Imidurea

1 Nonproprietary Names

USP–NF: Imidurea

2 Synonyms

Biopure 100; *Germall 115*; imidazolidinyl urea; methanebis[*N*,*N*′(5-ureido-2,4-diketotetrahydroimidazole)-*N*,*N*-dimethylol]; 1,1′-methylenebis{3-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]urea}; *Tri-Stat IU*.

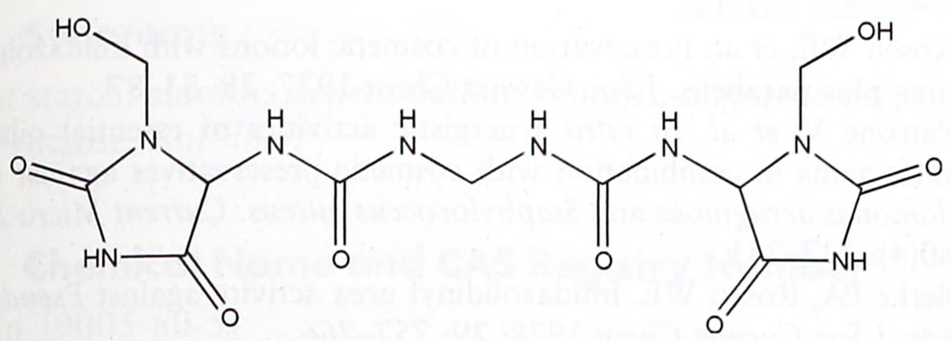
3 Chemical Name and CAS Registry Number

N,*N*″-Methylenebis{*N*′-[3-(hydroxymethyl)-2,5-dioxo-4-imidazolidinyl]urea} [39236-46-9] and [82852–50–4]

4 Empirical Formula and Molecular Weight

$C_{11}H_{16}N_8O_8$ 388.29 (for anhydrous)
$C_{11}H_{16}N_8O_8.H_2O$ 406.33 (for monohydrate)

5 Structural Formula



6 Functional Category

Antimicrobial preservative.

7 Applications in Pharmaceutical Formulation or Technology

Imidurea is a broad-spectrum antimicrobial preservative used in cosmetics and topical pharmaceutical formulations; typical concentrations used are 0.03–0.5% w/w. It is effective at pH 3–9 and is reported to have synergistic effects when used with parabens; *see* Section 10.

8 Description

Imidurea occurs as a white, free-flowing, odorless powder.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for imidurea.

Test	USP 40–NF 35 S1
Identification	+
Color and clarity of solution	+
pH (1% w/v solution)	6.0–7.5
Loss on drying	≤3.0%
Residue on ignition	≤3.0%
Heavy metals	≤0.001%
Nitrogen content (dried basis)	26.0–28.0%

10 Typical Properties

Acidity/alkalinity pH = 6.0–7.5 (1% w/v aqueous solution)

Antimicrobial activity Predominantly an antibacterial preservative, imidurea also has some selective antifungal properties. Used at concentrations between 0.03–0.5% w/w it is effective at pH 3–9, although preservative efficacy is best seen in slightly acidic solutions. Synergistic effects have been reported, and preservative activity is considerably enhanced, particularly against fungi, when used in combination with parabens.[1–3] A cosmetic formulation containing 0.5% imidurea, 0.2% methylparaben, and 0.1% propylparaben was effectively preserved against various *Pseudomonas* species.[4] For reported minimum inhibitory concentrations (MICs), *see* Table II.[5]

Table II: Minimum inhibitory concentrations (MICs) for imidurea.

Microorganism	MIC (μg/mL)
Aspergillus niger	8000
Candida albicans	8000
Escherichia coli	2000
Klebsiella pneumoniae	2000
Penicillium notatum	8000
Pseudomonas aeruginosa	2000
Pseudomonas cepacia	2000
Pseudomonas fluorescens	2000
Staphylococcus aureus	1000

Density 1.85 g/cm^3

Melting point 150°C

Solubility Soluble in water and in glycerol, but insoluble in almost all organic solvents.[5] *See also* Table III.

Table III: Solubility of imidurea.

Solvent	Solubility at 20°C
Ethanol	Very slightly soluble
Ethanol (90%)	Very slightly soluble
Ethanol (70%)	1 in 330
Ethanol (60%)	1 in 25
Ethanol (50%)	1 in 2.5
Ethanol (30%)	1 in 0.8
Ethylene glycol[a]	1 in 0.7
Glycerin[a]	1 in 1
Methanol	Very slightly soluble
Mineral oil	Practically insoluble
Propan-2-ol	Practically insoluble
Propylene glycol[a]	1 in 0.8
Sesame oil	Very slightly soluble
Water	1 in 0.5

(a) Slow to dissolve and requires heating and stirring.

Spectroscopy

NIR spectrum *see* Figure 1.

11 Stability and Storage Conditions

Imidurea is hygroscopic and should be stored in a well-closed container in a cool, dry place.