

## Certificate of Analysis

**Productname:** Sorbitani sesquioleas

**Inspection No:** 109575/1221/536  
**Batchnumber:** 21J29-T01-089576  
**Expiration date:** 01.06.2023  
**Analysed according to:** ČL 2017-Dopl.2018,Ph.Eur.10.0  
**Original Manuf. Date:** 31.5.2021

**Sample Unit:** 1 x 5 ml  
**Batch Size:** 3 x 1 l

**Identification of producer:** V01582  
**Batch no. of vendor:** 0001867706

	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	201		Hydroxyl value	Fagron CZ
Identification B	70 - 95	78		Iodine value	Fagron CZ
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Acid value	<=16,0	7,62			Fagron CZ
Hydroxyl value	180 - 215	201			Fagron CZ
Iodine value	70 - 95	78			Fagron CZ
Peroxide value	<=10,0	1,92			Fagron CZ
Saponification value	145 - 166	152			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	<=5,0	<0,1	%		Contract Lab
Palmitic acid	<=16,0	5,9	%		Contract Lab
Palmitoleic acid	<=8,0	1,0	%		Contract Lab
Stearic acid	<=6,0	1,5	%		Contract Lab
Oleic acid	65,0 - 88,0	75,2	%	GC	Contract Lab
Linoleic acid	<=18,0	14,1	%		Contract Lab
Linolenic acid	<=4,0	0,6	%		Contract Lab
Fatty acids of chain length >C18	<=4,0	1,0	%		Contract Lab
Water (Karl Fisher)	<=1,5	0,2	%		Fagron CZ
Total ash	<=0,5	0,1	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 228 521

**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QA  
**Date:** 07.12.2021  
**Conclusion:** **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.

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