

# Safety data sheet

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



## ROTI®Fair SDS-PAGE

article number: **1250**  
Version: **3.0 en**  
Replaces version of: 2019-11-11  
Version: (2)

date of compilation: 2016-11-15  
Revision: 2022-10-07

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

### 1.1 Product identifier

Identification of the substance **ROTI®Fair SDS-PAGE**  
Article number 1250  
Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory and analytical use  
Laboratory chemical  
Uses advised against: Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

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

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

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

Competent person responsible for the safety data 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<br>Beaumont Hospital | Beaumont Road | Dublin 9         | 01 809 2166 | <a href="https://www.poisons.ie/">https://www.poisons.ie/</a> |

## 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 |
|---------|-----------------------------------|-----------|---------------------------|------------------|
| 3.3     | Serious eye damage/eye irritation | 1         | Eye Dam. 1                | H318             |

For full text of abbreviations: see SECTION 16

### 2.2 Label elements

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

**Signal word**                      **Danger**

#### Pictograms

GHS05



#### Hazard statements

H318                                      Causes serious eye damage

#### Precautionary statements

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

P280                                      Wear protective gloves/eye protection

##### **Precautionary statements - response**

P305+P351+P338      IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310                                      Immediately call a POISON CENTER/doctor

**Hazardous ingredients for labelling:**                      Sodium dodecyl sulphate

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

Signal word: **Danger**

Symbol(s)



H318                                      Causes serious eye damage.

P280                                      Wear protective gloves/eye protection.

P305+P351+P338      IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310                                      Immediately call a POISON CENTER/doctor.

contains:                                      Sodium dodecyl sulphate

## 2.3 Other hazards

### **Results of PBT and vPvB assessment**

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

## **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

not relevant (mixture)

### 3.2 Mixtures

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### Description of the mixture

| Name of sub-stance      | Identifier                                   | Wt%     | Classification acc. to GHS   | Pictograms  | Notes |
|-------------------------|--|---------|--|---|-------|
| Glycine                 | CAS No<br>56-40-6<br><br>EC No<br>200-272-2  | 70 - 80 |  |   |       |
| TRIS                    | CAS No<br>77-86-1<br><br>EC No<br>201-064-4  | 15 - 20 |  |   |       |
| Sodium dodecyl sulphate | CAS No<br>151-21-3<br><br>EC No<br>205-788-1 | < 9     | Flam. Sol. 2 / H228<br>Acute Tox. 4 / H302<br>Acute Tox. 4 / H332<br>Skin Irrit. 2 / H315<br>Eye Dam. 1 / H318<br>STOT SE 3 / H335<br>Aquatic Chronic 3 / H412 | <br><br> |       |

| Name of sub-stance      | Identifier                                   | Specific Conc. Limits | M-Factors | ATE                        | Exposure route                    |
|-------------------------|--|-----------------------|-----------|----------------------------|-----------------------------------|
| Sodium dodecyl sulphate | CAS No<br>151-21-3<br><br>EC No<br>205-788-1 | -                     | -         | 1,200 mg/kg<br>3,9 mg/l/4h | oral<br>inhalation: dust/<br>mist |

For full text of abbreviations: see SECTION 16

## 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. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes hold-  
ing eyelids apart and consult an ophthalmologist.

#### Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

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

Irritant effects, Risk of serious damage to eyes, Risk of blindness

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### 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, 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: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>),  
May produce toxic fumes of carbon monoxide if burning.

### 5.3 Advice for firefighters

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

## 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 dust.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

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

#### Advice on how to contain a spill

Covering of drains. 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. 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.

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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.

#### 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.

#### 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: 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)

| Country | Name of agent      | CAS No | Identifier | TWA [mg/m <sup>3</sup> ] | STEL [mg/m <sup>3</sup> ] | Ceiling-C [mg/m <sup>3</sup> ] | 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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| Relevant DNELs of components of the mixture |          |           |                         |                                    |                   |                            |
|---|----------|-----------|-------------------------|------------------------------------|-------------------|----------------------------|
| Name of substance                           | CAS No   | End-point | Threshold level         | Protection goal, route of exposure | Used in           | Exposure time              |
| TRIS  | 77-86-1  | DNEL      | 117,5 mg/m <sup>3</sup> | human, inhalatory                  | worker (industry) | chronic - systemic effects |
| TRIS  | 77-86-1  | DNEL      | 166,7 mg/kg bw/day      | human, dermal                      | worker (industry) | chronic - systemic effects |
| Sodium dodecyl sulphate                     | 151-21-3 | DNEL      | 285 mg/m <sup>3</sup>   | human, inhalatory                  | worker (industry) | chronic - systemic effects |
| Sodium dodecyl sulphate                     | 151-21-3 | DNEL      | 4,060 mg/kg bw/day      | human, dermal                      | worker (industry) | chronic - systemic effects |

| Relevant PNECs of components of the mixture |          |           |                 |                       |                              |                              |
|---|----------|-----------|-----------------|-----------------------|------------------------------|------------------------------|
| Name of substance                           | CAS No   | End-point | Threshold level | Organism              | Environmental compartment    | Exposure time                |
| TRIS  | 77-86-1  | PNEC      | 300 mg/l        | aquatic organisms     | sewage treatment plant (STP) | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 0,176 mg/l      | aquatic organisms     | freshwater                   | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 0,018 mg/l      | aquatic organisms     | marine water                 | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 1,35 mg/l       | aquatic organisms     | sewage treatment plant (STP) | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 6,97 mg/kg      | aquatic organisms     | freshwater sediment          | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 0,697 mg/kg     | aquatic organisms     | marine sediment              | short-term (single instance) |
| Sodium dodecyl sulphate                     | 151-21-3 | PNEC      | 1,29 mg/kg      | terrestrial organisms | soil                         | short-term (single instance) |

## 8.2 Exposure controls

### Individual protection measures (personal protective equipment)

#### Eye/face protection



Use safety goggle with side protection.

#### Skin protection



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### • 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

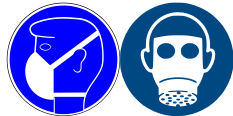
### • breakthrough times of the glove material

>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). P1 (filters at least 80 % of airborne particles, colour code: White).

### 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   | solid   |
| Form   | powder  |
| Colour   | white   |
| Odour  | this information is not available                         |
| 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  |

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|   |  |
|---|--|
| pH (value)  | 8,3 (in aqueous solution: 50 g/l, 25 °C) (aqueous solution of the substance) |
| Kinematic viscosity                                 | not relevant   |
| <u>Solubility(ies)</u>                              |  |
| Water solubility                                    | (soluble)  |
| <u>Partition coefficient</u>                        |  |
| Partition coefficient n-octanol/water (log value):  | this information is not available  |
| Vapour pressure                                     | not determined   |
| <u>Density and/or relative density</u>              |  |
| Density   | not determined   |
| Relative vapour density                             | information on this property is not available                                |
| Particle characteristics                            | No data available.   |
| <u>Other safety parameters</u>                      |  |
| Oxidising properties                                | none   |
| <b>9.2 Other information</b>                        |  |
| Information with regard to physical hazard classes: | hazard classes acc. to GHS (physical hazards): not relevant                  |
| Other safety characteristics:                       | There is no additional information.  |

## 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, Strong alkali

### 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.



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## SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

#### Classification procedure

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

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

#### Acute toxicity

Shall not be classified as acutely toxic.

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

| Name of substance       | CAS No   | Exposure route        | ATE         |
|-------------------------|----------|-----------------------|-------------|
| Sodium dodecyl sulphate | 151-21-3 | oral                  | 1.200 mg/kg |
| Sodium dodecyl sulphate | 151-21-3 | inhalation: dust/mist | 3,9 mg/l/4h |

#### Acute toxicity of components of the mixture

| Name of substance       | CAS No   | Exposure route | Endpoint | Value        | Species |
|-------------------------|----------|----------------|----------|--------------|---------|
| Glycine                 | 56-40-6  | oral           | LD50     | 7.930 mg/kg  | rat     |
| TRIS                    | 77-86-1  | oral           | LD50     | >5.000 mg/kg | rat     |
| TRIS                    | 77-86-1  | dermal         | LD50     | >5.000 mg/kg | rat     |
| Sodium dodecyl sulphate | 151-21-3 | oral           | LD50     | 1.200 mg/kg  | rat     |
| Sodium dodecyl sulphate | 151-21-3 | dermal         | LD50     | >2.000 mg/kg | rat     |

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

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).

#### Specific target organ toxicity - repeated exposure

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

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### 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 damage, risk of blindness

#### • If inhaled

Inhalation of dust may cause irritation of the respiratory system

#### • If on skin

Frequently or prolonged contact with skin may cause dermal irritation

#### • Other information

none

### 11.2 Endocrine disrupting properties

None of the ingredients are listed.

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

| Aquatic toxicity (acute) of components of the mixture |          |          |             |                       |               |
|---|----------|----------|-------------|-----------------------|---------------|
| Name of substance                                     | CAS No   | Endpoint | Value       | Species               | Exposure time |
| Glycine   | 56-40-6  | LC50     | >1.000 mg/l | fish                  | 96 h          |
| Glycine   | 56-40-6  | EC50     | >220 mg/l   | aquatic invertebrates | 48 h          |
| TRIS  | 77-86-1  | EC50     | >980 mg/l   | aquatic invertebrates | 48 h          |
| TRIS  | 77-86-1  | ErC50    | 473 mg/l    | algae                 | 48 h          |
| Sodium dodecyl sulphate                               | 151-21-3 | LC50     | 29 mg/l     | fish                  | 96 h          |
| Sodium dodecyl sulphate                               | 151-21-3 | ErC50    | >120 mg/l   | algae                 | 72 h          |

| Aquatic toxicity (chronic) of components of the mixture |          |          |             |                |               |
|---|----------|----------|-------------|----------------|---------------|
| Name of substance                                       | CAS No   | Endpoint | Value       | Species        | Exposure time |
| TRIS  | 77-86-1  | EC50     | >1.000 mg/l | microorganisms | 3 h           |
| Sodium dodecyl sulphate                                 | 151-21-3 | EC50     | 135 mg/l    | microorganisms | 3 h           |

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### Biodegradation

Data are not available.

### 12.2 Process of degradability

| Degradability of components of the mixture |          |                           |                  |      |        |        |
|--|----------|---------------------------|------------------|------|--------|--------|
| Name of substance                          | CAS No   | Process                   | Degradation rate | Time | Method | Source |
| Glycine                                    | 56-40-6  | oxygen depletion          | 76 – 82 %        | 14 d |        | ECHA   |
| TRIS                                       | 77-86-1  | biotic/abiotic            | 89 %             | 28 d |        |        |
| TRIS                                       | 77-86-1  | oxygen depletion          | 100,7 %          | 28 d |        | ECHA   |
| TRIS                                       | 77-86-1  | carbon dioxide generation | 65,9 %           | 28 d |        | ECHA   |
| TRIS                                       | 77-86-1  | DOC removal               | 97,1 %           | 28 d |        | ECHA   |
| Sodium dodecyl sulphate                    | 151-21-3 | biotic/abiotic            | 90 %             | 28 d |        |        |
| Sodium dodecyl sulphate                    | 151-21-3 | carbon dioxide generation | 95 %             | 28 d |        | ECHA   |

### 12.3 Bioaccumulative potential

Data are not available.

| Bioaccumulative potential of components of the mixture |          |     |                |          |
|--|----------|-----|----------------|----------|
| Name of substance                                      | CAS No   | BCF | Log KOW        | BOD5/COD |
| Glycine  | 56-40-6  |     | -3,21          |          |
| TRIS   | 77-86-1  |     | -1,56 (20 °C)  |          |
| Sodium dodecyl sulphate                                | 151-21-3 |     | ≤-2,03 (20 °C) |          |

### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

Data are not available.

### 12.6 Endocrine disrupting properties

None of the ingredients are listed.

### 12.7 Other adverse effects

Data are not available.

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## 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.

### 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.

### 13.3 Remarks

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

## SECTION 14: Transport information

- |  |   |
|--|---|
| 14.1 UN number or ID number  | not subject to transport regulations                                  |
| 14.2 UN proper shipping name   | not assigned  |
| 14.3 Transport hazard class(es)  | none  |
| 14.4 Packing group   | not assigned  |
| 14.5 Environmental hazards   | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user  | There is no additional information.                                   |
| 14.7 Maritime transport in bulk according to IMO instruments   | The cargo is not intended to be carried in bulk.                      |
| 14.8 <u>Information for each of the UN Model Regulations</u>   |   |
| <b>Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information</b> | Not subject to ADR, RID and ADN.                                      |
| <b>International Maritime Dangerous Goods Code (IMDG) - Additional information</b>                           | Not subject to IMDG.  |
| <b>International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information</b>                    | Not subject to ICAO-IATA.   |

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## 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 |
| Sodium dodecyl sulphate                                    | flammable / pyrophoric                          |        | R40         | 40 |
| Sodium dodecyl sulphate                                    | substances in tattoo inks and permanent make-up |        | R75         | 75 |

#### Legend

- R40
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
    - metallic glitter intended mainly for decoration,
    - artificial snow and frost,
    - 'whoopee' cushions,
    - silly string aerosols,
    - imitation excrement,
    - horns for parties,
    - decorative flakes and foams,
    - artificial cobwebs,
    - stink bombs.
  2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:  
'For professional users only'.
  3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
  4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

### 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:  
(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.

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### Legend

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

| 2012/18/EU (Seveso III) |                                       |   |       |
|-------------------------|---------------------------------------|---|-------|
| No                      | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | Notes |
|                         | not assigned                          |   |       |

### Deco-Paint Directive

|             |       |
|-------------|-------|
| VOC content | 5,5 % |
|-------------|-------|

### Industrial Emissions Directive (IED)

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

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

none of the ingredients are listed

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

none of the ingredients are listed

### Water Framework Directive (WFD)

| List of pollutants (WFD) |                            |        |           |         |
|--------------------------|----------------------------|--------|-----------|---------|
| Name of substance        | Name acc. to inventory     | CAS No | Listed in | Remarks |
| Sodium dodecyl sulphate  | Metals and their compounds |        | a)        |         |

### Legend

A) Indicative list of the main pollutants

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

none of the ingredients are listed

### Regulation on drug precursors

none of the ingredients are listed

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

none of the ingredients are listed

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

none of the ingredients are listed

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### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

### Other information

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

### National inventories

| Country | Inventory  | Status                     |
|---------|------------|----------------------------|
| AU      | AIIC       | all ingredients are listed |
| CA      | DSL        | all ingredients are listed |
| CN      | IECSC      | all ingredients are listed |
| EU      | ECSI       | all ingredients are listed |
| EU      | REACH Reg. | all ingredients are listed |
| JP      | CSCL-ENCS  | all ingredients are listed |
| KR      | KECI       | all ingredients are listed |
| MX      | INSQ       | all ingredients are listed |
| NZ      | NZIoC      | all ingredients are listed |
| PH      | PICCS      | all ingredients are listed |
| TR      | CICR       | all ingredients are listed |
| TW      | TCSI       | all ingredients are listed |
| US      | TSCA       | all ingredients are listed |

#### Legend

|            |   |
|------------|---|
| AIIC       | Australian Inventory of Industrial Chemicals                            |
| CICR       | Chemical Inventory and Control Regulation                               |
| CSCL-ENCS  | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL        | Domestic Substances List (DSL)  |
| ECSI       | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC      | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ       | National Inventory of Chemical Substances                               |
| KECI       | Korea Existing Chemicals Inventory                                      |
| NZIoC      | New Zealand Inventory of Chemicals                                      |
| PICCS      | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| REACH Reg. | REACH registered substances   |
| TCSI       | Taiwan Chemical Substance Inventory                                     |
| TSCA       | Toxic Substance Control Act   |

## 15.2 Chemical Safety Assessment

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

## SECTION 16: Other information

### Indication of changes (revised safety data sheet)

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

Restructuring: section 9, section 14



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| Section | Former entry (text/value)                             | Actual entry (text/value)  | Safety-relevant |
|---------|---|--|-----------------|
| 2.1     |   | Classification according to Regulation (EC) No 1272/2008 (CLP):<br>change in the listing (table)                             | yes             |
| 2.3     | Other hazards:<br>There is no additional information. | Other hazards  | yes             |
| 2.3     |   | Results of PBT and vPvB assessment:<br>This mixture does not contain any substances that are assessed to be a PBT or a vPvB. | yes             |

### 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)   |
| Aquatic Chronic | Hazardous to the aquatic environment - chronic hazard   |
| ATE             | Acute Toxicity Estimate   |
| BCF             | Bioconcentration factor   |
| BOD             | Biochemical Oxygen Demand   |
| 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  |
| COD             | Chemical oxygen demand  |
| DGR             | Dangerous Goods Regulations (see IATA/DGR)  |
| DNEL            | Derived No-Effect Level   |
| EC50            | Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance 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   |
| 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   |
| Flam. Sol.      | Flammable solid   |
| GHS             | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations   |
| IATA            | International Air Transport Association   |

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| Abbr.                | Descriptions of used abbreviations  |
|----------------------|---|
| IATA/DGR             | Dangerous Goods Regulations (DGR) for the air transport (IATA)  |
| ICAO                 | International Civil Aviation Organization   |
| 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  |
| log KOW              | n-Octanol/water   |
| NLP                  | No-Longer Polymer   |
| 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) |
| S.I. No. 619 of 2001 | Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001   |
| Skin Corr.           | Corrosive to skin   |
| Skin Irrit.          | Irritant to skin  |
| STEL                 | Short-term exposure limit   |
| STOT SE              | Specific target organ toxicity - single exposure  |
| SVHC                 | Substance of Very High Concern  |
| TWA                  | Time-weighted average   |
| VOC                  | Volatile Organic Compounds  |
| vPvB                 | Very Persistent and very Bioaccumulative  |

### Key literature references and sources for data

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

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).

### Classification procedure

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

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

| Code | Text   |
|------|--|
| H228 | Flammable solid.                                   |
| H302 | Harmful if swallowed.                              |
| H315 | Causes skin irritation.                            |
| H318 | Causes serious eye damage.                         |
| H332 | Harmful if inhaled.                                |
| H335 | May cause respiratory irritation.                  |
| H412 | Harmful 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.