

Safety data sheet

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



(-)-Epigallocatechin gallate ROTICHROM® HPLC

article number: **6361**
Version: **2.0 en**
Replaces version of: 2021-09-08
Version: (1)

date of compilation: 2021-09-08
Revision: 2024-03-01

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

1.1 Product identifier

| | |
|---------------------------------|---|
| Identification of the substance | (-)-Epigallocatechin gallate ROTICHROM® HPLC |
| Article number | 6361 |
| Registration number (REACH) | It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a). |
| EC number | 479-560-7 |
| CAS number | 989-51-5 |

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 private purposes (household). Food, drink and animal feedingstuffs. |

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 sheet: Department Health, Safety and Environment

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

1.4 Emergency telephone number

| 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/ |

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

| Section | Hazard class | Cat-egory | Hazard class and category | Hazard statement |
|---------|---|-----------|---------------------------|------------------|
| 3.10 | Acute toxicity (oral) | 4 | Acute Tox. 4 | H302 |
| 3.3 | Serious eye damage/eye irritation | 2 | Eye Irrit. 2 | H319 |
| 3.4S | Skin sensitisation | 1 | Skin Sens. 1 | H317 |
| 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, GHS09



Hazard statements

H302 Harmful if swallowed
H317 May cause an allergic skin reaction
H319 Causes serious eye irritation
H411 Toxic to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P273 Avoid release to the environment
P280 Wear protective gloves/eye protection/face protection

Precautionary statements - response

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell
P302+P352 IF ON SKIN: Wash with plenty of water
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Warning**

Symbol(s)



H317 May cause an allergic skin reaction.
P280 Wear protective gloves/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.

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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

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

SECTION 3: Composition/information on ingredients

3.1 Substances

| | |
|-------------------|---|
| Name of substance | (-)-Epigallocatechin gallate |
| Molecular formula | C ₂₂ H ₁₈ O ₁₁ |
| Molar mass | 458,4 g/mol |
| CAS No | 989-51-5 |
| EC No | 479-560-7 |

| Substance, Specific Conc. Limits, M-factors, ATE | | | |
|--|-----------|-----------|----------------|
| Specific Conc. Limits | M-Factors | ATE | Exposure route |
| - | - | 500 mg/kg | oral |

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

After contact with skin, wash immediately with plenty of water. In case of skin reactions, 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). Call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Vomiting, Irritation, Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

none

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SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings!
water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

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

Avoid contact with skin, eyes and clothes. Do not breathe dust.

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. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal.

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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid dust formation.

Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

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 dry place. Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 2 – 8 °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)

| Country | Name of agent | CAS No | Identifier | TWA [mg/m ³] | STEL [mg/m ³] | Ceiling-C [mg/m ³] | Notation | Source |
|---------|---------------------|--------|------------|--------------------------|---------------------------|--------------------------------|----------|----------------------|
| IE | dusts, non-specific | | OELV | 10 | | | i | S.I. No. 619 of 2001 |
| IE | dusts, non-specific | | OELV | 4 | | | r | S.I. No. 619 of 2001 |

Notation

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

i Inhalable fraction

r Respirable fraction

STEL 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)

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

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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

NBR (Nitrile rubber)

• material thickness

>0,11 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: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|--|---|
| Physical state | solid |
| Colour | whitish |
| Odour | odourless |
| Melting point/freezing point | not determined |
| Boiling point or initial boiling point and boiling range | not determined |
| Flammability | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit | not determined |
| Flash point | not applicable |
| Auto-ignition temperature | not determined |
| Decomposition temperature | not relevant |
| pH (value) | not applicable |
| Kinematic viscosity | not relevant |

Solubility(ies)

Water solubility 40 g/l at 20 °C (ECHA)

Partition coefficient

Partition coefficient n-octanol/water (log value): 1,1 (20 °C) (ECHA)

Soil organic carbon/water (log KOC) -0,05 (ECHA)

Vapour pressure not determined

Density and/or relative density

Density not determined

Relative vapour density Information on this property is not available.

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard classes: hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics:

Surface tension 72,6 mN/m (20 °C) (ECHA)

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SECTION 10: Stability and reactivity

10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

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

10.4 Conditions to avoid

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

10.5 Incompatible materials

There is no additional information.

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

Harmful if swallowed.

| Acute toxicity | | | | | |
|----------------|----------|-------------|---------|--------|--------|
| Exposure route | Endpoint | Value | Species | Method | Source |
| oral | LD50 | 2.170 mg/kg | mouse | | TOXNET |

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

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

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

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

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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

Data are not available.

• If in eyes

Causes serious eye irritation

• If inhaled

Data are not available.

• If on skin

May produce an allergic reaction, pruritis, localised redness

• Other information

none

11.2 Endocrine disrupting properties

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

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.

| Aquatic toxicity (acute) | | | | |
|--------------------------|----------|-----------------------|--------|---------------|
| Endpoint | Value | Species | Source | Exposure time |
| LC50 | 75 mg/l | fish | ECHA | 96 h |
| EC50 | 56 mg/l | aquatic invertebrates | ECHA | 24 h |
| ErC50 | 3,4 mg/l | algae | ECHA | 72 h |

12.2 Persistence and degradability

Theoretical Oxygen Demand: 1,466 mg/mg
Theoretical Carbon Dioxide: 2,112 mg/mg

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

| | |
|---------------------------|--------------------|
| n-octanol/water (log KOW) | 1,1 (20 °C) (ECHA) |
|---------------------------|--------------------|

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12.4 Mobility in soil

| | |
|--|--------------|
| The Organic Carbon normalised adsorption coefficient | -0,05 (ECHA) |
|--|--------------|

12.5 Results of PBT and vPvB assessment

Data are not available.

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.

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

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

- HP 4 irritant - skin irritation and eye damage
- HP 6 acute toxicity
- 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 3077 |
| IMDG-Code | UN 3077 |
| ICAO-TI | UN 3077 |

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14.2 UN proper shipping name

| | |
|----------------|--|
| ADRRID | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| IMDG-Code | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| ICAO-TI | Environmentally hazardous substance, solid, n.o.s. |
| Technical name | (-)-Epigallocatechin gallate |

14.3 Transport hazard class(es)

| | |
|-----------|---|
| ADRRID | 9 |
| IMDG-Code | 9 |
| ICAO-TI | 9 |

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.

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

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

| | |
|---|---|
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Particulars in the transport document | UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., ((-)-Epigallocatechin gallate), 9, III, (-) |
| Classification code | M7 |
| Danger label(s) | 9, "Fish and tree" |
|  | |
| Environmental hazards | yes (hazardous to the aquatic environment) |
| Special provisions (SP) | 274, 335, 375, 601 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 5 kg |
| Transport category (TC) | 3 |
| Tunnel restriction code (TRC) | - |

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| | |
|--|--|
| Hazard identification No | 90 |
| Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Additional information | |
| Classification code | M7 |
| Danger label(s) | 9, "Fish and tree" |
| | |
| Environmental hazards | Yes Hazardous to water |
| Special provisions (SP) | 274, 335, 375, 601 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 5 kg |
| Transport category (TC) | 3 |
| Hazard identification No | 90 |
| International Maritime Dangerous Goods Code (IMDG) - Additional information | |
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Particulars in the shipper's declaration | UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., ((-)-Epigallocatechin gallate), 9, III |
| Marine pollutant | yes (hazardous to the aquatic environment), ((-)-Epigallocatechin gallate) |
| Danger label(s) | 9, "Fish and tree" |
| | |
| Special provisions (SP) | 274, 335, 966, 967, 969 |
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 5 kg |
| EmS | F-A, S-F |
| Stowage category | A |
| International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information | |
| Proper shipping name | Environmentally hazardous substance, solid, n.o.s. |
| Particulars in the shipper's declaration | UN3077, Environmentally hazardous substance, solid, n.o.s., ((-)-Epigallocatechin gallate), 9, III |
| Environmental hazards | yes (hazardous to the aquatic environment) |
| Danger label(s) | 9, "Fish and tree" |
| | |
| Special provisions (SP) | A97, A158, A179, A197, A215 |

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| | |
|--------------------------|-------|
| Excepted quantities (EQ) | E1 |
| Limited quantities (LQ) | 30 kg |

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

| Dangerous substances with restrictions (REACH, Annex XVII) | | | | |
|--|---|--------|-------------|----|
| Name of substance | Name acc. to inventory | CAS No | Restriction | No |
| (-)-Epigallocatechin gallate | substances in tattoo inks and permanent make-up | | R75 | 75 |

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:
- 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;
 - 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;
 - 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;
 - 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:
 - 0,1 % by weight, if the substance is used solely as a pH regulator;
 - 0,01 % by weight, in all other cases;
 - 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;
 - 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:
 - "Rinse-off products";
 - "Not to be used in products applied on mucous membranes";
 - "Not to be used in eye products";
 - 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;
 - 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:
 - Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - 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:
 - the statement "Mixture for use in tattoos or permanent make-up";
 - a reference number to uniquely identify the batch;
 - the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient

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Legend

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

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 | 0 % |
|-------------|-----|

Industrial Emissions Directive (IED)

| | |
|-------------|-----|
| VOC content | 0 % |
|-------------|-----|

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)

not listed

Water Framework Directive (WFD)

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not listed

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)

not listed

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 |
|---------|------------|---------------------|
| CN | IECSC | substance is listed |
| EU | ECSI | substance is listed |
| EU | REACH Reg. | substance is listed |
| TW | TCSI | substance is listed |
| VN | NCI | substance is listed |

Legend

| | |
|------------|---|
| ECSI | EC Substance Inventory (EINECS, ELINCS, NLP) |
| IECSC | Inventory of Existing Chemical Substances Produced or Imported in China |
| NCI | National Chemical Inventory |
| REACH Reg. | REACH registered substances |
| TCSI | Taiwan Chemical Substance Inventory |

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

| Section | Former entry (text/value) | Actual entry (text/value) | Safety-relevant |
|---------|---------------------------|---|-----------------|
| 2.3 | | Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$. | yes |
| 14.8 | | Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Additional information | yes |
| 14.8 | | Classification code: M7 | yes |

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| Section | Former entry (text/value) | Actual entry (text/value) | Safety-relevant |
|---------|---------------------------|--|-----------------|
| 14.8 | | Danger label(s): 9, "Fish and tree" | yes |
| 14.8 | | Danger label(s): change in the listing (table) | yes |
| 14.8 | | Environmental hazards: Yes Hazardous to water | yes |
| 14.8 | | Special provisions (SP): 274, 335, 375, 601 | yes |
| 14.8 | | Excepted quantities (EQ): E1 | yes |
| 14.8 | | Limited quantities (LQ): 5 kg | yes |
| 14.8 | | Transport category (TC): 3 | yes |
| 14.8 | | Hazard identification No: 90 | yes |
| 15.1 | | National inventories: change in the listing (table) | yes |

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|-----------|---|
| ADR | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| ATE | Acute Toxicity Estimate |
| 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) |
| ED | Endocrine disruptor |
| 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) |

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| Abbr. | Descriptions of used abbreviations |
|----------------------|---|
| 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 |
| 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 |
| 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) |
| 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 |
|------|--|
| H302 | Harmful if swallowed. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| 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.