

## Serum Gonadotrophin Formulation

Version 2.1      Revision Date: 30.09.2023      SDS Number: 5445448-00007      Date of last issue: 04.04.2023  
Date of first issue: 20.02.2020

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Serum Gonadotrophin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360Fd May damage fertility. Suspected of damaging the unborn child.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
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.

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### 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.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Gonadotropin, pregnant mare serum	9002-70-4	Reproductive toxicity, Category 1B	>= 30 -< 50

### 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 (CO<sub>2</sub>)  
 Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire : Avoid generating dust; fine dust dispersed in air in sufficient

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fighting		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 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 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 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.

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- 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.
- 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.
- 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Gonadotropin, pregnant mare serum	9002-70-4	TWA	4 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	40 µg/100 cm <sup>2</sup>	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.

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### 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 : 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.

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### 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

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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

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### 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.

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### SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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#### Acute toxicity

Not classified based on available information.

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### 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.

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### 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 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



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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.

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## 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

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

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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****ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

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### SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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### SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023

Date format : dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Full text of other abbreviations**

AIC - 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

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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 - 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 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; TECI - Thailand Existing Chemicals Inventory; 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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