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



### Metol ≥99 %, ACS photo quality

article number: **4315**Version: **4.0 en**date of compilation: 2015-09-01
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Version: (3)

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

#### 1.1 Product identifier

Identification of the substance Metol ≥99 %, ACS photo quality

Article number 4315

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).

Index number in CLP Annex VI 650-031-00-4

EC number 200-237-1

CAS number 55-55-0

Alternative name(s) 4-(Methylamino)-phenol sulphate

#### 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

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)	4	Acute Tox. 4	H302
3.45	Skin sensitisation	1	Skin Sens. 1	H317
3.9	Specific target organ toxicity - repeated exposure	2	STOT RE 2	H373
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	Hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16

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

Delayed or immediate effects can be expected after short or long-term exposure. 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, GHS08, GHS09







#### **Hazard statements**

H302 Harmful if swallowed

H317 May cause an allergic skin reaction

H373 May cause damage to organs through prolonged or repeated exposure

H410 Very toxic to aquatic life with long lasting effects

#### **Precautionary statements**

# **Precautionary statements - prevention**

P260 Do not breathe dusts or mists
P273 Avoid release to the environment
P280 Wear protective gloves/eye protection

### **Precautionary statements - response**

P314 Get medical advice/attention if you feel unwell

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

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Symbol(s)







H317 May cause an allergic skin reaction.P280 Wear protective gloves/eye protection.

#### 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 Metol

Molecular formula  $C_{14}H_{20}N_2O_6S$ 

Molar mass 344,4 g/<sub>mol</sub>

CAS No 55-55-0

EC No 200-237-1

Index No 650-031-00-4

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

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	M-factor (acute) = 10	565 <sup>mg</sup> / <sub>kg</sub>	oral

# **SECTION 4: First aid measures**

### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

#### Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following skin contact

Wash with plenty of soap and water. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.

#### Following eye contact

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

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### Following ingestion

Rinse mouth with water (only if the person is conscious). Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. Call a doctor.

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

Vomiting, Allergic reactions

### 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>), Sulphur oxides (SOx)

#### 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. 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.

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### 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

Provision of sufficient ventilation. Avoid dust formation.

### 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

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. Protect from sunlight.

### **Incompatible substances or mixtures**

Observe hints for combined storage.

#### Consideration of other advice:

### **Ventilation requirements**

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.

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

#### 8.1 Control parameters

#### **National limit values**

## Occupational exposure limit values (Workplace Exposure Limits)

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

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#### Notation

Inhalable fraction 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 TWA

hours time-weighted average (unless otherwise specified)

#### 8.2 **Exposure controls**

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

### **Eye/face protection**





Use safety goggle with side protection.

#### Skin protection





### hand protection

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

#### type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 mm

#### breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### other protection measures

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

#### **Respiratory protection**





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

#### **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 - whitish

Odour odourless

Melting point/freezing point 260 °C (ECHA)

Boiling point or initial boiling point and boiling 300 °C at 971,2 hPa (ECHA)

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point 257 °C at 971,2 hPa (ECHA)

Auto-ignition temperature 531 °C (ECHA) (relative self-ignition temperature

for solids)

Decomposition temperature 260 °C

pH (value) 3,72 (in aqueous solution: 50 <sup>g</sup>/<sub>l</sub>, 26 °C) (ECHA)

Kinematic viscosity not relevant

Solubility(ies)

Water solubility 50 g/1 at 20 °C (TOXNET)

Partition coefficient

Partition coefficient n-octanol/water (log value): 0,79 (25 °C) (ECHA)

Vapour pressure not determined

Density and/or relative density

Density  $0.69 \, ^{\rm g}/_{\rm cm^3}$  at 20 °C (ECHA)

Relative vapour density Information on this property is not available.

Bulk density  $\sim 660 \, \mathrm{kg/m^3}$ 

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard hazard classes acc. to GHS

classes: (physical hazards): not relevant

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Other safety characteristics:

Temperature class (EU, acc. to ATEX)

T1

Maximum permissible surface temperature on the equipment: 450°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, Strong alkali, Acids, Acid chlorides, inorganic

#### 10.4 Conditions to avoid

Keep away from heat. UV-radiation/sunlight. Decompostion takes place from temperatures above: 260 °C.

### 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**

Harmful if swallowed.

### **Acute toxicity**

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	565 <sup>mg</sup> / <sub>kg</sub>	mouse		

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

### Serious eye damage/eye irritation

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

#### Respiratory or skin sensitisation

May cause an allergic skin reaction.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

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### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

### Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

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

#### If swallowed

central nervous system

#### • If in eyes

slightly irritant but not relevant for classification, Due to its pH value (see section 9), irritation of the skin and eyes cannot be ruled out

#### If inhaled

slightly irritant but not relevant for classification

#### • If on skin

May produce an allergic reaction, pruritis, localised redness

### Other information

Irritant effects

#### 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

Very toxic to aquatic life with long lasting effects.

### **Aquatic toxicity (acute)**

Endpoint	Value	Species	Source	Exposure time
EC50	0,019 <sup>mg</sup> / <sub>l</sub>	daphnia magna		96 h
LC50	0,019 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	96 h

### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 1,487  $^{\rm mg}/_{\rm mg}$  Theoretical Oxygen Demand (with nitrification): 1,684  $^{\rm mg}/_{\rm mg}$  Theoretical Carbon Dioxide: 1,789  $^{\rm mg}/_{\rm mg}$ 

\_ . . . . .

### **Biodegradation**

Not readily biodegradable.

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#### **Process of degradability**

Process	Degradation rate	Time
biotic/abiotic	30 %	d

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	0,79 (25 °C) (ECHA)
---------------------------	---------------------

#### 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. 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. 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 5** specific target organ toxicity (STOT)/aspiration toxicity

**HP 6** acute toxicity

**HP 13** sensitising

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.

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# **SECTION 14: Transport information**

#### 14.1 UN number or ID number

**ADRRID UN 3077 IMDG-Code UN 3077** ICAO-TI **UN 3077** 

14.2 UN proper shipping name

**ADRRID** ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

**IMDG-Code** ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

ICAO-TI Environmentally hazardous substance, solid,

Technical name 4-(Methylamino)-phenol sulphate, Metol

14.3 Transport hazard class(es)

9 **ADRRID** IMDG-Code 9 ICAO-TI 9

14.4 Packing group

**ADRRID** III **IMDG-Code** III ICAO-TI III

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.

### 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 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

UN3077, ENVIRONMENTALLY HAZARDOUS SUB-Particulars in the transport document

STANCE, SOLID, N.O.S., (4-(Methylamino)-phenol sulphate, Metol), 9, III, (-)

Classification code

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





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

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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

Tiazara facitameatori No

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

iiiioiiiiatioii

Classification code M7

**Danger label(s)** 9, "Fish and tree"

Environmental hazards Yes

Hazardous to water

**Special provisions (SP)** 274, 335, 375, 601

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
Transport category (TC) 3
Hazard identification No 90

International Maritime Dangerous Goods Code (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., (4-(Methylamino)-phenol

sulphate, Metol), 9, III

Marine pollutant yes (hazardous to the aquatic environment), (Metol)

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

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#### International Civil Aviation Organization (ICAO-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., (4-(Methylamino)-phenol sulphate,

Metol), 9, III

**Environmental hazards YES** (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

# 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
Metol	substances in tattoo inks and permanent make-up		R75	75

#### Leaend

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 type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight: (i) "Rinse-off products"; (ii) "Not to be used in products applied on mucous membranes";

(iii) "Not to be used in eye products"; (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in

the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

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

making a mark or design on his or her body.

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

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#### Legend

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 or points (a) to (g) or paragraph 1, the concentration limit laid 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 roint (a) (b) (c) or (d) of paragraph 1 of this entry or such stance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as

taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Supplier placing a mixture on the market for use for Alanuary 2022, the

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the

7. Suppliers placing a finiture on the flarket for use for fattooing purposes shall ensure that, after 4 january 2022, the mixture is marked with the following information:

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

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name, the CAS and EC number. Ingredients shall he listed in descending order by weight or yellowed the ingredients at the time of formulation. "Ingredient" means 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 ent does not need to be marked in accordance with this Regulation;

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 passible and marked in a world the installation.

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, 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	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes				
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100 200	56)				

#### Notation

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

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

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

#### **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)

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.

#### **National inventories**

Inventory	Status
AIIC	substance is listed
DSL	substance is listed
IECSC	substance is listed
ECSI	substance is listed
REACH Reg.	substance is listed
CSCL-ENCS	substance is listed
KECI	substance is listed
INSQ	substance is listed
	AIIC  DSL  IECSC  ECSI  REACH Reg.  CSCL-ENCS  KECI

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Country	Inventory	Status
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 List of Existing and New Chemical Substances (CSCL-ENCS)

CSCL-ENCS DSL ECSI IECSC INSQ KECI List of Existing and New Chemical Substances (CSCL-ENCS)

Domestic Substances List (DSL)

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
National Chemical Inventory
New Zealand Inventory of Chemicals
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

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

# **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 (ED) at a concentration of ≥ 0,1%.	yes
14.8	Classification code: 9	Classification code: M7	yes
15.1	VOC content: 0 % 0 <sup>g</sup> / <sub>l</sub>	VOC content: 0 %	yes
15.1		VOC content: 0 <sup>g</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 concerning 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)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

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Descriptions of used abbreviations
Dangerous Goods Regulations (see IATA/DGR)
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
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)
Endocrine disruptor
European Inventory of Existing Commercial Chemical Substances
European List of Notified Chemical Substances
Emergency Schedule
"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
International Air Transport Association
Dangerous Goods Regulations (DGR) for the air transport (IATA)
International Civil Aviation Organization
Technical instructions for the safe transport of dangerous goods by air
International Maritime Dangerous Goods Code
International Maritime Dangerous Goods Code
The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
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
No-Longer Polymer
Persistent, Bioaccumulative and Toxic
Registration, Evaluation, Authorisation and Restriction of Chemicals
Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
Short-term exposure limit
Substance of Very High Concern
Time-weighted average
Volatile Organic Compounds
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.

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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
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very 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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