

Specification

1.06290.1000 Sodium benzoate EMPROVE® ESSENTIAL Ph Eur, BP, NF, FCC, E 211

5	Specification	
Assay (acidimetric, calc. on anhydrous substance)	99.0 - 100.5	%
Assay (HPLC, calc. on anhydrous substance)	99.0 - 101.0	%
Identity (IR-spectrum)	passes test	
Identity (HPLC)	passes test	
Identity (wet chemistry)	passes test	
Appearance of solution (100 g/l, water)	clear and not more intense in color than reference solution Y6	
Acidity or alkalinity	passes test	
Chloride (CI)	≤ 200	ppm
Total chlorine	≤ 300	ppm
As (Arsenic)	≤ 3	ppm
Hg (Mercury)	≤ 1	ppm
Pb (Lead)	≤ 2	ppm
Residual solvents (ICH Q3C)	excluded by production process	
Multinuclear acids	passes test	
Oxidizable matter	passes test	
Water (according to Karl Fischer)	≤ 1.5	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*). Corresponds to Ph Eur, BP, NF, FCC, E 211

Dr. Sebastian Lips

Responsible laboratory manager quality control

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