according to the Globally Harmonized System



Serum Gonadotrophin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5445452-00007	Date of first issue: 20.02.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Serum Gonadotrophin Formulation
Manufacturer or supplier's de Company	etai :	ils MSD
Address	:	Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone	:	+1-908-740-4000
Emergency telephone number	:	+1-908-423-6000
E-mail address	:	EHSDATASTEWARD@msd.com
Recommended use of the ch	em	ical and restrictions on use
Recommended use Restrictions on use	:	Veterinary product Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification 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	 Prevention: P203 Obtain, read and follow all safety instructions before use. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response:

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P318 IF exposed or concerned, get medical advice.

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

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

4. FIRST AID MEASURES

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice 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
Protection of first-aiders	:	the skin. Dust contact with the eyes can lead to mechanical irritation. 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

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	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C	
	Unsuita media	able extinguishing	:	Dry chemical None known.	
	Specific hazards during fire- fighting		:	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. oustion products may be a hazard to health.
	Hazard ucts	ous combustion prod-	:	Carbon oxides Metal oxides Oxides of phosph	orus
	Specific ods	c 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
	Special for firef	protective equipment ighters	:		e, wear self-contained breathing apparatus. ective equipment.

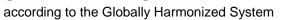
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective 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 con- tainer 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 surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine 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
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Static electricity may accumulate and ignite suspended dust causing an explosion.





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		and bonding, or	te precautions, such as electrical grounding inert atmospheres.
Lo	cal/Total ventilation	: If sufficient vent ventilation.	ilation is unavailable, use with local exhaust
Ad	vice on safe handling	 Do not get on sl Do not breathe Do not swallow. Avoid contact w Handle in accor practice, based sessment Keep container Minimize dust g Keep container Keep away from Take precautior 	dust. ith eyes. dance with good industrial hygiene and safety on the results of the workplace exposure as-
Co	nditions for safe storage	Store locked up Keep tightly close	sed.
Ma	terials to avoid		ance with the particular national regulations. h the following product types: agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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 expo- sure assessment demonstrates exposures outside the rec-

	ommended guidelines, use respiratory protection.
:	Particulates type

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M	aterial	: Chemical-res	istant gloves
mists or aerosols, wear the appropria Wear a faceshield or other full face pr		plasses with side shields or goggles. vironment or activity involves dusty conditions,	
Skin	and body protection	 Work uniform or laboratory coat. Additional body garments should be used based upon the being performed (e.g., sleevelets, apron, gauntlets, dispo- suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potenti contaminated clothing. 	
Hygie	ene measures	: If exposure to flushing syste place. When using o Wash contam The effective engineering o appropriate d industrial hyg	o chemical is likely during typical use, provide eye ems and safety showers close to the working do not eat, drink or smoke. hinated clothing before re-use. operation of a facility should include review of controls, proper personal protective equipment, egowning and decontamination procedures, iene monitoring, medical surveillance and the strative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour 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, han- dling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

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		explosion limit / Lower bility limit	:	No data available	
	Vapour	pressure	:	Not applicable	
	Relative	e vapour density	:	Not applicable	
	Relative	e density	:	No data available	9
	Density	1	:	No data available	
	Solubili Wat	ty(ies) er solubility	:	No data available	9
	Partitio octanol	n coefficient: n- /water	:	Not applicable	
		nition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ve properties	:	Not explosive	
	Oxidiziı	ng properties	:	The substance or	r mixture is not classified as oxidizing.
		lar weight	:	No data available	-
	Particle	-	:	No data available	

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, han- dling 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	:	Inhalation
exposure		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 - Assess-	:	No data available
ment		

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 develop- ment	:	Remarks: May cause birth defects. Based on data from similar materials
Reproductive toxicity - As- sessment	:	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:

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Expos Symp Speci LOAE Applic Expos	EL cation Route sure time otoms	: : : : : :	Rat 1.5 mg/kg Oral 3 Days No adverse effe Rat 10 mg/kg Oral 14 Days Reproductive or	

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

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	:	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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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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 IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Revision Date	:	30.09.2023
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 Agen- cy, http://echa.europa.eu/
Date format	:	dd.mm.yyyy

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; 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

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- 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.

IN / EN