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

#### Ammonia solution ROTIPURAN® 30 %, p.a., ACS

date of compilation: 11.08.2021 article number: CP17 Version: 1.0 en



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

#### **Product identifier** 1.1

Identification of the substance Ammonia solution ROTIPURAN® 30 %, p.a., ACS

Article number CP17

Registration number (REACH) not relevant (mixture)

Index number in CLP Annex VI [007-001-01-2] EC number [215-647-6]

CAS number [1336-21-6]

#### 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 products which come into contact with foodstuffs. Do not use for private

purposes (household).

#### 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 :Department Health, Safety and Environment

2.1

sheet:

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

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

# **SECTION 2: Hazards identification**

#### 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	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 (respirat- ory tract irritation)	3	STOT SE 3	H335
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400

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Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
4.1C	Hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

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, GHS09



#### **Hazard statements**

H290 May be corrosive to metals

H314 Causes severe skin burns and eye damage

H335 May cause respiratory irritation

H410 Very toxic to aquatic life with long lasting effects

#### **Precautionary statements**

#### **Precautionary statements - prevention**

P273 Avoid release to the environment

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

ing 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

Symbol(s)





Signal word: Danger





H314 Causes severe skin burns and eye damage.

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

Immediately call a POISON CENTER/doctor. P310

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contains: Ammonia ...%

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

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

#### **Substances**

not relevant (mixture)

#### 3.2 **Mixtures**

#### **Description of the mixture**

Name of sub- stance	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	30 - < 35	Skin Corr. 1B / H314 Eye Dam. 1 / H318 STOT SE 3 / H335 Aquatic Acute 1 / H400 Aquatic Chronic 2 / H411	<u>**</u>	B(a) GHS-HC IOELV

#### Notes

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

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ammonia%	CAS No 1336-21-6	STOT SE 3; H335: C ≥ 5 %	-	-	
	EC No 215-647-6				
	Index No 007-001-01-2				

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, Irritation, Cough, Dyspnoea

#### 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

#### Unsuitable extinguishing media

water jet

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

Vapours may form explosive mixtures with air. The product itself does not burn.

#### **Hazardous combustion products**

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

#### 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.

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#### **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).

#### Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

#### 6.4 Reference to other sections

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

#### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Use extractor hood (laboratory). Handle and open container with care. Provision of sufficient ventilation. Clear contaminated areas thoroughly.

#### Measures to protect the environment

Avoid release to the environment.

#### 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)** 

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Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	ammonia, anhyd- rous	7664-41- 7	IOELV	20	14	50	36				2000/39/ EC
MT	ammonia, anhyd- rous	7664-41- 7	OELV	20	14	50	36				CAP. 424

#### Notation

Ceiling-C STEL

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

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 exposur

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 of the mixture Name of sub-**CAS No** End-**Threshol Protection Used** in **Exposure time** goal, route of d level point stance exposure Ammonia ...% 1336-21-6 DNEL 47,6 mg/ human, inhalatworker (industry) chronic - systemic effects m<sup>3</sup> ory Ammonia ...% 1336-21-6 DNEL 47,6 mg/ human, inhalatworker (industry) acute - systemic effects ory Ammonia ...% 1336-21-6 DNEL human, inhalatchronic - local ef-14 mg/m<sup>3</sup> worker (industry) ory fects acute - local ef-Ammonia ...% 1336-21-6 DNEL 36 mg/m<sup>3</sup> human, inhalatworker (industry) fects ory DNEL Ammonia ...% 1336-21-6 6,8 mg/kg human, dermal worker (industry) chronic - systemic bw/day effects DNEL Ammonia ...% 1336-21-6 6,8 mg/kg human, dermal worker (industry) acute - systemic bw/day effects

Relevant PNECs of components of the mixture							
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time	
Ammonia%	1336-21-6	PNEC	0,001 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)	
Ammonia%	1336-21-6	PNEC	0,001 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	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.

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#### 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

Butyl caoutchouc (butyl rubber)

#### material thickness

>0,3 mm

#### · breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### • Splash protection - Protective gloves

• type of material: NBR (Nitrile rubber)

• material thickness: >0,11 mm

• breakthrough times of the glove material: >240 minutes (permeation: level 5)

#### other protection measures

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

#### **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 - light yellow
Odour stinging - like ammonia

Melting point/freezing point -87 °C

Boiling point or initial boiling point and boiling 27 °C at 1.013 mPa

range

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Flammability non-combustible
Lower and upper explosion limit 16 vol% - 30 vol%
Flash point not determined

Auto-ignition temperature 630 °C

Decomposition temperature not relevant

pH (value) >12

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): -1,38 (calculated value) not relevant (inorganic)

Vapour pressure 659 hPa at 20 °C

Density  $0.89 \, ^{\rm g}/_{\rm cm^3}$  at 20  $^{\circ}{\rm C}$ 

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

Temperature class (EU, acc. to ATEX) T1

Maximum permissible surface temperature on

the equipment: 450°C

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

#### 10.1 Reactivity

Substance or mixture corrosive to metals. Vapours may form explosive mixtures with air.

#### 10.2 Chemical stability

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

#### 10.3 Possibility of hazardous reactions

**Violent reaction with:** Aldehydes, Chlorine, Chlorates, Fluorine, Halogenated hydrocarbons, Oxidisers, Perchlorates, Phosphorus oxides (e.g. P2O5), Mercury, Nitric acid, Acid chlorides, inorganic, Oxygen, Strong acid, Chromium(VI) oxide, Hydrogen peroxide, => Explosive properties

#### 10.4 Conditions to avoid

Keep away from heat.

#### 10.5 Incompatible materials

different metals, copper, iron, zinc

#### 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.

#### 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**

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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

#### If on skin

causes severe burns, causes poorly healing wounds

#### Other information

none

#### 11.2 Endocrine disrupting properties

None of the ingredients are listed.

#### 11.3 Information on other hazards

There is no additional information.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

# 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/<sub>I</sub> algae 18 d

#### **Biodegradation**

Not readily biodegradable. The methods for determining the biological degradability are not applicable to inorganic substances.

#### 12.2 Process of degradability

Data are not available.

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

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#### 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.

#### **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

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

#### 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. Waste catalogue ordinance (Germany).

#### 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.

## **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADR/RID/ADN UN 2672 IMDG-Code UN 2672 ICAO-TI UN 2672

#### 14.2 UN proper shipping name

ADR/RID/ADN AMMONIA SOLUTION

IMDG-Code AMMONIA SOLUTION

ICAO-TI Ammonia solution

#### 14.3 Transport hazard class(es)

ADR/RID/ADN 8
IMDG-Code 8

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ICAO-TI 8

14.4 Packing group

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

**14.5** Environmental hazards hazardous to the aquatic environment

Environmentally hazardous substance (aquatic Ammonia ...%

environment):

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.

14.8 Information for each of the UN Model Regulations

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

Proper shipping name AMMONIA SOLUTION

Particulars in the transport document UN2672, AMMONIA SOLUTION, 8, III, (E), environ-

mentally hazardous

Classification code C5

Danger label(s) 8, "Fish and tree"





Environmental hazards yes (hazardous to the aguatic environment)

Special provisions (SP) 543

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 3

Tunnel restriction code (TRC) E

Hazard identification No 80

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name AMMONIA SOLUTION

Particulars in the shipper's declaration UN2672, AMMONIA SOLUTION, 8, III, MARINE

**POLLUTANT** 

Marine pollutant yes (P) (hazardous to the aquatic environment), (Ammonia

...%)

Danger label(s) 8, "Fish and tree"



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Special provisions (SP)

Excepted quantities (EQ) **F1** 

Limited quantities (LQ) 5 L

**EmS** F-A, S-B

Stowage category

18 - Alkalis Segregation group

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

Proper shipping name Ammonia solution

Particulars in the shipper's declaration UN2672, Ammonia solution, 8, III

**Environmental hazards YES** (hazardous to the aquatic environment)

Danger label(s) 8



Special provisions (SP) A64 Excepted quantities (EQ) E1 Limited quantities (LQ) 1 L

#### **SECTION 15: Regulatory information**

#### Safety, health and environmental regulations/legislation specific for the substance or mixture 15.1 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
Ammonia solution	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Ammonia%	substances in tattoo inks and permanent make-up		R75	75

#### Legend

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,

- S. Shall not be placed on the market if they contain a colouring agent, dilless required for iscar reasons, or perfutine, or both, if they:
   can be used as fuel in decorative oil lamps for supply to the general public, and
   present an aspiration hazard and are labelled with H304.
   4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- (CEN).
  5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following require-
- ments are met:

  (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage";

  (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';

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#### Legend

(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

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

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

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the

mixture in a concentration equal to or greater than 0,00005 % by weight;

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

(i) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

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

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

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

None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

#### **Seveso Directive**

2012/18/EU (Seveso III)							
No	Dangerous substance/hazard categories		y (tonnes) for the ap- r and upper-tier re- ements	Notes			
35	ammonia, anhydrous	50	200				

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

0 <sup>g</sup> / <sub>l</sub>
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#### **Industrial Emissions Directive (IED)**

VOC content	0 %
VOC content Water content was discounted	0 <sup>g</sup> / <sub>l</sub>

# 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
Ammonia%	Substances which contribute to eutrophication (in particular, nitrates and phosphates)		A)	

Legend

A) Indicative list of the main pollutants

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#### 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

#### **National inventories**

Country	Inventory	Status
AU	AICS	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

AICS Australian Inventory of Chemical Substances

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

Toxic Substance Control Act

#### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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## **SECTION 16: Other information**

#### **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
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 concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
CAP. 424	Occupational Health and Safety Authority Act (CAP. 424)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
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 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
IOELV	Indicative occupational exposure limit value

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Abbr.	Descriptions of used abbreviations
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)
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.

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 chapter 2 and 3)

Code	Text
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic 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.

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