SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   20 Spartan Road
   1619 Spartan, South Africa
   Telephone: +27119239300
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   +1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1A: H360Fd: May damage fertility. Suspected of damaging the unborn child.
   Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms: 
   Signal word: Danger
   Hazard statements: H360Fd: May damage fertility. Suspected of damaging the unborn child.
   H372: Causes damage to organs through prolonged or repeated exposure.
   Precautionary statements: Prevention:
Hazardous components which must be listed on the label:
Gonadotropin, chorionic

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonadotropin, pregnant mare serum</td>
<td>9002-70-4</td>
<td>232-663-9</td>
<td></td>
<td>Repr. 1B; H360Fd</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gonadotropin, chorionic</td>
<td>9002-61-3</td>
<td>232-660-2</td>
<td></td>
<td>Repr. 1A; H360Fd STOT RE 1; H372 (Ovary)</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).
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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
- 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.

**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.

**7.2 Conditions for safe storage, including any incompatibilities**

**Requirements for storage areas and containers:**
Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

**Advice on common storage:**
Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

**7.3 Specific end use(s)**

**Specific use(s):** No data available

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
</tbody>
</table>
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8.2 Exposure controls

**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**

- **Eye protection**: Wear the following personal protective equipment:
  - Safety goggles
- **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.
- **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).
- **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 (P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic 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
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: Not applicable
Relative vapour 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
  Auto-ignition temperature: No data available
  Decomposition temperature: No data available
Viscosity
  Viscosity, dynamic: No data available
  Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
  Flammability (liquids): No data available
  Molecular weight: No data available
  Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.
10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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.
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STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

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

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available
12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good
14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
- H360Fd: May damage fertility. Suspected of damaging the unborn child.
- H372: Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Organiza-
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Version: 5.2  Revision Date: 09.04.2021  SDS Number: 636544-00015  Date of last issue: 25.09.2020
Date of first issue: 03.05.2016

Further information

Classification of the mixture:
| Repr. 1A | H360Fd | Calculation method |
| STOT RE 1 | H372 | Calculation method |

Classification procedure:

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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