

Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
1.2	13.09.2019	3625063-00003	Date of first issue: 06.11.2018

SECTION 1: Identification of the hazardous chemical and of the supplier**Product identifier**

Product name : Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Chemical name :

CAS-No. : Not Assigned

Product code :

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Manufacturer or supplier's details

Company : Merck & Co., Inc

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

SECTION 2: Hazards identification**Classification of the hazardous chemical**

Reproductive toxicity : Category 1A

Specific target organ toxicity - repeated exposure : Category 1

Label elements

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.

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Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3: Composition and information of the ingredients of the hazardous chemical

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Gonadotropin, pregnant mare serum	9002-70-4	≥ 0.01 -< 0.3
Gonadotropin, chorionic	9002-61-3	≥ 0.01 -< 0.3

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 : Flush eyes with water as a precaution.
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.

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).

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Notes to physician : Treat symptomatically and supportively.

SECTION 5: Firefighting measures**Extinguishing media**

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

Unsuitable extinguishing media : None known.

Physicochemical hazards arising from the chemical

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Special protective equipment and precautions for fire-fighters

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

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.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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

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certain local or national requirements.

SECTION 7: Handling and storage

Handling

Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- 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 vapours or spray mist.
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.
Take care to prevent spills, waste and minimize release to the environment.

Storage

Conditions for safe storage, including any incompatibilities

- 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

SECTION 8: Exposure controls and personal protection

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 ³ (OEB 4)	Internal
		Wipe limit	40 µg/100 cm ²	Internal
Gonadotropin, chorionic	9002-61-3	TWA	3 µg/m ³	Internal
		Wipe limit	25 µg/100 cm ²	Internal
		TWA	OEB 4	Internal

- Appropriate engineering controls** : Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Individual protection measures, such as personal protective equipment

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Eye/face protection	:	Wear the following personal protective equipment: Safety glasses
Skin 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).
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.
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
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.

SECTION 9: Physical and chemical properties

Appearance	:	liquid
Colour	:	No data available
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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper	:	No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

SECTION 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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.

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

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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

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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 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.

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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
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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

SECTION 13: Disposal information**Disposal methods**

Waste from residues	:	Disposal of waste to be in accordance with the Environmental Quality (Scheduled Wastes) Regulations and other guidelines issuance by DOE and/or local 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**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

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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

Safety, health, and environmental regulations specific for the hazardous chemical

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013.

Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16: Other information

Further information

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

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 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

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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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