

Safety data sheet

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



Buffer solution pH 10,00 ROTI®Calipure, for complexometry, ready-for-use product

article number: **T188**
Version: **4.0 en**
Replaces version of: 2021-07-07
Version: (3)

date of compilation: 2018-10-29
Revision: 2023-07-03

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

1.1 Product identifier

Identification of the substance **Buffer solution pH 10,00 ROTI®Calipure, for complexometry, ready-for-use product**

Article number T188

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical
Laboratory and analytical use

Uses advised against: Do not use for squirting or spraying. Do not use for products which come into direct contact with the skin. Do not use for private purposes (household). Food, drink and animal feedingstuffs.

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG
Schoemperlenstr. 3-5
D-76185 Karlsruhe
Germany

Telephone:+49 (0) 721 - 56 06 0
Telefax: +49 (0) 721 - 56 06 149
e-mail: sicherheit@carlroth.de
Website: www.carlroth.de

Competent person responsible for the safety data sheet: :Department Health, Safety and Environment

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

1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https://www.poisons.ie/

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.2	Skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.8R	Specific target organ toxicity - single exposure (respiratory tract irritation)	3	STOT SE 3	H335
4.1C	Hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

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. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS05, GHS07



Hazard statements

H314 Causes severe skin burns and eye damage
H335 May cause respiratory irritation
H412 Harmful to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P260 Do not breathe mist/vapours/spray
P280 Wear protective gloves/eye protection/face protection

Precautionary statements - response

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 Immediately call a POISON CENTER/doctor

Hazardous ingredients for labelling: Ammonia ...%

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



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H314	Causes severe skin burns and eye damage.
H412	Harmful to aquatic life with long lasting effects.
P260	Do not breathe mist/vapours/spray.
P280	Wear protective gloves/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
contains:	Ammonia ...%

2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Ammonia ...%	CAS No 1336-21-6 EC No 215-647-6 Index No 007-001-01-2 REACH Reg. No 01-2119488876- 14-xxxx	5 – 10	Skin Corr. 1B / H314 Eye Dam. 1 / H318 STOT SE 3 / H335 Aquatic Acute 1 / H400 Aquatic Chronic 2 / H411		B(a) GHS-HC IOELV
Ammonium chloride	CAS No 12125-02-9 EC No 235-186-4 Index No 017-014-00-8 REACH Reg. No 01-2119487950- 27-xxxx	5 – 10	Acute Tox. 4 / H302 Eye Irrit. 2 / H319		GHS-HC

Notes

B(a): The classification refers to an aqueous solution

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

IOELV: Substance with a community indicative occupational exposure limit value

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Name of sub-stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ammonia ...%	CAS No 1336-21-6 EC No 215-647-6 Index No 007-001-01-2	STOT SE 3; H335: C ≥ 5 %	-	-	
Ammonium chloride	CAS No 12125-02-9 EC No 235-186-4 Index No 017-014-00-8	-	-	1.410 mg/kg	oral

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off immediately all contaminated clothing.

Following inhalation

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

Following skin contact

After contact with skin, wash immediately with plenty of water. Immediate medical treatment required because corrosive injuries that are not treated are hard to cure.

Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye.

Following ingestion

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

4.2 Most important symptoms and effects, both acute and delayed

Corrosion, Risk of blindness, Gastric perforation, Risk of serious damage to eyes, Irritation, Cough, Dyspnoea

4.3 Indication of any immediate medical attention and special treatment needed

none

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SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO_x)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

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

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handle and open container with care. Provision of sufficient ventilation. Clear contaminated areas thoroughly.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep 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: 15 – 25 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Notation	Source
EU	ammonia, anhydrous	7664-41-7	IOELV	20	14	50	36				2000/39/EC
IE	ammonium chloride	12125-02-9	OELV		10		20			fume	S.I. No. 619 of 2001
IE	ammonia, anhydrous	7664-41-7	OELV	20	14	50	36				S.I. No. 619 of 2001

Notation

Ceiling-C
fume As fume
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 substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Ammonia ...%	1336-21-6	DNEL	47,6 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Ammonia ...%	1336-21-6	DNEL	47,6 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects
Ammonia ...%	1336-21-6	DNEL	14 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
Ammonia ...%	1336-21-6	DNEL	36 mg/m ³	human, inhalatory	worker (industry)	acute - local effects
Ammonia ...%	1336-21-6	DNEL	6,8 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Ammonia ...%	1336-21-6	DNEL	6,8 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Ammonia ...%	1336-21-6	PNEC	0,001 mg/l	aquatic organisms	freshwater	short-term (single instance)
Ammonia ...%	1336-21-6	PNEC	0,001 mg/l	aquatic organisms	marine water	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection. Wear face protection.

Skin protection



• hand protection

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

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- **type of material**

NBR (Nitrile rubber)

- **material thickness**

>0,11 mm

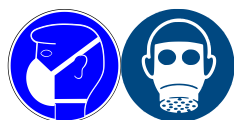
- **breakthrough times of the glove material**

>480 minutes (permeation: level 6)

- **other protection measures**

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

Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: K (against ammonia and organic ammonia derivatives, colour code: Green).

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
Odour	like ammonia
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	10 (20 °C)
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	miscible in any proportion
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	not relevant (inorganic)

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Vapour pressure	23 hPa at 20 °C
<u>Density and/or relative density</u>	
Density	0,984 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
<u>Other safety parameters</u>	
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:	
Miscibility	completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reaction with: Acids

10.4 Conditions to avoid

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

10.5 Incompatible materials

aluminium, copper, zinc, different metals

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

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

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
Ammonium chloride	12125-02-9	oral	1.410 mg/kg

Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Ammonium chloride	12125-02-9	oral	LD50	1.410 mg/kg	rat
Ammonium chloride	12125-02-9	dermal	LD50	>2.000 mg/kg	rat

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.

Specific target organ toxicity - single exposure

May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects)

• If in eyes

causes burns, Causes serious eye damage, risk of blindness

• If inhaled

Irritation to respiratory tract, cough, Dyspnoea

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- **If on skin**

causes severe burns, causes poorly healing wounds

- **Other information**

none

11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Ammonium chloride	12125-02-9	LC50	42,91 mg/l	fish	96 h
Ammonium chloride	12125-02-9	EC50	101 mg/l	aquatic invertebrates	48 h

Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Ammonia ...%	1336-21-6	EC50	2.700 mg/l	algae	18 d
Ammonium chloride	12125-02-9	ErC50	1.300 mg/l	algae	5 d
Ammonium chloride	12125-02-9	EC50	2.700 mg/l	algae	18 d

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Ammonium chloride	12125-02-9		-4,37	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

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12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

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 8 corrosive

HP 14 ecotoxic

13.3 Remarks

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

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 dangerous goods regulations |
| 14.6 Special precautions for user | 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. |

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14.8 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

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Buffer solution	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Ammonium chloride	inorganic ammonium salts		R65	65
Ammonium chloride	substances in tattoo inks and permanent make-up		R75	75
Ammonia ...%	substances in tattoo inks and permanent 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, 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

R65

1. Shall not be placed on the market, or used, in cellulose insulation mixtures or cellulose insulation articles after 14 July 2018 unless the emission of ammonia from those mixtures or articles results in a concentration of less than 3 ppm by volume (2,12 mg/m³) under the test conditions specified in paragraph 4.
A supplier of a cellulose insulation mixture containing inorganic ammonium salts shall inform the recipient or consumer of the maximum permissible loading rate of the cellulose insulation mixture, expressed in thickness and density.
A downstream user of a cellulose insulation mixture containing inorganic ammonium salts shall ensure that the maximum permissible loading rate communicated by the supplier is not exceeded.
2. By way of derogation, paragraph 1 shall not apply to placing on the market of cellulose insulation mixtures intended to be used solely for the production of cellulose insulation articles, or to the use of those mixtures in the production of cellulose insulation articles.
3. In the case of a Member State that, on 14 July 2016, has national provisional measures in place that have been authorised by the Commission pursuant to Article 129(2)(a), the provisions of paragraphs 1 and 2 shall apply from that date.
4. Compliance with the emission limit specified in the first subparagraph of paragraph 1 shall be demonstrated in accordance with Technical Specification CEN/TS 16516, adapted as follows:
 - (a) the duration of the test shall be at least 14 days instead of 28 days;
 - (b) the ammonia gas emission shall be measured at least once per day throughout the test;
 - (c) the emission limit shall not be reached or exceeded in any measurement taken during the test;
 - (d) the relative humidity shall be 90 % instead of 50 %;
 - (e) an appropriate method to measure the ammonia gas emission shall be used;
 - (f) the loading rate, expressed in thickness and density, shall be recorded during the sampling of the cellulose insulation mixtures or articles to be tested.

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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.
 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 mixture is marked with the following information:
 - (a) the statement "Mixture for use in tattoos or permanent make-up";
 - (b) a reference number to uniquely identify the batch;
 - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. 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.
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.

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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

2012/18/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	0 %
VOC content (Water content was discounted)	0 g/l

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content (Water content was discounted)	0 g/l

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)

Pollutant release and transfer registers (PRTR)			
Name of substance	CAS No	Remarks	Threshold for releases to air (kg/year)
Ammonia ...%	7664-41-7		10 000

Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Ammonium chloride	Substances which contribute to eutrophication (in particular, nitrates and phosphates)		a)	

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List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Ammonia ...%	Substances which contribute to eutrophication (in particular, nitrates and phosphates)		a)	

Legend

A) Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

Regulation on drug precursors

none of the ingredients are listed

Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

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

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

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	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
JP	ISHA-ENCS	not 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 (ACTIVE)

Legend

AIIC Australian Inventory of Industrial Chemicals
CICR Chemical Inventory and Control Regulation

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Legend

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
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
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

15.2 Chemical safety assessment

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.	yes
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information: Not subject to ADR, RID and ADN.		yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1	List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed. (Or Concentration of the substance in a mixture: $<0,1\%$ Mass concentration)	List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed.	yes
15.1	VOC content: 0 % 0 g/l	VOC content: 0 %	yes
15.1		VOC content (Water content was discounted): 0 g/l	yes
15.1		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.	yes
15.1		National inventories: change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
15.2	Chemical Safety Assessment: Chemical safety assessments for substances in this mixture were not carried out.	Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
Acute Tox.	Acute toxicity
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
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
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization

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Abbr.	Descriptions of used abbreviations
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
IOELV	Indicative occupational exposure limit value
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
log KOW	n-Octanol/water
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)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
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).

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).

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

Code	Text
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Disclaimer

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