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CERTIFICATE OF ANALYSIS

PRODUCT NAME: Glycerine (Vegetable Glycerine)

Einecs: 200-289-5 CAS: 56-81-5
Taken from: 07F18C
Batch dated: 23-01-2023
Batch number: 2023041016F18C
Production date: 23-1-2023
Remarks: 0

Analysis	Unit	min	max	Result	Method of analysis
Appearance			Colourless	Colourless	European Pharmacopoeia
Appearance of solution			Clear	pass	European Pharmacopoeia
Smell			Absent	absent	European Pharmacopoeia
Esters	ml 0.1 m HCl-solution	8.0		9.12	European Pharmacopoeia
Color (APHA)	Hazen		10	8	ISO 6271
Water	% (m/m)		0.5	0.0365	European Pharmacopoeia
Refractive index @ 20°C		1.471	1.474	1.474	European Pharmacopoeia
Density @ 20°C	g/cm ³	1.260		1.261	European Pharmacopoeia
Acidity	ml 0.1 m NaOH-solution		0.2	0.06	European Pharmacopoeia
Aldehydes	mg/kg		10	Passes test	European Pharmacopoeia
Halogenated compounds	mg/kg		30	Passes test	European Pharmacopoeia
Chlorides	mg/kg		10	Passes test	European Pharmacopoeia
Sugars			Negative	Negative	European Pharmacopoeia
Acrolein, Glucose, Ammonium compounds			Negative	Negative	REG(EU) 231/2012 no E422
Assay	% (m/m)	99.5		99.7	European Pharmacopoeia
3-MCPD	mg/kg		0.1	<0.05	GC/MS
Compliance with the items listed below is assured through regular monitoring analyses performed at an external lab.					
Identity A, B, C, D			pass		European Pharmacopoeia
Heavy metals calculated as Pb	mg/kg		max 5		US Pharmacopoeia
Arsenic	mg/kg		max 3		DiN EN 15763
Mercury	mg/kg		max 0.1		SOP M 2567
Cadmium	mg/kg		max 1		DiN EN 15763
Lead	mg/kg		max 2		DiN EN 15763
Nickel	mg/kg		max 20		DiN EN 15763
Sodium	% (m/m)		max 0.1		DiN EN 15510
Potassium	% (m/m)		max 0.1		DiN EN 15510
Sulfates	mg/kg		max 20		US Pharmacopoeia
Sulphated ash	% (m/m)		max 0.01		European Pharmacopoeia
Impurity A (DEG)	% (m/m)		max 0.1		European Pharmacopoeia
Any other impurity retention time less Glyc	% (m/m)		max 0.1		European Pharmacopoeia
Total of all impurities retention time greater Glyc	% (m/m)		max 0.5		European Pharmacopoeia
Butanetriols	% (m/m)		max 0.2		GC/MS
Acrolein			Confirms		RL G(IU) 231/2012 no E-422
Fatty acids and esters	%		max 0.1		Calculated as butyric acid