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



#### Kjeldahl tablets TCT (3,71 g)

article number: **9763** Version: **3.0 en** Replaces version of: 2017-02-03 Version: (2)

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

### 1.1 Product identifier

Identification of the substance

Article number

Registration number (REACH)

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not relevant (mixture)

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

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

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

# **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	2	Eye Irrit. 2	H319
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	Hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16

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# ° ROTH

### **The most important adverse physicochemical, human health and environmental effects** Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word Warning

Pictograms

GHS07, GHS09



#### **Hazard statements**

H319	Causes serious eye irritation
H410	Very toxic to aquatic life with long lasting effects

#### **Precautionary statements**

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

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

#### **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

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

Signal word: Warning

Symbol(s)



#### 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		
Potassium sulphate	CAS No 7778-80-5	≥80					
	EC No 231-915-5						
	REACH Reg. No 01-2119489441- 34-xxxx						
Titanium(IV) oxide	CAS No 13463-67-7	2,5 - < 10					
	EC No 236-675-5						
	REACH Reg. No 01-2119489379- 17-xxxx						
Copper(II) sulphate pentahydrate	CAS No 7758-99-8	2,5 - < 10	Acute Tox. 4 / H302 Eye Dam. 1 / H318		GHS-HC		
	EC No 616-477-9		Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	¥,			
	Index No 029-023-00-4						
	REACH Reg. No 01-2119520566- 40-xxxx						

#### 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	<b>M-Factors</b>	ΑΤΕ	Exposure route
Copper(II) sulph- ate pentahy- drate	CAS No 7758-99-8 EC No 616-477-9 Index No 029-023-00-4	-	M-factor (acute) = 10.0	481 <sup>mg</sup> / <sub>kg</sub>	oral

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.

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

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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

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

#### **Following ingestion**

Rinse mouth. Call a doctor if you feel unwell.

- **4.2 Most important symptoms and effects, both acute and delayed** Irritation
- **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

Non-combustible.

#### 5.3 Advice for firefighters

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

### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

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

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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

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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.

#### 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 protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

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

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place.

#### 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**

#### **Control parameters** 8.1

#### National limit values

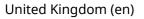
#### **Occupational exposure limit values (Workplace Exposure Limits)**

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
GB	titanium dioxide	13463-67-7	WEL	10			i	EH40/2005
GB	titanium dioxide	13463-67-7	WEL	4			r	EH40/2005

Notation

Inhalable fraction

Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified) STEL





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

Respirable fraction

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



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#### Notation TWA

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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)

Relevant DNELs of components of the mixture									
Name of sub- stance	CAS No	lo End- point Threshol Protection d level goal, route of exposure		Used in	Exposure time				
Potassium sulphate	lphate 7778-80-5 DNEL 21,3 mg/kg human, dermal worker (indus					chronic - systemic effects			
Potassium sulphate	7778-80-5	DNEL	37,6 mg/ m <sup>3</sup>	human, inhalat- ory	worker (industry)	chronic - systemic effects			
Copper(II) sulphate pentahydrate	7758-99-8	DNEL	1 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects			
Copper(II) sulphate pentahydrate	7758-99-8	DNEL	1 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects			
Copper(II) sulphate pentahydrate	7758-99-8	DNEL	137 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects			

#### **Relevant PNECs of components of the mixture**

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Potassium sulphate	7778-80-5	PNEC	0,68 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Potassium sulphate	7778-80-5	PNEC	0,068 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	1 5	
Potassium sulphate	7778-80-5	PNEC	10 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Potassium sulphate	7778-80-5	PNEC	6,8 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	water	intermittent re- lease
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	7,8 <sup>µg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	5,2 <sup>µg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	230 <sup>µg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	87 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	676 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	marine sediment	short-term (single instance)
Copper(II) sulphate pentahydrate	7758-99-8	PNEC	65 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)

### 8.2 Exposure controls

Individual protection measures (personal protective equipment)

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

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#### **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 consider-able 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.



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

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# **SECTION 9: Physical and chemical properties**

9.1						
	Physical state	solid				
	Form	tablets				
	Colour	light blue				
	Odour	odourless				
	Melting point/freezing point	not determined				
	Boiling point or initial boiling point and boiling range	not determined				
	Flammability	non-combustible				
	Lower and upper explosion limit	not determined				
	Flash point	not applicable				
	Auto-ignition temperature	not determined				
	Decomposition temperature	not relevant				
	pH (value)	3,5 – 4,5 (in aqueous solution: 50 <sup>g</sup> / <sub>l</sub> , 20 °C)				
	Kinematic viscosity	not relevant				
	Solubility(ies)					
	Water solubility	120 <sup>g</sup> / <sub>l</sub> at 20 °C				
	Partition coefficient					
	Partition coefficient n-octanol/water (log value):	not relevant (inorganic)				
	Vapour pressure	not determined				
	Density	2,7 <sup>g</sup> / <sub>cm³</sub> at 20 °C				
	Relative vapour density	information on this property is not available				
	Particle characteristics	No data available.				
	Other safety parameters					
	Oxidising properties	none				
9.2	Other information					
	Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant				
	Other safety characteristics:	There is no additional information.				



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# **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

Violent reaction with: 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.

## **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.

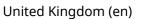
Acute toxicity estimate (ATE) of components of the mixture							
Name of substance         CAS No         Exposure route         ATE							
Copper(II) sulphate pentahydrate	7758-99-8	oral	481 <sup>mg</sup> / <sub>kg</sub>				

#### Acute toxicity of components of the mixture

<b>,</b> ,					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Potassium sulphate	7778-80-5	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat
Potassium sulphate	7778-80-5	oral	LD50	6.600 <sup>mg</sup> / <sub>kg</sub>	rat
Copper(II) sulphate pentahydrate	7758-99-8	oral	LD50	482 <sup>mg</sup> / <sub>kg</sub>	rat
Copper(II) sulphate pentahydrate	7758-99-8	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.





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

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#### Serious eye damage/eye irritation

Causes serious eye irritation.

### 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).

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

### Symptoms related to the physical, chemical and toxicological characteristics

#### • If swallowed

vomiting, nausea, gastrointestinal complaints

#### • If in eyes

Causes serious eye irritation

#### • If inhaled

Data are not available.

#### • If on skin

Data are not available.

#### 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

Very toxic to aquatic life with long lasting effects.

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

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Aquatic toxicity (a	atic toxicity (acute) of components of the mixture				
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Potassium sulphate	7778-80-5	LC50	680 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Copper(II) sulphate pentahydrate	7758-99-8	LC50	38,4 <sup>µg</sup> / <sub>l</sub>	fish	96 h

#### **Biodegradation**

The methods for determining the biological degradability are not applicable to inorganic substances.

12.2 Process of degradability

Data are not available.

- **12.3 Bioaccumulative potential** Data are not available.
- 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.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

#### Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

#### 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).

#### 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.

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#### **SECTION 14: Transport information** 14.1 UN number or ID number ADR/RID/ADN UN 3077 IMDG-Code UN 3077 ICAO-TI UN 3077 14.2 UN proper shipping name ADR/RID/ADN ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. IMDG-Code ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ICAO-TI Environmentally hazardous substance, solid, n.o.s. Technical name (hazardous ingredients) Copper(II) sulphate pentahydrate 14.3 Transport hazard class(es) 9 ADR/RID/ADN IMDG-Code 9 ICAO-TI 9 14.4 Packing group ADR/RID/ADN III IMDG-Code III ICAO-TI III 14.5 **Environmental hazards** hazardous to the aquatic environment Environmentally hazardous substance (aquatic Copper(II) sulphate pentahydrate environment): 14.6 Special precautions for user Provisions for dangerous goods (ADR) should be complied within the premises. Maritime transport in bulk according to IMO instruments 14.7 The cargo is not intended to be carried in bulk. 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

Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Particulars in the transport document	UN3077, ENVIRONMENTALLY HAZARDOUS SUB- STANCE, SOLID, N.O.S., (contains: Copper(II) sulphate pentahydrate), 9, III, (-)
Classification code	M7
Danger label(s)	9, "Fish and tree"

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Environmental hazards	<b>Yes</b> (hazardous to the aquatic environment)
Special provisions (SP)	274, 335, 375, 601
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	3
Tunnel restriction code (TRC)	-
Hazard identification No	90
Emergency Action Code	2Z
International Maritime Dangerous Goods Co	ode (IMDG) - Additional information
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Particulars in the shipper's declaration	UN3077, ENVIRONMENTALLY HAZARDOUS SUB- STANCE, SOLID, N.O.S., (contains: Copper(II) sulphate pentahydrate), 9, III
Marine pollutant	<b>Yes</b> (hazardous to the aquatic environment), (Copper(II) sulphate pentahydrate)
Danger label(s)	9, "Fish and tree"
Special provisions (SP)	274, 335, 966, 967, 969
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-F
Stowage category	A
International Civil Aviation Organization (IC	AO-IATA/DGR) - Additional information
Proper shipping name	Environmentally hazardous substance, solid, n.o.s.
Particulars in the shipper's declaration	UN3077, Environmentally hazardous substance, solid, n.o.s., (contains: Copper(II) sulphate pen- tahydrate), 9, III
Environmental hazards	<b>Yes</b> (hazardous to the aquatic environment)
Danger label(s)	9, "Fish and tree"
Special provisions (SP)	A97, A158, A179, A197, A215
Excepted quantities (EQ)	E1
Limited quantities (LQ)	30 kg

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

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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	Νο
Copper(II) sulphate pentahydrate	substances in tattoo inks and perman- ent make-up		R75	75

#### Legend

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such sub-stances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or R75 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 cat-egory 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: 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; mixture in a concentration equal to or greater than 0,00005 % by weight: (i) "Rinse-off products"; (i) "Not to be used in products applied on mucous membranes";
(ii) "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 in the conduction specified for that substance is present. (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 strictest is paragraph 1 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 apthat it then falls within a different one of those points from the one within which it fell previously, and the date of ap-plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 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. Im-writing the herearded as ingredients is 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



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



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#### Legend

this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredi-(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 concentra-

(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 para-

graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or gener-ate 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, the requirements of Regulation (EU) 2017/745 and of this provide the tatted of tatted of the tatted of the tatted of the tatted of tatted of the tatted of the tatted of the tatted of tatted of the tatted of tatt 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/	2012/18/EU (Seveso III)				
Νο	Dangerous substance/hazard categories Qualifying quantity (tonnes) for the application of lower and upper-tier re- quirements		Notes		
E1	environmental hazards (hazardous to the aquatic en- vironment, cat. 1)	100	200	56)	

#### Notation

56) Hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

#### **Deco-Paint Directive**

#### **Industrial Emissions Directive (IED)**

VOC content	0 %	
VOC content	0 <sup>g</sup> / <sub>l</sub>	

#### 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

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

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#### Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Titanium(IV) oxide	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		A)	
Titanium(IV) oxide	Metals and their compounds		A)	
Copper(II) sulphate pentahydrate	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		A)	
Copper(II) sulphate pentahydrate	Metals and their compounds		A)	
Potassium 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

#### **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	AICS	all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed

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



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ACH Reg. CL-ENCS	all ingredients are listed
CL-ENCS	
	not all ingredients are listed
A-ENCS	not all ingredients are listed
KECI	all ingredients are listed
INSQ	not all ingredients are listed
NZIoC	all ingredients are listed
PICCS	all ingredients are listed
CICR	all ingredients are listed
TCSI	all ingredients are listed
	not all ingredients are listed
PI C	CCS

#### Legend

AICS	Australian Inventory of Chemical Substances
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
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
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

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.1		The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	yes
2.2		Pictograms: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes

### Restructuring: section 9, section 14

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



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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3		Results of PBT and vPvB assessment: 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 naviga tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Ir land Waterways)	
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)	
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)	
Aquatic Acute	Hazardous to the aquatic environment - acute hazard	
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard	
ATE	Acute Toxicity Estimate	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)	
Ceiling-C	Ceiling value	
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	
DGR	Dangerous Goods Regulations (see IATA/DGR)	
DNEL	Derived No-Effect Level	
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi- fier of substances commercially available within the EU (European Union)	
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-li- cence/)	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
EmS	Emergency Schedule	
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	
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air	
IMDG	International Maritime Dangerous Goods Code	
IMDG-Code	International Maritime Dangerous Goods Code	

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Abbr.	Descriptions of used abbreviations	
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	
M-factor	Means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present	
NLP	No-Longer Polymer	
РВТ	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 (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
STEL	Short-term exposure limit	
SVHC	Substance of Very High Concern	
TWA	Time-weighted average	
VOC	Volatile Organic Compounds	
vPvB	Very Persistent and very Bioaccumulative	
WEL	Workplace exposure limit	

#### 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.	
H319	Causes serious eye irritation.	
H400	Very toxic to aquatic life.	
H410	Very toxic to aquatic life with long lasting effects.	
H411	Toxic to aquatic life with long lasting effects.	



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#### Disclaimer

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



