Quality Check Material: PUFA

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1. Product identifier

Trade name/designation:

Quality Check Material: PUFA

Other means of identification:
Biodiesel, Fatty Acid Methyl Ester, FAME

CAS No.:
67762-38-3

EC No.:
267-015-4

Additional information:
PUFA : polyunsaturated (≥ 4 double bonds) fatty acid methyl esters

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture:
The product is intended for research, analysis and scientific education.
Quality Check Material

Relevant identified uses:

	Life cycle stage [LCS]
SL:	Service life
	Sector of uses [SU]
SU 24:	Scientific research and development
	Product Categories [PC]
PC 21:	Laboratory chemicals
	Process categories [PROC]
PROC 9:	Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
PROC 15:	Use as laboratory reagent
PROC 19:	Manual activities involving hand contact
	Environmental release categories [ERC]
ERC 2:	Formulation into mixture (mixtures)

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Arbeitsgemeinschaft Qualitätsmanagement Biodiesel e.V. (AGQM)
Am Weidendamm 1A
10117 Berlin
Germany
Telephone: +49 (30) 726 259 80
Telefax: +49 (30) 726 259 85
E-mail: info@agqm-biodiesel.de
Website: www.agqm-biodiesel.de

E-mail (competent person): reach@agqm-biodiesel.de

1.4. Emergency telephone number

Giftnotruf Berlin/ Charité, 24h: +49 (30) 19240

REACH Compliance Office, +49 (30) 726 259 83 (Only available during office hours.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]
The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

Quality Check Material: PUFA

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: none
Supplemental hazard information: none
Precautionary statements: none

Special rules for supplemental label elements for certain mixtures:

No

2.3. Other hazards

Adverse human health effects and symptoms:

May cause minor eye irritation.
Vapors produced by heating the substance, or finely misted materials, may irritate the mucous membranes and cause dizziness, and nausea.

SECTION 3: Composition/information on ingredients

3.1. Substances

Description:

The substance consists mainly of saturated and unsaturated fatty acids methyl ester (chain length C16-C18).
The substance may contain residuals of glycerol and partial glycerides (total < 3.5%) and traces of methanol (< 0.2 %).
To improve the properties the substance may contain additives in small concentrations: Cold flow improvers consisting mainly of oligomers of vinyl acetate and other monomers and oxidation stabilizers containing mainly steric hindered phenols. The single active components do not exceed a concentration of 1000 mg/kg (0.1%) in relation to the whole substance.

Ingredients / Impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 67762-38-3 EC No.: 267-015-4 REACH No.: 01-2119471664-32-XXXX	**Fatty acids, C16-18 and C18-unsatd., Me esters** The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	= 100 weight-%

SECTION 4: First aid measures

4.1. Description of first aid measures

Following inhalation:

In case of accident by inhalation: remove casualty to fresh air and keep at rest. Seek medical attention if symptoms persist.

In case of skin contact:

After contact with skin, wash immediately with plenty of water and soap.
IF ON CLOTHING: Change contaminated, saturated clothing.

After eye contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

Following ingestion:

Do NOT induce vomiting.
Rinse mouth thoroughly with water.
If conscious, give half a litre of water to drink immediately.
Never give anything by mouth to an unconscious person or a person with cramps.

4.2. Most important symptoms and effects, both acute and delayed

May cause minor eye irritation.
Vapors produced by heating the substance, or finely misted materials, may irritate the mucous membranes and cause dizziness, and nausea.

Quality Check Material: PUFA

4.3. Indication of any immediate medical attention and special treatment needed

No special medical actions required.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Carbon dioxide (CO2)
Water mist
alcohol resistant foam
Extinguishing powder

Unsuitable extinguishing media:

Strong water jet (Water stream may splash the burning liquid and spread fire.)
Consider halon use may not be permissible in some countries.

5.2. Special hazards arising from the substance or mixture

In combustion emits toxic fumes of carbon dioxide / carbon monoxide.
Soaked rags or spill absorbents (i.e. oil dry, sacks, sand) can cause spontaneous combustion if stored near combustibles and not handled properly.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.
On danger by contact with substance: Wear protective gloves/protective clothing and eye protection/face protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Remove all sources of ignition.
If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point.
Mark out the contaminated area with signs and prevent access to unauthorised personnel.
Turn leaking containers leakside up to prevent the escape of liquid.

6.1.2. For emergency responders

No data available

6.2. Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas.
Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up:

Take up with oil-absorbing compound.
Recover large spills for salvage or disposal. Wash hard surfaces with safety solvent or detergent to remove remaining oil film.
Greasy nature will result in a slippery surface.

6.4. Reference to other sections

No data available

6.5. Additional information

If appropriate sections 8 and 13 shall be referred to.

Quality Check Material: PUFA

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Note: Fatty Acid Methyl Esters with longer chain length are not classified as dangerous according to the criteria of CLP (Regulation CE 1272/2008). Specific Risk Management Measures are therefore not required. Nevertheless, the exposure of workers during and after normal operations should be minimised by the use of good industrial hygiene practice.
Direct contact with the substance should be avoided.
When using do not eat, drink or smoke.
Used working clothes should not be worn outside the work area.
Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels:

Keep container tightly closed in a cool, well-ventilated place.

Hints on storage assembly:

Do not store together with: Oxidising agent, strong

Storage class (TRGS 510, Germany): 10 – Combustible liquids that cannot be assigned to any of the above storage classes

Further information on storage conditions:

Recommended storage temperature 15 °C - 25 °C
Below normal ambient temperatures, the material may solidify.

7.3. Specific end use(s)

Recommendation:

No sector specific guidance is available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

No data available

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	6.96 mg/m³	① DNEL worker ② Long-term – inhalation, systemic effects
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	23 mg/m³	① DNEL Consumer ② Long-term – inhalation, systemic effects
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	10 mg/kg bw/day	① DNEL worker ② Long-term - dermal, systemic effects
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	5 mg/kg bw/day	① DNEL worker ② Long-term - dermal, systemic effects

Quality Check Material: PUFA

Substance name	DNEL value	① DNEL type ② Exposure route
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	5 mg/kg bw/ day	① DNEL worker ② Long-term - oral, systemic effects

Substance name	PNEC Value	① PNEC type
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	2.504 mg/L	① PNEC aquatic, freshwater
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	0.2504 mg/L	① PNEC aquatic, marine water
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	520 mg/L	① PNEC sewage treatment plant
Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4	25.04 mg/L	① PNEC aquatic, intermittent release

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Wear eye/face protection.

Skin protection:

Hand protection:Wear protective gloves.
Suitable material: NBR (Nitrile rubber), Fluoropolymers
Breakthrough times and swelling properties of the material must be taken into consideration.

Respiratory protection:

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Other protection measures:

Has degreasing effect on the skin.
General health and safety measures: Wash hands and face before breaks and after work and take a shower if necessary.
Wash contaminated clothing before reuse.

8.2.3. Environmental exposure controls

No data available

8.3. Additional information

DNELs & PNECs
DNELs
Population/route | Exposure pattern | Value
Workers.....Inhalation, Long-term systemic effects: 6.96 mg/m³
.....Dermal, Long-term systemic effects: 10 mg/kg bw/day
Consumers...Inhalation, Long-term systemic effects: 23 mg/m³
.....Dermal, Long-term systemic effects: 5 mg/kg bw/day
.....Oral, Long-term systemic effects: 5 mg/kg bw/day
PNECs

Quality Check Material: PUFA

Compartment | Value
Water..... Freshwater: 2.504 mg/l
.....Marine water: 0.2504 mg/l
.....Intermittent releases: 25.04 mg/l
Sediment.....Not relevant
Soil..... .Not relevant
Sewage treatment: 520 mg/l
Secondary poisoning: Not relevant

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
Colour: yellowish
Odour: mild
flammability: No data available

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	*not applicable*		② Dissolved substance quantity: < 0.023 mg/l
Melting point	≥ -17 – ≤ 16 °C		① DIN ISO 3016
Freezing point	*not applicable*		
Initial boiling point and boiling range	≥ 302.5 – ≤ 570 °C		① ASTM D 7169 ② pressure: 1013 mbar
Flash point	≥ 120 – < 180 °C		① EN ISO 2719
Evaporation rate	*No data available*		
Auto-ignition temperature	*No data available*		
Upper/lower flammability or explosive limits	*not applicable*		
Vapour pressure	≥ 2 – ≤ 6 mbar	25 °C	① EN 13016-1
Vapour density	*No data available*		
Density	≥ 878 – ≤ 895 kg/m³	15 °C	① EN ISO 3675
Bulk density	*not applicable*		
Water solubility	≈ 0.023 mg/L		
Partition coefficient: n-octanol/water	≥ 6.2		① OECD 107
Dynamic viscosity	≥ 5.5 – ≤ 8 mPa* s	25 °C	① EN ISO 3104
Kinematic viscosity	*No data available*		
Self-ignition	≥ 256 – ≤ 266 °C		① Closed Flask ② The ignition delay observed at this temperature was 60 seconds and a Temperature increase at middle of the flask was 14 °C.

9.2. Other information

Flammability: Not readily flammable, > Flam. Liq. 4
Oxidising properties: Not oxidising.

SECTION 10: Stability and reactivity

10.1. Reactivity

Substance is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.The product is chemically stable under recommended conditions of storage, use and temperature.

Quality Check Material: PUFA

10.2. Chemical stability
Substance is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3. Possibility of hazardous reactions
The substance reacts with strong bases to form methanol.

10.4. Conditions to avoid
See incompatible materials.

10.5. Incompatible materials
Oxidising agent, strong
Alkali (lye), concentrated

10.6. Hazardous decomposition products
In combustion emits toxic fumes of carbon dioxide / carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity:
Acute toxicity (oral): LD_{50}: > 5000 mg/kg (Study is closely comparable to OECD 401; GLP)

Acute dermal toxicity:
Acute toxicity (dermal): Has been tested in a fixed dose test at 2000 mg/kg (C6-C12 ME, Rabbit): No sign of toxicity, Methode: EPA OPPTS 870.1200

Acute inhalation toxicity:
No data available
Based on the oral or dermal toxicity results and the low tendency of the substance to nebulise, no inhalation effects are expected.

Skin corrosion/irritation:
Skin corrosion/irritation: In general, esters of long-chain fatty acid methyl esters are always negative with relation to irritation (from C18 onward), while esters of short-chain fatty acids are always (slightly) positive (up to C10). Methode: OECD 404

Serious eye damage/irritation:
Serious eye damage/irritation: Conjunctivae effects were observed 1 hour after exposure. Slight chemosis and slight conjunctivae were observed in two animals and four animals, respectively. Two animals presented conjunctivae with diffuse, crimson colour and individual vessels not easily discernible. These effects were fully reversible within 1 day. Methode: OECD 405

Respiratory or skin sensitisation:
Respiratory sensitation: No information but no respiratory sensitation is expected.

Skin sensitation: Esterol C in corn oil was tested using the Guinea pig maximisation test.
No clinical signs and no deaths were noted during the study. No cutaneous reactions were observed after the challenge application. Under the experimental conditions of the study, it is concluded that Esterol C does not induce delayed contact hypersensitivity in guinea pig. Methode: OECD 406 (GLP)

Carcinogenicity:
Germ cell mutagenicity (bacteria), Esterol C: Ames test negative. Methode: OECD 471

In vitro cytogenicity test, Esterol C: Investigation in lymphocytes. negative Methode: OECD 473

In mammalian mutation test: Methyl myristate alone had no mitogenic activity. In combination with phytohemagglutinin, however, a comitogenic activity was found. Methode: EU Method B.17

Carcinogenicity: Methyl oleate and methyl 12-oxo-trans-10-octadecenoate have been tested for carcinogenicity by oral and subcutaneous administration. A positive effect of methyl oleate could not be assessed, while the results pointed to a promoter effect of methyl oxo-octadecenoate. Methode: EU Method B.32

Overall assessment on CMR properties No CMR properties are expected.

Quality Check Material: PUFA

Additional information:
Repeated dose toxicity (subacute, subchronic, chronic): Reproductive toxicity Developmental effects/ Fertility effects: The tested substance revealed no effect in Screening for reproduction for a dose of until 1000 mg/kg. Methode: OECD 422

STOT-single exposure: No information available.

STOT- repeated exposure: The tested substance revealed no effect in Screening for reproduction for a dose of until 1000 mg/kg. Methode: OECD 422

11.2. Information on other hazards
No data available

SECTION 12: Ecological information

12.1. Toxicity
Aquatic toxicity:
EC_{50} (48 h): 2504 mg/l Methode: OECD 202
EC_{50} (72 h): 73729 mg/l Methode: OECD 201

Terrestrial toxicity:
LC_{50}: (freshwater fish) 100000 mg/l

12.2. Persistence and degradability
Additional information:
Further ecological information: All methyl esters of fatty acids are readily biodegradable in water, soil and sediments. They pass the 10 days windows with 62% of degradation. Half life in the three compartment is less than 2 -3 days. In some case even less than 1 day. Methode: ISO 10712

12.3. Bioaccumulative potential
Partition coefficient: n-octanol/water:
≥ 6.2; Method: OECD 107

Accumulation / Evaluation:
All methyl esters of fatty acids are readily biodegradable in water, soil and sediments. They pass the 10 days windows with 62% of degradation. Half life in the three compartment is less than 2 -3 days. In some case even less than 1 day. Methode: ISO 10712

12.4. Mobility in soil
The substance is very poorly soluble in water and readily biodegradable. The equilibrium partitioning method, following a fugacity model III indicate a partition of the substance on sediments of 85.5%, based on log Koc > 5.63 at 22°C.
According to equilibrium partitioning Fugacity model III, the soil % is 1.61%, FAME have a soil primary biodegradation of less than 2 days.

12.5. Results of PBT and vPvB assessment

Fatty acids, C16-18 and C18-unsatd., Me esters CAS No.: 67762-38-3 EC No.: 267-015-4
Results of PBT and vPvB assessment: —

Fatty acids, C16-18 and C18-unsatd., Me esters is not regarded as PBT or vPvB based on physicochemical, environmental and toxicological properties. Fatty acids, C16-18 and C18-unsatd., Me esters is not regarded as P or vP based on readily biodegradability. Fatty acids, C16-18 and C18-unsatd., Me esters is not regarded as bioaccumulative based on the measured BCF of 3. The long-term no-observed effect concentration (Noec) for marine or freshwater organisms is not available because of the high biodegradation rate in environmental conditions.
The substance is not classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2).

12.6. Endocrine disrupting properties
No data available

Quality Check Material: PUFA

12.7. Other adverse effects

Further ecological information: The substance is considered as stable in the environmental range of pH. Hydrolysis happens with the presence of strong acids or basis, with release of methanol and fatty acids or its salts.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Incineration is recommended.

13.1.1. Product/Packaging disposal

Waste codes/waste designations according to EWC/AVV

Waste code product

07 01 99	(07) WASTES FROM ORGANIC CHEMICAL PROCESSES (01) Wastes from the manufacture, formulation, supply and use (MFSU) of basic organic chemicals (99) wastes not otherwise specified
07 06 99	(07) WASTES FROM ORGANIC CHEMICAL PROCESSES (06) Wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics (99) Wastes not otherwise specified
07 07 99	(07) WASTES FROM ORGANIC CHEMICAL PROCESSES (07) wastes from the MFSU of fine chemicals and chemical products not otherwise specified (99) Wastes not otherwise specified

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4. Packing group			
not relevant	not relevant	not relevant	not relevant
14.5. Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6. Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU legislation

Other regulations (EU):

This product is not assigned to a hazard category.

Quality Check Material: PUFA

Substance/mixture is not VOC relevant.

15.1.2. National regulations

[DE] National regulations

Störfallverordnung (12. BImschV)

for substances contained in the product:

This product is not assigned to a hazard category.

Water hazard class

WGK:

1 - slightly hazardous to water

Source:

AwSV, Nr. 834 (Rigoletto)

Other regulations, restrictions and prohibition regulations

Mainly local/national tax legislation and quality requirements (EN 14214 + additional regulations).

15.2. Chemical Safety Assessment

For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM	American Society for Testing and Materials
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC_{50}	Effective Concentration 50%
EN	European Standard
ERC	Environmental Release Category
EWC	European Waste Catalogue
GLP	Good Laboratory Practice
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
ISO	International Standards Organisation
KG	body weight
LC_{50}	Lethal (fatal) Concentration 50%
NFPA	National Fire Protection Association
OECD	Organisation for Economic Cooperation and Development
PBT	persistent and bioaccumulative and toxic
PC	Product category
PNEC	Predicted No Effect Concentration
PROC	Process Category
REACH	Registration, Evaluation and Authorization of Chemicals
RID	Dangerous goods regulations for transport by rail
SU	use category
TRGS	Technische Regeln für Gefahrstoffe
UN	United Nations

CSA: Chemical Safety Assessment
PBT: Substance with persistent, bioaccumulative and toxic properties.
vPvB: Substance with very persistent and very bioaccumulative properties.
MFSU: Manufacture, formulation, supply and use
RIGOLETTO: Database of the German Federal Environmental Agency, which contains the classification of substances according to their water hazard class (https//webrigoletto.uba.de/Rigoletto/Home/Search).

Quality Check Material: PUFA

16.3. Key literature references and sources for data
See annex

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]
The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15
No data available

16.6. Training advice
No data available

16.7. Additional information
This SDS is not required by Article 31 of Regulation 1907/2006/EU as the substance is not classified as hazardous, however, to comply with Article 32 of REACH and provide customers with relevant information the format of the SDS (according to Regulation 2015/830/EU) has been used.
Given data sheets are based on our present experiences, however they are no assurance of product properties and do not justify a contractual legal relationship.

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