

LOTE: VE6C210609

Page 1 of 3

oleon
a natural chemistry

Oleon NV c/o Oleon SAS
Rue Les Rives de l'Oise
F-60280 Venette
FRANCE

Certificate of Analysis

Loading date

18/06/2021

Ordernumber Oleon

85736801 900001 30530599 000020

Your reference / Date

BG-2.021/9.199 /

Product Information

Description GLYCERINE 4810
Glycerol

Quantity 3,000 TO

Batch VE6C210609 Sample 2/622178/00 / Production date 07/06/2021 / Expiration date 07/06/2023

Results of analysis	Unit	Results	Min.	Max.	Method
Refractive Index at 20°C		1,474	1,473	1,475	Eur.Ph.
Glycerol Content	%(m/m)	99,81	>= 99,70		APAG-GL-009
Assay	%(m/m)	99,8	99,0	101,0	USP-NF
Assay	%(m/m)	99,8	98,0	101,0	Eur.Ph.
Relative Density @ 20°C/20°C		1,264	1,258	1,268	Eur.Ph.
Colour APHA		2,5	<=	10,0	ISO 2211
Acidity	meq/100g	0,01	<=	0,08	ISO 1615
Acidity / ml 0,1 M NaOH	ml	0,03	<=	0,20	Eur.Ph.
Alkalinity / ml 0,1 M HCl	ml	0,00	<=	0,00	Eur.Ph.
Acidity or Alkalinity (EP)		Conform	-	-	Eur.Ph.
Odour		Conform	-	-	Oleon GLY07
Water	%(m/m)	0,19	<=	0,30	Eur.Ph./USP-NF
Specific gravity at 25°C	g/ml	1,2618	>= 1,2490		USP-NF
Identification A (Refractive index)		Conform	-	-	Eur.Ph.
Identification B (Infrared)		Conform	-	-	Eur.Ph.
Appearance of solution		Conform	-	-	Eur.Ph.
Aldehydes	ppm(m)	< 10	<=	10	Eur.Ph.
Esters / 0,1 M HCl	ml	> 8,0	>= 8,0		Eur.Ph.
Imp. A and related substances (EP)		Conform	-	-	Eur.Ph.
-impurity A (DEG)	%	< 0,1	<=	0,1	Eur.Ph.
-any other impurity eluting before glyc	%	< 0,1	<=	0,1	Eur.Ph.
-total impurities eluting after glyc	%	< 0,5	<=	0,5	Eur.Ph.
Halogenated compounds	ppm(m)	< 30	<=	30	Eur.Ph.
Sugars		Conform	-	-	Eur.Ph.
Chlorides	ppm	< 10	<=	10	Eur.Ph.
Sulphated ash	%	< 0,01	<=	0,01	Eur.Ph.

m. monthly - / q. quarterly - / t. four-monthly - / h. half-yearly - / y. yearly measured value

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Results of analysis	Unit	Results	Min.	Max.	Method
Residual solvents, Methanol	ppm	< 300 h <=		300	Eur.Ph./USP-NF
Identification B		Conform h -		-	USP-NF
Identification C		Conform h -		-	USP-NF
Residue on ignition	%(m/m)	< 0,01 h <=		0,01	USP-NF
Chloride	%(m/m)	< 0,001 h <=		0,001	USP-NF
Sulfate	%(m/m)	< 0,002 h <=		0,002	USP-NF
Limit of Chlorinated compounds	%(m/m)	< 0,003 h <=		0,003	USP-NF
Fatty acids & esters / 0.5 N NaOH	ml	< 1 h <=		1	USP-NF
Limit of DEG and related compounds		Conform h -		-	USP-NF
-any individual impurity (excl. DEG)	%	< 0,1 h <=		0,1	USP-NF
-total impurities including DEG	%	< 1,0 h <=		1,0	USP-NF
-Diethylene glycol	%	< 0,025 h <=		0,025	USP-NF
-Ethylene glycol	%	< 0,025 h <=		0,025	USP-NF

This product complies with the component's monograph as described in the current edition of the European Pharmacopoeia (Ph. Eur.).

This product complies with the component's monograph as described in the current edition of the US Pharmacopoeia (USP-NF).

The product is manufactured from vegetable raw materials.

The product does not contain any ingredients that are derived from GM sources. However relevant thresholds for adventitious or technically unavoidable cross-contamination as laid down in 1829/2003/EC are accepted. Moreover, the above mentioned material has not to be labeled according to Regulation (EC)1830/2003/EC concerning traceability and labeling of food and feed products manufactured from genetically modified organisms.

The product is in compliance with the consensus guideline CPMP/ICH/283/95 last updated February 2011 Q3C(5) concerning the residual solvents edited by EMEA.

The product complies with the microbiological purity criteria of European Pharmacopoeia monographs EP 2.6.12 and EP 2.6.13.

The product is food approved according to EU Regulation 231/2012 and EC Regulation 1333/2008.

The product complies with FDA §182.1320 on the GRAS status (Generally Recognized As Safe).

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Oleon SAS

Stéphanie Le Doare

If you have any questions relating to this certificate of Analysis please revert to your Oleon contact person

This document is system generated and does not require a signature.

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