

SAFETY DATA SHEET (SDS) — prepared in accordance with Regulation (EC) No 1907/2006 (REACH), Annex II, as amended by Regulation (EU) 2020/878.

⚠️ DRAFT — FOR RESEARCH USE ONLY (RUO). This document is a compliance draft. It must be reviewed, completed and validated by a qualified competent person before official issuance. Data marked "No data available" or "To be confirmed by competent person" must be verified against the manufacturer's Certificate of Analysis and authoritative literature. No regulatory values have been assumed or invented.

Safety Data Sheet — HGH 191AA (Somatropin)

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

1.1. Product identifier

- Product name: **HGH 191AA (Somatropin)**
- Product code (SKU): PL-HGH36
- Pack size: 12 mg per vial

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

- Identified use: **Strictly for laboratory research and analytical use only (Research Use Only, RUO).**
- Uses advised against: **NOT** for human or veterinary use, **NOT** for diagnostic or therapeutic use, **NOT** for use in or on the body, **NOT** for food, cosmetic or household use. Not a medicinal product within the meaning of Directive 2001/83/EC.

1.3. Details of the supplier of the safety data sheet

- Supplier: PeptidLabs
- Registered company name & address: *[to be completed — operating legal entity]*
- e-mail (competent person / SDS contact): info@peptidlabs.eu

1.4. Emergency telephone number

- +359 895 345 189 (availability: business hours — *confirm 24/7 arrangement if required for placing on the EU market*)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

- Not classified under CLP based on available data. Hazards not fully characterized. Handle with GLP precautions.**
- (Regulation (EC) No 1272/2008.) Toxicological and ecological data for this substance are limited or unavailable; in the absence of full data, treat as a substance of unknown toxicity.

2.2. Label elements (CLP)

- Hazard pictograms: None required based on available data.
- Signal word: None.
- Hazard statements: None assigned (data not sufficient for classification).
- Precautionary statements: P262 — Do not get in eyes, on skin, or on clothing. P270 — Do not eat, drink or smoke when using this product. P280 — Wear protective gloves/eye protection.

2.3. Other hazards

- PBT/vPvB assessment: Not determined (No data available).
- Research Use Only.** This product is supplied for research and is not intended, tested or approved for human or animal exposure.

SECTION 3: Composition / information on ingredients

3.1. Substances

Identifier	Value
Chemical / product name	HGH 191AA (Somatropin)
CAS No.	N/A (Research Chemical)
EC (EINECS) No.	No data available
Molecular formula	No data available
Molecular weight	No data available
Peptide sequence (if applicable)	No data available
Purity	≥ 99% (HPLC)

CAS numbers, where stated, were verified against the PubChem registry; "N/A (Research Chemical)" is used where no registered CAS was confirmed for the exact compound (novel, blend or uncharacterised) — this is acceptable for a research-use-only substance. Full disclosure of any classified impurities/stabilisers is subject to the manufacturer's CoA.

SECTION 4: First-aid measures

4.1. Description of first-aid measures

- **Inhalation:** Move to fresh air. If symptoms persist, obtain medical advice. Show this SDS.
- **Skin contact:** Remove contaminated clothing. Wash affected area with soap and water. If irritation develops, seek medical advice.
- **Eye contact:** Rinse cautiously with water for several minutes; remove contact lenses if present and easy to do. Continue rinsing. Seek medical advice.
- **Ingestion:** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Obtain medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed: No data available.

4.3. Indication of any immediate medical attention and special treatment needed: No specific antidote known. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media: Suitable — water spray, alcohol-resistant foam, dry chemical, carbon dioxide (CO₂).
Unsuitable — high-volume water jet.

5.2. Special hazards arising from the substance or mixture: Combustion may release carbon oxides (CO, CO₂) and nitrogen oxides (NO_x).

5.3. Advice for firefighters: Wear self-contained breathing apparatus (SCBA) and full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures: Wear appropriate PPE (Section 8).
Avoid generating and inhaling dust.

6.2. Environmental precautions: Prevent entry into drains, watercourses and soil.

6.3. Methods and material for containment and cleaning up: Collect mechanically; avoid dust generation. Place in a labelled container for disposal (Section 13). Clean the area afterwards.

SECTION 7: Handling and storage

7.1. Precautions for safe handling: Handle under GLP. Use local exhaust ventilation / fume hood when handling powders. Avoid dust formation, and contact with eyes, skin and clothing. Do not eat, drink or smoke. Wash hands after

handling.

7.2. Conditions for safe storage, including any incompatibilities: Store the sealed lyophilised vial at –20 °C, protected from light and moisture. After reconstitution, store at 2–8 °C and use within the validated period. Keep tightly closed. Keep away from oxidising agents.

7.3. Specific end use(s): Laboratory research use only.

SECTION 8: Exposure controls / personal protection

8.1. Control parameters: No occupational exposure limits (OEL) established for this substance (No data available).

8.2. Exposure controls:

- Engineering controls: Adequate ventilation; fume hood / local exhaust for powder handling.
 - Eye/face protection: Safety glasses with side shields (EN 166).
 - Skin protection: Chemical-resistant nitrile gloves (EN 374); laboratory coat.
 - Respiratory protection: Where dust may be generated, wear a particulate respirator (EN 149 FFP2 or better).
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Property	Value
Physical state	Solid (lyophilised powder)
Appearance / colour	White to off-white lyophilised (freeze-dried) powder
Odour	Odourless / No data available
pH	No data available
Melting point / freezing point	No data available
Boiling point	No data available
Flash point	No data available
Flammability	No data available
Solubility	Soluble in water / bacteriostatic water (typical for this class)
Partition coefficient (log K _{ow})	No data available
Molecular weight	No data available

9.2. Other information: No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity: Not reactive under normal conditions of use.

10.2. Chemical stability: Stable under the recommended storage conditions (Section 7).

10.3. Possibility of hazardous reactions: None known under normal handling.

10.4. Conditions to avoid: Heat, moisture, direct light, repeated freeze–thaw cycles.

10.5. Incompatible materials: Strong oxidising agents.

10.6. Hazardous decomposition products: Carbon oxides (CO, CO₂), nitrogen oxides (NO_x) on thermal decomposition.

SECTION 11: Toxicological information

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

- Acute toxicity: No data available
- Skin corrosion/irritation: No data available
- Serious eye damage/irritation: No data available
- Respiratory or skin sensitisation: No data available
- Germ cell mutagenicity / Carcinogenicity / Reproductive toxicity (CMR): No data available
- STOT (single / repeated exposure): No data available
- Aspiration hazard: No data available

No specific toxicological data are available for this substance. The absence of data does not imply the absence of hazard.

SECTION 12: Ecological information

- **12.1. Toxicity:** No data available
- **12.2. Persistence and degradability:** No data available
- **12.3. Bioaccumulative potential:** No data available
- **12.4. Mobility in soil:** No data available
- **12.5. Results of PBT and vPvB assessment:** Not determined.
- **12.6. Other adverse effects:** No data available. As a precaution, do not release into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods: Dispose of contents and container in accordance with Directive 2008/98/EC on waste and local/regional/national regulations, as laboratory chemical waste, through a licensed waste-disposal contractor. Do not empty into drains. Contaminated packaging must be disposed of as the contained product.

SECTION 14: Transport information

Regulation	Status
UN number	None
ADR/RID (road/rail)	Not classified as dangerous goods
IMDG (sea)	Not classified as dangerous goods
IATA (air)	Not classified as dangerous goods

14.x. Based on available information, this product in lyophilised/research-quantity form is **not regulated as a dangerous good for transport**. Transport in tightly closed, labelled containers. *Confirm against the specific consignment and carrier requirements.*

SECTION 15: Regulatory information

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

- **REACH (Reg. (EC) No 1907/2006):** This substance is supplied for scientific research and development. It is understood **not to be registered** under REACH on the basis of research use and/or the applicable tonnage threshold / PPORD provisions (to be confirmed by the supplier).
- **CLP (Reg. (EC) No 1272/2008):** No harmonised classification (Annex VI) identified for this substance based on available information.
- **Restrictions/Authorisation:** Not identified on REACH Annex XVII (restrictions) or Annex XIV (authorisation) based on available information (To be confirmed by competent person).
- **⚠ RESEARCH USE ONLY (RUO).** This product is **not** a medicinal product (Dir. 2001/83/EC), **not** a food or novel food (Reg. (EU) 2015/2283), **not** a food supplement (Dir. 2002/46/EC) and **not** a cosmetic (Reg. (EC) No 1223/2009).

It must not be sold, marketed or used for human or animal consumption, diagnosis or therapy.

15.2. Chemical safety assessment: A chemical safety assessment has not been carried out for this substance.

SECTION 16: Other information

Full text of abbreviations: CLP — Classification, Labelling and Packaging; REACH — Registration, Evaluation, Authorisation and Restriction of Chemicals; GLP — Good Laboratory Practice; OEL — Occupational Exposure Limit; PBT — Persistent, Bioaccumulative, Toxic; vPvB — very Persistent, very Bioaccumulative; PPORD — Product and Process Orientated Research and Development; RUO — Research Use Only; CMR — Carcinogenic, Mutagenic, Reprotoxic; STOT — Specific Target Organ Toxicity; SCBA — Self-Contained Breathing Apparatus.

Disclaimer: This Safety Data Sheet is a **draft** prepared to the structure of REACH Annex II for a research-use-only product. The information is based on the supplier's product data available at the revision date and on standard handling practice for this class of compound; fields without verified data are marked accordingly and were **not** populated with assumed values. It does **not** constitute a guarantee of any property and must be **reviewed and validated by a qualified competent person** before it is issued or relied upon. The recipient is responsible for safe use and for compliance with all applicable laws. No liability is accepted for use outside the stated Research-Use-Only scope.

Draft document provided for informational purposes based on currently available data. Strictly for laboratory and in-vitro research use only.

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