Safety Data Sheet

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

(This safety data sheet is for information only as it does not comply with the official language requirements of Article 31 (5) of REACH nor does it provide the national information in sections 8 and 15 as specified in Annex II of REACH.)

ProteoClean - Reagent B

Version number: 2.0
Replaces version of: 2024-04-15 (1)

Revision: 2025-04-09
First version: 2024-04-15

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

1.1 Product identifier

Trade name **ProteoClean - Reagent B**

Unique formula identifier (UFI) 7X80-T0JJ-000N-M8KP

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

Relevant identified uses Inhibitor of Reagent A

1.3 Details of the supplier of the safety data sheet

CLADE GmbH
Schelztorstraße 54-56
73728 Esslingen
Germany

Telephone: +49 711-400 52 400
e-mail: info@clade.io
Website: clade.io

e-mail (competent person) nathalie.kittel@clade.io

National contact Telephone: +49 711-400 52 400
e-Mail: info@clade.io

1.4 Emergency telephone number

As above or nearest toxicological information centre.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Classification

Section	Hazard class	Category	Hazard class and category	Hazard state-ment
3.1O	acute toxicity (oral)	4	Acute Tox. 4	H302
3.2	skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word warning

Pictograms

GHS07

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statements

P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to an authorized waste treatment facility.

Hazardous ingredients for labelling Guanadine hydrochloride

2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

3.2 Mixtures

Description of the mixture

Hazardous ingredients

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Guanadine hydrochloride	CAS No 50-01-1	25 – < 50	Acute Tox. 4 / H302 Acute Tox. 4 / H332		GHS-HC

Hazardous ingredients

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
	EC No 200-002-3 REACH Reg. No 01-2119977063-35-xxxx		Skin Irrit. 2 / H315 Eye Irrit. 2 / H319		

Notes

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

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Guanadine hydrochloride	-	-	773.6 $^{mg}/_{kg}$ 3.181 $^{mg}/_{l}$/4h	oral inhalation: dust/mist

Remarks

For full text of H-phrases: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Self-protection of the first aider.
Remove affected person from the danger area and lay down.
Do not leave affected person unattended.
Take off immediately all contaminated clothing.
In all cases of doubt, or when symptoms persist, seek medical advice.

Following inhalation

Provide fresh air.
If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

Following skin contact

Wash with plenty of soap and water.
Take off contaminated clothing.
If skin irritation occurs: Get medical advice/attention.

Following eye contact

Irrigate copiously with clean, fresh water, holding the eyelids apart.
Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Following ingestion

Rinse mouth. Do not induce vomiting.
Get medical advice/attention.

Notes for the doctor

None.

4.2 Most important symptoms and effects, both acute and delayed

Malaise.
Vomiting.
Diarrhoea.
Nausea.
Irritating to eyes and skin.
Harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, fire extinguishing powder, carbon dioxide (CO_2)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.
Hazardous decomposition products: Section 10.

Hazardous combustion products

nitrogen oxides (NO_x), carbon monoxide (CO), carbon dioxide (CO_2), hydrogen chloride (HCl)

5.3 Advice for firefighters

Keep containers cool with water spray.
In case of fire and/or explosion do not breathe fumes.
Co-ordinate firefighting measures to the fire surroundings.
Do not allow firefighting water to enter drains or water courses.
Collect contaminated firefighting water separately.
Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133)

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.
Ventilate affected area.
Eliminate all ignition sources if safe to do so.
Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

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

Bunding.
Covering of drains.

Advice on how to clean up a spill

Collect spillage.
Absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal.
Ventilate affected area.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not get in eyes, on skin, or on clothing.

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.
Keep away from sources of ignition - No smoking.

Measures to protect the environment

Avoid release to the environment.
Do not empty into drains; dispose of this material and its container at hazardous or special waste collection point.

Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.
Wash hands after use.
Preventive skin protection (barrier creams/ointments) is recommended.
Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Flammability hazards

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Incompatible substances or mixtures

Incompatible materials: see section 10.
Store away from oxidizing agents.

Protect against external exposure, such as

frost

Consideration of other advice

Keep away from food, drink and animal feedingstuffs.

Ventilation requirements

Provision of sufficient ventilation.

Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.
Keep cool.

Packaging compatibilities

Keep only in original container.

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)
This information is not available.

Human health values

Relevant DNELs of components

Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Guanadine hydro-	50-01-1	DNEL	3.5 mg/m³	human, inhalat-	worker (industry)	chronic - systemic

Relevant DNELs of components						
Name of sub-stance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
chloride				ory		effects
Guanadine hydro-chloride	50-01-1	DNEL	1 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

8.2 Exposure controls

Appropriate engineering controls

Use local and general ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection. (EN 166)

Hand protection

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
IIR: isobutene-isoprene (butyl) rubber	no information available	no information available
FKM: fluoro-elastomer	no information available	no information available
NBR: acrylonitrile-butadiene rubber	no information available	no information available

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.

Body protection

Protective clothing against liquid chemicals.
(EN 13832, EN 340, EN 13034, EN 14605).

Respiratory protection

In case of inadequate ventilation wear respiratory protection.
(EN 136, EN 140, EN 14387, EN 143, EN 149).

Environmental exposure controls

Use appropriate container to avoid environmental contamination.
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	blue
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	6 – 8 (20 °C)
Kinematic viscosity	not determined
Dynamic viscosity	not determined
Solubility(ies)	
Water solubility	not miscible in any proportion
Partition coefficient n-octanol/water (log value)	not determined
Vapour pressure	not determined
Density and/or relative density	
Density	1.122 $^{g}/_{cm^3}$
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)

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

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.
See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.
Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification procedure

If not otherwise specified the classification is based on:
Ingredients of the mixture (additivity formula).

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

Acute toxicity

Test data are not available for the complete mixture.
Harmful if swallowed.

Acute toxicity estimate (ATE)

Oral 1,682 $^{mg}/_{kg}$

Acute toxicity of components

Acute toxicity estimate (ATE) of components

Name of substance	CAS No	Exposure route	ATE
Guanadine hydrochloride	50-01-1	oral	773.6 $^{mg}/_{kg}$
Guanadine hydrochloride	50-01-1	inhalation: dust/mist	3.181 $^{mg}/_{l}$/4h

Acute toxicity of components

Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
Guanadine hydrochloride	50-01-1	oral	LD50	773.6 $^{mg}/_{kg}$	rat, female	OECD Guideline 401	ECHA
Guanadine hydrochloride	50-01-1	inhalation: dust/mist	LC50	3.181 $^{mg}/_{l}$/4h	rat, female	OECD Guideline 403	ECHA
Guanadine hydrochloride	50-01-1	dermal	LD50	>2,000 $^{mg}/_{kg}$	rabbit	OECD Guideline 402	ECHA

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation
Skin sensitisation

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Respiratory sensitisation

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Germ cell mutagenicity

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Carcinogenicity

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Reproductive toxicity

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Specific target organ toxicity - single exposure

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Specific target organ toxicity - repeated exposure

Classification could not be established because:
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

Endocrine disrupting properties

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

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity (acute)

Based on available data, the classification criteria are not met.

Aquatic toxicity (acute) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
Guanadine hydrochloride	50-01-1	LC50	48 h	1,758 $^{mg}/_{l}$	orfe (Leuciscus idus)	DIN 38412 T.15	ECHA
Guanadine hydrochloride	50-01-1	EC50	48 h	70.2 $^{mg}/_{l}$	daphnia magna	OECD Guideline 202	ECHA
Guanadine hydrochloride	50-01-1	ErC50	72 h	33.5 $^{mg}/_{l}$	algae (raphidocelis subcapitata)	EU method C.3	ECHA

Aquatic toxicity (chronic)

Based on available data, the classification criteria are not met.

Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
Guanadine hydrochloride	50-01-1	NOEC	35 d	181 $^{mg}/_{l}$	fathead minnow (Pimephales promelas)	OECD Guideline 210	ECHA
Guanadine hydrochloride	50-01-1	NOEC	21 d	2.9 $^{mg}/_{l}$	daphnia magna	OECD Guideline 211	ECHA
Guanadine hydrochloride	50-01-1	NOEC	72 h	6.3 $^{mg}/_{l}$	algae (raphidocelis subcapitata)	OECD Guideline 201	ECHA
Guanadine hydrochloride	50-01-1	LOEC	35 d	424 $^{mg}/_{l}$	fathead minnow (Pimephales	OECD Guideline 210	ECHA

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
					promelas)		
Guanadine hydrochloride	50-01-1	LOEC	21 d	4.2 – 6.09 $^{mg}/_{l}$	daphnia magna	OECD Guideline 211	ECHA

12.2 Persistence and degradability

Biodegradation

No data available.

Persistence

No data available.

12.3 Bioaccumulative potential

Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW
Guanadine hydrochloride	50-01-1	-	<-1.7 (pH value: 7.4, 20 °C)

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

Remarks

Wassergefährdungsklasse, WGK (water hazard class): 1.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

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

Remarks

Please consider the relevant national or regional provisions.

SECTION 14: Transport information

14.1	**UN number or ID number**	
	ADN	ID9006
	ADR/RID	-
	IMDG-Code	-
	ICAO-TI	-
14.2	**UN proper shipping name**	
	ADN	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
	ADR/RID	-
	IMDG-Code	-
	ICAO-TI	-
14.3	**Transport hazard class(es)**	
	ADN	9
	ADR/RID	-
	IMDG-Code	-
	ICAO-TI	-
14.4	**Packing group**	-
14.5	**Environmental hazards**	environmentally hazardous (ADN)
14.6	**Special precautions for user**	-
14.7	**Maritime transport in bulk according to IMO instruments**	-

14.8 **Information for each of the UN Model Regulations**

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

Not subject to ADR.
Not subject to RID.
Product is subject of ADN-regulation. (Dangerous only when carried in tanker vessels)

European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) Additional information

Number of cones/blue lights 0

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

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	CAS No	Restriction
ProteoClean - Reagent B	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	-	R3
Guanadine hydrochloride	substances in tattoo inks and permanent make-up	-	R75

Legend

R3 1. Shall not be used in:
- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, 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.’;

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

Legend

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:
(i) “Rinse-off products”;
(ii) “Not to be used in products applied on mucous membranes”;
(iii) “Not to be used in eye products”;
(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture “for tattooing purposes” means injection or introduction of the mixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
(a) the statement “Mixture for use in tattoos or permanent make-up”;
(b) a reference number to uniquely identify the batch;

Legend

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. “Ingredient” means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.
The information shall be clearly visible, easily legible and marked in a way that is indelible.
The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.
Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes.
9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).
10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

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

None of the ingredients are listed.

Seveso Directive

Not assigned.

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

None of the ingredients are listed.

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.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this mixture by the supplier.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
3.2	-	Hazardous ingredients: change in the listing (table)
14.1	UN number or ID number: not assigned	UN number or ID number
14.2	-	ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
14.3	-	ADN: 9
14.5	Environmental hazards: -	Environmental hazards: environmentally hazardous (ADN)
14.8	-	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) Additional information: Not subject to ADR. Not subject to RID. Product is subject of ADN-regulation. (Dangerous only when carried in tanker vessels)
14.8	-	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN) Additional information
14.8	-	Number of cones/blue lights: 0
14.8	-	International Maritime Dangerous Goods Code (IMDG) Additional information: Not subject to IMDG.
14.8	-	International Civil Aviation Organization (ICAO-IATA/DGR) Additional information: Not subject to ICAO-IATA.

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
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
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
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
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
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
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 dur-

Abbr.	Descriptions of used abbreviations
	ing a specified time interval
LOEC	Lowest Observed Effect Concentration
log KOW	n-Octanol/water
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
SVHC	Substance of Very High Concern
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.
Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN).
International Maritime Dangerous Goods Code (IMDG).
Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties.
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.
H332	Harmful if inhaled.

Responsible for the safety data sheet

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Disclaimer

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