according to Regulation (EC) No. 1907/2006 (REACH)

#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666 date of compilation: 2021-09-14 Version: 1.0 en

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

#### **Product identifier** 1.1

Identification of the substance Fatty acid methyl ester mixture ROTICHROM®

8666 Article number

Registration number (REACH) not relevant (mixture)

Alternative name(s) **FAME** 

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes

(household).

#### 1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 **Telefax:** +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data :Department Health, Safety and Environment

sheet:

sicherheit@carlroth.de e-mail (competent person):

#### 1.4 **Emergency telephone number**

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	01 809 2166	https:// www.poisons.ie/

#### **SECTION 2: Hazards identification**

#### Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class		Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.1I	Acute toxicity (inhal.)	3	Acute Tox. 3	H331
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	3.3 Serious eye damage/eye irritation		Eye Irrit. 2	H319

Ireland (en) Page 1 / 20



according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.6	Carcinogenicity	2	Carc. 2	H351
3.7	Reproductive toxicity	2	Repr. 2	H361d
3.9	Specific target organ toxicity - repeated exposure	1	STOT RE 1	H372

For full text of abbreviations: see SECTION 16

#### The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure.

#### 2.2 Label elements

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

Signal word Danger

#### **Pictograms**

GHS06, GHS08



#### **Hazard statements**

H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H351	Suspected of causing cancer
H361d	Suspected of damaging the unborn child
H372	Causes damage to organs through prolonged or repeated exposure

#### **Precautionary statements**

#### **Precautionary statements - prevention**

P202	Do not handle until all safety precautions have been read and understood
P260	Do not breathe mist/vapours/spray
P270	Do not eat, drink or smoke when using this product
P280	Wear protective gloves/eye protection

### **Precautionary statements - response**

P302+P352 IF ON SKIN: Wash with plenty of water P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

**Hazardous ingredients for labelling:** Trichloromethane

Labelling of packages where the contents do not exceed 125 ml  $\,$ 

Signal word: **Danger** 

Symbol(s)





Ireland (en) Page 2 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

H331 Toxic if inhaled.

H351

Suspected of causing cancer.
Suspected of damaging the unborn child. H361d

Causes damage to organs through prolonged or repeated exposure. H372

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist/vapours/spray.

P270 Do not eat, drink or smoke when using this product.

P280

Wear protective gloves/eye protection.
IF exposed or concerned: Get medical advice/attention. P308+P313

contains: Trichloromethane

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

# SECTION 3: Composition/information on ingredients

#### 3.1 **Substances**

not relevant (mixture)

#### 3.2 **Mixtures**

#### Description of the mixture

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Trichloromethane	CAS No 67-66-3 EC No 200-663-8 Index No 602-006-00-4 REACH Reg. No 01-2119486657- 20-xxxx	80 - < 100	Acute Tox. 4 / H302 Acute Tox. 3 / H331 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Carc. 2 / H351 Repr. 2 / H361d STOT RE 1 / H372		GHS-HC IARC: 2B IOELV

#### Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/

2008/EC, Annex VI)
IARC group 2B: possibly carcinogenic to humans (International Agency for Research on Cancer)

2B: IOELV: Substance with a community indicative occupational exposure limit value

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Trichlorometh- ane	CAS No 67-66-3 EC No 200-663-8 Index No 602-006-00-4	-	-	908 <sup>mg</sup> / <sub>kg</sub> 3 <sup>mg</sup> / <sub>l</sub> /4h	oral inhalation: va- pour

For full text of abbreviations: see SECTION 16

Ireland (en) Page 3 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures



#### **General notes**

Self-protection of the first aider.

#### Following inhalation

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

#### Following skin contact

Rinse skin with water/shower. In case of skin irritation, consult a physician.

#### Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Irritation, Nausea, Vomiting, Dizziness, Headache, Cough, Vertigo, Spasms, Dyspnoea, Unconsciousness

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

none

# **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings water spray, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

#### Unsuitable extinguishing media

water jet

#### 5.2 Special hazards arising from the substance or mixture

None.

# **Hazardous combustion products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Hydrogen chloride (HCl), Hydrogen halides (HX)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

Ireland (en) Page 4 / 20

according to Regulation (EC) No. 1907/2006 (REACH)

# ROTH

#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Do not breathe vapour/spray. Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Provide adequate ventilation.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains.

#### Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

#### Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Use extractor hood (laboratory). Avoid exposure. When not in use, keep containers tightly closed.

#### Advice on general occupational hygiene

Wash hands before breaks and after work.

#### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a cool place.

#### **Incompatible substances or mixtures**

Observe hints for combined storage.

#### Consideration of other advice:

Store locked up.

#### **Ventilation requirements**

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °C

#### 7.3 Specific end use(s)

No information available.

Ireland (en) Page 5 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

# **SECTION 8: Exposure controls/personal protection**

#### 8.1 **Control parameters**

#### **National limit values**

#### **Occupational exposure limit values (Workplace Exposure Limits)**

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	chloroform	67-66-3	IOELV	2	10						2000/39/ EC
ΙE	chloroform	67-66-3	OELV	2	9,8						S.I. No. 619 of 2001

#### Notation

Ceiling-C STEL

Ceiling value is a limit value above which exposure should not occur Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified) Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8

TWA

hours time-weighted average (unless otherwise specified)

#### Relevant DNELs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Trichloromethane	67-66-3	56-3 DNEL 2,5 mg/m³ human, inhal ory		human, inhalat- ory	worker (industry)	chronic - systemic effects
Trichloromethane	67-66-3	DNEL	333 mg/m³	human, inhalat- ory	worker (industry)	acute - systemic effects
Trichloromethane	67-66-3	DNEL 2,5 mg/m³ human, inhalat- ory		worker (industry)	chronic - local ef- fects	
Trichloromethane	67-66-3	DNEL	IEL 0,94 mg/kg human, dermal bw/day		worker (industry)	chronic - systemic effects

#### Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Trichloromethane	67-66-3	PNEC	0,146 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Trichloromethane	67-66-3	PNEC	0,015 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Trichloromethane	67-66-3	PNEC	0,048 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Trichloromethane	67-66-3	PNEC	0,45 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Trichloromethane	67-66-3	PNEC	0,09 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	marine sediment	short-term (single instance)
Trichloromethane	67-66-3	PNEC	0,56 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)

Ireland (en) Page 6 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

#### **Eye/face protection**





Use safety goggle with side protection.

#### Skin protection





#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### type of material

FKM (fluoro rubber)

#### material thickness

≥0,4 mm

#### · breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### **Respiratory protection**





Respiratory protection necessary at: Aerosol or mist formation. Type: AX (gas filters and combined filters against low-boiling point organic compounds, colour code: Brown).

#### **Environmental exposure controls**

Keep away from drains, surface and ground water.

Ireland (en) Page 7 / 20

according to Regulation (EC) No. 1907/2006 (REACH)

# Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666



# **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state liquid

Colour colourless
Odour characteristic

Melting point/freezing point -63 °C data apply to the main component

Boiling point or initial boiling point and boiling 61 °C at 1.013 hPa data apply to the main com-

range ponent

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point not determined

Auto-ignition temperature not determined

Decomposition temperature not relevant

pH (value) not determined

Kinematic viscosity not determined

Solubility(ies)

Water solubility not determined

Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure 211 hPa at 20 °C

data apply to the main component

Density  $1,48 \, {}^{9}/_{cm^{3}}$  at 20 °C data apply to the main com-

ponent

Relative vapour density information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard hazard classes acc. to GHS

classes: (physical hazards): not relevant

Other safety characteristics: There is no additional information.

Ireland (en) Page 8 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

# **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

**Violent reaction with:** strong oxidiser, Acetone, Alkali metals, Alkaline earth metal, Metal powder, Mineral acids, Nitro compound, Peroxides, => Explosive properties

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

plastic and rubber, Light metals

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

# **SECTION 11: Toxicological information**

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

Test data are not available for the complete mixture.

#### **Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### Classification according to GHS (1272/2008/EC, CLP)

#### **Acute toxicity**

Harmful if swallowed. Toxic if inhaled.

## Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE	
Trichloromethane	67-66-3	oral	908 <sup>mg</sup> / <sub>kg</sub>	
Trichloromethane	67-66-3	inhalation: vapour	3 <sup>mg</sup> / <sub>l</sub> /4h	

#### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Trichloromethane	67-66-3	oral	LD50	908 <sup>mg</sup> / <sub>kg</sub>	rat

#### Skin corrosion/irritation

Causes skin irritation.

#### Serious eye damage/eye irritation

Causes serious eye irritation.

Ireland (en) Page 9 / 20

according to Regulation (EC) No. 1907/2006 (REACH)

# ROTH

#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### **Respiratory or skin sensitisation**

Shall not be classified as a respiratory or skin sensitiser.

#### **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Suspected of causing cancer.

#### Reproductive toxicity

Suspected of damaging the unborn child.

#### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

#### Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### Symptoms related to the physical, chemical and toxicological characteristics

#### If swallowed

vomiting, nausea

#### • If in eyes

Causes serious eye irritation

#### • If inhaled

vertigo, dizziness, cough, headache

#### • If on skin

causes skin irritation

#### Other information

Other adverse effects: Spasms, Dyspnoea, Unconsciousness, Loss of righting reflex, and ataxia

#### 11.2 Endocrine disrupting properties

None of the ingredients are listed.

#### 11.3 Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

#### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture								
Name of sub- stance	Species	Exposure time						
Trichloromethane	67-66-3	EC50	152,5 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h			
Trichloromethane	67-66-3	ErC50	13,3 <sup>mg</sup> / <sub>l</sub>	algae	72 h			

Ireland (en) Page 10 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

# Aquatic toxicity (chronic) of components of the mixture

	Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Т	richloromethane	67-66-3	EC50	0,48 <sup>mg</sup> / <sub>l</sub>	microorganisms	24 h

## **Biodegradation**

Data are not available.

#### 12.2 Process of degradability

# Degradability of components of the mixture

Name of substance	CAS No	Process	Degrada- tion rate	Time	Method	Source
Trichlorometh- ane	67-66-3	biotic/abiotic	0 %	14 d		

#### 12.3 Bioaccumulative potential

Data are not available.

#### Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Trichloromethane	67-66-3		1,97 (25 °C)	

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

#### 12.7 Other adverse effects

Data are not available.

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

Ireland (en) Page 11 / 20

according to Regulation (EC) No. 1907/2006 (REACH)

# ROTH

#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

# **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADR/RID/ADN UN 1888
IMDG-Code UN 1888
ICAO-TI UN 1888

### 14.2 UN proper shipping name

ADR/RID/ADN CHLOROFORM
IMDG-Code CHLOROFORM
ICAO-TI Chloroform

#### 14.3 Transport hazard class(es)

ADR/RID/ADN 6.1
IMDG-Code 6.1
ICAO-TI 6.1

#### 14.4 Packing group

ADR/RID/ADN III
IMDG-Code III
ICAO-TI III

#### 14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

#### 14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

#### 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

#### 14.8 Information for each of the UN Model Regulations

# Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Proper shipping name CHLOROFORM

Particulars in the transport document UN1888, CHLOROFORM, 6.1, III, (E)

Classification code T1

Danger label(s) 6.1



Ireland (en) Page 12 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

Special provisions (SP)	802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60

#### International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name CHLOROFORM

Particulars in the shipper's declaration UN1888, CHLOROFORM, 6.1, III

Marine pollutant Danger label(s) 6.1



Special provisions (SP) 
Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-A, S-A

Stowage category A

**Segregation group** 10 - Liquid halogenated hydrocarbons

#### International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name Chloroform

Particulars in the shipper's declaration UN1888, Chloroform, 6.1, III

Danger label(s) 6.1



Excepted quantities (EQ) E1
Limited quantities (LQ) 2 L

# **SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Ireland (en) Page 13 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Fatty acid methyl ester mixture	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Trichloromethane	chloroform	67-66-3	R32-38	32
Trichloromethane	substances in tattoo inks and perman- ent make-up		R75	75

#### Legend

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes, - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,

Articles not complying with paragraph 1 shall not be placed on the market.
 Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume,

- can be used as fuel in decorative oil lamps for supply to the general public, and
   present an aspiration hazard and are labelled with H304.

  4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- (CEN).

  5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage"; (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage'; (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black

opaque containers not exceeding 1 litre by 1 December 2010.'; 1. Shall not be placed on the market, or used, R32-38

as substances

- as substances,
   as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1 % by weight, where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics.
  2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures containing them in concentrations equal to or greater than 0,1 % by weight is visibly, legibly and indelibly marked as follows: indelibly marked as follows: 'For use in industrial installations only'. By way of derogation this provision shall not apply to:

(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC.

Page 14 / 20 Ireland (en)

according to Regulation (EC) No. 1907/2006 (REACH)

# Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### Legend

**R75** 

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the

(f) in the case of a substance is the invalid in the legislation (EC) No 1223/2009 (17), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(ii) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

Page 15 / 20 Ireland (en)

according to Regulation (EC) No. 1907/2006 (REACH)

# ROTH

#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### Legend

9. This entry does not apply to substances that are gases at temperature of 20  $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50  $^{\circ}$ C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

### List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

#### **Seveso Directive**

2012/	2012/18/EU (Seveso III)						
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements					
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)			

#### Notation

- 41) Category 2, all exposure routes
  - category 3, inhalation exposure route

#### **Deco-Paint Directive**

OC content	92 % , 1.362 <sup>g</sup> / <sub>l</sub>
------------	---

#### **Industrial Emissions Directive (IED)**

VOC content	90 %
VOC content	1.332 <sup>g</sup> / <sub>l</sub>

# Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

# Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Pollutant release and transfer registers (PRTR)					
Name of substance	CAS No	Remarks	Threshold for releases to air (kg/year)		
Trichloromethane	67-66-3		500		

#### Water Framework Directive (WFD)

Ireland (en) Page 16 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

#### List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Trichloromethane	trichloromethane (chloroform)	67-66-3	B)	
Trichloromethane	trichloromethane	67-66-3	C)	
Trichloromethane	Organohalogen compounds and substances which may form such compounds in the aquatic environment		A)	
Trichloromethane	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment		A)	

#### Legend

A) B) C)

Indicative list of the main pollutants List of priority substances in the field of water policy Environmental Quality Standards for Priority Substances and certain other pollutants

#### Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

#### **Regulation on drug precursors**

none of the ingredients are listed

#### Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

#### Regulation concerning the export and import of hazardous chemicals (PIC)

chemicals subject to the international prior informed consent (PIC) procedure (the 'PIC procedure').

Name of substance	Name acc. to inventory	CAS No	Category / subcategory	Use limita- tion
Trichloromethane	chloroform	67-66-3	i(2)	b

#### Legend

Use limitation: ban (for the sub-category or sub-categories concerned) according to Union legislation Sub-category: i(2) - industrial chemical for public use b i(2)

#### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

#### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

#### **National inventories**

Ireland (en) Page 17 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

Country	Inventory	Status
AU	AICS	not all ingredients are listed
CA	DSL	not all ingredients are listed
CA	NDSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	not all ingredients are listed

Legend

AICS CICR CSCL-ENCS

Australian Inventory of Chemical Substances
Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances
Korea Existing Chemicals Inventory
Non-domestic Substances List (NDSL)
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH registered substances DSL ECSI IECSC INSQ KECI **NDSL** 

NZIoC PICCS

REACH Reg. REACH registered substances
TCSI Taiwan Chemical Substance Inventory
TSCA Toxic Substance Control Act

#### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## **SECTION 16: Other information**

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
ATE	Acute Toxicity Estimate

Ireland (en) Page 18 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



# Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

Abbr.	Descriptions of used abbreviations
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substance
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causin 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an ide fier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United N tions
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulatio (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality durin specified time interval
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration

Ireland (en) Page 19 / 20

according to Regulation (EC) No. 1907/2006 (REACH)



#### Fatty acid methyl ester mixture ROTICHROM® ME 17

article number: 8666

Abbr.	Descriptions of used abbreviations
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	Reproductive toxicity
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### **Classification procedure**

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H351	Suspected of causing cancer.
H361d	Suspected of damaging the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.

#### **Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Ireland (en) Page 20 / 20