

Certificate of Analysis

Product name: **Acidum flufenamicum**

Batch number / Weight: **22A14-B06-222253 / 25 G**

Analysed according to: **Monograph/EP (for Res.Solv.)**

Number of analysis / Inspection Code **22A14-B06 / INS-22-3600**

Reference Code / No.: **V01520 / FA2109007**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Absorbance ratio	0,55 - 0,59	0,58		
Absorbance	0,28 - 0,31	0,30		
Copper	<=20	<20	ppm	
Related substances	<=0,2	Conform	%	
Loss on drying	<=0,5	0,01	%	
Sulphated ash	<=0,1	<0,01	%	
3-Aminobenzotrifluoride	<=100	<100	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Toluen	<= 880	141	ppm	
N,N-Dimethylformamide	<= 890	<15	ppm	
Assay Flufenamic acid	99,0 - 101,0	100,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

fagron.pl Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 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 EL Spol

Release:

Ewelina Gadzinowska

Qualified Person

05-09-2022

Expiration: 01-09-2024

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