

Certificate of Analysis

Product name: Natrii benzoas

Batch number / Weight: 21J13-B06-223913 / 250 G

Analysed according to: Ph. Eur. 10.8

Number of analysis / Inspection Code 21J13-B06 / INS-21-5747

Reference Code / No.: V01149 / 2133

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder, granules or flakes	Conform		
Identification A	White / 120 - 124	Conform	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / colour <=Y6	Conform		
Acidity or alkalinity	Conform	0,01 ml HCl		
Halogenated compounds	<=200 (ionised chlorine)	Conform	ppm	
	<=300 (total chlorine)	Conform	ppm	
Loss on drying	<= 2,0	0,11	%	
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)	100,05	%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

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: Ewelina Gadzinowska Qualified Person

26-10-2022

Expiration: 15-08-2024

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