



### Serum Gonadotrophin Formulation

				f last issue: 04/04/2023 f first issue: 02/20/2020
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#### **SECTION 1. IDENTIFICATION**

Product name	:	Serum Gonadotrophin Formulation
Other means of identification	:	No data available

#### Manufacturer or supplier's details

Company name of supplier	:	Merck & Co., Inc
Address	:	126 E. Lincoln Avenue
		Rahway, New Jersey U.S.A. 07065
Telephone	:	908-740-4000
Emergency telephone	:	1-908-423-6000
E-mail address	:	EHSDATASTEWARD@merck.com

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

Recommended use	:	Veterinary product
Restrictions on use	:	Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in ac	cordance with the Hazardous Products Regulations	
Reproductive toxicity	: Category 1B	

GHS label elements Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H360Fd May damage fertility. Suspected of damaging the un- born child.
Precautionary Statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P280 Wear protective gloves, protective clothing, eye protection and face protection.
		Response: P308 + P313 IF exposed or concerned: Get medical attention.
		Storage: P405 Store locked up.
		<b>Disposal:</b> P501 Dispose of contents and container to an approved waste

P501 Dispose of contents and container to an approved waste disposal plant.

according to the Hazardous Products Regulations



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#### Other hazards

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	Common	CAS-No.	Concentration (% w/w)
	Name/Synonym		
Gonadotropin, preg-	No data availa-	9002-70-4	>= 30 - < 60 *
nant mare serum	ble		>= 30 <sup>-</sup> < 00
* • • •			

Actual concentration or concentration range is withheld as a trade secret

#### 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	:	
uolayou		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 (CO2)
		Dry chemical
Unsuitable extinguishing	:	None known.

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medi Spec fighti	ific hazards during fire	:	concentrations, ar potential dust exp	dust; fine dust dispersed in air in sufficient nd in the presence of an ignition source is a losion hazard. bustion products may be a hazard to health.
Haza ucts	rdous combustion prod-	:	Carbon oxides Metal oxides Oxides of phosph	orus
Spec ods	ific extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
	ial protective equipment e-fighters	:		e, wear self-contained breathing apparatus. ective equipment.
SECTION	6. ACCIDENTAL RELE	ASI	EMEASURES	
tive e	onal precautions, protec- equipment and emer- y procedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
Envir	onmental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
	ods and materials for ainment and cleaning up	:	container for disper Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the a Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

### 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.

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Ac	Advice on safe handling		:	<ul> <li>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 sa 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 environment.</li> </ul>		
Co	Conditions for safe storage		:	Keep in properly labeled containers. Store locked up. Keep tightly closed.		
Ma	Materials to avoid		:	Store in accordance with the particular national regulations. 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 parame- ters / Permissible concentration	Basis
Gonadotropin, pregnant mare serum	9002-70-4	TŴA	4 µg/m3 (OEB 4)	Internal
		Wipe limit	40 µg/100 cm2	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. 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. : Particulates type

according to the Hazardous Products Regulations

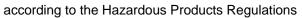


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Material		: Chemical-resis	tant gloves			
Remarks Eye protection		: Wear safety gla If the work envi mists or aeroso Wear a faceshi	<ul> <li>Consider double gloving.</li> <li>Wear safety glasses with side shields or goggles. If the work environment 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.</li> </ul>			
Skin and body protection		Additional body task being perf disposable suit Use appropriat	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.			
Hygiene measures		: If exposure to or eye flushing sy working place. When using do Wash contamin The effective or engineering con appropriate des	chemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. nated clothing before re-use. peration of a facility should include review of ntrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the			

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	white
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	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	:	No data available



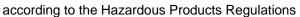


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	flamma	ability limit			
		explosion limit / Lower ability limit	:	No data available	9
	Vapor	pressure	:	Not applicable	
	Relativ	e vapor density	:	Not applicable	
	Relativ	e density	:	No data available	9
	Density	4	:	No data available	)
	Solubil Wat	ity(ies) ter solubility	:	No data available	
	Partitio octano	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ity cosity, kinematic	:	Not applicable	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	ılar weight	:	No data available	9
	Particle	e size	:	No data available	9

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. 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 Hazardous decomposition products		Oxidizing agents 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

#### 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

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

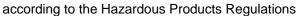
Not classified based on available information.



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-	iratory sensitization lassified based on avail	able	information.			
Components:						
Gona	dotropin, pregnant m	are s	serum:			
Rema	arks	:	No data available	9		
	n cell mutagenicity lassified based on avail	able	information.			
Com	ponents:					
Gona	dotropin, pregnant m	are s	serum:			
	toxicity in vivo	:	Test Type: Cytog Species: Mouse Application Route Result: positive Remarks: Not cla	enetic assay e: Intraperitoneal injection assified due to data which are conclusive ent for classification.		
	i <b>nogenicity</b> lassified based on avail	able	information.			
Components:						
Gona	adotropin, pregnant m	ares	serum:			
Carci ment	nogenicity - Assess-	÷	No data available	9		
Repr	oductive toxicity					
May o	damage fertility. Suspec	cted	of damaging the u	nborn child.		
Com	ponents:					
Gona	dotropin, pregnant m	are s	serum:			
Effect	ts on fertility	:		e: Subcutaneous 10 μg/kg		
Effect	ts on fetal development	:		ause birth defects. om similar materials		
Repro sessr	oductive toxicity - As- nent	:	animal experime	of adverse effects on development, based nts., Clear evidence of adverse effects on nd fertility, based on animal experiments.		





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#### 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
Symptoms	: No adverse effects.
Species	: Rat
	10 //

Species		Rai
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 Ingestion		Remarks: May produce an allergic reaction. Remarks: May be harmful if swallowed.

### 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	<ul> <li>Empty containers should be taken to an approved waste handling site for recycling or disposal.</li> <li>If not otherwise specified: Dispose of as unused product.</li> </ul>

#### **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

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

Not applicable for product as supplied.

#### **Domestic regulation**

**TDG** Not regulated as a dangerous good

Special precautions for user

Not applicable

#### SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:		
AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

AIIC - 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;





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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 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

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 Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/30/2023 mm/dd/yyyy

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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