SAFETY DATA SHEET

Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<tbody>
<tr>
<td>5.1</td>
<td>2020/09/25</td>
<td>636534-00014</td>
<td>2020/09/10</td>
<td>2016/05/03</td>
</tr>
</tbody>
</table>

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

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: Danger

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 protec-
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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>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;= 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.
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 released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and dis-
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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>
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</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**
- Material: 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. 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 range**
- No data available
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.
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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.

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
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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
Persistance 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.
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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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
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16. OTHER INFORMATION

Further information

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<tbody>
<tr>
<td>Date format</td>
<td>yyyy/mm/dd</td>
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Full text of other abbreviations

All 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.