

Please note that the certificates of analysis are also conveniently available on your BASF online portal.

Fax No

2021-04-21

Certificate No 4568

Page 1 of 4

Inspection Certificate 3.1 according to EN 10204

Fish oil PronovaPure® 46:38 EE EU
 190KG Steel drums
 Purchase Order/Customer Product#
 1100208011
 00000000050510982

Material 50510982
 Order
 Delivery
 Lot 0022354456
 Lot/Qty KG
 Total KG
 Transport

Date of manufacture: 04-02-2020 Retest Date: 03-02-2023 (Date format: DD-MM-YYYY)

Test	Specification	Result	Method
Description			
Appearance	Light yellow liquid	Light yellow liquid	PhEur 1250
Appearance	Slight fish-like odour	Slight fish-like odour	PhEur 1250
Identity			
EPA Identity	Positive	Positive	PhEur 1250/2.4.29 ¹
Eicosapentaenoic acid ethyl ester			
DHA Identity	Positive	Positive	PhEur 1250/2.4.29 ¹
Docosahexaenoic acid ethyl ester			
Assay			
C20:5 n-3, EPA EE	-	47.9 area %	PhEur 1250/2.4.29 ¹
Eicosapentaenoic acid ethyl ester			
C22:6 n-3, DHA EE	-	36.3 area %	PhEur 1250/2.4.29 ¹
Docosahexaenoic acid ethyl ester			
Total omega-3 acid EEs	-	93.0 area %	PhEur 1250/2.4.29 ¹
EPA, DHA, C18:3 n-3, C18:4 n-3, C20:4 n-3, C21:5 n-3, C22:5 n-3			
C20:5 n-3, EPA EE	430 - 495 mg/g	469 mg/g	PhEur 1250/2.4.29 ¹
Eicosapentaenoic acid ethyl ester			
C22:6 n-3, DHA EE	347 - 403 mg/g	358 mg/g	PhEur 1250/2.4.29 ¹
Docosahexaenoic acid ethyl ester			

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.

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PronovaPure® 46:38 EE EU

190KG Steel drums

Purchase Order/Customer Product#

1100208011

00000000050510982

Material 50510982

Order

Delivery

Lot 0022354456

Lot/Qty KG

Total KG

Transport

Test	Specification	Result	Method
EPA and DHA EEs	800 - 880 mg/g	827 mg/g	PhEur 1250/2.4.29 ¹
Total omega-3 acid EEs	Min 90 %(w/w)	91 %(w/w)	PhEur 1250/2.4.29 ¹
EPA, DHA, C18:3 n-3, C18:4 n-3, C20:4 n-3, C21:5 n-3, C22:5 n-3			
C20:5 n-3, EPA FA	-	429 mg/g	PhEur 1250/2.4.29 ¹
Eicosapentaenoic acid as free fatty acid			
C22:6 n-3, DHA FA	-	329 mg/g	PhEur 1250/2.4.29 ¹
Docosahexaenoic acid as free fatty acid			
Related compounds			
Largest unidentified single peak	Max 0.5 area %	0.2 area %	PhEur 1250/2.4.29 ¹
Total unidentified peaks	Max 2.0 area %	0.7 area %	PhEur 1250/2.4.29 ¹
Antioxidant			
Mixed tocopherols	Min 1 mg/g	1 mg/g	611081
Organic impurities			
Acid value	Max 1.0 mg KOH/g	< 0.05 mg KOH/g	PhEur 1250/2.5.1
Peroxide value	Max 2.0 meq/kg	< 0.5 meq/kg	PhEur 1250/2.5.5
Anisidine value	Max 10.0	2.2	PhEur 1250/2.5.36
Total oxidation (Totox)	Max 12	3	611136
Absorbance at 233 nm	Max 0.50 AU	0.27 AU	PhEur 1250/2.2.25
Oligomers	Max 1.0 area %	0.2 area %	PhEur 1250/2.2.30
Cholesterol	Max 3.0 mg/g	0.6 mg/g	PhEur 1250/2.4.32
Periodic analyses			
Periodic analyses tested	-	040220 ddmmyy	-

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1100208011

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Material	50510982
Order	
Delivery	
Lot	0022354456
Lot/Qty	KG
Total	KG
Transport	0000000001033623963

Test	Specification	Result	Method
The following parameters are tested at regular intervals.			
Inorganic impurities			
Hg, Mercury	Max 0.02 mg/kg	< 0.005 mg/kg	USP <233>
Pb, Lead	Max 0.02 mg/kg	< 0.008 mg/kg	USP <233>
Cd, Cadmium	Max 0.01 mg/kg	< 0.002 mg/kg	USP <233>
As, Arsenic	Max 0.1 mg/kg	< 0.017 mg/kg	USP <233>
Organic impurities			
Dioxins (WHO TEQ) Sum PCDDs/PCDFs	Max 1 pg/g	0.32 pg/g	US EPA 1613
Dioxins and dioxin-like PCBs (WHO TEQ) Sum PCDDs/PCDFs, non-ortho and mono-ortho PCBs	Max 2.9 pg/g	0.52 pg/g	US EPA 1613/1668
PCBs IUPAC no: 28, 52, 101, 118, 138, 153, 180	Max 0.015 mg/kg	0.00193 mg/kg	US EPA 1668
PCBs Sum 209 congeners	Max 0.029 mg/kg	0.00216 mg/kg	US EPA 1668
Benzo(a)pyrene	Max 1 ng/g	< 0.5 ng/g	611536
PAHs benzo(a)pyrene, benzo(a)anthracene, benzo(b)fluoranthene and chrysene	Max 5 ng/g	0 ng/g	611536
Brominated flame retardants PBDEs IUPAC no: 28, 47, 49, 99, 100, 153, 154	Max 3 ng/g	0.17 ng/g	US EPA 1614

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Lot

0022354456

Lot/Qty

KG

Total

KG

Transport

Comments:

PronovaPure 46:38 EE EU complies with the European Pharmacopoeia Monograph Omega-3-acid ethyl esters 90 (1250), GOE D Voluntary monograph and EU regulation 1881/2006, as amended for metals, dioxins and PCBs, and polycyclic aromatic hydrocarbons (PAHs).

PronovaPure 46:38 EE EU is intended for use as a dietary ingredient only, and shall not be used as an active pharmaceutical ingredient.

¹ The calculation of EPA and DHA as free fatty acids is part of the in-house method 611128.

Analysis controlled and approved by:
Sead Alijagic - Quality Control Engineer
Date: 28-02-2020 14:16:48

Certificate of Analysis approved by:
Lisa Grennes Lein - Qualified Person
Date: 12-03-2020 10:09:32

Manufacturer : BASF AS
Framnesveien 41
NO-3222 Sandefjord
Norway

Report number: 547

This Certificate of Analysis is prepared and signed electronically in a validated system.

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