

**Melting point** 128–132°C

**Partition coefficients**

Mineral oil : water = 0.043 at 22–24°C;

Peanut oil : water = 0.11 at 22–24°C.

**Solubility** see Table III.

**Table III:** Solubility of bronopol.

Solvent	Solubility at 20°C
Cottonseed oil	Slightly soluble
Ethanol (95%)	1 in 2
Glycerol	1 in 100
Isopropyl myristate	1 in 200
Mineral oil	Slightly soluble
Propan-2-ol	1 in 4
Propylene glycol	1 in 2
Water	1 in 4

**Spectroscopy**

NIR spectrum see Figure 1.

## 11 Stability and Storage Conditions

Bronopol is stable and its antimicrobial activity is practically unaffected when stored as a solid at room temperature and ambient relative humidity for up to 2 years.<sup>(3)</sup>

The pH of a 1.0% w/v aqueous solution is 5.0–6.0 and falls slowly during storage; solutions are more stable in acid conditions. Half-lives of bronopol in buffered aqueous solutions at 0.03% w/v are shown in Table IV.<sup>(9)</sup>