

# Safety data sheet

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



**ROTI®Fair 0.5M EDTA 500ml / pouch**

article number: **1031**

Version: **1.0 en**

date of compilation: 10.03.2025

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

### 1.1 Product identifier

Identification of the substance **ROTI®Fair 0.5M EDTA 500ml / pouch**  
Article number 1031  
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). Food, drink and animal feeding-stuffs.

### 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

### 1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
Giftzentrale München	Ismaninger Str. 22	81675 München	+49/(0)89 19240	www.toxikologie.mri.tum.de

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.9	Specific target organ toxicity - repeated exposure	2	STOT RE 2	H373

For full text of abbreviations: see SECTION 16

**The most important adverse physicochemical, human health and environmental effects**

Delayed or immediate effects can be expected after short or long-term exposure.



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## 2.3 Other hazards

### Results of PBT and vPvB assessment

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

### Endocrine disrupting properties

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





## SECTION 3: Composition/information on ingredients

### 3.1 Substances

not relevant (mixture)

### 3.2 Mixtures

#### Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Ethylenediamine tetraacetic acid disodium salt dihydrate	CAS No 6381-92-6  EC No 205-358-3	60 – 80	Acute Tox. 4 / H332 STOT RE 2 / H373	 	
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	CAS No 13235-36-4  EC No 603-569-9	25 – 40	Acute Tox. 4 / H302 Eye Dam. 1 / H318	 	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 substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ethylenediamine tetraacetic acid disodium salt dihydrate	CAS No 6381-92-6  EC No 205-358-3	-	-	$>1 \text{ mg}/4\text{h}$	inhalation: dust/mist
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	CAS No 13235-36-4  EC No 603-569-9	-	-	$>1.780 \text{ mg}/\text{kg}$	oral

#### Remarks

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.

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## 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 holding 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

Risk of blindness, Risk of serious damage to eyes

## 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, alcohol resistant foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

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

Combustible.

#### Hazardous combustion products

In case of fire may be liberated: 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. Retain contaminated washing water and dispose of it.

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## 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.

## 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

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

### Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

storage class (LGK):

### 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
DE	dust		AGW	10	20		Y, i	TRGS 900
DE	dust		AGW	1,25	2,5		Y, r	TRGS 900

#### Notation

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

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### Notation

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)
Y	A risk of developmental toxicity does not need to be expected if the occupational exposure limit value and the biological limit value (BGW) are adhered to

### Relevant DNELs of components

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - systemic effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects

### Relevant PNECs of components

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	2,2 mg/l	aquatic organisms	freshwater	short-term (single instance)
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	0,22 mg/l	aquatic organisms	marine water	short-term (single instance)
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	PNEC	43 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	2,83 mg/l	aquatic organisms	freshwater	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	0,283 mg/l	aquatic organisms	marine water	short-term (single instance)

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Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	50 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	1,1 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



#### • hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### • material thickness

>0,11 mm

#### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### • other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### Respiratory protection



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

Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (DGUV-Rule 112/190).

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### Environmental exposure controls

Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	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 relevant (solid)
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	7,95 – 8,05 (25 °C)
Kinematic viscosity	not relevant

#### Solubility(ies)

Water solubility ~100 g/l at 20 °C (soluble)

#### Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure not determined

#### Density and/or relative density

Density not determined

Relative vapour density not relevant (solid)

Particle characteristics No data available.

#### Other safety parameters

Oxidising properties none

### 9.2 Other information

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



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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

### 10.4 Conditions to avoid

Keep away from heat.

### 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

Harmful if inhaled.

Acute toxicity estimate (ATE) of components			
Name of substance	CAS No	Exposure route	ATE
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	inhalation: dust/mist	>1 mg/l/4h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oral	>1.780 mg/kg

Acute toxicity of components					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	oral	LD50	2.800 mg/kg	rat
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oral	LD50	>1.780 - < 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.

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### 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

May cause damage to organs (respiratory system) through prolonged or repeated exposure (if inhaled).

Hazard category	Target organ	Exposure route
2	respiratory system	if inhaled

### 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

cough, pain, choking, and breathing difficulties, varying degrees of pulmonary injury

#### • If on skin

Data are not available.

#### • Other information

none

### 11.2 Endocrine disrupting properties

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

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment.

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV):

WGK 2, obviously hazardous to water (Germany)

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### Aquatic toxicity (acute) of components

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	LC50	41 mg/l	bluegill ( <i>Lepomis macrochirus</i> )	96 h
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	EC50	610 mg/l	daphnia magna	24 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	LC50	>100 mg/l	fish	96 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	EC50	>114 mg/l	aquatic invertebrates	48 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	ErC50	>60 mg/l	algae	72 h

### Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	EC50	56 mg/l	<i>Pseudomonas putida</i>	8 h
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	NOEC	25,7 mg/l	zebra fish ( <i>Danio rerio</i> )	35 d
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	LOEC	50 mg/l	daphnia magna	21 d
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	NOEC	≥35,1 mg/l	fish	35 d
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	LOEC	50 mg/l	aquatic invertebrates	21 d

## 12.2 Persistence and degradability

0,6331 mg/mg

### Degradability of components

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oxygen depletion	78 %	56 d		ECHA

## 12.3 Bioaccumulative potential

Data are not available.

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Bioaccumulative potential of components				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Ethylenediamine tetraacetic acid disodium salt dihydrate	6381-92-6	1,8		
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	1,8	-13,17 (25 °C)	

## 12.4 Mobility in soil

Data are not available.

## 12.5 Results of PBT and vPvB assessment

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

## 12.6 Endocrine disrupting properties

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

## 12.7 Other adverse effects

Data are not available.

## 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.

#### Waste treatment of containers/packagings

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

### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

#### Properties of waste which render it hazardous

- HP 4 irritant - skin irritation and eye damage
- HP 5 specific target organ toxicity (STOT)/aspiration toxicity
- HP 6 acute toxicity

### 13.3 Remarks

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

## SECTION 14: Transport information

14.1 UN number or ID number	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 dan-

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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

### Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Not subject to ADR, RID and ADN.

### 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.

## 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
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	substances in tattoo inks and permanent make-up		R75	75

#### Legend

- R75 1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
- (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

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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.

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	0 %
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### Industrial Emissions Directive (IED)

VOC content	0 %
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### 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
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	Metals and their compounds		a)	
Ethylenediamine tetraacetic acid disodium salt dihydrate	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

### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

### National regulations (Germany)

### Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water)(AwSV)

Wassergefährdungsklasse, WGK 2 (obviously hazardous to water)  
(water hazard class):

### Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass concentration	Notation
5.2.1	total dust, including micro-dust		≥ 25 wt%	0,2 kg/h	20 mg/m <sup>3</sup>	2)

#### Notation

2) Even with a mass flow smaller than or equal to 0.20 kg/h, a mass concentration of 0.15 g/m<sup>3</sup> in waste gas may not be exceeded

### Storage of hazardous substances in non-stationary containers (TRGS 510) (Germany)

Storage class (LGK): 11 (combustible solids)



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### 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	not 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

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

## SECTION 16: Other information

### 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)
AGW	Workplace exposure limit
ATE	Acute Toxicity Estimate



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Abbr.	Descriptions of used abbreviations
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)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
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
LGK	Lagerklasse (storage class according to TRGS 510, Germany)
LOEC	Lowest Observed Effect Concentration
log KOW	n-Octanol/water
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure

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Abbr.	Descriptions of used abbreviations
SVHC	Substance of Very High Concern
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)
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.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties. 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
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H373	May cause damage to organs (respiratory system) through prolonged or repeated exposure (if inhaled).

### Disclaimer

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