SAFETY DATA SHEET
Human Chorionic Gonadotropin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION
   Product name: Human Chorionic Gonadotropin Formulation
   Manufacturer or supplier’s details
   Company: MSD
   Address: 50 Tuas West Drive
            Singapore - Singapore 638408
   Telephone: 908-740-4000
   Emergency telephone number: 65 6697 2111 (24/7/365)
   E-mail address: EHSDATASTEWARD@msd.com
   Telefax: 908-735-1496
   Recommended use of the chemical and restrictions on use
   Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION
   GHS Classification
   Reproductive toxicity: Category 1A
   Specific target organ toxicity - repeated exposure: 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.
   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

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, chorionic</td>
<td>9002-61-3</td>
<td>&gt;= 90 -&lt;= 100</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. 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

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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

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 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/PERSOANL 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, chorionic</td>
<td>9002-61-3</td>
<td>TWA</td>
<td>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>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>OEB 4</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

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. 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 : off-white

Odour : odourless

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

Flash point : Not applicable

Evaporation rate : No data available

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 : 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. 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.

Skin corrosion/irritation: Not classified based on available information.
Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

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

Components:

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.
Components:

Gonadotropin, chorionic:
Target Organs: Ovary
Assessment: Causes damage to organs through prolonged or repeated exposure.

Aspiration toxicity
Not classified based on available information.

Experience with human exposure
Components:
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**

**Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations:** This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

- Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
- Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

**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: dd.mm.yyyy

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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 Marine Dangerous Goods Code; IPI - International Physical危险物质 Data Base; JECFA - Joint FAO/WHO Expert Committee on Food Additives; OECD - Organisation for Economic Co-operation and Development; PEL - Permissible Exposure Limit; PNEC - Predicted No Effect Concentration; PMCA - Permissible Medium Concentration; PIR - Permissible Individual Response; PIVCS - Permissible Vehicle Containment System; ROS - Risk of Skin; RvP - Risk of Poisoning; SC - Special Cautions; SD - Standard of the German Standardisation Institute; SITRAIR - Standard of the Institute of Toxicological Research; SME - SME Chemical Substances; SPL - Standard of the German Standardisation Institute; SPM - Standard of the German Standardisation Institute; TBA - Risk of Skin; TD - Threshold for the Dermal Absorption; TDL - Threshold Limit Value for the Derma- l Absorption; TDI - Threshold Limit Value for the Inhalation Absorption; TDIa - Threshold Limit Value for the Dermal Absorption; TLV - Threshold Limit Value; TLV-A - Threshold Limit Value for the Inhalation Absorption; TLV-CT - Threshold Limit Value for the Inhalation Absorption; TLV-D - Threshold Limit Value for the Dermal Absorption; TLV-I - Threshold Limit Value for the Inhalation Absorption; TLV-L - Threshold Limit Value for the Inhalation Absorption; TLV-L-A - Threshold Limit Value for the Inhalation Absorption; TLV-M - Threshold Limit Value for the Inhalation Absorption; TLV-P - Threshold Limit Value for the Inhalation Absorption; TLV-TWA - Threshold Limit Value for the Inhalation Absorption; TWA - Threshold Limit Value for the Inhalation Absorption; WHO - World Health Organization; ZG - Zonelasten.
Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisati- 
on for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentra-
tion 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 Devel-
opment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioac-
cumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-
es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 
1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-
tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tem-
perature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Trans-
portation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - Unit-
ed Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 
vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials In-
formation System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, infor-
mation 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 
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rial is used in combination with any other materials or in any process, unless specified in the text. 
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intended manner of handling, use, processing and storage, including an assessment of the ap-
propriateness of the SDS material in the user's end product, if applicable.

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