SAFETY DATA SHEET

Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version 5.1  Revision Date: 2020/09/25  SDS Number: 636534-00014  Date of last issue: 2020/09/10  Date of first issue: 2016/05/03

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
          Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Ovary)

GHS label elements
Hazard pictograms: 

Signal word: Danger
Hazard statements: H360Fd May damage fertility. Suspected of damaging the unborn child. H372 Causes damage to organs (Ovary) through prolonged or repeated exposure if swallowed.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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 disposal plant.

Other hazards which do not result in classification
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>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;= 0.3 -&lt; 10</td>
</tr>
<tr>
<td>Gonadotropin, chorionic</td>
<td>9002-61-3</td>
<td>&gt;= 1 -&lt; 10</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. Causes damage to organs through prolonged or repeated exposure if swallowed.
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)
- Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Sulphur oxides
- Metal oxides
- Oxides of phosphorus

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

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 re-
leased 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

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. Wash skin thoroughly after handling. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<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>
<tr>
<td>Gonadotropin, chorionic</td>
<td>9002-61-3</td>
<td>TWA</td>
<td>OEB 4 (3 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>25 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Engineering measures: Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.

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: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.
Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety goggles

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: white
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling: No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac- : May form explosive dust-air mixture during processing, han-
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 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 : 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.

**Gonadotropin, chorionic:**

**Effects on fertility**

- **Test Type:** Fertility
- **Species:** Rat
- **Application Route:** Intravenous injection
- **Fertility:** LOAEL: 8.89 mg/kg body weight
- **Result:** Effects on fertility

- **Test Type:** Fertility
- **Application Route:** Intraperitoneal injection
- **Fertility:** LOAEL: 0.883 mg/kg body weight
- **Result:** Effects on fertility

- **Test Type:** Fertility
- **Species:** Monkey
- **Fertility:** LOAEL: 0.224 mg/kg body weight
- **Result:** Effects on fertility

**Effects on foetal development**

- **Test Type:** Embryo-foetal development
- **Species:** Hamster
- **Application Route:** Intraperitoneal injection
- **Embryo-foetal toxicity:** LOAEL: 60 mg/kg body weight
- **Result:** Embryo-foetal toxicity

**Reproductive toxicity - Assessment**

- **Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.**
- **Some evidence of adverse effects on development, based on animal experiments.**

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Ovary) through prolonged or repeated exposure if swallowed.

**Components:**

**Gonadotropin, chorionic:**

- **Target Organs:** Ovary
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.
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.

Gonadotropin, chorionic:
Inhalation: Target Organs: ovaries
Symptoms: effects on menstruation, gynecomastia, Headache, mental depression, Irritability, restlessness, Fatigue

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
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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
- Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
- Hazardous substances approved for use: Not applicable
- Prohibited substances: Not applicable
- Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
- Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable
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The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format: yyyy/mm/dd

Full text of other abbreviations

AICS - 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; 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; 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 - Not 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.

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