

Certificate of Analysis

Product name:	Natrii benzoas			
Batch number / Weight:	22K29-B09-225077 / 1 KG			
Analysed according to:	Ph.Eur.11.1			
Number of analysis / Inspectior	1 Code 22K29-B09 / INS-23-2072			
Reference Code / No.:	V01149 / 22436			
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 <=Y6	Conform		
Acidity or alkalinity	Conform	0,05	ml NaOH	
Halogenated compounds	<=200 (ionised chlorine)	Conform	ppm	
	<=300 (total chlorine)	Conform	ppm	
Loss on drying	<= 2,0	0,20	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	0/	Data producer
Assay Sodium benzoate TSE/BSE-statement:	99,0 - 100,5 (dried substance) No contamination with TSE/BSE-risk materials	99,98 Conform	%m/m	Data producer
		Conform <10	CELI/a	Data producer
Total aerobic microbial count (TA Total yeasts and moulds (TYMC)		<10 <10	CFU/g CFU/g	
Total yeasts and mounds (TTNIC)	X-10 ⁻²	<10	CF0/g	

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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 Sołtysik Qualified Person

14-04-2023

Expiration: 23-10-2025

Conclusion: APPROVED

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