



Certificate of Analysis

Productname: Ichthammolum

Inspection No: J01273/0322/536
Batchnumber: 21K19-T07-094641
Expiration date: 30.04.2027
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.5.2021

Sample Unit: 1 x 10 g
Batch Size: 89 x 50 g

Identification of producer: V00662
Batch no. of vendor: 0080521415Ö5/21

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Dense,blackish-brown liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		Precipitate	Fagron CZ
Identification B	Conform	Conform		Ammonium salts	Fagron CZ
Identification C	Conform	Conform		Sulfate	Fagron CZ
TESTS					
Acidity or alkalinity	Conform	Conform			Fagron CZ
Relative density	1,040 - 1,085	1,056		50% V/V	Fagron CZ
Sulfated ash	<=0,3	0,01	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
ASSAY					
dry matter	50,0 - 56,0	52,4	%	105°C	Fagron CZ
total ammonia	4,5 - 7,0	5,5	%	Dried	Fagron CZ
organically combined sulfur	>=10,5	15,1	%	Dried	Fagron CZ
sulfur in the form of sulfate	<=20,0	14,6	%		Fagron CZ

Quality: API

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521

Performed by: Ing. Petra Drábková

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 14.03.2022

Conclusion: **APPROVED**

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