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



#### 4-(Dimethylamino)pyridine PEPTIPURE® ≥99 %

article number: **6988**Version: **4.0 en**date of compilation: 2019-07-23
Revision: 2024-03-02

Replaces version of: 2023-03-17

Version: (3)

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

#### 1.1 Product identifier

Identification of the substance 4-(Dimethylamino)pyridine PEPTIPURE® ≥99 %

Article number 6988

Registration number (REACH) 01-2120115012-81-xxxx

EC number 214-353-5
CAS number 1122-58-3
Alternative name(s) DMAP

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 
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 Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https:// www.poisons.ie/

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#### **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
3.10	Acute toxicity (oral)		Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	2	Acute Tox. 2	H310
3.1I	Acute toxicity (inhal.)	3	Acute Tox. 3	H331
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.8	Specific target organ toxicity - single exposure	1	STOT SE 1	H370
4.1C	Hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16

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

Immediate effects can be expected after short-term exposure. Spillage and fire water can cause pollution of watercourses.

#### 2.2 Label elements

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

Signal word Dan	ger
-----------------	-----

#### **Pictograms**

GHS05, GHS06, GHS08, GHS09









#### **Hazard statements**

H301+H331	Toxic if swallowed or if inhaled
H310	Fatal in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H370	Causes damage to organs (nervou

H370 Causes damage to organs (nervous system)
H411 Toxic to aquatic life with long lasting effects

#### **Precautionary statements**

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

P273 Avoid release to the environment

P280 Wear protective gloves/eye protection/face protection

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

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P310 Immediately call a POISON CENTER/doctor

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

Signal word: Danger

Symbol(s)







H301+H331 Toxic if swallowed or if inhaled. H310 Fatal in contact with skin. H318 Causes serious eye damage.

H370 Causes damage to organs (nervous system).

P280 Wear protective gloves/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

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

do. Continue rinsing.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **Endocrine disrupting properties**

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

## SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Name of substance 4-(Dimethylamino)pyridine

Molecular formula  $C_7H_{10}N_2$  Molar mass  $122,2\,^g/_{mol}$ 

REACH Reg. No 01-2120115012-81-xxxx

CAS No 1122-58-3 EC No 214-353-5

#### Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	140 <sup>mg</sup> / <sub>kg</sub> 90 <sup>mg</sup> / <sub>kg</sub> 1 <sup>mg</sup> / <sub>l</sub> /4h	oral dermal inhalation: dust/ mist

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#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures



#### **General notes**

Take off immediately all contaminated clothing. Self-protection of the first aider.

#### Following inhalation

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

#### Following skin contact

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water. In case of skin irritation, consult a physician.

#### 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 immediately and drink plenty of water. Call a physician immediately.

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

Risk of blindness, Risk of serious damage to eyes, Irritation, Diarrhoea, Nausea, Vomiting, Headache, Dizziness, Drowsiness, Irritant effects, Cough, Dyspnoea

#### 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 (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

#### 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. Wear full chemical protective clothing.

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#### **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. If substance has entered a water course or sewer, inform the responsible authority.

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

#### Advice on how to contain a spill

Covering of drains. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal. 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

Provision of sufficient ventilation. Use extractor hood (laboratory). Handle and open container with care. Avoid dust formation. Clear contaminated areas thoroughly.

#### Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

#### 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:

Store locked up.

#### **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.

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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)**

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
IE	dusts, non-specific		OELV	10			i	S.I. No. 619 of 2001
IE	dusts, non-specific		OELV	4			r	S.I. No. 619 of 2001

#### Notation

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

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)

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) TWA

#### **Human health values**

Relevant DN	Relevant DNELs and other threshold levels						
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time			
DNEL	0,05 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects			
DNEL	0,1 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects			
DNEL	0,01 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects			

#### **Environmental values**

#### **Relevant PNECs and other threshold levels**

End- point	Threshold level	Organism	Environmental com- partment	Exposure time
PNEC	0,004 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)
PNEC	0 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)
PNEC	50 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	0,038 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	0,004 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)
PNEC	0,004 <sup>mg</sup> / <sub>kg</sub>	terrestrial organisms	soil	short-term (single instance)

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#### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

#### **Eye/face protection**





Use safety goggle with side protection.

#### Skin protection





#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. 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). P3 (filters at least 99,95 % of airborne particles, colour code: White).

#### **Environmental exposure controls**

Keep away from drains, surface and ground water.

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

#### 9.1 Information on basic physical and chemical properties

Physical state solid

Form powder, crystalline

Colour white - cream

Odour faintly perceptible - like: - amine

Melting point/freezing point 112 °C at 1.013 hPa (ECHA) Boiling point or initial boiling point and boiling 162 °C at 66,6 hPa (ECHA)

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point 124 °C

Auto-ignition temperature not determined

Decomposition temperature not relevant

pH (value) 10,23 (in aqueous solution:  $0,1 \frac{g}{l}$ , 22 °C) (ECHA)

Kinematic viscosity not relevant

Solubility(ies)

Water solubility ~76 <sup>g</sup>/<sub>l</sub> at 25 °C

Partition coefficient

Partition coefficient n-octanol/water (log value): 1,34 (pH value: 7, 25 °C) (ECHA)

Soil organic carbon/water (log KOC) 1,778 (ECHA)

Vapour pressure 1,33 hPa at 25 °C

Density and/or relative density

Density 0,96 g/<sub>cm³</sub> at 22 °C

Relative vapour density Information on this property is not available.

Bulk density  $\sim$ 520 kg/<sub>m³</sub>

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

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Information with regard to physical hazard

classes:

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

Other safety characteristics:

Temperature class (EU, acc. to ATEX)

,

T2
Maximum permissible surface temperature on

the equipment: 300°C

## **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, Acids,

Dangerous/dangerous reactions with: Nitrites, Nitrate, Nitric acid and nitrous acid

#### 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

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

### **Acute toxicity**

Toxic if swallowed. Fatal in contact with skin. Toxic if inhaled.

#### Acute toxicity **Exposure route Endpoint Value Species** Method Source 140 mg/kg oral LD50 rat **ECHA** 90 <sup>mg</sup>/<sub>kg</sub> **ECHA** dermal LD50 rabbit

#### Skin corrosion/irritation

Causes skin irritation.

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

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#### **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

Causes damage to organs (nervous system).

Hazard category	Target organ	Exposure route
1	nervous system	if exposed

#### 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

diarrhoea, vomiting, nausea

#### • If in eyes

Causes serious eye damage, risk of blindness

#### If inhaled

cough, irritant effects, Dyspnoea

#### • If on skin

causes skin irritation

#### Other information

Ingestion causes nausea, weakness and central nervous system effects, Headache, Dizziness, Drowsiness, Spasms, This information is based upon the present state of our knowledge. Substance not yet fully tested.

#### 11.2 Endocrine disrupting properties

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

#### 11.3 Information on other hazards

There is no additional information.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

Toxic to aquatic life with long lasting effects.

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#### Aquatic toxicity (acute)

Endpoint	Value	Species	Source	Exposure time
LC50	11,6 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h
EC50	1,82 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h
ErC50	4,22 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h

#### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 2,095 mg/mg Theoretical Oxygen Demand (with nitrification): 2,652 <sup>mg</sup>/<sub>mg</sub> Theoretical Carbon Dioxide: 2,522 <sup>mg</sup>/<sub>mg</sub>

#### **Process of degradability**

Process	Degradation rate	Time
oxygen depletion	0 %	28 d

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	1,34 (pH value: 7, 25 °C) (ECHA)
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#### 12.4 Mobility in soil

The Organic Carbon normalised adsorption coefficient	1,778 (ECHA)
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#### 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Endocrine disrupting properties

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

#### Other adverse effects

Data are not available.

## **SECTION 13: Disposal considerations**

#### 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.

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#### Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

#### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

#### Properties of waste which render it hazardous

**HP 4** irritant - skin irritation and eye damage

**HP 5** specific target organ toxicity (STOT)/aspiration toxicity

**HP 6** acute toxicity

HP 14 ecotoxic

#### 13.3 Remarks

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

## **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADRRID	UN 2811
IMDG-Code	UN 2811
ICAO-TI	UN 2811

#### 14.2 UN proper shipping name

ADRRID	TOXIC SOLID, ORGANIC, N.O.S.
IMDG-Code	TOXIC SOLID, ORGANIC, N.O.S.
ICAO-TI	Toxic solid, organic, n.o.s.

Technical name 4-(Dimethylamino)pyridine

#### 14.3 Transport hazard class(es)

ADRRID	6.1
IMDG-Code	6.1
ICAO-TI	6.1

#### 14.4 Packing group

ADRRID	II
IMDG-Code	II
ICAO-TI	II

**14.5** Environmental hazards hazardous to the aquatic environment

#### 14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

#### 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

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#### 14.8 Information for each of the UN Model Regulations

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

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

Particulars in the transport document UN2811, TOXIC SOLID, ORGANIC, N.O.S., (4-(Di-

methylamino)pyridine), 6.1, II, (D/E), environ-mentally hazardous

Classification code T2

Danger label(s) 6.1, "Fish and tree"

**Environmental hazards** yes (hazardous to the aquatic environment)

Special provisions (SP) 274, 614, 802(ADN)

Excepted quantities (EQ) E4 Limited quantities (LQ) 500 g Transport category (TC) 2 D/E Tunnel restriction code (TRC) Hazard identification No 60

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code T2

Danger label(s) 6.1, "Fish and tree"



**Environmental hazards** 

Hazardous to water

**Special provisions (SP)** 274, 614, 802(ADN)

**Excepted quantities (EQ)** E4 Limited quantities (LQ) 500 q **Transport category (TC)** 2 **Hazard identification No** 60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

UN2811, TOXIC SOLID, ORGANIC, N.O.S., (4-(Di-Particulars in the shipper's declaration

methylamino)pyridine), 6.1, II, MARINE POLLUT-

Marine pollutant yes (hazardous to the aquatic environment)

Danger label(s) 6.1, "Fish and tree"

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Stowage category

Special provisions (SP) 274 Excepted quantities (EQ) **E4** Limited quantities (LQ) 500 q **EmS** F-A, S-A

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

Proper shipping name Toxic solid, organic, n.o.s.

Particulars in the shipper's declaration UN2811, Toxic solid, organic, n.o.s., (4-(Dimethyl-

В

amino)pyridine), 6.1, II

**Environmental hazards Yes** (hazardous to the aquatic environment)

6.1 Danger label(s)



Special provisions (SP) A3, A5 Excepted quantities (EQ) **E4** Limited quantities (LQ) 1 kg

## 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
4-(Dimethylamino)pyridine	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 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;

(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:

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#### Legend

(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 (g) In the case of a substance for which a condition is specified in column i (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.

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

13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall for the purposes of applying this entry to that substance, he treated as graph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as

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:

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 to the list of ingredients in accordance with the nomenciature 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 ingredients are not accordance to the process of th

ent 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 para-

graph. 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 or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

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



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#### **Seveso Directive**

2012/18/EU (Seveso III)				
No	No Dangerous substance/hazard categories Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		Notes	
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)
H3	STOT specific target organ toxicity - single exposure (cat. 1)	50	200	42)

#### **Notation**

41)

- Category 2, all exposure routes - category 3, inhalation exposure route STOT SE category 1

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

VOC content	100 %
VOC content	960 <sup>g</sup> / <sub>l</sub>

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

VOC content	100 %
VOC content	960 <sup>g</sup> / <sub>l</sub>

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

not listed

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

not listed

#### **Water Framework Directive (WFD)**

not listed

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

not listed

## **Regulation on drug precursors**

not listed

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

not listed

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

not listed

### Regulation on persistent organic pollutants (POP)

not listed

#### Other information

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

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#### **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
JP	ISHA-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

AIIC Australian Inventory of Industrial Chemicals
CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)

CSCL-ENCS
DSL
Domestic Substances List (DSL)
ECSI
ECSI
ECSI
Inventory of Existing Chemical Substances Produced or Imported in China
INSQ
INVENTIGATION
INVEN

**TSCA Toxic Substance Control Act** 

#### **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

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

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1		National inventories: change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	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.	yes

#### **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concer ing the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substance
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
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causir 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 idea fier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United N 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
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 durin specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic

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Abbr.	Descriptions of used abbreviations
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)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

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

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H370	Causes damage to organs (nervous system).
H411	Toxic to aquatic life with long lasting effects.

#### Disclaimer

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

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