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

Acrylamide ≥99 %, BioScience Grade, 4x crystalline

article number: 0189 date of compilation: 18.11.2015

Version: **5.0 en** Revision: 02.03.2024 Replaces version of: 10.06.2022

Version: (4)

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

Product identifier 1.1

Identification of the substance **Acrylamide** ≥99 %, BioScience Grade, 4x crystal-

line

Article number 0189

Registration number (REACH) 01-2119463260-48-xxxx

Index number in CLP Annex VI 616-003-00-0

EC number 201-173-7 CAS number 79-06-1

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 products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

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**

SECTION 2: Hazards identification

Classification of the substance or mixture 2.1

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	4	Acute Tox. 4	H312
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315

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Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.45	Skin sensitisation		Skin Sens. 1	H317
3.5	Germ cell mutagenicity	1B	Muta. 1B	H340
3.6	Carcinogenicity	1B	Carc. 1B	H350
3.7	Reproductive toxicity	2	Repr. 2	H361f
3.9	Specific target organ toxicity - repeated exposure	1	STOT RE 1	H372

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure.

2.2 Label elements

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

Signal word Danger

Pictograms

GHS06, GHS08





Hazard statements

H301	Toxic if swallowed
H312+H332	Harmful in contact with skin or if inhaled
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H340	May cause genetic defects
H350	May cause cancer
H361f	Suspected of damaging fertility
H372	Causes damage to organs through prolonged or repeated exposure

Precautionary statements

Precautionary statements - prevention

P201 Obtain special instructions before use

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

Precautionary statements - response

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

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Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)





H301 Toxic if swallowed.

H317 May cause an allergic skin reaction.

H340 May cause genetic defects.

H350 May cause cancer.

H361f Suspected of damaging fertility.

H372 Causes damage to organs through prolonged or repeated exposure.

P201 Obtain special instructions before use.

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

P302+P352 IF ON SKIN: Wash with plenty of soap and water. P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

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

Name of substance Acrylamide

Molecular formula C₃H₅NO

Molar mass 71,08 g/_{mol}

REACH Reg. No 01-2119463260-48-xxxx

CAS No 79-06-1

EC No 201-173-7

Index No 616-003-00-0

Substance of Very High Concern (SVHC)

Name of substance	CAS No	EC No	Listed in	Remarks
Acrylamide	79-06-1	201-173-7	Candidate list	Carc. A57a Muta. A57b

Legend

Candidate Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Carc. A57a Carcinogenic (article 57a) Muta. A57b Mutagenic (article 57b)

Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	100 ^{mg} / _{kg} 1.141 ^{mg} / _{kg} >1,5 ^{mg} / _l /4h	oral dermal inhalation: dust/ mist

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SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

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

Following skin contact

After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

Following ingestion

Rinse mouth immediately and drink plenty of water. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Allergic reactions (such as skin rashes, hives, asthma or anaphylactic shock), Irritation, Loss of righting reflex, and ataxia, Poisoning effect on central nervous system can cause convulsions, laboured breathing and loss of consciousness

4.3 Indication of any immediate medical attention and special treatment needed

Give sodium sulfate as laxative (1 tablespoon in 1 glass of water).

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible. Vapours are heavier than air, spread along floors and form explosive mixtures with air.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO₂)

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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.

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 dust.

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. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

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

Provision of sufficient ventilation. Use extractor hood (laboratory). Avoid exposure. Avoid dust formation. Clear contaminated areas thoroughly.

Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep container tightly closed. Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Protect against external exposure, such as

UV-radiation/sunlight

Consideration of other advice:

Store locked up.

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Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °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)

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	acrylamide	79-06-1	IOELV	0,1			Н	2017/2398/ EU

Notation

Ceiling-C

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

Absorbed through the skin

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) Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 TWA

hours time-weighted average (unless otherwise specified)

Human health values

Relevant DNELs and other threshold levels						
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time		
DNEL	120 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects		
DNEL	120 mg/m³	human, inhalatory	worker (industry)	acute - local effects		
DNEL	3 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects		

Environmental values

Relevant PNECs and other threshold levels End-**Threshold Organism Environmental com-Exposure time** point level partment **PNEC** 0,032 ^{mg}/_l aquatic organisms freshwater short-term (single instance) $2^{\mu g}/_{I}$ **PNEC** aquatic organisms marine water short-term (single instance) **PNEC** 0,2 ^{mg}/_I sewage treatment plant aquatic organisms short-term (single instance) (STP)

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8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection.

Skin protection





hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. 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: Dust formation. Particulate filter device (EN 143). P3 (filters at least 99,95 % of airborne particles, colour code: White). Type: A-P2 (combined filters against particles and organic gases and vapours, colour code: Brown/White).

Environmental exposure controls

Keep away from drains, surface and ground water.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state solid

Form crystalline Colour white

Odour odourless

Melting point/freezing point 84,5 °C at 1.013 hPa (ECHA)

Boiling point or initial boiling point and boiling 232 °C at 1.013 hPa

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point 138 °C

Auto-ignition temperature not determined

Decomposition temperature >175 °C

pH (value) 5 – 8 (in aqueous solution: 50 g/_I, 20 °C)

Kinematic viscosity not relevant

Solubility(ies)

Water solubility 2.155 g_{\parallel} at 30 °C (ECHA)

Partition coefficient

Partition coefficient n-octanol/water (log value): -0,9 (pH value: ~7, 20 °C) (ECHA)

Vapour pressure 0,009 hPa at 25 °C

Density and/or relative density

Density $1,13 \, {}^{\rm g}/{}_{\rm cm^3}$ at 20 ${}^{\rm o}{\rm C}$

Relative vapour density 2,45 (air = 1) Bulk density $\sim 500 \, {\rm kg/m^3}$

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard hazard classes acc. to GHS

classes: (physical hazards): not relevant

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Other safety characteristics:

Temperature class (EU, acc. to ATEX)

T2

Maximum permissible surface temperature on the equipment: 300°C

SECTION 10: Stability and reactivity

10.1 Reactivity

Can polymerise exothermically if heated, exposed to air, sunlight or by addition of free radical initiators. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

If heated

Vapours may form explosive mixtures with air.

10.2 Chemical stability

Danger of polymerisation.

10.3 Possibility of hazardous reactions

Violent reaction with: Bases, Oxidisers, Peroxides, Sulphuric acid

10.4 Conditions to avoid

UV-radiation/sunlight. Keep away from heat. Decompostion takes place from temperatures above: $>175\,^{\circ}\text{C}$.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5. Peroxides.

SECTION 11: Toxicological information

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

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

Acute toxicity

Toxic if swallowed. Harmful in contact with skin. Harmful if inhaled.

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	354 ^{mg} / _{kg}	rat		ECHA
dermal	LD50	1.141 ^{mg} / _{kg}	rabbit		ECHA

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

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Germ cell mutagenicity

May cause genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Suspected of damaging fertility.

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Data are not available.

• If in eyes

Causes serious eye irritation

If inhaled

causes slight to moderate irritation

• If on skin

causes skin irritation, May produce an allergic reaction, pruritis, localised redness

Other information

Other adverse effects: Liver and kidney damage, Loss of righting reflex, and ataxia, Poisoning effect on central nervous system can cause convulsions, laboured breathing and loss of consciousness

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.

Aquatic toxicity (acute)							
Endpoint	Value	Species	Source	Exposure time			
EC50	98 ^{mg} / _l	aquatic invertebrates	ECHA	48 h			

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12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): 1,351 mg / $_{mg}$ Theoretical Oxygen Demand (with nitrification): 2,251 mg / $_{mg}$

Theoretical Carbon Dioxide: 1,857 mg/mg

Biodegradation

The substance is readily biodegradable.

Process	of deara	adability
1 1 0 0 0 0 3 3	oi acqit	MUDITLY

Process	Degradation rate	Time
biotic/abiotic	100 %	28 d
oxygen depletion	7,4 %	5 d

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	-0,9 (pH value: ~7, 20 °C) (ECHA)
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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

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.

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.

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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 6 acute toxicity **HP 7** carcinogenic

HP 10 toxic for reproduction

HP 11 mutagenic **HP 13** sensitising

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

ADR UN 2074
IMDG-Code UN 2074
ICAO-TI UN 2074

14.2 UN proper shipping name

ADR ACRYLAMIDE, SOLID IMDG-Code ACRYLAMIDE, SOLID ICAO-TI Acrylamide, solid

14.3 Transport hazard class(es)

ADR 6.1 IMDG-Code 6.1 ICAO-TI 6.1

14.4 Packing group

ADR III
IMDG-Code III
ICAO-TI III

14.5 Environmental hazards non-environmentally hazardous acc. to the dan-

gerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

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 ACRYLAMIDE, SOLID

Particulars in the transport document UN2074, ACRYLAMIDE, SOLID, 6.1, III, (E)

Classification code T2
Danger label(s) 6.1

Special provisions (SP) 802(ADN)

Excepted quantities (EQ)

Limited quantities (LQ)

Transport category (TC)

Tunnel restriction code (TRC)

E

Hazard identification No

60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name ACRYLAMIDE, SOLID

Particulars in the shipper's declaration UN2074, ACRYLAMIDE, SOLID, 6.1, III

Marine pollutant -

Danger label(s) 6.1

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
EmS F-A, S-A

Stowage category A

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

Proper shipping name Acrylamide, solid

Particulars in the shipper's declaration UN2074, Acrylamide, solid, 6.1, III

Danger label(s) 6.1

Excepted quantities (EQ) E1

Limited quantities (LQ) 10 kg

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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
Acrylamide	acrylamide	79-06-1	R60	60
Acrylamide	carcinogenic		R28-30	28
Acrylamide	germ cell mutagenic (mutagenic)		R28-30	29
Acrylamide	substances in tattoo inks and permanent make-up		R75	75

Legend

- R28-30 1. Shall not be placed on the market, or used,
 - as substances
 - as constituents of other substances, or,
 - in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater

either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'.

- 2. By way of derogation, paragraph 1 shall not apply to:
 (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
 (b) cosmetic products as defined by Directive 76/768/EEC;
 (c) the following fuels and oil products:
 motor fuels which are covered by Directive 98/70/EC,

- mineral oil products intended for use as fuel in mobile or fixed combustion plants,

- fuels sold in closed systems (e.g. liquid gas bottles);
 (d) artists' paints covered by Regulation (EC) No 1272/2008;
 (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;
 (f) devices covered by Regulation (EU) 2017/745.
- R60 Shall not be placed on the market or used as a substance or constituent of mixtures in a concentration, equal to or greater than 0,1 % by weight for grouting applications after 5 November 2012.

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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

Substance of Very High Concern (SVHC)						
Name acc. to invent- ory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of in- clusion
acrylamide	79-06-1	Candidate list	Carc. A57a Muta. A57b			30.03.2010

Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV Carc. A57a Carcinogenic (article 57a)

Muta. A57b Carcinogenic (article 57a)

Mutagenic (article 57b)

Seveso Directive

2012/	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	100 %
VOC content	1.130 ^g / _l

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content	0 ⁹ / ₁

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

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Water Framework Directive (WFD)

List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Acrylamide	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	

Legend

a) Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

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

not listed

Regulation on persistent organic pollutants (POP)

not 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	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed

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Country	Inventory	Status
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

AIIC CICR CSCL-ENCS DSL ECSI Australian Inventory of Industrial Chemicals

Chemical Inventory of Industrial Chemicals
Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances IECSC INSQ

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

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- relev- ant
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1	VOC content: 100 % 1.130 ^g / _l	VOC content: 100 %	yes
15.1		VOC content: 1.130 ^g / _l	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	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
2017/2398/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
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
Carc.	Carcinogenicity

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Abbr.	Descriptions of used abbreviations
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
EmS	Emergency Schedule
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
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
Muta.	Germ cell mutagenicity
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
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

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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). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H301	Toxic if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H340	May cause genetic defects.
H350	May cause cancer.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs through prolonged or repeated exposure.

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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