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



Ammonia solution 25 %, Ph.Eur.

article number: **2610**Version: **3.0 en**date of compilation: 2021-08-11
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Version: (2)

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

1.1 Product identifier

Identification of the substance Ammonia solution 25 %, Ph.Eur.

Article number 2610

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]

Unique formula identifier (UFI) MU21-K0QG-Q007-FG82

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 Department Health, Safety and Environment

sheet:

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/

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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	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
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

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 ...%

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Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)



H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

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.
Immediately call a POISON CENTER/doctor. P310

Ammonia ...% contains:

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 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	≥ 25	Skin Corr. 1B / H314 Eye Dam. 1 / H318 STOT SE 3 / H335 Aquatic Acute 1 / H400 Aquatic Chronic 2 / H411	<u>*</u>	B GHS-HC IOELV

Notes

Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

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	STOT SE 3; H335: C ≥ 5 %	-	-	
	215-647-6 Index No 007-001-01-2				

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.

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



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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.

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

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)

	ou itr 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
ı	EU	ammonia, anhyd- rous	7664-41- 7	IOELV	20	14	50	36				2000/39/ EC
	IE	ammonia, anhyd- rous	7664-41- 7	OELV	20	14	50	36				S.I. No. 619 of 2001

Notation

Ceiling-C STEL

TWA

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)

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 sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time			
Ammonia%	1336-21-6	DNEL	47,6 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects			

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Relevant DNELs of components

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Ammonia%	1336-21-6	DNEL	47,6 mg/ m³	human, inhalat- ory	worker (industry)	acute - systemic effects
Ammonia%	1336-21-6	DNEL	14 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects
Ammonia%	1336-21-6	DNEL	36 mg/m³	human, inhalat- ory	worker (industry)	acute - local ef- fects
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

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Ammonia%	1336-21-6	PNEC	0,001 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Ammonia%	1336-21-6	PNEC	0,001 ^{mg} / _l	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.

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)

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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 -55 °C

Boiling point or initial boiling point and boiling 38 °C at 1.013 mPa

range

Flammability non-combustible

Lower and upper explosion limit 16 vol% (LEL) - 30 vol% (UEL)

Flash point not determined

Auto-ignition temperature 630 °C

Decomposition temperature not relevant pH (value) >12 (20 °C)

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)

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Vapour pressure 447 hPa at 20 °C

Density and/or relative density

Density $0.91 \, \mathrm{g/_{cm^3}}$ 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

Temperature class (EU, acc. to ATEX)

Maximum permissible surface temperature on

the equipment: 450°C

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.

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SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

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

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

Acute toxicity

Shall not be classified as acutely toxic.

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

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

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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

Very toxic to aquatic life with long lasting effects.

Aquatic toxicity (c	Aquatic toxicity (chronic) of components							
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time			
Ammonia%	1336-21-6	EC50	2.700 ^{mg} / _l	algae	18 d			

12.2 Persistence and degradability

Biodegradation

Not readily biodegradable.

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

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



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

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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 5 specific target organ toxicity (STOT)/aspiration toxicity

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

ADRRID UN 2672 IMDG-Code UN 2672 ICAO-TI UN 2672

14.2 UN proper shipping name

ADRRID AMMONIA SOLUTION IMDG-Code AMMONIA SOLUTION ICAO-TI Ammonia solution

14.3 Transport hazard class(es)

ADRRID 8
IMDG-Code 8
ICAO-TI 8

14.4 Packing group

ADRRID III
IMDG-Code III
ICAO-TI III

14.5 Environmental hazards hazardous to the aquatic environment

Environmentally hazardous substance (aquatic environment):

Ammonia ...%

4.6 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

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

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

Classification code C5

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





Environmental hazards Yes

Hazardous to water

Special provisions (SP) 543

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 3

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)

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





Special provisions (SP) -

Excepted quantities (EQ) E1

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Limited quantities (LQ) 5 L

EmS F-A, S-B

Stowage category

Segregation group 18 - Alkalis

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 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

Leaend

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 lokes.

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market.

3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they

can be used as fuel in decorative oil lamps for supply to the general public, and present an aspiration hazard and are labelled with H304.

- 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN)
- 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
- (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil
- or even sucking the wick of lamps may lead to life-threatening lung damage";

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

 (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.';

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Legend

R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(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

(f) in the case of a substance is the invalid in the legislation (EC) No 1223/2009 (17), 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

Seveso Directive

2012/	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

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
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

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)	
VN	NCI	all ingredients are listed	

Legend

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

TSCA **Toxic Substance Control Act**

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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- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance at a concentration of ≥ 0,1%.	yes
2.3	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1		National inventories: change in the listing (table)	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
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
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)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances

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Abbr.	Descriptions of used abbreviations
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
LEL	Lower explosion limit (LEL)
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 (Regula- tions 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
UEL	Upper explosion limit (UEL)
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).

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Classification procedure

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
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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