

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

## Formaldehyde solution 37 % p.A.

Version number: GHS 1.0 Date of compilation: 2021-12-15

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

1.1 Product identifier

Identification of the substance Formaldehyde solution 37 % p.A.

**Registration number (REACH)** 01-2119488953-20-xxxx, 01-2119513723-45-xxxx

CAS number 50-00-0
Article number LC-5936

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

**Relevant identified uses**General use

**Uses advised against** Do not use for squirting or spraying. Do not use

for products which come into direct contact with

the skin.

1.3 Details of the supplier of the safety data sheet

NeoFroxx GmbH Marie-Curie-Str. 3 D-64683 Einhausen Germany

Telephone: +49 (6251) 989 24 - 0 e-mail: info@neofroxx.com Website: neofroxx.com

e-mail (competent person) info@neofroxx.com (neoFroxx GmbH)

1.4 Emergency telephone number

Poison	centre
1 013011	CCITCIC

Country	Name	Postal code/city	Telephone
United Kingdom	ted Kingdom National Poisons Information Service		111

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and cat- egory	Hazard state- ment
3.10	acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	acute toxicity (inhal.)	3	Acute Tox. 3	H331
3.2	skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.45	skin sensitisation	1	Skin Sens. 1	H317
3.5	germ cell mutagenicity	2	Muta. 2	H341
3.6	carcinogenicity	1B	Carc. 1B	H350

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For full text of abbreviations: see SECTION 16.

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

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis.

#### 2.2 Label elements

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

- Signal word danger

- Pictograms

GHS05, GHS06, GHS08





#### - Hazard statements

H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects.

May cause cancer. H350

#### - Precautionary statements

P201 Obtain special instructions before use.

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

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protec-

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

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

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.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

#### 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.

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

#### 3.1 **Substances**

Name of substance Formaldehyde solution 37 % p.A.

**Identifiers** 

01-2119488953-20-xxxx 01-2119513723-45-xxxx REACH Reg. No

CAS No 50-00-0 EC No 200-001-8 36 - 38 % **Purity** 

Specific Conc. Limits	M-Factors	ATE	Exposure route
Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0.2 %	•	277.8 <sup>mg</sup> / <sub>kg</sub> 833.3 <sup>mg</sup> / <sub>kg</sub> 8.333 <sup>mg</sup> / <sub>l</sub> /4h	oral dermal inhalation: vapour

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

#### 4.1 Description of first aid measures

#### **General notes**

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

#### Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

#### Following skin contact

Wash with plenty of soap and water.

#### Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

#### 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

Water spray, BC-powder, Carbon dioxide (CO2)

#### Unsuitable extinguishing media

Water jet

#### 5.2 Special hazards arising from the substance or mixture

#### **Hazardous combustion products**

Carbon monoxide (CO), Carbon dioxide (CO2)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Remove persons to safety.

#### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

#### 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

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

#### **Appropriate containment techniques**

Use of adsorbent materials.

#### 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

#### Recommendations

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

Use local and general ventilation. Use only in well-ventilated areas.

#### Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

#### 7.3 Specific end use(s)

See section 16 for a general overview.

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

#### 8.1 **Control parameters**

Occupational exposure limit values (Workplace Exposure Limits)

Coun- try	Name of agent	CAS No	Identi- fier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [mg/m³]		Source
EU	formaldehyde	50-00-0	IOELV	0.3	0.37	0.74	0.6		sect	2019/ 983/EU
GB	formaldehyde	50-00-0	WEL	2	2.5	2	2.5			EH40/ 2005

Notation

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

sect

limit value of 0,62 mg/m3 or 0,5 ppm for the health care, funeral and embalming sectors until 11 July 2024 short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute peri-STEL

od (unless otherwise specified) TWA

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**

Relevant DNELs and other threshold levels

Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	9 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	0.375 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
DNEL	0.75 mg/m³	human, inhalatory	worker (industry)	acute - local effects
DNEL	240 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects
DNEL	37 μg/cm²	human, dermal	worker (industry)	chronic - local effects

#### **Environmental values**

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Endpoint	Threshold level	Organism	Environmental compartment	Exposure time		
PNEC	0.44 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)		
PNEC	0.44 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)		
PNEC	0.19 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)		
PNEC	2.3 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)		
PNEC	2.3 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)		
PNEC	0.2 <sup>mg</sup> / <sub>kg</sub>	terrestrial organisms	soil	short-term (single instance)		

#### 8.2 **Exposure controls**

#### **Appropriate engineering controls**

General ventilation.

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## Individual protection measures (personal protective equipment)

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

Wear eye/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. In the case of wanting to use the gloves again, clean them before taking off and air them well. 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.

- Type of material

CR: chloroprene (chlorobutadiene) rubber

- Material thickness

min. 0,65 mm

- Breakthrough times of the glove material

>240 minutes (permeation: level 5)

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

#### Respiratory protection

Type: ABEK (combined filters against gases and vapours, colour code: Brown/Grey/Yellow/Green).

#### **Environmental exposure controls**

Use appropriate container to avoid environmental contamination. 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
Odour	stinging
Melting point/freezing point	-18.8 °C
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	395 °C at 1,013 hPa (ЕСНА)
Decomposition temperature	not relevant
pH (value)	2.8 - 4

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Kinematic viscosity	2.531 <sup>mm²</sup> / <sub>s</sub> at 20 °C
Solubility(ies)	not determined

#### **Partition coefficient**

Partition coefficient n-octanol/water (log value)	this information is not available
Soil organic carbon/water (log KOC)	1.202 (ECHA)

Vapour pressure	not determined
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#### Density and/or relative density

Density	≥1.069 - ≤1.12 <sup>g</sup> / <sub>cm³</sub> at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)

#### 9.2 Other information

#### Other safety characteristics

Temperature class (EU, acc. to ATEX)	T2 (maximum permissible surface temperature on the equip-
	ment: 300°C)

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

#### 10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

#### 10.2 Chemical stability

See below "Conditions to avoid".

#### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

#### 10.4 Conditions to avoid

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

#### 10.5 Incompatible materials

Oxidisers

#### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. 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**

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

- Acute toxicity estimate (ATE)

 $\begin{array}{ll} \text{Oral} & 277.8 \ ^{\text{mg}}/_{\text{kg}} \\ \text{Dermal} & 833.3 \ ^{\text{mg}}/_{\text{kg}} \\ \text{Inhalation: vapour} & 8.333 \ ^{\text{mg}}/_{\text{l}}/4\text{h} \end{array}$ 

#### Skin corrosion/irritation

Causes severe skin burns and eye damage.

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Respiratory or skin sensitisation

May cause an allergic skin reaction.

#### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Carcinogenicity

May cause cancer.

#### **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

#### Specific target organ toxicity - single exposure

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

#### Specific target organ toxicity - repeated exposure

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

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### 11.2 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.

#### **Biodegradation**

The substance is readily biodegradable.

#### 12.2 Persistence and degradability

Process of degradability		
Process	Degradation rate	Time
DOC removal	99 %	28 d

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#### 12.3 Bioaccumulative potential

Data are not available.

#### 12.4 Mobility in soil

Henry's law constant	0.034 <sup>Pa m³</sup> / <sub>mol</sub> at 25 °C
The Organic Carbon normalised adsorption coefficient	1.202 (ECHA)

#### 12.5 Results of PBT and vPvB assessment

Data are not available.

#### 12.6 Endocrine disrupting properties

Not listed.

#### 12.7 Other adverse effects

Data are not available.

#### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

#### 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. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

#### Remarks

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

#### **SECTION 14: Transport information**

14.1	UN	number	or ID	number

ADR/RID/ADN	UN 2209
IMDG-Code	UN 2209
ICAO-TI	UN 2209

## 14.2 UN proper shipping name

ADR/RID/ADN	FORMALDEHYDE SOLUTION
IMDG-Code	FORMALDEHYDE SOLUTION
ICAO-TI	Formaldehyde solution

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

**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.

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

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

Classification code	C9
Danger label(s)	8



Special provisions (SP)	533
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	3
Tunnel restriction code (TRC)	Е
Hazard identification No	80
Emergency Action Code	2X

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

Marine pollutant Danger label(s) 8



Special provisions (SP) Excepted quantities (EQ) E1
Limited quantities (LQ) 5 L
EmS F-A, S-B
Stowage category A

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

Danger label(s) 8



Excepted quantities (EQ) E1
Limited quantities (LQ) 1 L

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#### **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
Formaldehyde solution 37 % p.A.	formaldehyde	50-00-0	R72	72
Formaldehyde solution 37 % p.A.	this product meets the criteria for classi- fication in accordance with Regulation No 1272/2008/EC		R3	3
Formaldehyde solution 37 % p.A.	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, or both,
- 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: (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 suck-
- ing 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.';
- 1. Shall not be placed on the market after 1 November 2020 in any of the following: R72
  - (a) clothing or related accessories;
  - (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;
  - (c) footwear;
  - if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Ap-
  - pendix 12.

    2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.
  - 3. Paragraph 1 shall not apply to:
  - (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;
  - (b) non-textile fasteners and non-textile decorative attachments;
  - (c) second-hand clothing, related accessories, textiles other than clothing or footwear
  - (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners
  - 4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (\*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (\*\*).

    5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only
  - once or for a limited time and are not intended for subsequent use for the same or a similar purpose.
  - 6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.
  - 7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly. (\*) Regulation (EU) 2016/425 of the European Parliament and of the Council of of 9 March 2016 on personal protective equip-
  - ment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51). (\*\*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/ 385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

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Legend

R75

 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;

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

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(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

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.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, 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 mix-

ture 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. 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;

(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/

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

not listed

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

VOC content 100 %
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#### **Industrial Emissions Directive (IED)**

VOC content	100 %
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#### **Water Framework Directive (WFD)**

List of pollutants (	WFD)
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Name of substance	CAS No	Listed in	Remarks
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Legend

A)

Indicative list of the main pollutants

#### Regulation on persistent organic pollutants (POP)

Not listed.

#### **National inventories**

Country	Inventory	Status
EU	REACH Reg.	substance is listed
US	TSCA	substance is listed

Legend

REACH Reg. REACH registered substances
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**

#### **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
2019/983/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)

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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)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
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
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
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)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
IOELV	Indicative occupational exposure limit value
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
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

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Abbr.	Descriptions of used abbreviations
WEL	Workplace exposure limit

#### 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).

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

Code	Text
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H350	May cause cancer.

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product. The information is intended to give you guidelines for the safe handling of the product mentioned in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material produced in this way, unless expressly stated otherwise.

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