Safety Data Sheet

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

GENERIC EU SDS - NO COUNTRY SPECIFIC DATA

Pelikloon control monoclonal

Version number: 1.0 | Date of compilation: 15.01.2024

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

1.1 Product identifier

Trade name	**Pelikloon control monoclonal**
Registration number (REACH)	not relevant (mixture)
Article number	K1156

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

Relevant identified uses	For laboratory professional use only.

1.3 Details of the supplier of the safety data sheet

Sanquin Reagents B.V.
Plesmanlaan 125
1066 CX Amsterdam
Netherlands

Telephone: +31 20 4570707
e-mail: reagents@sanquin.nl
Website: www.sanquin.org/reagents

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)

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

Hazards not otherwise classified

Safety data sheet available on request.

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture).

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
Bovine Albumin	CAS No 9048-46-8 EC No 232-936-2	5 – < 10	Acute Tox. 4 / H302	

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Bovine Albumin	CAS No 9048-46-8	-	-	500 $^{mg}/_{kg}$	oral

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.

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.

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)

There is no additional information.

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

No data available.

8.2 Exposure controls

Appropriate engineering controls

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

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)	7,1 – 7,6
Kinematic viscosity	not determined

Solubility

Water solubility	miscible in any proportion

Partition coefficient n-octanol/water (log value)	this information is not available

Vapour pressure	2,3 kPa at 20 °C calculated value, referring to a component of the mixture

Density and/or relative density

Density	not determined
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)

9.2 Other information

There is no additional information.

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

Other safety characteristics

Miscibility	Completely miscible with water.

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).

Classification acc. to GHS

This mixture does not meet the criteria for classification.

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components

Name of substance	CAS No	Exposure route	ATE
Bovine Albumin	9048-46-8	oral	500 mg/kg

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

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

Other information

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

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 in a concentration of ≥ 0,1%.

12.6 Endocrine disrupting properties

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

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

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 information - national regulations - additional information (UN RTDG)

Not subject to transport regulations: UN RTDG

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
Bovine Albumin	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	R3	3

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 ash-trays,
- 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.’;

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

None of the ingredients are listed.

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.

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

Revision

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Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ATE	Acute Toxicity Estimate
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
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
LEL	Lower explosion limit (LEL)
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
UN RTDG	UN Recommendations on the Transport of Dangerous Good
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.

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
H302	Harmful if swallowed.

Disclaimer

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