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

NDF-solution (neutral detergent solution)

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

Product identifier 1.1

Identification of the substance **NDF-solution** (neutral detergent solution)

Article number 9943

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

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

with foodstuffs. Do not use for private purposes

(household).

1.3 Details of the supplier of the safety data sheet

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

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

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

sheet:

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

1.4 **Emergency telephone number**

SECTION 2: Hazards identification

Classification of the substance or mixture 2.1

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

| Section | Hazard class | Cat- egory | Hazard class and category | Hazard statement |
|---------|-----------------------|---------------|---------------------------|---------------------|
| 3.7 | Reproductive toxicity | 1B | Repr. 1B | H360FD |

For full text of abbreviations: see SECTION 16

2.2 **Label elements**

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

Signal word Danger

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Pictograms

GHS08



Hazard statements

H360FD May damage fertility. May damage the unborn child

Precautionary statements

Precautionary statements - prevention

P201 Obtain special instructions before use

P280 Wear protective gloves/eye protection/face 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

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

For professional users only

Hazardous ingredients for labelling: Di-Sodium tetraborate decahydrate

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)



H360FD May damage fertility. May damage the unborn child.

P201 Obtain special instructions before use.

P280 Wear protective gloves/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

contains: Di-Sodium tetraborate decahydrate

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 |
|--|---|------|--|------------|--------|
| Ethylenediamine tet- raacetic acid disodi- um salt dihydrate | CAS No 6381-92-6 EC No 205-358-3 | 1-<5 | Acute Tox. 4 / H332 STOT RE 2 / H373 | <u>(1)</u> | |
| di-Sodium tetraborate decahydrate | CAS No 1303-96-4 EC No 215-540-4 Index No 005-011-00-4 | <1 | Eye Irrit. 2 / H319 Repr. 1B / H360FD | ! | GHS-HC |

Notes

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

| Name of sub- stance | Identifier | Specific Conc. Limits | M-Factors | ATE | Exposure route |
|---|---------------------|-----------------------|-----------|-------------------------------------|---------------------------|
| Ethylenediam- ine tetraacetic acid disodium | CAS No 6381-92-6 | - | - | >1 ^{mg} / _l /4h | inhalation: dust/ mist |
| salt dihydrate | EC No 205-358-3 | | | | |

Substance of Very High Concern (SVHC)

| Name of substance | Name acc. to invent- ory | CAS No | EC No | Listed in | Remarks |
|--------------------------------------|--------------------------------------|-----------|-----------|----------------|------------|
| di-Sodium tetraborate decahydrate | disodium tetraborate, an- hydrous | 1330-43-4 | 215-540-4 | Candidate list | Repr. A57c |

Legend

candidate Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV list

Repr. A57c Toxic for reproduction (article 57c)

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.

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Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

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

Irritant effects

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, alcohol resistant foam, 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: Nitrogen oxides (NOx)

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 vapour/spray.

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.

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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.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid exposure.

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

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

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)

This information is not available.

Relevant DNELs of components of the mixture

| Name of sub- stance | CAS No | End- point | Threshol d level | Protection goal, route of exposure | Used in | Exposure time | |
|---|--------------------|---------------|------------------------|--|-------------------|-------------------------------|--|
| Ethylenediamine tetraacetic acid dis- odium salt di- hydrate | 6381-92-6 | DNEL | 1,5 mg/m³ | human, inhalat- ory | worker (industry) | chronic - local ef- fects | |
| Ethylenediamine tetraacetic acid dis- odium salt di- hydrate | 6381-92-6 | DNEL | 3 mg/m³ | human, inhalat- ory | worker (industry) | acute - local ef- fects | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 DNEL 6,7 | | 6,7 mg/m ³ | human, inhalat- ory | worker (industry) | chronic - systemic effects | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 | DNEL | 316,4 mg/ kg bw/day | human, dermal | worker (industry) | chronic - systemic effects | |

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Relevant PNECs of components of the mixture

| Name of sub- stance | | | Threshol d level | Organism | Environmental compartment | Exposure time | | | |
|---|----------------------|---|--|----------------------------|---------------------------------|---------------------------------|--|--|--|
| Ethylenediamine tetraacetic acid dis- odium salt di- hydrate | acid dis- alt di- | | 2,2 ^{mg} / _l | aquatic organ- isms | freshwater | short-term (single instance) | | | |
| Ethylenediamine tetraacetic acid dis- odium salt di- hydrate | 6381-92-6 | 12-6 PNEC 0,22 ^{mg} / _I aquatic organisms | | marine water | short-term (single instance) | | | | |
| Ethylenediamine tetraacetic acid dis- odium salt di- hydrate | 6381-92-6 | PNEC | 43 ^{mg} / _l | aquatic organ- isms | sewage treatment plant (STP) | short-term (single instance) | | | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 | PNEC | 2,9 ^{mg} / _l | aquatic organ- isms | freshwater | short-term (single instance) | | | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 | PNEC | 2,9 ^{mg} / _l | aquatic organ- isms | | | | | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 | PNEC | PNEC 10 ^{mg} / _l aquatic organisms sev | | sewage treatment plant (STP) | short-term (single instance) | | | |
| di-Sodium tetrabor- ate decahydrate | 1303-96-4 | PNEC | 5,7 ^{mg} / _{kg} | terrestrial organ- isms | 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





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)

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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: Aerosol or mist formation. P2 (filters at least 94 % 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 liquid

Colour colourless

Odour faintly perceptible

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling ~100 °C at 1.013 hPa

range

Flammability non-combustible

Lower and upper explosion limit 0,9 vol% (LEL) - 9,2 vol% (UEL)

Flash point not determined
Auto-ignition temperature not determined
Decomposition temperature not relevant

pH (value) ~7 (20 °C)

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): not relevant (inorganic)

Vapour pressure 23 hPa at 20 °C

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Density and/or relative density

Density 1,016 g/_{cm³} at 20 °C

Relative vapour density information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

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

Other safety characteristics:

Miscibility completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No known hazardous reactions.

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

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.

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Acute toxicity estimate (ATE) of components of the mixture

| Name of substance | CAS No | Exposure route | ATE |
|---|-----------|-----------------------|-------------------------------------|
| Ethylenediamine tetraacetic acid disodium salt dihydrate | 6381-92-6 | inhalation: dust/mist | >1 ^{mg} / _l /4h |

Acute toxicity of components of the mixture

| Name of substance | CAS No | Exposure route | Endpoint | Value | Species |
|---|-----------|----------------|----------|--------------------------------------|---------|
| Ethylenediamine tetraacetic acid dis- odium salt dihydrate | 6381-92-6 | oral | LD50 | 2.800 ^{mg} / _{kg} | rat |
| di-Sodium tetraborate decahydrate | 1303-96-4 | oral | LD50 | >2.500 ^{mg} / _{kg} | rat |
| di-Sodium tetraborate decahydrate | 1303-96-4 | dermal | LD50 | >2.000 ^{mg} / _{kg} | rabbit |

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

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

Respiratory or skin sensitisation

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

May damage the unborn child. May damage fertility.

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).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

vomiting, nausea

• If in eyes

causes slight to moderate irritation

If inhaled

Data are not available.

• If on skin

irritant effects

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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 sub- stance | CAS No | Endpoint | Value | Species | Exposure time |
|--|-----------|----------|----------------------------------|-------------------------------------|------------------|
| Ethylenediamine tet- raacetic acid disodi- um salt dihydrate | 6381-92-6 | LC50 | 41 ^{mg} / _l | bluegill (Lepomis mac- rochirus) | 96 h |
| Ethylenediamine tet- raacetic acid disodi- um salt dihydrate | 6381-92-6 | EC50 | 610 ^{mg} / _l | daphnia magna | 24 h |

Aquatic toxicity (chronic) of components of the mixture

| Name of sub- stance | CAS No | Endpoint | Value | Species | Exposure time |
|--|-----------|----------|---------------------------------|--------------------|------------------|
| Ethylenediamine tet- raacetic acid disodi- um salt dihydrate | 6381-92-6 | EC50 | 56 ^{mg} / _l | Pseudomonas putida | 8 h |

12.2 Persistence and degradability

Data are not available.

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 |
|--|-----------|-----|------------------------------|----------|
| Ethylenediamine tetraacetic acid disodium salt dihydrate | 6381-92-6 | 1,8 | | |
| di-Sodium tetraborate decahy- drate | 1303-96-4 | | -1,53 (pH value: 7,5, 22 °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.

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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.

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 10 toxic for reproduction

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 num | ber or ID num | ber n | าot sub | iect to | trans | port red | gulations |
|------|--------|---------------|--------------|---------|---------|-------|----------|-----------|
| | | | | | | | | |

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 dan-

gerous 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 Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information Not subject to IMDG.

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

Not subject to ICAO-IATA.

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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 |
|-----------------------------------|--|--------|-------------|----|
| NDF-solution | this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC | | R3 | 3 |
| di-Sodium tetraborate decahydrate | toxic for reproduction | | R28-30 | 30 |
| di-Sodium tetraborate decahydrate | substances in tattoo inks and perman- ent make-up | | R75 | 75 |

Legend

- R28-30 1. Shall not be placed on the market, or used,
 - as substances
 - as constituents of other substances, or,
 - in mixtures.

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'.
- 2. By way of derogation, paragraph 1 shall not apply to:
 (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
 (b) cosmetic products as defined by Directive 76/768/EEC;

- (c) the following fuels and oil products:
 motor fuels which are covered by Directive 98/70/EC,
- mineral oil products intended for use as fuel in mobile or fixed combustion plants,

- fuels sold in closed systems (e.g. liquid gas bottles);
 (d) artists' paints covered by Regulation (EC) No 1272/2008;
 (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;
 (f) devices covered by Regulation (EU) 2017/745.

 1. Shall not be used in:
- R3
 - 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
 - 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage"; (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage'; (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the g

 - 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

(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

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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Legend

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

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market of a mixture for tattooing purposes, or to the dask 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, 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

| Substance of Very High Concern (SVHC) | | | | | | |
|---------------------------------------|---------------|----------------|------------|-------------------------|----------------|------------------------|
| Name acc. to invent- ory | CAS No | Listed in | Remarks | Latest application date | Sunset date | Date of in- clusion |
| disodium tetraborate, an- hydrous | 1330- 43-4 | Candidate list | Repr. A57c | | | 18.06.2010 |

Legend

candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Toxic for reproduction (article 57c) Repr. A57c

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 – 10 % 3.236 ^g / _l |
|-------------|---|
|-------------|---|

Industrial Emissions Directive (IED)

| VOC content | 0,5 – 1 % |
|--|-----------------------------------|
| VOC content (Water content was discounted) | 323,6 ^g / _l |

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)

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List of pollutants (WFD) Name of substance **CAS No** Listed in **Remarks** Name acc. to inventory di-Sodium tetraborate decahy-Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment di-Sodium tetraborate decahy-Metals and their compounds a) drate Ethylenediamine tetraacetic acid Metals and their compounds a) disodium salt dihydrate

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

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 | not 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 | not all ingredients are listed |
| KR | KECI | not all ingredients are listed |
| MX | INSQ | all ingredients are listed |
| NZ | NZIoC | all ingredients are listed |
| PH | PICCS | all ingredients are listed |
| | | |

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| Country | Inventory | Status |
|---------|-----------|--------------------------------|
| TR | CICR | not all ingredients are listed |
| TW | TCSI | all ingredients are listed |
| US | TSCA | not all ingredients are listed |

Legend

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

CSCL-ENCS
DSL
Domestic Substances List (DSL)
ECSI
ECS 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
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)

| Section | Former entry (text/value) | Actual entry (text/value) | Safety- relev- ant |
|---------|--|---|--------------------------|
| 2.2 | Hazardous ingredients for labelling: 2-Ethoxyethanol, Di-Sodium tetraborate decahy- drate | Hazardous ingredients for labelling: Di-Sodium tetraborate decahydrate | yes |
| 2.2 | contains: 2-Ethoxyethanol, Di-Sodium tetraborate decahy- drate | contains: Di-Sodium tetraborate decahydrate | yes |
| 14.8 | Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information: Not subject to ADR, RID and ADN. | | yes |
| 15.1 | | Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table) | yes |
| 15.1 | | Substance of Very High Concern (SVHC): change in the listing (table) | yes |
| 15.1 | VOC content: 5 – 10 % 1.925 ⁹ / _I | VOC content: 5 – 10 % 3.236 ^g / _l | yes |
| 15.1 | VOC content (Water content was discounted): 192,5 ⁹ / _l | VOC content (Water content was discounted): 323,6 ^g / _l | yes |
| 15.1 | | List of pollutants (WFD): change in the listing (table) | yes |
| 15.1 | | National inventories: change in the listing (table) | yes |

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Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations | |
|------------|---|--|
| Acute Tox. | Acute toxicity | |
| ADR | Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road) | |
| 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) | |
| 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 ident fier of substances commercially available within the EU (European Union) | |
| EINECS | European Inventory of Existing Commercial Chemical Substances | |
| ELINCS | European List of Notified Chemical Substances | |
| Eye Dam. | Seriously damaging to the eye | |
| Eye Irrit. | Irritant to the eye | |
| GHS | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions | |
| IATA | International Air Transport Association | |
| 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 specified time interval | |
| LEL | Lower explosion limit (LEL) | |
| 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 | |
| Repr. | Reproductive toxicity | |

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| Abbr. | Descriptions of used abbreviations |
|---------|--|
| STOT RE | Specific target organ toxicity - repeated exposure |
| SVHC | Substance of Very High Concern |
| UEL | Upper explosion limit (UEL) |
| 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). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

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

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

| Code | Text |
|--------|--|
| H319 | Causes serious eye irritation. |
| H332 | Harmful if inhaled. |
| H360FD | May damage fertility. May damage the unborn child. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |

Disclaimer

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

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