

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)  
(This safety data sheet is for information only as it does not  
comply with the official language requirements of Article 31 (5)  
of REACH nor does it provide the national information in sections  
8 and 15 as specified in Annex II of REACH.)

## AquaClean MFD

Version number: 2.0  
Replaces version of: 2024-05-02 (1)

Revision: 2024-06-03  
First version: 2024-05-02

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

#### 1.1 Product identifier

**Trade name** AquaClean MFD  
**Unique formula identifier (UFI)** D690-A0MQ-X004-M9AV

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

**Relevant identified uses** Cleaning solution for MIRA analyzers

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

CLADE GmbH Telephone: +49 711-400 52 400  
Schelztorstraße 54-56 e-mail: info@clade.io  
73728 Esslingen Website: clade.io  
Germany

**e-mail (competent person)** nathalie.kittel@clade.io

**National contact** Telephone: +49 711-400 52 400  
e-Mail: info@clade.io

#### 1.4 Emergency telephone number

As above or nearest toxicological information centre.

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Classification				
Section	Hazard class	Category	Hazard class and category	Hazard statement
3.4S	skin sensitisation	1	Skin Sens. 1	H317

For full text of abbreviations: see SECTION 16

## 2.2 Label elements

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

**Signal word** warning

### Pictograms

**GHS07**



### Hazard statements

**H317** May cause an allergic skin reaction.

### Precautionary statements

**P261** Avoid breathing mist/vapours/spray.

**P280** Wear protective gloves/protective clothing/eye protection/face protection.

**P333+P313** If skin irritation or rash occurs: Get medical advice/attention.

**P362+P364** Take off contaminated clothing and wash it before reuse.

**P501** Dispose of contents/container to an authorized waste treatment facility.

**Hazardous ingredients for labelling** 2-methyl-2H-isothiazol-3-one

**Additional labelling requirements** see section 15 of the safety data sheet

### Derogations from labelling requirements

### Labelling of packages where the contents do not exceed 125 ml

**Signal word** warning

### Pictograms

**GHS07**



### Hazard statements

**H317** May cause an allergic skin reaction.

### Precautionary statements

**P261** Avoid breathing mist/vapours/spray.

**P280** Wear protective gloves/protective clothing/eye protection/face protection.

**P333+P313** If skin irritation or rash occurs: Get medical advice/attention.

**P362+P364** Take off contaminated clothing and wash it before reuse.

**P501** Dispose of contents/container to an authorized waste treatment facility.

**Contains** 2-methyl-2H-isothiazol-3-one

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## 2.3 Other hazards

### Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0,1\%$ .

### Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not relevant (mixture).

### 3.2 Mixtures

#### Description of the mixture

Hazardous ingredients					
Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	CAS No 94667-33-1  REACH Reg. No 01-2119950327-36-xxxx	0.01 – < 0.1	Acute Tox. 4 / H302 Skin Corr. 1B / H314 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		-
2-methyl-2H-isothiazol-3-one	CAS No 2682-20-4  EC No 220-239-6  Index No 613-326-00-9  REACH Reg. No 01-2120764690-50-xxxx	< 0.01	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 2 / H330 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Skin Sens. 1A / H317 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410 EUH071		GHS-HC

#### Notes

GHS- Harmonised classification (the classification of the substance corresponds to the entry in the list according to  
HC: 1272/2008/EC, Annex VI)

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	-	M-factor (acute) = 10 M-factor (chronic) = 10	500 mg/kg	oral

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Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
2-methyl-2H-isothiazol-3-one	Skin Sens. 1A; H317: C ≥ 0.0015 %	M-factor (acute) = 10 M-factor (chronic) = 1	232 mg/kg 242 mg/kg 0.5 mg/l/4h 0.11 mg/l/4h	oral dermal inhalation: vapour inhalation: dust/ mist

## Remarks

For full text of H-phrases: see SECTION 16

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General notes

Self-protection of the first aider.  
Remove affected person from the danger area and lay down.  
Do not leave affected person unattended.  
Take off immediately all contaminated clothing.  
In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following inhalation

Provide fresh air.  
If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

#### Following skin contact

Take off contaminated clothing.  
After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water.  
If skin irritation or rash occurs: Get medical advice/attention.

#### Following eye contact

Irrigate copiously with clean, fresh water, holding the eyelids apart.  
Remove contact lenses, if present and easy to do. Continue rinsing.

#### Following ingestion

Rinse mouth. Do not induce vomiting.  
Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

Vomiting.  
Diarrhoea.  
Nausea.  
May cause an allergic skin reaction.

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

None.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO<sub>2</sub>)

#### Unsuitable extinguishing media

water jet

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

Hazardous decomposition products: Section 10.

#### Hazardous combustion products

nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

Non-combustible.

Keep containers cool with water spray.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

#### Special protective equipment for firefighters

Wear self-contained breathing apparatus

## SECTION 6: Accidental release measures

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

#### For non-emergency personnel

Remove persons to safety.

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

#### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

## 6.3 Methods and material for containment and cleaning up

### Advice on how to clean up a spill

Collect spillage.

Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

### Appropriate containment techniques

Use of adsorbent materials.

### 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

Avoid contact with skin and eyes.

Do not breathe vapour/spray.

### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

### Specific notes/details

None.

### Measures to protect the environment

Avoid release to the environment.

### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

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

#### Flammability hazards

None.

#### Incompatible substances or mixtures

Incompatible materials: see section 10.

Store away from oxidizing agents.

**Protect against external exposure, such as**

frost

**Consideration of other advice**

Keep away from food, drink and animal feeding stuffs.

**Ventilation requirements**

Provision of sufficient ventilation.

**Specific designs for storage rooms or vessels**

Keep container tightly closed and in a well-ventilated place.

**Packaging compatibilities**

Keep only in original container.

**7.3 Specific end use(s)**

No information available.

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

**8.1 Control parameters**

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

This information is not available

**Human health values**

Relevant DNELs of components						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
2-methyl-2H-isothiazol-3-one	2682-20-4	DNEL	0.021 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects

**Environmental values**

Relevant PNECs of components				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
2-methyl-2H-isothiazol-3-one	2682-20-4	PNEC	3.39 µg/l	freshwater
2-methyl-2H-isothiazol-3-one	2682-20-4	PNEC	3.39 µg/l	marine water
2-methyl-2H-isothiazol-3-one	2682-20-4	PNEC	0.23 mg/l	sewage treatment plant (STP)
2-methyl-2H-isothiazol-3-one	2682-20-4	PNEC	0.047 mg/kg	soil

## 8.2 Exposure controls

### Appropriate engineering controls

Use local and general ventilation.

### Individual protection measures (personal protective equipment)

#### Eye/face protection

Wear eye/face protection. (EN 166).

#### Hand protection

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
NBR: acrylonitrile-butadiene rubber	no information available	no information available

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

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.

#### Body protection

Protective clothing against liquid chemicals.  
(EN 13832, EN 340, EN 14605).

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.  
(EN 136, EN 140, EN 14387, EN 143, EN 149).

#### Environmental exposure controls

Use appropriate container to avoid environmental contamination.  
Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Physical state</b>	liquid
<b>Colour</b>	blue
<b>Odour</b>	faintly perceptible
<b>Melting point/freezing point</b>	not determined
<b>Boiling point or initial boiling point and boiling range</b>	>100 °C
<b>Flammability</b>	non-combustible



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<b>Lower and upper explosion limit</b>	not determined
<b>Flash point</b>	not determined
<b>Auto-ignition temperature</b>	not determined
<b>Decomposition temperature</b>	not relevant
<b>pH (value)</b>	~6 (25 °C)
<b>Kinematic viscosity</b>	not determined
<b>Dynamic viscosity</b>	not determined
<b>Solubility(ies)</b>	
Water solubility	not miscible in any proportion
<b>Partition coefficient n-octanol/water (log value)</b>	not determined
<b>Vapour pressure</b>	not determined
<b>Density and/or relative density</b>	
Density	~1 g/cm <sup>3</sup> at 25 °C
Relative vapour density	information on this property is not available
<b>Particle characteristics</b>	not relevant (liquid)
<b>9.2 Other information</b>	
<b>Information with regard to physical hazard classes</b>	hazard classes acc. to GHS (physical hazards): not relevant
<b>Other safety characteristics</b>	there is no additional information

## 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.

See below "Conditions to avoid".

### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

### 10.4 Conditions to avoid

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

**10.5 Incompatible materials**

oxidisers

**10.6 Hazardous decomposition products**

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

Hazardous combustion products: see section 5.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Classification procedure**

If not otherwise specified the classification is based on:  
Ingredients of the mixture (additivity formula).

**Classification according to GHS (1272/2008/EC, CLP)****Acute toxicity**

Test data are not available for the complete mixture.

**Acute toxicity of components**

Acute toxicity estimate (ATE) of components			
Name of substance	CAS No	Exposure route	ATE
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	oral	500 mg/kg
2-methyl-2H-isothiazol-3-one	2682-20-4	oral	232 mg/kg
2-methyl-2H-isothiazol-3-one	2682-20-4	dermal	242 mg/kg
2-methyl-2H-isothiazol-3-one	2682-20-4	inhalation: vapour	0.5 mg/l/4h
2-methyl-2H-isothiazol-3-one	2682-20-4	inhalation: dust/mist	0.11 mg/l/4h

Acute toxicity of components							
Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	oral	LD50	232 - 249 mg/kg	rat, male	EPA OPPTS 870.1100	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	oral	LD50	120 mg/kg	rat, female	EPA OPPTS 870.1100	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	dermal	LD50	242 mg/kg	rat	OECD Guideline 402	ECHA

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Acute toxicity of components							
Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	inhalation: dust/mist	LC50	0.11 mg/μ4h	rat	OECD Guideline 403	ECHA

## Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

## Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

## Respiratory or skin sensitisation

### Skin sensitisation

May cause an allergic skin reaction.

## Respiratory sensitisation

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Germ cell mutagenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity (acute)

Based on available data, the classification criteria are not met.

#### Aquatic toxicity (acute) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	LC50	96 h	0.52 mg/l	bluegill (Lepomis macrochirus)	EPA OPPTS 850.1075	ECHA
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	LC50	96 h	0.62 mg/l	carp (cyprinus carpio)	OECD Guideline 203	ECHA
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	EC50	48 h	0.1 mg/l	daphnia magna	OECD Guideline 202	ECHA
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	94667-33-1	ErC50	72 h	0.34 mg/l	algae (Scenedesmus subspicatus)	OECD Guideline 201	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	EC50	96 h	0.069 mg/l	algae (Skeletonema costatum)	OECD Guideline 201	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	EC50	48 h	1.6 mg/l	daphnia magna	EPA OPP 72-2	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	LC50	48 h	0.934 mg/l	daphnia magna	OECD Guideline 202	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	LC50	96 h	4.77 mg/l	rainbow trout (Oncorhynchus mykiss)	OECD Guideline 203	ECHA

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Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	ErC50	96 h	>0.072 mg/l	algae (Skelet-onema cost-atum)	OECD Guideline 201	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	EbC50	96 h	0.063 mg/l	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA

## Aquatic toxicity (chronic)

Based on available data, the classification criteria are not met.

## Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	EC50	21 d	1.4 mg/l	daphnia magna	OECD Guideline 211	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	EC50	3 h	41 mg/l	activated sludge of a predominantly domestic sewage	OECD Guideline 209	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	EC50	16 h	2.3 mg/l	activated sludge (Pseudomonas putida)	DIN EN ISO 10712	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	NOEC	21 d	0.044 mg/l	daphnia magna	OECD Guideline 211	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	NOEC	33 d	2.1 mg/l	fathead minnow (Pimephales promelas)	OECD Guideline 210	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	LOEC	21 d	0.089 mg/l	daphnia magna	OECD Guideline 211	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	LOEC	33 d	4.2 mg/l	fathead minnow (Pimephales promelas)	OECD Guideline 210	ECHA

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Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	growth (Eb-Cx) 10%	16 h	1 mg/l	activated sludge (Pseudomonas putida)	DIN EN ISO 10712	ECHA

## 12.2 Persistence and degradability

### Biodegradation

Test data are not available for the complete mixture.

### Degradability of components

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
2-methyl-2H-isothiazol-3-one	2682-20-4	carbon dioxide generation	47.6 %	29 d	OECD Guideline 301 B	ECHA
2-methyl-2H-isothiazol-3-one	2682-20-4	oxygen depletion	0 %	28 d	OECD Guideline 301 D	ECHA

### Persistence

No data available.

## 12.3 Bioaccumulative potential

### Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW
2-methyl-2H-isothiazol-3-one	2682-20-4	5.75	-0.486

## 12.4 Mobility in soil

No data available.

## 12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of  $\geq 0,1\%$ .

## 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0,1\%$ .

## 12.7 Other adverse effects

Data are not available.

## Remarks

Wassergefährdungsklasse, WGK (water hazard class): 1.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.  
Handle contaminated packages in the same way as the substance itself.

## Remarks

Please consider the relevant national or regional provisions.

## SECTION 14: Transport information

<b>14.1</b>	<b>UN number or ID number</b>	not assigned
<b>14.2</b>	<b>UN proper shipping name</b>	-
<b>14.3</b>	<b>Transport hazard class(es)</b>	-
<b>14.4</b>	<b>Packing group</b>	-
<b>14.5</b>	<b>Environmental hazards</b>	-
<b>14.6</b>	<b>Special precautions for user</b>	-
<b>14.7</b>	<b>Maritime transport in bulk according to IMO instruments</b>	-

## 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

Name	Name acc. to inventory	CAS No	Restriction
AquaClean MFD	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3
2-methyl-2H-isothiazol-3-one	substances in tattoo inks and permanent make-up	-	R75

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Name	Name acc. to inventory	CAS No	Restriction
N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate	substances in tattoo inks and permanent make-up	-	R75

## Legend

- R3
1. Shall not be used in:
    - 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,
  2. Articles not complying with paragraph 1 shall not be placed on the market.
  3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
    - 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.;



## 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 weight;
  - (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;
    - (ii) 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 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:
    - (i) "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 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.
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 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:

## Legend

- (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;
- (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.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °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.

## Seveso Directive

Not assigned.

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

None of the ingredients are listed.

**Regulation 648/2004/EC on detergents**

Labelling of contents	
Wt%	Constituents
-	enzymes (subtilisin, Amylase, Lipase, triacylglycerol) perfumes (D-LIMONENE) preservation agents (N,N-Didecyl-N-methyl-poly(oxyethyl) ammonium propionate, METHYLISOTHIAZOLINONE, BENZISOTHIAZOLINONE)

**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)**

None of the ingredients are listed.

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

None of the ingredients are listed.

**15.2 Chemical Safety Assessment**

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

**SECTION 16: Other information****Indication of changes (revised safety data sheet)**

Indication of changes (revised safety data sheet)		
Section	Former entry (text/value)	Actual entry (text/value)
15.1	-	Labelling of contents: change in the listing (table)

**Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)

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Abbr.	Descriptions of used abbreviations
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EbC50	≡ 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
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 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 identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
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 Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
IMDG	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 Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LOEC	Lowest Observed Effect Concentration

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Abbr.	Descriptions of used abbreviations
log KOW	n-Octanol/water
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
SVHC	Substance of Very High Concern
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.

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 section 2 and 3)

Code	Text
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.

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Code	Text
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

## Responsible for the safety data sheet

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## Disclaimer

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