according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



Tetrachloroethylene ≥99,5 %, for synthesis

article number: 4737 date of compilation: 2017-01-24 Version: 5.0 en Revision: 2024-03-03

Replaces version of: 2022-08-31

Version: (4)

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

Product identifier 1.1

Identification of the substance **Tetrachloroethylene** ≥99,5 %, for synthesis

Article number 4737

Registration number (REACH) 01-2119475329-28-xxxx

Index number in CLP Annex VI 602-028-00-4 EC number 204-825-9 CAS number 127-18-4

Alternative name(s) Perchloroethylene

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). Food, drink and animal feeding-

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

sheet:

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

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

Emergency telephone number 1.4

| Name | Street | Postal code/city | Telephone | Website |
|---|---------------|------------------|-----------------|-----------------------------|
| National Poisons Information Centre Beaumont Hospital | Beaumont Road | Dublin 9 | +353 1 809 2166 | https:// www.poisons.ie/ |

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

| Section | Hazard class | Cat- egory | Hazard class and category | Hazard statement |
|---------|---|---------------|---------------------------|---------------------|
| 3.2 | Skin corrosion/irritation | 2 | Skin Irrit. 2 | H315 |
| 3.3 | Serious eye damage/eye irritation | 2 | Eye Irrit. 2 | H319 |
| 3.45 | Skin sensitisation | 1 | Skin Sens. 1 | H317 |
| 3.6 | Carcinogenicity | 2 | Carc. 2 | H351 |
| 3.8D | Specific target organ toxicity - single exposure (narcotic effects, drowsiness) | 3 | STOT SE 3 | H336 |
| 4.1C | Hazardous to the aquatic environment - chronic hazard | 2 | Aquatic Chronic 2 | H411 |

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

| Signal word | Warning |
|-------------|---------|
|-------------|---------|

Pictograms

GHS07, GHS08, GHS09







Hazard statements

| H315 | Causes skin irritation |
|------|---|
| H317 | May cause an allergic skin reaction |
| H319 | Causes serious eye irritation |
| H336 | May cause drowsiness or dizziness |
| H351 | Suspected of causing cancer |
| H411 | Toxic to aquatic life with long lasting effects |

Precautionary statements

Precautionary statements - prevention

P260 Do not breathe mist/vapours/spray P273 Avoid release to the environment

Precautionary statements - response

P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

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Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Symbol(s)







H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness. H351 Suspected of causing cancer.

P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

Endocrine disrupting properties

The substance has an endocrine disrupting potential.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Tetrachloroethylene

Molecular formula C₂Cl₄

Molar mass 165,8 g/_{mol}

REACH Reg. No 01-2119475329-28-xxxx

CAS No 127-18-4 EC No 204-825-9 Index No 602-028-00-4

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician. 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.

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Following ingestion

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

Vomiting, Gastrointestinal complaints, Allergic reactions, Irritation, Cough, Dyspnoea, Headache, Vertigo, Dizziness, Drowsiness, Narcosis

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 (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen chloride (HCl), Hydrogen halides (HX)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

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

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

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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.

Reference to other sections 6.4

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.

Measures to protect the environment

Avoid release to the environment.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed. Store in a dry place. May cause decomposition by long-term light influence.

Incompatible substances or mixtures

Observe hints for combined storage.

Protect against external exposure, such as

direct light irradiation, UV-radiation/sunlight, humidity

Consideration of other advice:

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

7.3 Specific end use(s)

No information available.

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 | tetrachloroethylene | 127-18-4 | IOELV | 20 | 138 | 40 | 275 | | | Н | 2017/ 164/EU |
| IE | tetrachloroethylene | 127-18-4 | OELV | 20 | 138 | 40 | 275 | | | H | S.I. No. 619 of 2001 |

Notation

Ceiling-C Ceiling value is a limit value above which exposure should not occur

Absorbed through the skin

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Notation

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) **STEL**

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)

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 quide.

type of material

FKM: fluoro-elastomer

material thickness

0,7mm

breakthrough times of the glove material

>480 minutes (permeation: level 6)

Splash protection - Protective gloves

• type of material: NBR (Nitrile rubber)

• material thickness: >0,3 mm

• breakthrough times of the glove material: >240 minutes (permeation: level 5)

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: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

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Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state liquid

Colour colourless
Odour like ether

Melting point/freezing point -22 °C at 101,3 kPa (ECHA)

Boiling point or initial boiling point and boiling

range

121,4 °C at 101,3 kPa (ECHA)

>650 °C at 1 atm (ECHA)

Flammability non-combustible

Lower and upper explosion limit not determined

Flash point not determined

Decomposition temperature >140 °C

pH (value) not determined Kinematic viscosity not determined

Dynamic viscosity 0,844 mPa s at 25 °C

Solubility(ies)

Water solubility $0,15 \, {}^{9}/_{L}$ at 25 °C (ECHA)

Partition coefficient

Auto-ignition temperature

Partition coefficient n-octanol/water (log value): 2,53 (pH value: ~7, 23 °C) (ECHA)

Vapour pressure 2,5 kPa at 25 °C

Density and/or relative density

Density $1,61 \, {}^{\rm g}/{}_{\rm cm^3}$ at 25 °C (ECHA)

Relative vapour density 5,73 (air = 1)

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

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Other safety characteristics:

Temperature class (EU, acc. to ATEX)

Τ1

Maximum permissible surface temperature on the equipment: 450°C

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

Moisture-sensitive. May cause decomposition by long-term light influence.

10.3 Possibility of hazardous reactions

Danger of explosion: Alkali metals, Aluminium, Nitrogen oxides (NOx), Oxygen+Alkali hydroxide (caustic alkali),

Exothermic reaction with: Alkaline earth metal, Metal powder, Oxidisers, Strong alkali, Strong acid

10.4 Conditions to avoid

Humidity. Direct light irradiation. UV-radiation/sunlight. Keep away from heat. Decompostion takes place from temperatures above: >140 °C.

10.5 Incompatible materials

different plastics

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

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity

| Exposure route | Endpoint | Value | Species | Method | Source |
|----------------|----------|-------------------------------------|---------|--------|--------|
| oral | LD50 | 3.835 ^{mg} / _{kg} | rat | | ECHA |

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Suspected of causing cancer.

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Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness.

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (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, gastrointestinal complaints

• If in eyes

Causes serious eye irritation

If inhaled

headache, vertigo, cough, Dyspnoea, dizziness, fatique, narcosis

If on skin

Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc, has degreasing effect on the skin, causes skin irritation, risk of absorption via the skin, May produce an allergic reaction, pruritis, localised redness

Other information

Other adverse effects: Liver and kidney damage

11.2 Endocrine disrupting properties

This substance is known as an "endocrine disruptor".

Endocrine disrupting chemicals (EDC)

| Name of substance | CAS No | Combined cat- egory | Human health category | Wildlife cat- egory |
|---------------------|----------|------------------------|--------------------------|------------------------|
| Tetrachloroethylene | 127-18-4 | CAT2 | CAT2 | CAT3 |

Legend

Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption Category 3 - no evidence of endocrine disruption or no data available CAT2 CAT3

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

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| Aquatic | toxicity | (acute) |
|----------------|----------|---------|
|----------------|----------|---------|

| Endpoint | Value | Species | Source | Exposure time |
|----------|-----------------------------------|-----------------------|--------|------------------|
| LC50 | 5 ^{mg} / _l | fish | ECHA | 96 h |
| EC50 | 8,5 ^{mg} / _l | aquatic invertebrates | ECHA | 48 h |
| ErC50 | 3,64 ^{mg} / _l | algae | ECHA | 72 h |

12.2 Persistence and degradability

Theoretical Oxygen Demand: 0,193 mg/mg Theoretical Carbon Dioxide: 0,5308 mg/mg

12.3 **Bioaccumulative potential**

Does not significantly accumulate in organisms.

| n-octanol/water (log KOW) | 2,53 (pH value: ~7, 23 °C) (ECHA) |
|---------------------------|-----------------------------------|
| BCF | 49 (ECHA) |

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Endocrine disrupting properties

This substance is known as an "endocrine disruptor".

Endocrine disrupting chemicals (EDC)

| Name of substance | CAS No | Combined cat- egory | Human health category | Wildlife cat- egory |
|---------------------|----------|------------------------|--------------------------|------------------------|
| Tetrachloroethylene | 127-18-4 | CAT2 | CAT2 | CAT3 |

Legend

CAT2 CAT3 Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption Category 3 - no evidence of endocrine disruption or no data available

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

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. Avoid release to the environment. Refer to special instructions/safety data sheets.

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Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

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.

Properties of waste which render it hazardous

irritant - skin irritation and eye damage

HP7 carcinogenic

HP 13 sensitising HP 14 ecotoxic

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. Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

| ADRRID | UN 1897 |
|-----------|---------|
| IMDG-Code | UN 1897 |
| ICAO-TI | UN 1897 |

14.2 UN proper shipping name

| ADRRID | TETRACHLOROETHYLENE |
|-----------|---------------------|
| IMDG-Code | TETRACHLOROETHYLENE |
| ICAO-TI | Tetrachloroethylene |

14.3 Transport hazard class(es)

| ADRRID | 6.1 |
|-----------|-----|
| IMDG-Code | 6.1 |
| ICAO-TI | 6.1 |

14.4 Packing group

| ADRRID | III |
|-----------|-----|
| IMDG-Code | III |
| ICAO-TI | III |

14.5 Environmental hazards hazardous to the aquatic environment

14.6 Special precautions for user

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

Maritime transport in bulk according to IMO instruments 14.7

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

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Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)Additional information

Proper shipping name TETRACHLOROETHYLENE

Particulars in the transport document UN1897, TETRACHLOROETHYLENE, 6.1, III, (E), en-

vironmentally hazardous

Classification code T1

Danger label(s) 6.1, "Fish and tree"

Environmental hazards yes (hazardous to the aquatic environment)

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

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code T1

Danger label(s) 6.1, "Fish and tree"

Environmental hazards Yes

Hazardous to water

Special provisions (SP) 802(ADN)

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 L
Transport category (TC) 2
Hazard identification No 60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name TETRACHLOROETHYLENE

Particulars in the shipper's declaration UN1897, TETRACHLOROETHYLENE, 6.1, III, MAR-

INE POLLUTANT

Marine pollutant yes (P) (hazardous to the aquatic environment)

Danger label(s) 6.1, "Fish and tree"

Special provisions (SP)

Excepted quantities (EQ) E1

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Limited quantities (LQ) 5 L

EmS F-A, S-A

Stowage category

Segregation group 10 - Liquid halogenated hydrocarbons

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

Proper shipping name Tetrachloroethylene

Particulars in the shipper's declaration UN1897, Tetrachloroethylene, 6.1, III

Environmental hazards YES (hazardous to the aquatic environment)

Danger label(s) 6.1

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

SECTION 15: Regulatory information

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

Dangerous substances with restrictions (REACH, Annex XVII)

| Name of substance | Name acc. to inventory | CAS No | Restriction | No |
|---------------------|--|--------|-------------|----|
| Tetrachloroethylene | this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC | | R3 | 3 |
| Tetrachloroethylene | substances in tattoo inks and permanent make-up | | R75 | 75 |

Legend

- 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,

- 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
- ments 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.';

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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

(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.

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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

Not listed.

Seveso Directive

| 2012/18/EU (Seveso III) | | | | |
|-------------------------|--|---|-------|--|
| No | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | Notes | |
| E2 | environmental hazards (hazardous to the aquatic environment, cat. 2) | 200 500 | 57) | |

Notation

57) Hazardous to the Aquatic Environment in category Chronic 2

Deco-Paint Directive

| VOC content | 100 % |
|-------------|-----------------------------------|
| VOC content | 1.610 ^g / _l |

Industrial Emissions Directive (IED)

| VOC content | 100 % |
|-------------|-----------------------------------|
| VOC content | 1.610 ^g / _l |

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

not 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 (kg/year) | | | | | |
| Tetrachloroethylene | 127-18-4 | | 2 000 | | |

Water Framework Directive (WFD)

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List of pollutants (WFD)

| Name of substance | Name acc. to inventory | CAS No | Listed in | Remarks |
|---------------------|--|----------|-----------|---------|
| Tetrachloroethylene | tetrachloroethylene | 127-18-4 | c) | |
| Tetrachloroethylene | Organohalogen compounds and substances which may form such compounds in the aquatic environment | | a) | |
| Tetrachloroethylene | Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment | | a) | |

Legend

Indicative list of the main pollutants Environmental Quality Standards for Priority Substances and certain other pollutants

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

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

not listed

Regulation on persistent organic pollutants (POP)

not 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

| Country | Inventory | Status |
|---------|------------|---------------------|
| AU | AIIC | substance is listed |
| CA | DSL | substance is listed |
| CN | IECSC | substance is listed |
| EU | ECSI | substance is listed |
| EU | REACH Reg. | substance is listed |
| JP | CSCL-ENCS | substance is listed |
| KR | KECI | substance is listed |
| MX | INSQ | substance is listed |
| NZ | NZIoC | substance is listed |
| | | |

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| Country | Inventory | Status |
|---------|-----------|------------------------------|
| PH | PICCS | substance is listed |
| TR | CICR | substance is listed |
| TW | TCSI | substance is listed |
| US | TSCA | substance is listed (ACTIVE) |
| VN | NCI | substance is listed |

Legend

AIIC Australian Inventory of Industrial Chemicals Chemical Inventory and Control Regulation List of Existing and New Chemical Substances (CSCL-ENCS) CICR CSCL-ENCS DSL ECSI IECSC

Domestic Substances List (DSL)

INSO

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
National Chemical Inventory
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS) NZIoC

PICCS

REACH Reg. REACH registered substances TCSI Taiwan Chemical Substance Inventory

TSCA **Toxic Substance Control Act**

15.2 Chemical safety assessment

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

| Section | Former entry (text/value) | Actual entry (text/value) | Safety- relev- ant |
|---------|--|--|--------------------------|
| 2.2 | | Labelling of packages where the contents do not exceed 125 ml: change in the listing (table) | yes |
| 15.1 | VOC content: 100 % 1.610 ^g / _l | VOC content: 100 % | yes |
| 15.1 | | VOC content: 1.610 ^g / _l | yes |
| 15.1 | | National inventories: change in the listing (table) | yes |
| 15.2 | Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance. | Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant. | yes |

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Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|-------------|--|
| 2017/164/EU | Commission Directive establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU |
| ADR | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| BCF | Bioconcentration factor |
| CAS | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances) |
| Ceiling-C | Ceiling value |
| CLP | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| 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) |
| 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 |
| 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) |
| 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 Regulation (EC) No 1272/2008 |
| IOELV | Indicative occupational exposure limit value |
| 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 |
| NLP | No-Longer Polymer |
| PBT | Persistent, Bioaccumulative and Toxic |
| ppm | Parts per million |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail) |

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| Abbr. | Descriptions of used abbreviations |
|-------------------------|---|
| S.I. No. 619 of 2001 | Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 |
| STEL | Short-term exposure limit |
| 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.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

| Code | Text |
|------|--|
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness. |
| H351 | Suspected of causing cancer. |
| H411 | Toxic to aquatic life with long lasting effects. |

Disclaimer

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

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