

Certificate of Analysis

Product name:	Natrii benzoas			
Batch number / Weight:	22K29-B09-221931 / 250 G			
Analysed according to:	Ph.Eur.11.0			
Number of analysis / Inspec	tion 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	Conform	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		Data producer
Assay Sodium benzoate	99,0 - 100,5 (dried substance)	99,98	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

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

Release: Dominika Sołtysik Qualified Person

31-03-2023

Expiration: 23-10-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

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