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

# Choline hydroxide 48-50 % in water

article number: 3406 date of compilation: 2016-10-12 Version: **2.0 en** Revision: 2022-02-02

Replaces version of: 2016-10-12

Version: (1)

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

#### **Product identifier** 1.1

Identification of the substance Choline hydroxide 48-50 % in water

Article number 3406

Registration number (REACH) not relevant (mixture)

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

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).

#### 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

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

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

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

# **SECTION 2: Hazards identification**

#### Classification of the substance or mixture 2.1

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.2	Skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318

For full text of abbreviations: see SECTION 16

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# 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.

#### **Label elements** 2.2

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

Signal word **Danger** 

**Pictograms** 

GHS05



# **Hazard statements**

H314 Causes severe skin burns and eye damage

# **Precautionary statements**

# **Precautionary statements - prevention**

P280 Wear protective gloves/protective clothing/eye protection/face protection

# **Precautionary statements - response**

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

with water [or shower]

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

lenses, if present and easy to do. Continue rinsing

Immediately call a POISON CENTER/doctor P310

Hazardous ingredients for labelling: Choline hydroxide

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

Signal word: Danger

Symbol(s)



H314 Causes severe skin burns and eye damage.

Wear protective gloves/protective clothing/eye protection/face protection. P280

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing.
Immediately call a POISON CENTER/doctor. P310

contains: Choline hydroxide

#### 2.3 Other hazards

# Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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# **SECTION 3: Composition/information on ingredients**

# 3.1 Substances

not relevant (mixture)

#### 3.2 Mixtures

# **Description of the mixture**

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Choline hydroxide	CAS No 123-41-1 EC No 204-625-1	48 – 50	Skin Corr. 1 / H314 Eye Dam. 1 / H318		

For full text of abbreviations: see SECTION 16

# **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

Provide fresh air.

#### 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.

# Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately. If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects).

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

Corrosion, Risk of blindness, Gastric perforation, Risk of serious damage to eyes

# 4.3 Indication of any immediate medical attention and special treatment needed

none

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# **SECTION 5: Firefighting measures**

# 5.1 Extinguishing media



# Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

# Unsuitable extinguishing media

water jet

# 5.2 Special hazards arising from the substance or mixture

Ingredients of the mixture combustible. The product itself does not burn.

# **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 vapour/spray.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

# 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains.

# Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

# 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.

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# **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Handle and open container with care. Clear contaminated areas thoroughly.

# 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

Keep in a cool place.

# **Incompatible substances or mixtures**

Observe hints for combined storage.

Consideration of other advice:

# Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °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)**

This information is not available.

# Relevant DNELs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Choline hydroxide	123-41-1	DNEL	146,7 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Choline hydroxide	123-41-1	DNEL	10,4 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

# Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Choline hydroxide	123-41-1	PNEC	0,604 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Choline hydroxide	123-41-1	PNEC	0,06 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Choline hydroxide	123-41-1	PNEC	112,9 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Choline hydroxide	123-41-1	PNEC	10,47 <sup>mg</sup> / kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Choline hydroxide	123-41-1	PNEC	0,226 <sup>mg</sup> / kg	aquatic organ- isms	marine sediment	short-term (single instance)

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# Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Choline hydroxide	123-41-1	PNEC	1,734 <sup>mg</sup> / kg	terrestrial organ- isms	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





# 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: Aerosol or mist formation.

#### **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 liquid

Colour colourless - light yellow - light red

Odour this information is not available

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range

Flammability non-combustible
Lower and upper explosion limit not determined
Flash point not determined

Auto-ignition temperature 380 °C

Decomposition temperature not relevant pH (value) not determined Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Solubility in toluene insoluble (< 1 mg/l)

Partition coefficient

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

Vapour pressure not determined

Density and/or relative density

Density  $1,08 \, {}^{9}/_{\mathrm{cm}^{3}}$  at 20  ${}^{\circ}\mathrm{C}$ 

Relative vapour density information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

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

Other safety characteristics:

Miscibility completely miscible with water

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Temperature class (EU, acc. to ATEX)

T2

Maximum permissible surface temperature on the equipment: 300°C

# **SECTION 10: Stability and reactivity**

# 10.1 Reactivity

This material is not reactive under normal ambient conditions.

# 10.2 Chemical stability

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

# 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Acids

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

# 10.5 Incompatible materials

There is no additional information.

# 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

# SECTION 11: Toxicological information

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

# **Classification procedure**

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

# **Acute toxicity**

Shall not be classified as acutely toxic.

# 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.

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# Specific target organ toxicity - single exposure

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

# Specific target organ toxicity - repeated exposure

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

# **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

# Symptoms related to the physical, chemical and toxicological characteristics

#### If swallowed

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

Data are not available.

#### • If on skin

causes severe burns, causes poorly healing wounds

#### Other information

none

# 11.2 Endocrine disrupting properties

None of the ingredients are listed.

# 11.3 Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

# 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

#### Aquatic toxicity (acute) of components of the mixture Exposure time Name of sub-**CAS No Endpoint Value Species** stance Choline hydroxide 123-41-1 LC50 >10.000 <sup>mg</sup>/<sub>I</sub> fish 96 h Choline hydroxide 123-41-1 EC50 ≥500 <sup>mg</sup>/<sub>I</sub> aquatic invertebrates 24 h Choline hydroxide >500 <sup>mg</sup>/<sub>l</sub> 72 h 123-41-1 ErC50 algae

Aquatic toxicity (chronic) of components of the mixture							
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time		
Choline hydroxide	123-41-1	LC50	>95,5 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	21 d		
Choline hydroxide	123-41-1	EC50	58,9 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	21 d		

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# **Biodegradation**

Data are not available.

# 12.2 Process of degradability

# Degradability of components of the mixture

Name of substance	CAS No	Process	Degrada- tion rate	Time	Method	Source
Choline hy- droxide	123-41-1	oxygen deple- tion	>75 %	5 d		ECHA

# 12.3 Bioaccumulative potential

Data are not available.

# Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Choline hydroxide	123-41-1	3,16	-2,25 (pH value: 11,3, 25 °C)	

# 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

# 12.6 Endocrine disrupting properties

None of the ingredients are listed.

### 12.7 Other adverse effects

Data are not available.

# **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods



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

# Sewage disposal-relevant information

Do not empty into drains.

# Waste treatment of containers/packagings

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

# 13.2 Relevant provisions relating to waste

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

#### 13.3 Remarks

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

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# **SECTION 14: Transport information**

# 14.1 UN number or ID number

ADR/RID/ADN UN 3267
IMDG-Code UN 3267
ICAO-TI UN 3267

# 14.2 UN proper shipping name

ADR/RID/ADN CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S. IMDG-Code CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

ICAO-TI Corrosive liquid, basic, organic, n.o.s.

Technical name (hazardous ingredients) Choline hydroxide

# 14.3 Transport hazard class(es)

ADR/RID/ADN 8
IMDG-Code 8
ICAO-TI 8

# 14.4 Packing group

ADR/RID/ADN II
IMDG-Code II
ICAO-TI II

**14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous 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

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

Proper shipping name CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

Particulars in the transport document

UN3267, CORROSIVE LIQUID, BASIC, ORGANIC,
NOS. (contains: Chaling by drovide). S. II. (F)

N.O.S., (contains: Choline hydroxide), 8, II, (E)

Classification code C7
Danger label(s) 8



Special provisions (SP) 274
Excepted quantities (EQ) E2
Limited quantities (LQ) 1 L

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Transport category (TC) 2
Tunnel restriction code (TRC) E
Hazard identification No 80
Emergency Action Code 2X

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

Proper shipping name CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

Particulars in the shipper's declaration UN3267, CORROSIVE LIQUID, BASIC, ORGANIC,

N.O.S., (Choline hydroxide, solution), 8, II

Marine pollutant -

Danger label(s) 8



Special provisions (SP) 274

Excepted quantities (EQ) E2

Limited quantities (LQ) 1 L

EmS F-A, S-B

Stowage category B

Segregation group 18 - Alkalis

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

Proper shipping name Corrosive liquid, basic, organic, n.o.s.

Particulars in the shipper's declaration UN3267, Corrosive liquid, basic, organic, n.o.s.,

(Choline hydroxide, solution), 8, II

Danger label(s) 8



Special provisions (SP)

Excepted quantities (EQ)

Limited quantities (LQ)

A3

E2

Limited quantities (LQ)

0,5 L

# **SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

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# Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Choline hydroxide	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Choline hydroxide	substances in tattoo inks and perman- ent make-up		R75	75

#### Legend

R3

1. Shall not be used in:
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes,

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market.

3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, as that if they is the statement of or both, if they

- or both, if they.
  can be used as fuel in decorative oil lamps for supply to the general public, and
  present an aspiration hazard and are labelled with H304.
  4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- (CEN).
  5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
- ments are met:
  (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage";
  (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
  (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.';

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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 weight:

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

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

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

(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 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.



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#### Legend

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

None of the ingredients are 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					
	not assigned							

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

VOC content	50 % , 1.177 <sup>g</sup> / <sub>l</sub>
	·

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

VOC content	0 %
VOC content Water content was discounted	0 <sup>g</sup> / <sub>l</sub>

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

none of the ingredients are listed

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

none of the ingredients are listed

# **Water Framework Directive (WFD)**

none of the ingredients are listed

# Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

# **Regulation on drug precursors**

none of the ingredients are listed

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

none of the ingredients are listed

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

none of the ingredients are listed

# Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

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#### Other information

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

#### **National inventories**

Country	Inventory	Status
AU	AICS	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed

Legend

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

DSL ECSI IECSC

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
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS)
Taiwan Chemical Substance Inventory

Taiwan Chemical Substance Inventory

**Toxic Substance Control Act** 

# 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

# **SECTION 16: Other information**

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

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		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.	yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

# **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
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
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
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
Eye Dam.	Seriously damaging to the eye

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Abbr.	Descriptions of used abbreviations
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
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
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

# Key literature references and sources for data

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

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

# **Classification procedure**

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

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# Disclaimer

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

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