1. PRODUCT AND COMPANY IDENTIFICATION

**Chemical product name**: Serum Gonadotrophin Formulation

**Supplier’s company name, address and phone number**

- **Company name of supplier**: MSD
- **Address**: Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
- **Telephone**: 048-588-8411
- **E-mail address**: EHSDATASTEWARD@msd.com
- **Emergency telephone number**: +1-908-423-6000

**Recommended use of the chemical and restrictions on use**

- **Recommended use**: Veterinary product

2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

- **Reproductive toxicity**: Category 1B

**GHS label elements**

- **Hazard pictograms**
- **Signal word**: Danger
- **Hazard statements**: H360Fd May damage fertility. Suspected of damaging the unborn child.

**Precautionary statements**

- **Prevention**: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- **Response**: P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- **Storage**: P405 Store locked up.
- **Disposal**: P501 Dispose of contents/ container to an approved waste
SAFETY DATA SHEET
Serum Gonadotrophin Formulation

Version 1.1 Revision Date: 2020/10/10 SDS Number: 5445453-00002 Date of last issue: 2020/02/20 Date of first issue: 2020/02/20

disposal plant.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Gonadotropin, pregnant mare serum</td>
<td>9002-70-4</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact:
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
May damage fertility. Suspected of damaging the unborn child.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician:
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Storage:
- Conditions for safe storage: Keep in properly labelled containers.
  - Store locked up.
  - Keep tightly closed.
  - Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
- Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment:

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonadotropin, pregnant mare serum</td>
<td>9002-70-4</td>
<td>TWA</td>
<td>4 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>40 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
- Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**Personal protective equipment**

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**
- Particulates type

**Hand protection**
- Chemical-resistant gloves

**Remarks**
- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Consider double gloving.

**Eye protection**
- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**
- Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state**
- Powder

**Colour**
- White

**Odour**
- No data available

**Odour Threshold**
- No data available

**Melting point/freezing point**
- No data available

**Boiling point, initial boiling point and boiling range**
- No data available

**Flammability (solid, gas)**
- May form explosive dust-air mixture during processing, handling or other means.

**Flammability (liquids)**
- No data available

**Lower explosion limit and upper explosion limit / flammability limit**
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
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<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
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<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
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<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
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<tr>
<td>Viscosity</td>
<td>Not applicable</td>
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<td>Viscosity, kinematic</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Vapour pressure</td>
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<td>Density and / or relative density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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</tr>
<tr>
<td>Relative vapour density</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
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<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reactions**:
  - May form explosive dust-air mixture during processing, handling or other means.
  - Can react with strong oxidizing agents.
- **Conditions to avoid**: Heat, flames and sparks.
- **Incompatible materials**: Avoid dust formation, Oxidizing agents.

### 11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure:

- Inhalation
- Skin contact
- Ingestion
- Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**Gonadotropin, pregnant mare serum:**
- **Acute oral toxicity:** LD50 (Mouse): 120 mg/kg
- **Remarks:** No data available
- **Acute inhalation toxicity:** Remarks: No data available
- **Acute dermal toxicity:** Remarks: No data available
- **Acute toxicity (other routes of administration):** LD50 (Mouse): > 1,700 mg/kg
  - Application Route: Intravenous
  - LD50 (Mouse): > 1,700 mg/kg
  - Application Route: Subcutaneous
  - LD50 (Rat): 500 mg/kg
  - Application Route: Intravenous
  - LD50 (Rat): 500 mg/kg
  - Application Route: Subcutaneous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Gonadotropin, pregnant mare serum:**
- **Remarks:** No data available

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Gonadotropin, pregnant mare serum:**
- **Remarks:** No data available

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.
Components:

Gonadotropin, pregnant mare serum:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Gonadotropin, pregnant mare serum:
Genotoxicity in vivo:
Test Type: Cytogenetic assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Not classified due to data which are conclusive although insufficient for classification.

Carcinogenicity
Not classified based on available information.

Components:

Gonadotropin, pregnant mare serum:
Carcinogenicity - Assessment: No data available

Reproductive toxicity
May damage fertility. Suspected of damaging the unborn child.

Components:

Gonadotropin, pregnant mare serum:
Effects on fertility:
Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: LOAEL: 10 µg/kg
Result: Effects on fertility
Remarks: May cause adverse reproductive effects. Based on data from similar materials

Effects on foetal development:
Remarks: May cause birth defects. Based on data from similar materials

Reproductive toxicity - Assessment:
Remarks: Some evidence of adverse effects on development, based on animal experiments. Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Gonadotropin, pregnant mare serum:**
- **Species:** Rat
- **NOAEL:** 1.5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 3 Days
- **Symptoms:** No adverse effects

- **Species:** Rat
- **LOAEL:** 10 mg/kg
- **Application Route:** Oral
- **Exposure time:** 14 Days
- **Target Organs:** Reproductive organs

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

**Components:**

**Gonadotropin, pregnant mare serum:**
- **Inhalation:** Symptoms: Headache, Fatigue, mood swings, altered mental status, Oedema, Allergic reactions, Effects on fertility

- **Skin contact:** Remarks: May produce an allergic reaction.

- **Ingestion:** Remarks: May be harmful if swallowed.

12. ECOLOGICAL INFORMATION

**Ecotoxicity**
No data available

**Persistence and degradability**
No data available

**Bioaccumulative potential**
No data available

**Mobility in soil**
No data available

**Hazardous to the ozone layer**
Not applicable

**Other adverse effects**
No data available
13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable

**Substances Prevented From Impairment of Health**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**
Not applicable
<table>
<thead>
<tr>
<th>Substances Subject to be Notified Names</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substances Subject to be Indicated Names</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ordinance on Prevention of Hazards Due to Specified Chemical Substances</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ordinance on Prevention of Lead Poisoning</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ordinance on Prevention of Tetraalkyl Lead Poisoning</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ordinance on Prevention of Organic Solvent Poisoning</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Poisonous and Deleterious Substances Control Law</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof</td>
<td>Not applicable</td>
</tr>
<tr>
<td>High Pressure Gas Safety Act</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive Control Law</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vessel Safety Law</td>
<td>Not regulated as a dangerous good</td>
</tr>
<tr>
<td>Aviation Law</td>
<td>Not regulated as a dangerous good</td>
</tr>
<tr>
<td>Marine Pollution and Sea Disaster Prevention etc Law</td>
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<tr>
<td>Bulk transportation</td>
<td>Not classified as noxious liquid substance</td>
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<tr>
<td>Pack transportation</td>
<td>Not classified as marine pollutant</td>
</tr>
<tr>
<td>Narcotics and Psychotropics Control Act</td>
<td></td>
</tr>
<tr>
<td>Narcotic or Psychotropic Raw Material (Export / Import Permission)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Specific Narcotic or Psychotropic Raw Material (Export / Import permission)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Waste Disposal and Public Cleansing Law</td>
<td></td>
</tr>
<tr>
<td>Industrial waste</td>
<td></td>
</tr>
</tbody>
</table>

The components of this product are reported in the following inventories:

AICS : not determined
SAFETY DATA SHEET

Serum Gonadotrophin Formulation

Version 1.1
Revision Date: 2020/10/10
SDS Number: 5445453-00002
Date of last issue: 2020/02/20
Date of first issue: 2020/02/20

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; ICSO - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text.
Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

JP / EN