

## Certificate of Analysis

**Product name:** **Propylthiouracilum**

**Batch number / Weight:** **22G05-B02-225211 / 25 G**

**Analysed according to:** **Ph.Eur.10.8**

**Number of analysis / Inspection Code** **22G05-B02 / INS-22-6082**

**Reference Code / No.:** **V01085 / 10059/2205B529**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	217 - 221	219,1	°C	
Identification B	Conform	Conform		
Thiourea and related substances	Conform	Conform		
Loss on drying	<=0,5	0,15	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Propylthiouracil	98,0 - 100,5	99,68	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	

fagron.pl

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

Release:

Agnieszka Pszczółka

Qualified Person

28-11-2022

Expiration: 31-05-2027

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