SECTION 1. IDENTIFICATION

Product name: Serum Gonadotrophin Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms: 

Signal Word: Danger
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air. 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 and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonadotropin, pregnant mare serum</td>
<td>9002-70-4</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Serum Gonadotrophin Formulation

Section 6. Accident 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 spills 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.

Section 7. Handling and Storage

- 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.

Conditions for safe storage:
- Keep in properly labeled 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
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters:

50 Million particles per cubic foot
- Value type (Form of exposure): TWA (total dust)
- Basis: OSHA Z-3

15 mg/m³
- Value type (Form of exposure): TWA (total dust)
- Basis: OSHA Z-3

5 mg/m³
- Value type (Form of exposure): TWA (respirable fraction)
- Basis: OSHA Z-3

15 Million particles per cubic foot
- Value type (Form of exposure): TWA (respirable fraction)
- Basis: OSHA Z-3

10 mg/m³
- Value type (Form of exposure): PEL (Total dust)
- Basis: CAL PEL

5 mg/m³
- Value type (Form of exposure): PEL (respirable dust fraction)
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Gonadotropin, pregnant mare serum | 9002-70-4 | TWA | 4 μg/m³ (OEB 4) | Internal

**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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**: Chemical-resistant gloves

**Remarks**: 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.

**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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : white
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : Not applicable
Relative vapor density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) : Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
**Decomposition temperature**: No data available

**Viscosity**
- **Viscosity, kinematic**: Not applicable

**Explosive properties**: Not explosive

**Oxidizing properties**: The substance or mixture is not classified as oxidizing.

**Molecular weight**: No data available

**Particle size**: No data available

---

**SECTION 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.
- Avoid dust formation.

**Incompatible materials**: Oxidizing agents

**Hazardous decomposition products**: No hazardous decomposition products are known.

---

**SECTION 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
- **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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
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
IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.
NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

Reproductive toxicity - Assessment: 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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Serum Gonadotrophin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>09/30/2023</td>
<td>5445458-00007</td>
<td>04/04/2023</td>
<td>02/20/2020</td>
</tr>
</tbody>
</table>

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, Edema, Allergic reactions, Effects on fertility.
Skin contact : Remarks: May produce an allergic reaction.
Ingestion : Remarks: May be harmful if swallowed.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
No data available

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
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.

SECTION 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.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium phosphate, dihydrate</td>
<td>10028-24-7</td>
<td>5000</td>
<td>94339</td>
</tr>
</tbody>
</table>

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Reproductive toxicity

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- D-mannitol 69-65-8
- Gonadotropin, pregnant mare serum 9002-70-4
- Sodium phosphate, monobasic, dihydrate 13472-35-0
- Sodium phosphate, dihydrate 10028-24-7

California List of Hazardous Substances
- Sodium phosphate, dihydrate 10028-24-7

The ingredients of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Serum Gonadotrophin Formulation

Version 2.1  Revision Date: 09/30/2023  SDS Number: 5445458-00007  Date of last issue: 04/04/2023  Date of first issue: 02/20/2020

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLAMMABILITY</td>
<td>3</td>
</tr>
<tr>
<td>PHYSICAL HAZARD</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Ducts
CAL PEL / PEL : Permissible exposure limit
OSHA Z-3 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; IC50 - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-
US / Z8