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

#### Putrescin ≥99 %, for biochemistry

article number: 8379 date of compilation: 11.09.2019 Version: 3.0 en Revision: 02.03.2024

Replaces version of: 14.09.2022

Version: (2)

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

#### **Product identifier** 1.1

Identification of the substance **Putrescin** ≥99 %, for biochemistry

Article number 8379

Registration number (REACH) It is not required to list the identified uses be-

cause the substance is not subject to registration

according to REACH (< 1 t/a).

EC number 203-782-3 CAS number 110-60-1

#### 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 squirting or spraying. Do not use

> for products which come into direct contact with the skin. Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household). Food, drink and animal

feedingstuffs.

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

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

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

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

sheet:

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

#### 1.4 **Emergency telephone number**

#### SECTION 2: Hazards identification

#### 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
2.6	Flammable liquid	3	Flam. Liq. 3	H226
2.16	Substance or mixture corrosive to metals	1	Met. Corr. 1	H290
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302

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Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.1D	Acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	Acute toxicity (inhal.)	2	Acute Tox. 2	H330
3.2	Skin corrosion/irritation	1B	Skin Corr. 1B	H314

For full text of abbreviations: see SECTION 16

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

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. The product is combustible and can be ignited by potential ignition sources.

#### 2.2 Label elements

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

Signal word Danger

#### **Pictograms**

GHS02, GHS05, GHS06







#### **Hazard statements**

H226	Flammable liquid and vapour
H290	May be corrosive to metals
	Harmful if swallowed
H302	
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H330	Fatal if inhaled

#### **Precautionary statements**

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

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking

P260 Do not breathe gas/mist/vapours/spray

P280 Wear protective gloves/eye protection/face protection

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing 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)







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H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H330 Fatal if inhaled.

P260 Do not breathe gas/mist/vapours/spray.

P280 Wear protective gloves/eye protection/face protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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.

#### 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 Putrescin Molecular formula  $C_4H_{12}N_2$  Molar mass  $88,15\,^g/_{mol}$  CAS No 110-60-1 EC No 203-782-3

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

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	740 <sup>mg</sup> / <sub>kg</sub> 300 <sup>mg</sup> / <sub>k</sub> g 0,5 <sup>mg</sup> / <sub>l</sub> /4h	oral dermal inhalation: vapour

### **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

After contact with skin, wash immediately with plenty of water. Immediate medical treatment required because corrosive injuries that are not treated are hard to cure.

#### 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. Protect uninjured eye.

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#### **Following ingestion**

Rinse mouth immediately and drink plenty of water. Rinse mouth with water (only if the person is conscious). Call a physician immediately. If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects). Call a doctor.

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

Corrosion, Vomiting, Risk of blindness, Gastric perforation, Cough

#### 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. In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours may form explosive mixtures with air.

#### **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. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

#### **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. Avoidance of ignition sources.

### 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

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



Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

#### Advice on general occupational hygiene

Thorough skin-cleansing after handling the product. When using do not smoke.

### 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.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

#### 7.3 Specific end use(s)

No information available.

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### **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

**National limit values** 

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

This information is not available.

#### **Human health values**

Relevant DNELs and other threshold levels					
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time	
DNEL	7,3 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects	
DNEL	7,3 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects	
DNEL	7,3 mg/m³	human, inhalatory	worker (industry)	chronic - local effects	
DNEL	7,3 mg/m³	human, inhalatory	worker (industry)	acute - local effects	

#### **Environmental values**

Relevant PNECs and other threshold levels					
End- point	Threshold level	Organism	Environmental com- partment	Exposure time	
PNEC	0,73 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)	
PNEC	0,073 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)	
PNEC	3,25 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)	
PNEC	0,648 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)	
PNEC	0,148 <sup>mg</sup> / <sub>kg</sub>	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. Wear face protection.

### **Skin protection**





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#### 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 quide.

#### type of material

Butyl caoutchouc (butyl rubber)

#### material thickness

0,7mm

#### 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.

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

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

Physical state solid

Colour colourless - white

Odour pungent

Melting point/freezing point 28 °C (ECHA)

Boiling point or initial boiling point and boiling 158 – 159 °C at 1.013 hPa (ECHA)

range

Flammability flammable liquid in accordance with GHS criteria

Lower and upper explosion limit 0,7 vol% (LEL) - 11,2 vol% (UEL)

Flash point 45 °C at 1.013 hPa (ECHA)

Auto-ignition temperature not determined

Decomposition temperature not relevant
pH (value) not applicable

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Kinematic viscosity 2,184 mm²/s at 25 °C not relevant

Dynamic viscosity 1,915 mPa s at 25 °C

Solubility(ies)

Water solubility 1.000 g/I (TOXNET)

Partition coefficient

Partition coefficient n-octanol/water (log value): -0,84 (25 °C) (ECHA)

Vapour pressure 4,36 hPa at 25 °C

Density and/or relative density

Density  $0.877 \,^{9}/_{cm^3}$  at 25 °C (ECHA)

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:

Corrosive to metals category 1: corrosive to metals

Other safety characteristics:

Surface tension  $0,033 \, ^{\text{N}}/_{\text{m}} \, (40 \, ^{\circ}\text{C}) \, (\text{ECHA})$ 

Temperature class (EU, acc. to ATEX) T2

Maximum permissible surface temperature on

the equipment: 300°C

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

It's a reactive substance. Risk of ignition. Substance or mixture corrosive to metals. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

#### If heated

Risk of ignition.

### 10.2 Chemical stability

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

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#### 10.3 Possibility of hazardous reactions

**Violent reaction with:** strong oxidiser, Aldehydes, Ketone, Nitrate, Phenols, Acid chlorides, inorganic, Acids

#### 10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from moisture.

#### 10.5 Incompatible materials

different metals

#### 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**

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

Acute toxicity						
Exposure route	Endpoint	Value	Species	Method	Source	
oral	LD50	740 <sup>mg</sup> / <sub>kg</sub>	rat		ECHA	

#### Skin corrosion/irritation

Causes severe skin burns and eye damage.

### Serious eye damage/eye irritation

Causes serious eye damage.

### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

### **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

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

#### If swallowed

If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects)

#### If in eyes

causes burns, Causes serious eye damage, risk of blindness

#### If inhaled

cough, Dyspnoea

#### • If on skin

causes severe burns, causes poorly healing wounds

#### 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

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)					
Endpoint	Value	Species	Source	Exposure time	
LC50	730 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h	
EC50	6 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	96 h	

#### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 1,996  $^{\rm mg}/_{\rm mg}$  Theoretical Oxygen Demand (with nitrification): 2,768  $^{\rm mg}/_{\rm mg}$  Theoretical Carbon Dioxide: 1,997  $^{\rm mg}/_{\rm mg}$ 

#### **Biodegradation**

The substance is readily biodegradable.

### Process of degradability

Process	Degradation rate	Time
carbon dioxide generation	≥89 %	28 d

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	-0,84 (25 °C) (ECHA)
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#### 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

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

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 3** flammable **HP 6** acute toxicity

HP8 corrosive

#### 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

ADR UN 3286
IMDG-Code UN 3286
ICAO-TI UN 3286

#### 14.2 UN proper shipping name

ADR FLAMMABLE LIQUID, TOXIC, CORROSIVE, N.O.S. IMDG-Code FLAMMABLE LIQUID, TOXIC, CORROSIVE, N.O.S.

ICAO-TI Flammable liquid, toxic, corrosive, n.o.s.

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	Technical name	Putrescin
14.3	Transport hazard class(es)	
	ADR	3 (6.1) (8)
	IMDG-Code	3 (6.1) (8)
	ICAO-TI	3 (6.1) (8)
14.4	Packing group	
	ADR	II
	IMDG-Code	II
	ICAO-TI	II
14.5	Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations

#### 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.

### 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	FLAMMABLE LIQUID, TOXIC, CORROSIVE, N.O.S.
Particulars in the transport document	UN3286, FLAMMABLE LIQUID, TOXIC, CORROSIVE, N.O.S., (Putrescin), 3 (6.1+8), II, (D/E)
Classification code	FTC
Danger label(s)	3+6.1+8







Special provisions (SP) 274, 802(ADN)

Excepted quantities (EQ) E2
Limited quantities (LQ) 1 L
Transport category (TC) 2
Tunnel restriction code (TRC) D/E
Hazard identification No 368

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#### International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name FLAMMABLE LIQUID, TOXIC, CORROSIVE, N.O.S.

UN3286, FLAMMABLE LIQUID, TOXIC, CORROS-Particulars in the shipper's declaration

IVE, N.O.S., (Putrescin), 3 (6.1+8), II, 45°C c.c.

Marine pollutant

Danger label(s) 3+6.1+8







Special provisions (SP) 274 Excepted quantities (EQ) E2 Limited quantities (LQ) 1 L **EmS** F-E, S-C

Stowage category

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

Proper shipping name Flammable liquid, toxic, corrosive, n.o.s.

Particulars in the shipper's declaration UN3286, Flammable liquid, toxic, corrosive, n.o.s.,

(Putrescin), 3 (6.1+8), II

Danger label(s) 3+6.1+8







Excepted quantities (EQ) E2 Limited quantities (LQ) 0,5 L

## **SECTION 15: Regulatory information**

#### Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1 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
Putrescin	flammable / pyrophoric		R40	40
Putrescin	substances in tattoo inks and permanent make-up		R75	75

#### Legend

Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following: - metallic glitter intended mainly for decoration,

- artificial snow and frost, 'whoopee' cushions,
- silly string aerosols,
- imitation excrement,
- horns for parties,
- decorative flakes and foams,
- artificial cobwebs,
- stink bombs
- 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of

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substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.

3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).

4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

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#### Legend

**R75** 

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

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the

(f) in the case of a substance is the invalid in the legislation (EC) No 1223/2009 (17), 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 concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

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

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

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

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

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

Not listed.

#### **Seveso Directive**

2012/	2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories		(tonnes) for the ap- and upper-tier re- ments	Notes
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)

#### Notation

- Category 2, all exposure routes - category 3, inhalation exposure route

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

VOC content	100 %
VOC content	877 <sup>g</sup> / <sub>l</sub>

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

VOC content	100 %
VOC content	877 <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

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#### 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.

#### **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	NDSL	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
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 CSCL-ENCS ECSI IECSC INSQ

Australian Inventory of Industrial Chemicals
List of Existing and New Chemical Substances (CSCL-ENCS)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances

Korea Existing Chemicals Inventory

NCI National Chemical Inventory
NCI National Chemical Inventory
NDSL Non-domestic Substances List (NDSL)
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances
TCSL Taiwan Chemical Substances

Taiwan Chemical Substance Inventory **TSCA Toxic Substance Control Act** 

#### 15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

## **SECTION 16: Other information**

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

Sect	tion	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.	3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1	VOC content: 100 % 877 <sup>9</sup> / <sub>I</sub>	VOC content: 100 %	yes
15.1		VOC content: 877 <sup>9</sup> / <sub>l</sub>	yes
15.1		National inventories: change in the listing (table)	yes

### **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
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
EmS	Emergency Schedule
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
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 during a specified time interval
LEL	Lower explosion limit (LEL)
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
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

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

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

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

Code	Text
H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H330	Fatal 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.

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