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



date of compilation: 2016-07-14

Revision: 2023-07-20

Kjeldahl tablets (free of mercury and selenium) 5 g

article number: **HN19** Version: **3.0 en** Replaces version of: 2022-01-11 Version: (2)

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

1.1 Product identifier

Identification of the substance

Article number

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Registration number (REACH)

not relevant (mixture)

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

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/

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class		Hazard class and category	Hazard statement
4.1C	Hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

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



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2.2 Label elements Labelling according to Regulation (EC) No 1272/2008 (CLP) **Signal word** Not required Not required **Pictograms Hazard statements** H412 Harmful to aquatic life with long lasting effects **Precautionary statements Precautionary statements - prevention** P273 Avoid release to the environment **Precautionary statements - disposal** P501 Dispose of contents/container in accordance with local/regional/national/international regulations Labelling of packages where the contents do not exceed 125 ml Signal word: Not required. H412 Harmful to aquatic life with long lasting effects. 2.3 **Other hazards Results of PBT and vPvB assessment** Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$. **Endocrine disrupting properties** Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$. SECTION 3: Composition/information on ingredients

3.1 **Substances**

not relevant (mixture)

3.2 **Mixtures**

Description of the mixture

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Copper(II) sulphate	CAS No 7758-98-7 EC No 231-847-6 Index No 029-004-00-0	1 - < 2,5	Acute Tox. 4 / H302 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410		GHS-HC

Notes

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

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

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Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ΑΤΕ	Exposure route
Copper(II) sulph- ate	CAS No 7758-98-7	-	-	482 ^{mg} / _{kg}	oral
	EC No 231-847-6				
	Index No 029-004-00-0				

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

No special measures are necessary.

Following inhalation

Provide fresh air.

Following skin contact

Rinse skin with water/shower.

Following eye contact

Rinse cautiously with water for several minutes.

Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

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, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

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



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5.2 Special hazards arising from the substance or mixture

Non-combustible.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

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. 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. 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

Avoid dust formation.

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

Store in a dry place.

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.

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



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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
IE	titanium dioxide	13463-67-7	OELV	10			i	S.I. No. 619 of 2001
IE	titanium dioxide	13463-67-7	OELV	4			r	S.I. No. 619 of 2001

Notation

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

 i
 Inhalable fraction

 r
 Respirable fraction

 STEL
 Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (unless otherwise specified)

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

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

Relevant DNELs of components of the mixture									
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time			
Copper(II) sulphate	7758-98-7	DNEL	1 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects			
Copper(II) sulphate	7758-98-7	DNEL	1 mg/m ³	human, inhalat- ory	worker (industry)	chronic - local ef- fects			
Copper(II) sulphate	7758-98-7	DNEL	137 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects			

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Copper(II) sulphate	7758-98-7	PNEC	7,8 ^{µg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Copper(II) sulphate	7758-98-7	PNEC	5,2 ^{µg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Copper(II) sulphate	7758-98-7	PNEC	230 ^{µg} / _I	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Copper(II) sulphate	7758-98-7	PNEC	87 ^{mg} / _{kg}	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Copper(II) sulphate	7758-98-7	PNEC	676 ^{mg} / _{kg}	aquatic organ- isms	marine sediment	short-term (single instance)
Copper(II) sulphate	7758-98-7	PNEC	65 ^{mg} / _{kg}	terrestrial organ- isms	soil	short-term (single instance)

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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 consider-able 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

>0,11 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

other protection measures

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

Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P1 (filters at least 80 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

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



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SECTION 9: Physical and chemical properties

9.1	Information on basic physical and chemical properties						
	Physical state	solid					
	Form	tablets					
	Colour	light grey					
	Odour	odourless					
	Melting point/freezing point	not determined					
	Boiling point or initial boiling point and boiling range	(unknown) not determined					
	Flammability	non-combustible					
	Lower and upper explosion limit	not determined					
	Flash point	not applicable					
	Auto-ignition temperature	>400 °C					
	Decomposition temperature	>560 °C					
	pH (value)	4,53 (in aqueous solution: 50 ^g / _l , 20 °C)					
	Kinematic viscosity	not relevant					
	Solubility(ies)						
	Water solubility	245 ^g / _l at 20 °C					
	Partition coefficient						
	Partition coefficient n-octanol/water (log value):	not relevant (inorganic)					
	Vapour pressure	not determined					
	Density and/or relative density						
	Density	2,7 ^g / _{cm³} at 20 °C					
	Relative vapour density	information on this property is not available					
	Bulk density	1.230 – 1.400 ^{kg} / _{m³}					
	Particle characteristics	No data available.					
	Other safety parameters						
	Oxidising properties	none					
9.2	Other information						
	Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant					
	Other safety characteristics:	There is no additional information.					

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



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SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat. Decompositon takes place from temperatures above: >560 °C. Protect from moisture.

10.5 Incompatible materials

alkalis, corrosive to steel

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

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

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture					
Name of substance CAS No Exposure route ATE					
Copper(II) sulphate	7758-98-7	oral	482 ^{mg} / _{kg}		

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Copper(II) sulphate	7758-98-7	oral	LD50	482 ^{mg} / _{kg}	rat
Copper(II) sulphate	7758-98-7	dermal	LD50	>2.000 ^{mg} / _{kg}	rat

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

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

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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

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

vomiting, nausea

• If in eyes

Data are not available.

• If inhaled

Data are not available.

• If on skin

Data are not available.

• Other information

none

11.2 Endocrine disrupting properties

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

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Aquatic toxicity (acute) of components of the mixture					
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Copper(II) sulphate	7758-98-7	LC50	193 ^{µg} / _l	fish	96 h

12.2 Persistence and degradability

Data are not available.

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



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12.3 Bioaccumulative potential

Data are not available.

- **12.4 Mobility in soil** Data are not available.
- **12.5** Results of PBT and vPvB assessment Does not contain a PBT-/vPvB-substance in a concentration of $\ge 0,1\%$.

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

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

Waste treatment of containers/packagings

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

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous HP 14 ecotoxic

HP 14 ecolo

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
- 14.2 UN proper shipping name
- 14.3 Transport hazard class(es)
- 14.4 Packing group
- 14.5 Environmental hazards

14.6 Special precautions for user

There is no additional information.

not subject to transport regulations

not assigned

none

not assigned

non-environmentally hazardous acc. to the dangerous goods regulations

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



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Maritime transport in bulk according to IMO instruments 14.7 The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information Not subject to ICAO-IATA.

SECTION 15: Regulatory information

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
Copper(II) sulphate	substances in tattoo inks and perman- ent make-up		R75	75

Leaend R75

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

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant

category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

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

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

(i) 0,1 % by weight, if the substance is used solely as a pH regulator;
(ii) 0,01 % by weight, in all other cases;
(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
(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; the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 to (g) of paragraph 1, the strictest concentration limit laid down in points (a) to (g) of paragraph 1, the strictest concentration limit laid down in points (a) to (g) of paragraph 1, the strictest concentration limit laid down in points (a) to (g) of paragraph 1, the strictest in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023: (a) Pigment Blue 15:3 (CI 74160, EC No 215-524-7, 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 ap-plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 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.

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Legend	
	6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listir 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 th
	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, t
	mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up";
	(b) a reference number to uniquely identify the batch;
	(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient
	names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the
	IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients sl be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" mean
	any substance added during the process of formulation and present in the mixture for use for tattooing purposes.
	purities 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 ingre
	ent 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 concentra
	tion limit specified in Appendix 13;
	(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) belo
	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) N
	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 po
	(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 t procedure with the information marked on the package or included in the instructions for use pursuant to this par
	graph.
	8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used
	tattooing purposes.
	9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or ger
	ate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 5 00-0, EC No 200-001-8).
	a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a
	10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accendence, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device, within the same meaning. Where the placing on the market or use may ively as a medical device or an accessory to a medical device or an accessory to a medical device. The same meaning device, the requirements of Regulation (EU) 2017 Regulation shall apply cumulatively.
	substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list
lone o	f the ingredients are listed.
Savasa	Directive
567630	Diective
2012/	18/EU (Seveso III)
2012/	

No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements	Notes
	not assigned		

Deco-Paint Directive

VOC content	0 %
VOC content	0 g/l

Industrial Emissions Directive (IED)

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

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VOC content	0 %
VOC content	0 g/l

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

none of the ingredients are listed

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

none of the ingredients are listed

Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Copper(II) sulphate	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)	
Copper(II) sulphate	Metals and their compounds		a)	

Legend

A) Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

Regulation on drug precursors

none of the ingredients are listed

Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

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

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

National inventories

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

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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	all ingredients are listed	
TW	TCSI	all ingredients are listed	
US	TSCA	all ingredients are listed (ACTIVE)	

Legend

Legena	
AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical safety assessment

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

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	yes
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional in- formation: Not subject to ADR, RID and ADN.		yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1	Restrictions according to REACH, Annex XVII: none of the ingredients are listed	Restrictions according to REACH, Annex XVII	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1	VOC content: 0 % , 0 ^g / _l	VOC content: 0 %	yes
15.1		VOC content: 0 ^g / _l	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: Chemical safety assessments for substances in this mixture were not carried out.	Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations	
Acute Tox.	Acute toxicity	
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing 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	
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an iden fier of substances commercially available within the EU (European Union)	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
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 Na- tions	
IATA	International Air Transport Association	
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)	

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Abbr.	Descriptions of used abbreviations
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
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
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

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

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

Code	Text
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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Code	Text
H412	Harmful to aquatic life with long lasting effects.

Disclaimer

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