

Certificate of Analysis

Product name: **Natrii benzoas**
Batch number / Weight: **23C22-B06-228843 / 1 KG**
Analysed according to: **Ph.Eur.11.1**
Number of analysis / Inspection Code **23C22-B06 / INS-23-2994**
Reference Code / No.: **V01149 / 2306**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder, granules or flakes	Conform		
Identification A	White / 120 - 124	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / colour $\leq Y_6$	Conform		
Acidity or alkalinity	Conform	0,05ml HCl		
Halogenated compounds	≤ 200 (ionised chlorine)	Conform	ppm	
	≤ 300 (total chlorine)	Conform	ppm	
Loss on drying	$\leq 2,0$	0,23	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Sodium benzoate	99,0 - 100,5 (dried substance)	99,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total aerobic microbial count (TA)	$\leq 10^3$	< 10	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 10	CFU/g	

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Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:
Dominika Soltysik
Qualified Person

17-06-2023

Expiration: 05-02-2026

Conclusion: APPROVED

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl