

Monoclonal antibody in borate buffer

Version number: 1.0

Date of compilation: 11.02.2025

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

1.1 Product identifier

Trade name	Monoclonal antibody in borate buffer
Registration number (REACH)	not relevant (mixture)
Article number	M9160BBC, M9048BBC, M9089BBC, M9117BBC, M9174BBC, M9049BBC, M9118BBC, M9053BBC, M9087BBD, M9139BBD

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

Relevant identified uses	For laboratory professional use only.
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1.3 Details of the supplier of the safety data sheet

Essange Reagents
Plesmanlaan 125
1066 CX Amsterdam
Netherlands

Telephone: +31 20 4570707
e-mail: info@essange-reagents.nl
Website: www.essange-reagents.com

e-mail (competent person) safety@essange-reagents.nl

1.4 Emergency telephone number

Emergency information service	+31 20 4570707 This number is only available during the following office hours: Mon-Fri 09:00 - 17:00, (CET)
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

This mixture does not meet the criteria for classification.

Code	Supplemental hazard information
EUH210	safety data sheet available on request

2.2 Label elements

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

- signal word Not required.
- pictograms Not required.
- supplemental hazard information
EUH210 Safety data sheet available on request.

2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$. (Section 11 & 12).

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

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3.2 Mixtures

The product does not contain any other ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.

Name of substance	Identifier	Wt%	Classification acc. to GHS	Notes
Boric acid	CAS No 10043-35-3 EC No 233-139-2 Index No 005-007-00-2 REACH Reg. No 01-2119486683-25- xxxx	< 0,3	Repr. 1B / H360FD	11 GHS-HC

Notes

11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is $\geq 0,3\%$.

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

Remarks

All the percentages given are percentages by weight unless stated otherwise. For full text of H-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. 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. In case of respiratory tract irritation, consult a physician.

Following skin contact

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

Following eye contact

Irrigate copiously with clean, fresh water for at least 15 minutes, 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 with water (only if the person is conscious). 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

Water spray; Alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO₂);
Co-ordinate firefighting measures to the fire surroundings.

Unsuitable extinguishing media

Water jet.

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5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

During fire hazardous fumes/smoke could be produced.

5.3 Advice for firefighters

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 (SCBA). Standard protective clothing for firefighters.

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.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece).

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

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- incompatible substances or mixtures

Keep away from alkalis, oxidising substances, acids.

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Control of effects

Protect against external exposure, such as

High temperatures. UV-radiation/sunlight. Frost.

Consideration of other advice

Store in a well-ventilated place. Keep container tightly closed.

- packaging compatibilities

Only packagings which are approved (e.g. acc. to the Dangerous Goods Regulations) may be used.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

No information available. Countries not listed may have their own country specific values.

Relevant DNELs/DMELs/PNECs and other threshold levels

Relevant DNELs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Boric acid	10043-35-3	DNEL	8,3 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	392 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	4,15 mg/m ³	human, inhalatory	consumer (private households)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	196 mg/kg bw/day	human, dermal	consumer (private households)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	0,98 mg/kg bw/day	human, oral	consumer (private households)	chronic - systemic effects
Boric acid	10043-35-3	DNEL	0,98 mg/kg bw/day	human, oral	consumer (private households)	acute - systemic effects

Relevant PNECs of components						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Boric acid	10043-35-3	PNEC	13,7 mg/l	aquatic organisms	water	intermittent release
Boric acid	10043-35-3	PNEC	2,9 mg/l	aquatic organisms	freshwater	short-term (single instance)
Boric acid	10043-35-3	PNEC	2,9 mg/l	aquatic organisms	marine water	short-term (single instance)
Boric acid	10043-35-3	PNEC	10 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Boric acid	10043-35-3	PNEC	5,7 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation. Provide eyewash stations and safety showers at the workplace.

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Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection (EN 166).

Skin protection



Chemical protective clothing. Protective clothing (EN 340 & EN ISO 13688).

Hand protection



Wear suitable gloves. 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. Chemical protection gloves are suitable, which are tested according to EN 374. The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- type of material

PVC: polyvinyl chloride, CR: chloroprene (chlorobutadiene) rubber, Nitrile rubber

- breakthrough time of the glove material

Use gloves with a minimum breakthrough time of the glove material: >10 minutes (permeation: level 1).

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Type: ABEK-P2 (combined filters against gases, vapours and particles, colour code: Brown/Grey/Yellow/Green/White).

Environmental exposure controls

Take appropriate precautions to avoid uncontrolled release into the environment. 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	various
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C calculated value, referring to a component of the mixture
Flammability	non-combustible
Lower and upper explosion limit	LEL: UEL: not determined
Flash point	not applicable
Auto-ignition temperature	not relevant
Decomposition temperature	no data available
pH (value)	8,7 – 8,9
Kinematic viscosity	not determined

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Solubility

Water solubility	miscible in any proportion
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Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	2,3 kPa at 20 °C calculated value, referring to a component of the mixture
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Density and/or relative density

Density	not determined
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Relative vapour density	information on this property is not available
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Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
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Other safety characteristics

Miscibility	Completely miscible with water.
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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

There are no specific conditions known which have to be avoided.

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 toxicological effects

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).

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Classification acc. to GHS

This mixture does not meet the criteria for classification.

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity of components					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Boric acid	10043-35-3	oral	LD50	3.450 mg/kg	rat
Boric acid	10043-35-3	dermal	LD50	>2.000 mg/kg	rabbit

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

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.

11.2 Information on other hazards

Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

Endocrine disrupting chemicals (EDC)				
Name of substance	CAS No	Human health category	Wildlife category	Reference decision
Boric acid	10043-35-3	CAT1	CAT2	DHI 2006

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals

CAT2 Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

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Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Boric acid	10043-35-3	LC50	447 mg/l	fish	96 h
Boric acid	10043-35-3	LOEC	99,4 mg/l	fish	96 h
Boric acid	10043-35-3	NOEC	13 mg/l	fish	96 h

Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Boric acid	10043-35-3	EC50	180,6 mg/l	aquatic invertebrates	24 h
Boric acid	10043-35-3	NOEC	18 mg/l	fish	87 d
Boric acid	10043-35-3	LOEC	108 mg/l	fish	14 d

12.2 Persistence and degradability

Data are not available.

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 at a concentration of $\geq 0,1\%$.

12.6 Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

Endocrine disrupting chemicals (EDC)				
Name of substance	CAS No	Human health category	Wildlife category	Reference decision
Boric acid	10043-35-3	CAT1	CAT2	DHI 2006

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals

CAT2 Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packages

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. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

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SECTION 14: Transport information

14.1 UN number or ID number	not subject to transport regulations
14.2 UN proper shipping name	not relevant
14.3 Transport hazard class(es)	none
14.4 Packing group	not assigned
14.5 Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations
14.6 Special precautions for user	There is no additional information.
14.7 Maritime transport in bulk according to IMO instruments	No data available.

Additional 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, RID and ADN.

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

This Safety Data Sheet is purely informative and does comply with EU regulations, but not with country-specific regulations.

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	Restriction	No
Boric acid	toxic for reproduction	R28-30	30
Boric acid	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 than:
 - 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;

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Legend

- (f) devices covered by Regulation (EU) 2017/745.
- 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 weight;
 - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitizer 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;
 - (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.

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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 inventory	CAS No	Listed in	Remarks
boric acid	10043-35-3	Candidate list	Repr. A57c

Legend

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

Repr. A57c Toxic for reproduction (article 57c)

Seveso Directive

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		

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
Boric acid	Substances and preparations, or the breakdown products of such, which have been proved to possess 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 (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

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

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Safety Data Sheet

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

GENERIC EU SDS - NO COUNTRY SPECIFIC DATA

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Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
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)
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)
DMEL	Derived Minimal Effect Level
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
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
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
LEL	Lower explosion limit (LEL)
LOEC	Lowest Observed Effect Concentration
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Repr.	Reproductive toxicity
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
vPvB	Very Persistent and very Bioaccumulative

Safety Data Sheet

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

GENERIC EU SDS - NO COUNTRY SPECIFIC DATA

Monoclonal antibody in borate buffer

Version number: 1.0

Date of compilation: 11.02.2025

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.

UN Recommendations on the Transport of Dangerous Good. 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
H360FD	May damage fertility. May damage the unborn child.

Disclaimer

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