

Safety data sheet

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



Potassium hydroxide solution ROTI®Volum 0,1 mol/l - 0,1 N

article number: **1YP7**

Version: **2.0 en**

Replaces version of: 2023-01-19

Version: (1)

date of compilation: 2023-01-19

Revision: 2024-09-21

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

1.1 Product identifier

| | |
|---------------------------------|--|
| Identification of the substance | Potassium hydroxide solution ROTI®Volum 0,1 mol/l - 0,1 N |
| Article number | 1YP7 |
| 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)

| Section | Hazard class | Cat-egory | Hazard class and category | Hazard statement |
|---------|--|-----------|---------------------------|------------------|
| 2.16 | Substance or mixture corrosive to metals | 1 | Met. Corr. 1 | H290 |
| 3.2 | Skin corrosion/irritation | 1A | Skin Corr. 1A | H314 |
| 3.3 | Serious eye damage/eye irritation | 1 | Eye Dam. 1 | H318 |

For full text of abbreviations: see SECTION 16

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The most important adverse physicochemical, human health and environmental effects

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

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

Precautionary statements

Precautionary statements - prevention

P280

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

Precautionary statements - response

P303+P361+P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]

P305+P351+P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310

Immediately call a POISON CENTER/doctor

Hazardous ingredients for labelling:

Potassium hydroxide

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Hazard pictogram(s):



H314

Causes severe skin burns and eye damage.

P280

Wear protective gloves/protective clothing/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:

Potassium hydroxide

Labelling of packages where the contents do not exceed 10 ml

Signal word:

Not required

Hazard pictogram(s):



Hazard statements:

Not required

Precautionary statements:

Not required

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2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

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



SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

Description of the mixture

| Name of substance | Identifier | Wt% | Classification acc. to GHS | Pictograms | Notes |
|---------------------|---|---------|---|---|--------|
| Potassium hydroxide | CAS No 1310-58-3 EC No 215-181-3 Index No 019-002-00-8 REACH Reg. No 01-2119487136- 33-xxxx | 10 - 11 | Met. Corr. 1 / H290 Acute Tox. 4 / H302 Skin Corr. 1A / H314 Eye Dam. 1 / H318 |   | GHS-HC |

Notes

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

| Name of substance | Identifier | Specific Conc. Limits | M-Factors | ATE | Exposure route |
|---------------------|---|---|-----------|-----------|----------------|
| Potassium hydroxide | CAS No 1310-58-3 EC No 215-181-3 Index No 019-002-00-8 | Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$ Skin Irrit. 2; H315: $0,5\% \leq C < 2\%$ Eye Dam. 1; H318: $C \geq 2\%$ Eye Irrit. 2; H319: $0,5\% \leq C < 2\%$ | - | 333 mg/kg | oral |

Remarks

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off immediately all contaminated clothing. Self-protection of the first aider.

Following inhalation

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

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Following skin contact

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

Following eye contact

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

Following ingestion

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

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

none

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.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

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

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

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

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Other information relating to spills and releases

Place in appropriate containers for disposal.

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

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

Advice on general occupational hygiene

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

7.2 Conditions for safe storage, including any incompatibilities

Keep only in original container.

Incompatible substances or mixtures

Observe hints for combined storage. Incompatible materials: see section 10.

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 |
|---------|---------------------|-----------|------------|-----------|--------------------------|------------|---------------------------|-----------------|--------------------------------|----------|----------------------|
| IE | potassium hydroxide | 1310-58-3 | OELV | | | | 2 | | | | S.I. No. 619 of 2001 |

Notation

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

STEL Short-term exposure limit: a limit value above which exposure 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)

Relevant DNELs of components

| Name of substance | CAS No | Endpoint | Threshold level | Protection goal, route of exposure | Used in | Exposure time |
|---------------------|-----------|----------|---------------------|------------------------------------|-------------------|-------------------------|
| Potassium hydroxide | 1310-58-3 | DNEL | 1 mg/m ³ | human, inhalatory | worker (industry) | chronic - local effects |

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8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection. Wear face protection.

Skin protection



• hand protection

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

• type of material

NBR (Nitrile rubber)

• material thickness

0,3 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

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

Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. P2 (filters at least 94 % of airborne particles, colour code: White). Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190).

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 - clear |
| Odour | odourless |
| Melting point/freezing point | not determined |

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| | |
|--|-----------------|
| Boiling point or initial boiling point and boiling range | not determined |
| 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) | >13 (20 °C) |
| Kinematic viscosity | not determined |

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): not relevant (inorganic)

Vapour pressure not determined

Density and/or relative density

Density 1,02 g/cm³ at 20 °C

Relative vapour density Information on this property is not available.

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard classes:

Corrosive to metals category 1: corrosive to metals

Other safety characteristics:

Miscibility completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

Substance or mixture corrosive to metals.

10.2 Chemical stability

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

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10.3 Possibility of hazardous reactions

Violent reaction with: Strong acid, Ammonium compounds, Azides, Alkaline earth metal, Halogenated hydrocarbons, Hydrocarbons, Metals, Strong oxidiser, Phosphorus

Dangerous/dangerous reactions with: Metals (due to the release of hydrogen in an acid/alkaline medium),
=> Explosion risk

10.4 Conditions to avoid

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

10.5 Incompatible materials

aluminium, different metals, zinc, tin

Release of flammable materials with

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

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

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

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components

| Name of substance | CAS No | Exposure route | ATE |
|---------------------|-----------|----------------|-----------|
| Potassium hydroxide | 1310-58-3 | oral | 333 mg/kg |

Acute toxicity of components

| Name of substance | CAS No | Exposure route | Endpoint | Value | Species |
|---------------------|-----------|----------------|----------|-----------|---------|
| Potassium hydroxide | 1310-58-3 | oral | LD50 | 333 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.

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Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

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

• If in eyes

causes burns, Causes serious eye damage, risk of blindness

• If inhaled

Data are not available.

• If on skin

causes severe burns, causes poorly healing wounds

• Other information

none

11.2 Endocrine disrupting properties

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

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

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

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

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. 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 4 irritant - skin irritation and eye damage

HP 8 corrosive

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

| | |
|-----------|---------|
| ADRRID | UN 1814 |
| IMDG-Code | UN 1814 |
| ICAO-TI | UN 1814 |

14.2 UN proper shipping name

| | |
|-----------|------------------------------|
| ADRRID | POTASSIUM HYDROXIDE SOLUTION |
| IMDG-Code | POTASSIUM HYDROXIDE SOLUTION |
| ICAO-TI | Potassium hydroxide solution |

14.3 Transport hazard class(es)

| | |
|-----------|---|
| ADRRID | 8 |
| IMDG-Code | 8 |
| ICAO-TI | 8 |

14.4 Packing group

| | |
|-----------|----|
| ADRRID | II |
| IMDG-Code | II |
| ICAO-TI | II |

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous 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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14.8 Information for each of the UN Model Regulations

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) Additional information

| | |
|---------------------------------------|--|
| Proper shipping name | POTASSIUM HYDROXIDE SOLUTION |
| Particulars in the transport document | UN1814, POTASSIUM HYDROXIDE SOLUTION, 8, II, (E) |
| 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 |

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Additional information

| | |
|----------------------------|----|
| Classification code | C5 |
| Danger label(s) | 8 |



| | |
|---------------------------------|-----|
| Excepted quantities (EQ) | E2 |
| Limited quantities (LQ) | 1 L |
| Transport category (TC) | 2 |
| Hazard identification No | 80 |

International Maritime Dangerous Goods Code (IMDG) - Additional information

| | |
|--|---|
| Proper shipping name | POTASSIUM HYDROXIDE SOLUTION |
| Particulars in the shipper's declaration | UN1814, POTASSIUM HYDROXIDE SOLUTION, 8, II |
| Marine pollutant | - |
| Danger label(s) | 8 |



| | |
|--------------------------|----------|
| Special provisions (SP) | - |
| Excepted quantities (EQ) | E2 |
| Limited quantities (LQ) | 1 L |
| EmS | F-A, S-B |

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| | |
|-------------------|--------------|
| Stowage category | A |
| Segregation group | 18 - Alkalis |

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

| | |
|--|---|
| Proper shipping name | Potassium hydroxide solution |
| Particulars in the shipper's declaration | UN1814, Potassium hydroxide solution, 8, II |
| 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

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 |
| Potassium hydroxide solution | this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC | | R3 | 3 |
| Potassium hydroxide | substances in tattoo inks and permanent make-up | | R75 | 75 |

Legend

- R3
- 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,
 - Articles not complying with paragraph 1 shall not be placed on the market.
 - 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.
 - 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).
 - 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.;
- 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;

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Legend

- (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.
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.

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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)

none of the ingredients are listed

Water Framework Directive (WFD)

| List of pollutants (WFD) | | | | |
|--------------------------|----------------------------|--------|-----------|---------|
| Name of substance | Name acc. to inventory | CAS No | Listed in | Remarks |
| Potassium hydroxide | Metals and their compounds | | 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.

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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) |
| VN | NCI | 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 |
| ISHA-ENCS | Inventory of Existing and New Chemical Substances (ISHA-ENCS) |
| KECI | Korea Existing Chemicals Inventory |
| NCI | National Chemical Inventory |
| NZIoC | New Zealand Inventory of Chemicals |
| PICCS | Philippine Inventory of Chemicals and Chemical Substances (PICCS) |
| REACH Reg. | REACH registered substances |
| 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 |
|---------|---------------------------|---|-----------------|
| 2.2 | | Labelling of packages where the contents do not exceed 125 ml: change in the listing (table) | yes |
| 2.2 | | Hazard pictogram(s): | yes |
| 2.2 | | Hazard pictogram(s):: change in the listing (table) | yes |
| 2.2 | | Labelling of packages where the contents do not exceed 10 ml | yes |

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| Section | Former entry (text/value) | Actual entry (text/value) | Safety-relevant |
|---------|--|---|-----------------|
| 2.2 | | Signal word: Not required | yes |
| 2.2 | | Hazard pictogram(s): | yes |
| 2.2 | | Hazard pictogram(s): change in the listing (table) | yes |
| 2.2 | | Hazard statements: Not required | yes |
| 2.2 | | Precautionary statements: Not required | yes |
| 2.3 | Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB. | Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance at a concentration of $\geq 0,1\%$. | yes |
| 2.3 | | Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$. | 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 | | National inventories: change in the listing (table) | yes |
| 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 |
|------------|---|
| 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) |
| 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) |
| ED | Endocrine disruptor |
| 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 |

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| Abbr. | Descriptions of used abbreviations |
|----------------------|---|
| Eye Irrit. | Irritant to the eye |
| GHS | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations |
| IATA | International Air Transport Association |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA) |
| ICAO | International Civil Aviation Organization |
| ICAO-TI | Technical instructions for the safe transport of dangerous goods by air |
| IMDG | International Maritime Dangerous Goods Code |
| IMDG-Code | International Maritime Dangerous Goods Code |
| index No | The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 |
| LD50 | Lethal Dose 50 %: the LD50 corresponds to the dose 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 (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 |
| 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 |
|------|--|
| H290 | May be corrosive to metals. |
| H302 | Harmful if swallowed. |
| 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.