

**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

**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.

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- **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.

**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.

### **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.

### **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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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**SECTION 9: Physical and chemical properties**

**· 9.1 Information on basic physical and chemical properties**

**· General Information**

**· Appearance:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Clear
<b>· Odour:</b>	Characteristic
<b>· Odour threshold:</b>	Not determined.

**· pH-value:** Not determined.

**· Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	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:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	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:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic at 20 °C:</b>	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 (carcinogenicity, 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**

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

### **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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**Trade name: Purified Immunoglobulin**

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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.**

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