PROGEN

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 18.01.2022 Version number 4 Revision: 08.03.2021

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

· **1.1 Product identifier**

· **Trade name: Purified Immunoglobulin**

· **Article number:** 690001-691999
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the mixture** Laboratory chemicals

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
PROGEN Biotechnik GmbH
Maaßstraße 30
D-69123 Heidelberg Tel.: 06221/8278-0

· **Further information obtainable from:** SDS@progen.com
· **1.4 Emergency telephone number:** +49 6221-8278-0

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **2.3 Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:** Void
· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.
· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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· ***5.3 Advice for firefighters***
· ***Protective equipment:*** *No special measures required.*

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SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures*** *Not required.*
· ***6.2 Environmental precautions:*** *No special measures required.*
· ***6.3 Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· ***6.4 Reference to other sections***
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling*** *No special measures required.*
· ***Information about fire - and explosion protection:*** *No special measures required.*

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage:***
· ***Requirements to be met by storerooms and receptacles:*** *No special requirements.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:*** *Store in a cool place.*
· ***7.3 Specific end use(s)*** *No further relevant information available.*

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SECTION 8: Exposure controls/personal protection

· ***8.1 Control parameters***
· ***Additional information about design of technical facilities:*** *No further data; see item 7.*
· ***Ingredients with limit values that require monitoring at the workplace:***
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· ***Additional information:*** *The lists valid during the making were used as basis.*

· ***8.2 Exposure controls***
· ***Personal protective equipment:***
· ***General protective and hygienic measures:***
The usual precautionary measures are to be adhered to when handling chemicals.
· ***Respiratory protection:*** *Not required.*
· ***Protection of hands:***
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· ***Material of gloves***
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.
· ***Penetration time of glove material***
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye protection:** Goggles recommended during refilling

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Fluid
Colour:	Clear
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Not applicable.
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not determined.
Upper:	Not determined.
· **Vapour pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with water:**	Not miscible or difficult to mix.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic at 20 °C:	0 s (DIN 53211/4)
· **Solvent content:**	
VOC (EC)	0.00 %
Solids content:	100.0 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known.
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.

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· **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**		
26628-22-8 sodium azide		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
· **Additional toxicological information:**
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Not hazardous for water.
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation** Smaller quantities can be disposed of with household waste.

· **European waste catalogue**	
18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 02 00	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection

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· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· **14.1 UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **14.2 UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **14.3 Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **14.4 Packing group** · **ADR, IMDG, IATA**	Void
· **14.5 Environmental hazards:** · **Marine pollutant:**	No
· **14.6 Special precautions for user**	Not applicable.
· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **UN "Model Regulation":**	Void

SECTION 15: Regulatory information

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

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**
None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**
None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
None of the ingredients is listed.

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:**

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· ***Contact:*** *Fr. Dr. I. Berger, Fr. Dr. D. Holzinger*

· ***Abbreviations and acronyms:***

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

· **** Data compared to the previous version altered.***