

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

### Natronlauge 45 %

Revision: 20.01.2023

Version number: 3.2 Replaces version of: 18.08.2021 (2)

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

#### 1.1 Product identifier

#### Trade name

Registration number (REACH)

EC number Index number in CLP Annex VI CAS number Alternative name(s)

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01-2119457892-27-xxxx Not relevant (mixture) 215-185-5 011-002-00-6 1310-73-2 Natriumhydroxid-Lösung 45 %

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

#### Relevant identified uses

Industrial use

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

FRIEDRICH SCHARR KG Liebknechtstraße 50 70565 Stuttgart Germany

Telephone: +49 711 7868-0 Telefax: +49 711 7868-489 e-mail: info@scharr.de Website: www.scharr.de

e-mail (competent person)

produktsicherheit@scharr.de

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

Poison centre			
Country	Name	Postal code/city	Telephone
Germany	Giftinformation Freiburg	79106 Freiburg im Bre- isgau	+49 (0)761 19240

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

#### 2.1 Classification of the substance or mixture

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

Hazard class	Category	Hazard class and cat- egory	Hazard state- ment
substance or mixture corrosive to metals	1	Met. Corr. 1	H290
skin corrosion/irritation	1A	Skin Corr. 1A	H314
serious eye damage/eye irritation	1	Eye Dam. 1	H318



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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



#### - hazard statements

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.

tements
Do not breathe dust/fume/gas/mist/vapours/spray.
Wear protective gloves/protective clothing/eye protection/face protection/hearing protec- tion/
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Absorb spillage to prevent material damage.
Dispose of contents/container to industrial combustion plant.

- hazardous ingredients for labelling

sodium hydroxide

#### 2.3 **Other hazards**

of no significance

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

#### 3.1 **Substances**

Not relevant (mixture)

REACH Reg. No	01-2119457892-27-xxxx
EC No	215-185-5
CAS No	1310-73-2
Index No	011-002-00-6

#### 3.2 **Mixtures**

Description of the mixture



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Name of substance	Identifier	Wt%	Classificatio	n acc. to GHS	Pictograms
water	CAS No 7732-18-5	50 - 60			
	EC No 231-791-2				
sodium hydroxide	CAS No 1310-73-2 EC No 215-185-5 REACH Reg. No 01-2119457892-27- xxxx	40 - 50	Skin Corr.	. 1 / H290 1A / H314 . 1 / H318	
Name of substance	Specific Conc. Limits		M-Factors	ATE	Exposure route
sodium hydroxide	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 %		-	-	

For full text of abbreviations: see SECTION 16.

#### **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. 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. Self-protection of the first aider.

#### 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. Call a physician immediately.

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

Breathing difficulties. Headache. Vertigo.

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

Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Dam. 1; H318: C ≥ 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %

Subsequent observance for pneumonia and pulmonary oedema. Supervise the blood circulation.



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#### **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media

Suitable extinguishing media

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

Unsuitable extinguishing media

Water jet

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

Danger of bursting container. Substance or mixture corrosive to metals.

#### 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.

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

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

#### For non-emergency personnel

Remove persons to safety. Ventilate affected area. Avoidance of ignition sources.

#### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Provision of sufficient ventilation.

#### 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.



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### **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. Never add water to this product.

- handling of incompatible substances or mixtures

Do not mix with acids.

#### 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

Managing of associated risks

- corrosive conditions

Store in corrosive resistant container with a resistant inner liner.

Shelf-life

Protect against external exposure, such as

frost

- Lagerklasse (storage class according to TRGS 510, 8 B (non-combustible corrosive materials (except only corrosive to metals))

- 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.

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

#### 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)								
Coun- try	Name of sub- stance	CAS No	Identifi- er	TWA [ppm]	TWA [mg/ m³]	STEL [ppm]	STEL [mg/ m³]	Source
AT	sodium hydroxide	1310-73-2	МАК		2			GKV
СН	sodium hydroxide	1310-73-2	МАК		2		2	SUVA

Notation

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

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)



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Relevant DNELs of components of the mixture						
Name of sub- stance	CAS No	End- point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
sodium hydroxide	1310-73-2	DNEL	1 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects

#### 8.2 Exposure controls

Appropriate engineering controls

General ventilation.

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 leaktightness/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

PE: polyethylene, CR: chloroprene (chlorobutadiene) rubber, IIR: isobutene-isoprene (butyl) rubber

- material thickness> 0,35 mm- breakthrough times of the glove material0,4 mm

>120 minutes (permeation: level 4)

- other protection measures

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

#### Respiratory protection

[In case of inadequate ventilation] wear respiratory protection. Type: AX (gas filters and combined filters against lowboiling point organic compounds, colour code: Brown).

#### 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	odourless
Melting point/freezing point	10 °C



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Boiling point or initial boiling point and boiling range	135 °C
Evaporation rate	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
pH (value)	14 (20 °C) (base)
Solubility(ies)	
Water solubility	miscible in any proportion

#### Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	not determined
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#### Density and/or relative density

Density	1,478 <sup>g</sup> / <sub>cm³</sub> at 20 °C
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Particle characteristics	not relevant (liquid)	

#### 9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	

Miscibility	Completely miscible with water.
Solid content	45 %



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

#### 10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". Substance or mixture corrosive to metals.

#### 10.2 Chemical stability

See below "Conditions to avoid".

#### 10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

#### 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.

Release of flammable materials with:

Light metals (due to the release of hydrogen in an acid/alkaline medium)

#### **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.

#### **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.

#### 11.2 Information on other hazards

There is no additional information.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

Acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment. Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV): WGK 1, slightly hazardous to water (Germany)

Aquatic toxicity (acute) of components of the mixture									
Name of substance	Name of substance         CAS No         Endpoint         Value         Species         Exposure time								
sodium hydroxide	1310-73-2	LC50	45,4 <sup>mg</sup> / <sub>l</sub>	rainbow trout (Onco- rhynchus mykiss)	96 h				
sodium hydroxide	1310-73-2	EC50	40,4 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h				

#### 12.2 Persistence and degradability

Biodegradation

Data are not available.

#### 12.3 Bioaccumulative potential

Data are not available.

#### 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.



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

#### 13.1 Waste treatment methods

Waste treatment-relevant information

Recycling/reclamation of other inorganic materials.

#### 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.

#### **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.

#### 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 1824
	IMDG-Code	UN 1824
	ICAO-TI	UN 1824
14.2	UN proper shipping name	
	ADR/RID/ADN	SODIUM HYDROXIDE SOLUTION
	IMDG-Code	SODIUM HYDROXIDE SOLUTION
	ICAO-TI	Sodium hydroxide solution
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.



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Transport of dangerous goods by road information	d, rail and inland waterway (ADR/RID/ADN) - additional
Classification code	C5
Danger label(s)	8
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	80
International Maritime Dangerous Go	oods Code (IMDG) - additional information
Marine pollutant	-
Danger label(s)	8
Special provisions (SP)	-
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-A, S-B
Stowage category	Α
Segregation group	18 - Alkalis
International Civil Aviation Organizat	ion (ICAO-IATA/DGR) - additional information
Danger label(s)	8
Special provisions (SP)	A3
Excepted quantities (EQ)	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



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> **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	Restriction
sodium hydroxide	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	R3
sodium hydroxide	substances in tattoo inks and permanent make- up	R75

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, 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: (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;

(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 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.

(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/ 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.



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Legend

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.

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

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

#### List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

none of the ingredients are listed

#### **Seveso Directive**

2012/ <sup>-</sup>	18/EU (Seveso III)		
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier require- ments	Notes
	not assigned		

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

VOC content

0 %

# 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)

List of pollutants (WFD)					
Name of substance	CAS No	Listed in	Remarks		
sodium hydroxide		a)			

Legend

A) Indicative list of the main pollutants

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

None of the ingredients are listed.

#### National regulations (Austria)

Ordinance on combustible liquids (VbF)

not assigned (flash point higher than 55 °C, water miscible)

#### **National regulations (Germany)**



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

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# Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 1 slightly hazardous to water (water hazard class)

#### Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass concen- tration	Notation
5.2.5	organic substances		≥ 25 wt%	0,5 <sup>kg</sup> / <sub>h</sub>	50 <sup>mg</sup> / <sub>m³</sub>	3)

Notation

3) a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m<sup>3</sup>, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

#### **National regulations Switzerland**

#### Ordinance on the incentive tax on volatile organic compounds (VOCV)

The product is exempt from the tax. Product in which the VOC content does not exceed 3 per cent (% by weight).

#### **National inventories**

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

Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act



acc. to Regulation (EC) No. 1907/2006 (REACH),

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### 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)

Section	Former entry (text/value)	Actual entry (text/value)
1.1	Registration number (REACH): 01-2119457892-27-xxxx	Registration number (REACH): 01-2119457892-27-xxxx Not relevant (mixture)
3.2		Description of the mixture: change in the listing (table)
8.2	Type of material: NBR: acrylonitrile-butadiene rubber, FKM: fluoro- elastomer	Type of material: PE: polyethylene, CR: chloroprene (chlorobutadiene) rubber, IIR: isobutene-isoprene (butyl) rubber
8.2	Material thickness: 0,4 mm	Material thickness: > 0,35 mm
8.2	Breakthrough times of the glove material: >480 minutes (permeation: level 6)	Breakthrough times of the glove material: 0,4 mm
		>120 minutes (permeation: level 4)
8.2	Protective gloves Splash protection	
8.2	Type of material: NBR: acrylonitrile-butadiene rubber FKM: fluoro-elastomer	
8.2	Respiratory protection: In case of inadequate ventilation wear respiratory protection.	Respiratory protection: [In case of inadequate ventilation] wear respiratory protection. Type: AX (gas filters and combined filters against low-boiling point organic compounds, colour code: Brown).
12.2	Persistence and degradability: Data are not available.	Persistence and degradability

#### 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 concern- ing 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)	
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	



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Abbr.	Descriptions of used abbreviations	
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 identi- fier 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	
Eye Dam.	Seriously damaging to the eye	
Eye Irrit.	Irritant to the eye	
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions	
GKV	Grenzwerteverordnung	
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	
Met. Corr.	Substance or mixture corrosive to metals	
NLP	No-Longer Polymer	
PBT	Persistent, Bioaccumulative and Toxic	
ppm	Parts per million	
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	
STEL	Short-term exposure limit	
SUVA	Grenzwerte am Arbeitsplatz, Suva	
SVHC	Substance of Very High Concern	
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)	
TWA	Time-weighted average	
VOC	Volatile Organic Compounds	



acc. to Regulation (EC) No. 1907/2006 (REACH),

amended by 2020/878/EU

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Abbr.	Descriptions of used abbreviations
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	
H290	May be corrosive to metals.	
H314	Causes severe skin burns and eye damage.	
H318	Causes serious eye damage.	

#### Disclaimer

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