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



# Formamide ≥99,5 %, BioScience-Grade, RNAse/DNAse free, deionized

article number: P040 date of compilation: 2015-10-22 Version: 4.0 en Revision: 2024-03-02

Replaces version of: 2023-07-19

Version: (3)

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

#### **Product identifier** 1.1

Identification of the substance **Formamide** ≥99,5 %, BioScience-Grade, RNAse/

DNAse free, deionized

Article number P040

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

cause the substance is not subject to registration

according to REACH (< 1 t/a).

Index number in CLP Annex VI 616-052-00-8

EC number 200-842-0

CAS number 75-12-7

#### 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 products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

#### 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

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

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
3.6	Carcinogenicity	2	Carc. 2	H351
3.7	Reproductive toxicity	1B	Repr. 1B	H360FD
3.9	Specific target organ toxicity - repeated exposure	2	STOT RE 2	H373

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.

#### 2.2 Label elements

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

Signal word Danger

**Pictograms** 

GHS08



#### **Hazard statements**

H351 Suspected of causing cancer

H360FD May damage fertility. May damage the unborn child

H373 May cause damage to organs (blood) through prolonged or repeated exposure

(if swallowed)

### **Precautionary statements**

# **Precautionary statements - prevention**

P201 Obtain special instructions before use P260 Do not breathe mist/vapours/spray

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

### **Precautionary statements - response**

P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)



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H351 Suspected of causing cancer.

H360FD May damage fertility. May damage the unborn child.

P201 Obtain special instructions before use.

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

P308+P313 IF exposed or concerned: Get medical advice/attention.

#### 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 Formamide

Molecular formula CH<sub>3</sub>NO

Molar mass  $45,02 \, {}^{9}/_{mol}$ 

CAS No 75-12-7

EC No 200-842-0

Index No 616-052-00-8

# **Substance of Very High Concern (SVHC)**

Name of substance	CAS No	EC No	Listed in	Remarks
Formamide	75-12-7	200-842-0	Candidate list	Repr. A57c

Legend

Candidate Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

list

Repr. A57c Toxic for reproduction (article 57c)

# **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**

Rinse skin with water/shower.

#### 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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Symptoms and effects are not known to date.

# 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 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

Combustible.

# **Hazardous combustion products**

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. 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

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. Retain contaminated washing water and dispose of it.

# 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).

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# 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. Avoid exposure.

# 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 container tightly closed.

### **Incompatible substances or mixtures**

Observe hints for combined storage.

Consideration of other advice:

### Specific designs for storage rooms or vessels

Recommended storage temperature: -20 °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)**

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
IE	formamide	75-12-7	OELV	10	18						S.I. No. 619 of 2001

Notation

TWA

Ceiling-C Ceiling value is a limit value above which exposure should not occur STEL Short-term exposure limit: a limit value above which exposure shoul

Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-

minute period (unless otherwise specified)

Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

#### **Human health values**

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Relevant DNE	Relevant DNELs and other threshold levels				
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time	
DNEL	6,66 mg/m³	human, inhalatory	worker (industry)	chronic - local effects	
DNEL	6,6 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects	
DNEL	0,952 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects	

#### **Environmental values**

Relevant	Relevant PNECs and other threshold levels					
End- point	Threshold level	Organism	Environmental com- partment	Exposure time		
PNEC	5 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	water	intermittent release		
PNEC	0,5 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)		
PNEC	0,5 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)		
PNEC	100 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)		
PNEC	1,26 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)		
PNEC	0,151 <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.

#### 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)

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#### material thickness

≥0,3 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. Type: A (against organic gases and vapours with a boiling point of > 65 °C , colour code: Brown).

### **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 liquid

Colour colourless - light yellow

Odour like ammonia

Melting point/freezing point 2,6 °C (ECHA)

Boiling point or initial boiling point and boiling 218,3 °C at 1.013 hPa (ECHA)

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit 2,7 vol% (LEL) - 19 vol% (UEL) Flash point 152 °C at 1.013 hPa (ECHA)

Auto-ignition temperature >500 °C at 1.013 hPa (ECHA) (auto-ignition tem-

perature (liquids and gases))

Decomposition temperature >140 °C at 1.013 hPa (ECHA)

pH (value) 5 – 6 (20 °C)

Kinematic viscosity 3,331  $^{\text{mm}^2}$ / $_{\text{s}}$  at 20 °C Dynamic viscosity 3,764 mPa s at 20 °C

Solubility(ies)

Water solubility  $1.000 \, ^{9}/_{1}$  at 25 °C (ECHA)

Partition coefficient

Partition coefficient n-octanol/water (log value): -0,82 (25 °C) (ECHA)

Soil organic carbon/water (log KOC) 0,93 (ECHA)

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Vapour pressure 1,001 hPa at 55,01 °C

Density and/or relative density

Density  $1,13 \, {}^{\rm g}/{}_{\rm cm^3}$  at 20 °C (ECHA)

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

classes:

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

Other safety characteristics:

Temperature class (EU, acc. to ATEX)

Maximum permissible surface temperature on

the equipment: 450°C

# **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### If heated

Vapours may form explosive mixtures with air.

#### 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 acid, Strong alkali, Hydrogen peroxide, => Explosive properties

# 10.4 Conditions to avoid

Keep away from heat. Decompostion takes place from temperatures above: >140 °C at 1.013 hPa.

#### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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# **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**

Shall not be classified as acutely toxic.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
inhalation: vapour	LC50	>21 <sup>mg</sup> / <sub>l</sub> /4h	rat	acute inhalation toxicity	
oral	LD50	5.325 <sup>mg</sup> / <sub>kg</sub>	rat		ECHA
dermal	LD50	>3.000 <sup>mg</sup> / <sub>kg</sub>	rat		ECHA

#### 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

Shall not be classified as a respiratory or skin sensitiser.

# **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

# Carcinogenicity

Suspected of causing cancer.

### Reproductive toxicity

May damage the unborn child. May damage fertility.

### 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 (blood) through prolonged or repeated exposure (if swallowed).

Hazard category	Target organ	Exposure route
2	blood	if swallowed

# **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

# Symptoms related to the physical, chemical and toxicological characteristics

#### If swallowed

Data are not available.

# • If in eyes

Data are not available.

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#### If inhaled

Data are not available.

#### • If on skin

Frequently or prolonged contact with skin may cause dermal irritation

### Other information

Liver and kidney damage, Loss of righting reflex, and ataxia

# 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	6.569 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h
EC50	>500 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	48 h
ErC50	>500 <sup>mg</sup> / <sub>l</sub>	algae	ECHA	72 h

# **Aquatic toxicity (chronic)**

Endpoint	Value	Species	Source	Exposure time
EC50	>1.000 <sup>mg</sup> / <sub>l</sub>	microorganisms	ECHA	30 min

# 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 0,3554  $^{\rm mg}$ / $_{\rm mg}$  Theoretical Oxygen Demand (with nitrification): 1,777  $^{\rm mg}$ / $_{\rm mg}$  Theoretical Carbon Dioxide: 0,9775  $^{\rm mg}$ / $_{\rm mg}$ 

### **Biodegradation**

The substance is readily biodegradable.

Process of degradability				
Process	Degradation rate	Time		
biotic/abiotic	90 – 100 %	28 d		
DOC removal	4 %	1 d		

#### **Bioaccumulative potential** 12.3

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	-0,82 (25 °C) (ECHA)
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# 12.4 Mobility in soil

Henry's law constant	0 <sup>Pa m³</sup> / <sub>mol</sub> at 25 °C (ECHA)
The Organic Carbon normalised adsorption coefficient	0,93 (ECHA)

#### 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

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 7** carcinogenic

**HP 10** toxic for reproduction

#### 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	not subject to transport regulations
14.2	UN proper shipping name	not assigned

**14.3 Transport hazard class(es)** none

**14.4 Packing group** not assigned

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

gerous goods regulations

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#### Special precautions for user 14.6

There is no additional information.

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

The cargo is not intended to be carried in bulk.

### Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information Not subject to ICAO-IATA.

# SECTION 15: Regulatory information

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

Restrictions according to REACH, Annex XVII

### Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Formamide	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Formamide	toxic for reproduction		R28-30	30
Formamide	substances in tattoo inks and permanent make-up		R75	75

# Legend

R28-30 1. Shall not be placed on the market, or used,

- as substances,

- as constituents of other substances, or,

- in mixtures

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, - the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'

2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;

(c) the following fuels and oil products:
- motor fuels which are covered by Directive 98/70/EC,

- mineral oil products intended for use as fuel in mobile or fixed combustion plants,

- fuels sold in closed systems (e.g. liquid gas bottles);
(d) artists' paints covered by Regulation (EC) No 1272/2008;
(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;
(f) devices covered by Regulation (EU) 2017/745.

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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,
- 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 require-
- 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 opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite some supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite supply to the general public are packaged in black opposite
- opaque containers not exceeding 1 litre by 1 December 2010.';

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**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

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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#### 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

Substance of Very High Concern (SVHC)						
Name acc. to invent- ory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of in- clusion
formamide	75-12-7	Candidate list	Repr. A57c			2012-06-18

#### Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Repr. A57c Toxic for reproduction (article 57c)

#### **Seveso Directive**

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	100 %
VOC content	1.130 <sup>g</sup> / <sub>l</sub>

# **Industrial Emissions Directive (IED)**

VOC content	100 %
VOC content	1.130 <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)

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#### List of pollutants (WFD) Name of substance **CAS No** Listed in **Remarks** Name acc. to inventory Formamide Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment

#### Legend

a)

Indicative list of the main pollutants

# 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**

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
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

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Legend

Australian Inventory of Industrial Chemicals 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

AIIC CSCL-ENCS DSL ECSI IECSC INSQ KECI NATIONAL Inventory of Chemical Substances

KECI Korea Existing Chemicals Inventory

NCI National Chemical Inventory

NZIOC New Zealand Inventory of Chemicals

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

This probability between Inventory

TCSI TSCA Taiwan Chemical Substance Inventory

**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
2.2		Hazard statements: 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	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes

# **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)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
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
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

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Abbr.	Descriptions of used abbreviations
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
IMDG	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
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
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	Reproductive toxicity
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
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). 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)

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Code	Text
H351	Suspected of causing cancer.
H360FD	May damage fertility. May damage the unborn child.
H373	May cause damage to organs (blood) through prolonged or repeated exposure (if swallowed).

# 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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