



## Certificate of Analysis

**Productname:** Methylis salicylas

**Inspection No:** K04014/0823/536

**Batchnumber:** 22L05-T07-104767

**Expiration date:** 13.01.2027

**Analysed according to:** Ph.Eur.11.0

**Original Manuf. Date:** 13.1.2022

**Sample Unit:** 1 x 2 ml

**Batch Size:** 25 x 100 ml

**Identification of producer:** V01558

**Batch no. of vendor:** RMS2201311

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or light yellow liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear, <=Y7	Conform		2 ml/10 ml alcohol	Fagron CZ
Acidity	<=0,4	0,0	ml	0,1M NaOH	Fagron CZ
Relative density	1,182 - 1,188	1,185			Fagron CZ
Refractive index	1,535 - 1,538	1,536			Fagron CZ
Related substances	Conform	Conform		GC	Fagron PL
Impurity B	<=50	36,4	ppm		Fagron PL
Unspecified impurities	<= 0,10	<0,05	%		Fagron PL
Total impurities	<=0,5	0,004	%		Fagron PL
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
ASSAY					
Methyl salicylate	99,0 - 101,0	100,4	%		Fagron CZ

Quality: API

**Performed by:** Pavla Šlězarová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QP

**Date:** 13.09.2023

**Conclusion:** **APPROVED**

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