

**PrymaLab****SAFETY DATA SHEET**

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DOCUMENT NUMBER

PL-SDS-083

REVISION

1.0

REVISION DATE

October 3, 2026

FORMAT

GHS / OSHA HCS 2012**SAFETY DATA SHEET · SOLUTION, PRELOADED AUTOINJECTOR PEN****HMG (Menotropins)**

Solution, preloaded autoinjector pen · covers 1 catalogue item · mixture classification

**NOT CLASSIFIED**

Not classified as hazardous under OSHA HCS 2012 (29 CFR 1910.1200) or UN GHS. No pictogram, signal word or hazard statement is required. Handle as a pharmacologically active laboratory chemical.

For laboratory research use only. Not for human or veterinary use; not a drug, food, dietary supplement, cosmetic or household product. Read this sheet before handling and keep it with the material.

1 IDENTIFICATION

Product identifier	HMG (Menotropins) — solution, preloaded autoinjector pen
Catalogue items covered	Preloaded Autoinjector hMG (Menotropins) 3ml Pen 150IU PL-HMG-3ML-PEN
Synonyms / chemical names	HMG (Menotropins): Human menopausal gonadotropin: urinary FSH and LH; potency assigned in IU by bioassay (CAS 61489-71-2)
Recommended use	Laboratory research chemical for in-vitro and animal-model studies by trained personnel.
Restrictions on use	Not for human or veterinary use, diagnosis or therapy. Not for use as a drug, food, dietary supplement, cosmetic or in household products. Not for resale to the public for personal use.
Supplier	PrymaLab LLC (PrymaLab Analytical), 3705 Music Branch Rd, Ashland, KY 41102, United States · Tel. +1 (606) 465-9063 · michael@prymalab.net · https://prymalab.net
Emergency telephone	Poison Help (US, 24 h): 1-800-222-1222 · Supplier (business hours, US Eastern): +1 (606) 465-9063

2 HAZARD(S) IDENTIFICATION**CLASSIFICATION OF THE MIXTURE**

Not classified as hazardous under OSHA HCS 2012 (29 CFR 1910.1200) or UN GHS Rev. 7.

None of the ingredients is present at or above the generic concentration limits that would classify the mixture (Section 3 lists the ingredient classifications and concentrations).

LABEL ELEMENTS

No pictogram, signal word, hazard statement or precautionary statement is required. Recommended precautions: wear gloves, a laboratory coat and eye protection; avoid generating dust or aerosols; wash hands after handling; do not eat, drink or smoke in the laboratory.

HAZARDS NOT OTHERWISE CLASSIFIED / OTHER HAZARDS

- Pharmacologically active material. Accidental injection, ingestion or absorption may produce systemic effects consistent with the compound's mechanism of action; see Section 11.
- Sharps hazard.** The device contains a needle. Needle-stick injury can inject the solution and transmit blood-borne pathogens between users; never recap or share devices.
- Contains benzyl alcohol (0.9% w/v) as preservative. Below the concentration limits for classification; may still cause a mild allergic reaction in benzyl-alcohol-sensitised individuals. Preserved solutions must not be used in neonates.
- The active ingredient(s) (< 10% of the mixture) have no acute toxicity data.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Sterile aqueous solution in bacteriostatic water (0.9% benzyl alcohol), supplied in a 3 mL glass cartridge inside a preloaded autoinjector pen fitted with a needle.

INGREDIENT	CAS NO.	FORMULA	CONCENTRATION	QUANTITY	INGREDIENT CLASSIFICATION (GHS)
HMG (Menotropins) Human menopausal gonadotropin: urinary FSH and LH; potency assigned in IU by bioassay	61489-71-2	Not applicable (glycoprotein mixture)	as labelled (< 10 % w/v)	150 IU per 3 mL pen	Repr. 1B · H360 STOT RE 1 · H372
Benzyl alcohol (preservative) Benzyl alcohol, antimicrobial preservative (0.9% w/v in bacteriostatic water)	100-51-6	C ₇ H ₈ O	0.9% w/v	—	Acute tox. oral 4 · H302 Acute tox. inhalation 4 · H332 Eye irrit. 2A · H319 Skin sens. 1B · H317

INGREDIENT	CAS NO.	FORMULA	CONCENTRATION	QUANTITY	INGREDIENT CLASSIFICATION (GHS)
Water for injection Water for injection	7732-18-5	H ₂ O	balance to 100 %	—	not classified

Peptides are supplied as the acetate or trifluoroacetate salt unless stated otherwise; the counter-ion and residual water make up the balance of a lyophilized product. Concentration limits used for mixture classification follow OSHA HCS 2012 Appendix A.

4 FIRST-AID MEASURES

Inhalation	Move the person to fresh air and keep comfortable for breathing. If breathing is difficult or symptoms persist, call a POISON CENTER or doctor.
Skin contact	Take off contaminated clothing. Wash the skin with plenty of soap and water. If irritation or a rash develops, get medical advice.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do; continue rinsing. If eye irritation persists, get medical advice.
Ingestion	Rinse mouth. Do not induce vomiting. Call a POISON CENTER or doctor if you feel unwell.
Accidental injection	For an accidental needle-stick: wash the site with soap and water, do not squeeze, cover with a dressing and seek medical advice; report the incident according to your laboratory's sharps procedure.
Most important symptoms and effects	No specific symptoms are known. pharmacologically active material: systemic effects consistent with its mechanism of action are possible after accidental injection, ingestion or absorption.
Indication of immediate medical attention	Treat symptomatically. Show this safety data sheet to the attending physician. No specific antidote is known.

5 FIRE-FIGHTING MEASURES

Suitable extinguishing media	Water spray, carbon dioxide, dry chemical or alcohol-resistant foam. Use measures appropriate to the surrounding fire.
Unsuitable extinguishing media	None known. Do not use a high-pressure water jet on powders (dust dispersion).
Specific hazards	Aqueous solution containing 0.9% benzyl alcohol; not flammable and does not support combustion. Thermal decomposition may release carbon monoxide, carbon dioxide and nitrogen oxides.
Protective equipment for fire-fighters	Self-contained breathing apparatus and full protective clothing. Prevent run-off from entering drains.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions	Wear the protective equipment in Section 8. Keep unprotected people away. Avoid contact with eyes and skin; beware of broken glass and exposed needles.
Environmental precautions	Do not allow material to reach drains, surface water or soil. Quantities supplied are small; collect for disposal.
Methods for cleaning up	Absorb small spills with paper towel or an inert absorbent, place in a sealed container for disposal and clean the area with water and detergent. Pick up broken glass with tongs or forceps, never by hand. Decontaminate surfaces with 70 % alcohol or detergent and water.

7 HANDLING AND STORAGE

Precautions for safe handling	Handle the device as a sharp: never recap or reuse needles, keep fingers away from the needle, and discard used devices into a rigid sharps container. Avoid splashes to eyes and skin. Wash hands after handling. Do not eat, drink or smoke in the handling area.
Conditions for safe storage	Store at 2–8 °C in the original carton, protected from light. Do not freeze; discard if the solution has frozen or is discoloured or cloudy. Once in use, keep the device capped between uses. Keep the container tightly closed and labelled, out of reach of unauthorised persons.
Storage temperature	2–8 °C, protected from light; do not freeze
Incompatible materials	Strong oxidising agents, strong acids and bases.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational exposure limits	Benzyl alcohol: no OSHA PEL, ACGIH TLV or NIOSH REL; AIHA WEEL 10 ppm (44 mg/m ³) 8-h TWA. Present at 0.9%. No occupational exposure limits have been established for the active ingredient(s).
Engineering controls	Good general laboratory ventilation. An eyewash station should be available.
Eye / face protection	Safety glasses with side shields (ANSI Z87.1 / EN 166); goggles where splashing is possible.
Skin protection	Nitrile gloves (inspect before use; change after contamination) and a laboratory coat.
Respiratory protection	Not normally required with the engineering controls above. Not required for the solution under normal laboratory use.
Hygiene measures	Wash hands after handling and before breaks. Remove contaminated clothing. Do not pipette by mouth.

9 PHYSICAL AND CHEMICAL PROPERTIES

Physical state / appearance	Liquid. Clear, colourless to faintly yellow aqueous solution.
Odour / odour threshold	Odourless to faint aromatic odour (benzyl alcohol)
pH	Approximately 4.5–7.0 (bacteriostatic water, USP) unless adjusted
Melting / freezing point	About 0 °C (aqueous solution)
Boiling point	About 100 °C (aqueous solution)
Flash point / flammability	Not flammable; aqueous solution (benzyl alcohol flash point 93–101 °C, present at 0.9%)
Vapour pressure / density	As water (about 2.3 kPa at 20 °C)
Relative density	About 1.00–1.02 g/mL at 20 °C
Solubility	Aqueous solution; miscible with water
Partition coefficient (log P _{ow})	Not applicable
Auto-ignition / decomposition temperature	Not applicable (aqueous solution); dissolved peptide degrades on heating
Molecular formula / mass	HMG (Menotropins): Not applicable (glycoprotein mixture), FSH about 30 kDa and LH about 28.5 kDa glycoform averages

10 STABILITY AND REACTIVITY

Reactivity	No hazardous reactivity under normal laboratory conditions.
Chemical stability	Stable when stored as recommended (Section 7). Solutions degrade over time; discard discoloured or cloudy solutions.
Possibility of hazardous reactions	None known.
Conditions to avoid	Heat, direct light, moisture, freezing, repeated freeze–thaw cycles.
Incompatible materials	Strong oxidising agents, strong acids and bases; Heat and moisture.
Hazardous decomposition products	Carbon oxides and nitrogen oxides on combustion. No hazardous decomposition under recommended storage.

11 TOXICOLOGICAL INFORMATION

Likely routes of exposure: Accidental needle–stick injection; skin and eye contact from splashes; ingestion is unlikely.

Symptoms related to the physical, chemical and toxicological characteristics: No specific symptoms are known. pharmacologically active material: systemic effects consistent with its mechanism of action are possible after accidental injection, ingestion or absorption.

HMG (Menotropins) Human menopausal gonadotropin: urinary FSH and LH; potency assigned in IU by bioassay · CAS 61489-71-2**Substance classification adopted:** Repr. 1B · H360 STOT RE 1 · H372

The only exact-match SDS (ProSpec) is an uninformative template. Classified by read-across to manufacturer SDSs for closely related gonadotropins (Organon follitropin, MSD gonadotropins: Repr. 1A/1B, STOT RE 1).

Acute toxicity, oral	No data available for hMG. Analogue data: serum gonadotrophin (PMSG) oral LD50 mouse 120 mg/kg (MSD SDS) - analogue only, do not transfer to hMG
Acute toxicity, dermal	No data available
Acute toxicity, inhalation	No data available
Skin corrosion/irritation	Not available (ProSpec). MSD gonadotropin SDS: possible allergic reaction on skin contact
Serious eye damage/irritation	Not available
Respiratory or skin sensitisation	Not available (ProSpec). Human urine-derived glycoprotein - allergic/hypersensitivity reactions are described in the Menopur prescribing information; MSD gonadotropin SDS lists allergic reactions on inhalation
Germ cell mutagenicity	Not available
Carcinogenicity	Not listed by IARC, NTP or OSHA
Reproductive toxicity	Not available (ProSpec). Pharma analogues: Organon recombinant FSH formulation Repr. 1B H360FD (reduced estrous cycles, embryonic resorptions in rats/rabbits); MSD PMSG Repr. 1B H360Fd (LOAEL 10 µg/kg s.c., rat fertility); MSD hCG Repr. 1A (LOAEL 0.224 mg/kg, monkey fertility).
STOT, single exposure	Not available
STOT, repeated exposure	Not available for hMG. Analogues: STOT RE 1 (ovary) H372 for hCG/PMSG and rFSH formulations (MSD, Organon)
Aspiration hazard	Not available

- Lyophilised recombinant or purified protein. Inhalation of protein dusts can sensitise susceptible individuals; avoid generating dust and handle the dry powder in a ventilated enclosure. Not classified for respiratory sensitisation because no substance-specific data exist.
- Derived from animal tissue or human urine. Sourced and processed to minimise adventitious-agent risk; handle with standard biological precautions.
- WADA Prohibited List class S2.2.

Mixture classification: the ingredient classifications above were combined using the additivity and cut-off rules of OSHA HCS 2012 Appendix A (acute toxicity estimate calculation; 10% cut-off for skin and eye irritation; 0.1% for carcinogenicity, reproductive toxicity and respiratory sensitisation; 1.0% for skin sensitisation and STOT; 20% for respiratory tract irritation).

Carcinogen listings: no ingredient is listed as a carcinogen by IARC, NTP or OSHA.

12 ECOLOGICAL INFORMATION

HMG (Menotropins): Not available (ProSpec). No ecotoxicity data for gonadotropins in any SDS reviewed; proteins are readily biodegradable in principle.

Persistence and degradability: peptides and amino acids are expected to biodegrade readily; benzyl alcohol is readily biodegradable (92–96% in 14 days, OECD 301C). Bioaccumulative potential: low (hydrophilic, log P_{ow} < 3 where known). Mobility in soil: water-soluble; mobile. PBT/vPvB: not expected to meet the criteria. Other adverse effects: none known. Do not release concentrated material to the environment.

13 DISPOSAL CONSIDERATIONS

Dispose of unused material and contaminated packaging through a licensed chemical-waste contractor in accordance with federal (40 CFR 261), state and local regulations; the material is not a listed RCRA hazardous waste. Do not pour down the drain. Small residues may be inactivated with 10% bleach for 30 minutes before disposal where local rules allow. Used pens and needles are regulated medical sharps: place them in a rigid, puncture-resistant sharps container and dispose of through a sharps program. Empty glass vials and cartridges: remove labels or deface them before recycling or disposal.

14 TRANSPORT INFORMATION

DOT (49 CFR) / IATA / IMDG	Not regulated as a dangerous good for transport by road (DOT 49 CFR), air (IATA/ICAO) or sea (IMDG). Not a marine pollutant. Ship refrigerated or frozen as required by Section 7; the coolant (dry ice, UN 1845) is regulated when used.
UN number / proper shipping name / class / packing group	Not applicable.

15 REGULATORY INFORMATION

OSHA Hazard Communication Standard (29 CFR 1910.1200)	Not classified as hazardous. This sheet is provided voluntarily.
TSCA (Toxic Substances Control Act)	HMG (Menotropins): not listed on the TSCA Inventory (supplied for research and development; 40 CFR 720.36); Benzyl alcohol: listed on the TSCA Inventory; Water: listed on the TSCA Inventory.
SARA Title III (Sections 302, 311/312, 313), CERCLA	No ingredient is listed as an extremely hazardous substance (Section 302), a Section 313 toxic chemical or a CERCLA hazardous substance.
California Proposition 65	No ingredient is listed as known to the State of California to cause cancer or reproductive toxicity.
State right-to-know lists	Benzyl alcohol is listed on the Massachusetts, New Jersey and Pennsylvania right-to-know lists.
US FDA	The active substance is also the active ingredient of an approved drug product (menotropins (Menopur)); the material described here is not that approved product, has not been manufactured under cGMP for human use and is sold for laboratory research use only.
US DEA controlled substances	No ingredient is scheduled under the Controlled Substances Act at the revision date.
Anti-doping (information only)	HMG (Menotropins): WADA Prohibited List, class S2.
International	The classification in Section 2 applies equally under EU CLP (Regulation (EC) 1272/2008) and other UN GHS implementations; peptides of this kind are generally not registered under REACH (research and development use).

16 OTHER INFORMATION

Revision	Revision 1.0, October 3, 2026 — first issue. Prepared by PrymaLab Analytical, PrymaLab LLC.
Classification method	Calculated from the ingredient classifications (Section 3) with the OSHA HCS 2012 Appendix A mixture rules; ingredient classifications were adopted from the supplier safety data sheets listed below with the PrymaLab policy adjustments stated in Section 11. Policy: Cayman Chemical is the primary reference for research peptides and novel small molecules and Sigma-Aldrich/Merck for commodity chemicals; a more conservative manufacturer or ECHA classification is adopted where internally consistent; SARMs, GLP-1 receptor agonists, GnRH analogues and gonadotropins carry reproductive-toxicity classifications by expert judgement.
Sources consulted	ProSpec-Tany TechnoGene; ProSpec product page; Organon; MSD Animal Health; Sigma-Aldrich; Sigma-Aldrich / Supelco; MilliporeSigma; Sigma-Aldrich BVBA; Aldrich; American Regent - Sterile Water for Injection, USP; Hospira/Pfizer - Bacteriostatic Water for Injection.
Abbreviations	ATE acute toxicity estimate · CAS Chemical Abstracts Service · GHS Globally Harmonized System · HCS Hazard Communication Standard · IARC International Agency for Research on Cancer · LD50/LC50 median lethal dose/concentration · NTP National Toxicology Program · OEL occupational exposure limit · PEL permissible exposure limit · STOT specific target organ toxicity · TLV threshold limit value · WADA World Anti-Doping Agency.

The information in this safety data sheet is believed to be accurate as of the revision date and is given in good faith for the guidance of trained laboratory personnel handling the material described. It relates only to the specific material designated and may not be valid for the material used in combination with other substances or in any process. No warranty, express or implied, is made as to its completeness; users must make their own determination of suitability and comply with all applicable laws. PrymaLab products are sold for laboratory research use only and are not intended for human or veterinary use. © 2026 PrymaLab LLC.