



Certificate of Analysis

Productname: Sorbitani sesquioleas

Inspection No: J01523/0322/536

Batchnumber: 22A21-T08-093441

Expiration date: 30.10.2023

Analysed according to: ČL 2017-Dopl.2018, Ph.Eur. 10.0

Original Manuf. Date: 30.10.2021

Sample Unit: 1 x 5 ml

Batch Size: 481 x 100 ml

Identification of producer: V01582

Batch no. of vendor: 0001925183

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Pale yellow or slightly brownish-yellow paste, which becomes a viscous, oily, brownish-yellow liquid at about 25 °C.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,99	Conform			Fagron CZ
IDENTIFICATION					
Identification A	180 - 215	189		Hydroxyl value	Fagron CZ
Identification B	70 - 95	77		Iodine value	Fagron CZ
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Acid value	<=16,0	8,3			Fagron CZ
Hydroxyl value	180 - 215	189			Fagron CZ
Iodine value	70 - 95	77			Fagron CZ
Peroxide value	<=10,0	1,19			Fagron CZ
Saponification value	145 - 166	150			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	<=5,0	<5,0	%		Contract Lab
Palmitic acid	<=16,0	4,8	%		Contract Lab
Palmitoleic acid	<=8,0	1,0	%		Contract Lab
Stearic acid	<=6,0	1,5	%		Contract Lab
Oleic acid	65,0 - 88,0	77,8	%	GC	Contract Lab
Linoleic acid	<=18,0	10,7	%		Contract Lab
Linolenic acid	<=4,0	0,5	%		Contract Lab
Fatty acids of chain length >C18	<=4,0	0,4	%		Contract Lab
Water (Karl Fisher)	<=1,5	0,22	%		Fagron CZ
Total ash	<=0,5	0,2	%		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	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Quality: Excipient

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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