



Vers 2.1	sion	Revision Date: 2023/09/30	-	S Number: 5451-00007	Date of last issue: 2023/04/04 Date of first issue: 2020/02/20
1. P	RODUC	T AND COMPANY IDI	ENT	FICATION	
	Product	t name	:	Serum Gonadotr	ophin Formulation
	Manufa	acturer or supplier's d	letai	ls	
	Compa	ny	:	MSD	
	Address	S	:	126 E. Lincoln Av Rahway, New Je	venue rsey U.S.A. 07065
	Telepho	one	:	908-740-4000	
	Emerge	ency telephone number	:	1-908-423-6000	
	E-mail a	address	:	EHSDATASTEW	/ARD@msd.com
	Recom	mended use of the ch	nemi	ical and restriction	ons on use
		mended use tions on use	:	Veterinary produ	ct
	Restrict		•		
2. H	AZARD	S IDENTIFICATION			
	GHS C	lassification			
	Reprod	uctive toxicity	:	Category 1B	
	GHS la	bel elements			
	Hazard	pictograms	:		

Signal word

Hazard statements

: Danger

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

Precautionary statements

: Prevention:

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/ face protection.

Response:

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



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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 -< 60

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 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		Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	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

SAFETY DATA SHEET



Serum Gonadotrophin Formulation

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Suita	ble extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical	
Unsu medi	iitable extinguishing	:	None known.	
	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. pustion products may be a hazard to health.
Haza ucts	ardous combustion prod-	:	Carbon oxides Metal oxides Oxides of phosph	orus
ods	ific extinguishing meth-	:	cumstances and t Use water spray t Remove undamag so. Evacuate area.	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 refighters			e, wear self-contained breathing apparatus. rective equipment.
6. ACCID	ENTAL RELEASE MEAS	SUF	RES	
tive e	onal precautions, protec- equipment and emer- y procedures	:		ective equipment. ing advice (see section 7) and personal pro- 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	:	tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the atr Local or national r posal of this mate employed in the c mine which regula Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

7. HANDLING AND STORAGE



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	nical measures	causing an exp Provide adequa and bonding, o	ate precautions, such as electrical grounding rinert atmospheres.				
Local/Total ventilation Advice on safe handling		 If sufficient ventilation is unavailable, use with local exhaust ventilation. Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. 					
		Handle in acco practice, basec sessment Keep container	rdance with good industrial hygiene and safety I on the results of the workplace exposure as-				
		Keep container Keep away fror Take precautio	r closed when not in use. n heat and sources of ignition. nary measures against static discharges. revent spills, waste and minimize release to the				
	tions for safe storage	: Keep in proper Store locked up Keep tightly clo Store in accord	used. lance with the particular national regulations.				
water	ials to avoid	: Do not store wi Strong oxidizin	th the following product types: g 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	TWA	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-



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	ter type protection		essment demonstrates exposure ad guidelines, use respiratory pr es type			
Ma	aterial	: Chemic	-resistant gloves			
Remarks Eye protection		: Wear sa If the wo mists or Wear a	Consider double gloving. 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 approach			
Skin and body protection		: Work ur Additior task bei posable Use app	orm or laboratory coat. I body garments should be used g performed (e.g., sleevelets, a uits) to avoid exposed skin surf opriate degowning techniques t ated clothing.	pron, gauntlets, dis- aces.		
Hygie	ne measures	: If expos eye flus ing plac When u Wash c The effe appropr industria	re to chemical is likely during ty ng systems and safety showers	s close to the work- se. d include review of ptective equipment, ation procedures,		
9. PHYSIC	AL AND CHEMICAL	PROPERTIES				
Appea	arance	: powde				
Colou	r	: white				
Odou	r	: No data	available			
Odou	r Threshold	: No data	available			
pН		: No data	available			

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-



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			dling or other me	ans.
Flam	mability (liquids)	:	No data available	9
	er explosion limit / Upper nability limit	:	No data available	9
	er explosion limit / Lower nability limit	:	No data available	9
Vapo	our pressure	:	Not applicable	
Relat	tive vapour density	:	Not applicable	
Relat	tive density	:	No data available	9
Dens	sity	:	No data available	9
	bility(ies) /ater solubility	:	No data available	9
	tion coefficient: n-	:	Not applicable	
	nol/water -ignition temperature	:	No data available	9
Deco	mposition temperature	:	No data available	9
Visco Vi	osity iscosity, kinematic	:	Not applicable	
Explo	osive properties	:	Not explosive	
Oxidi	zing properties	:	The substance o	r mixture is not classified as oxidizing.
Mole	cular weight	:	No data available	9
Partie	cle size	:	No data available	9

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 Hazardous decomposition	:	Oxidizing agents



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produ				
	OLOGICAL INFORM			
Inform expos	nation on likely routes sure	s of :	Inhalation Skin contact Ingestion Eye contact	
Acute	e toxicity			
Not cl	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Gona	dotropin, pregnant	mare	serum:	
Acute	oral toxicity	:	LD50 (Mouse):	120 mg/kg
Acute	inhalation toxicity	:	Remarks: No d	ata available
Acute	dermal toxicity	:	Remarks: No d	ata available
	toxicity (other routes istration)	of :	LD50 (Mouse): Application Ro	> 1,700 mg/kg ute: Intravenous
			LD50 (Mouse): Application Ro	> 1,700 mg/kg ute: Subcutaneous
			LD50 (Rat): 50 Application Rot	0 mg/kg ute: Intravenous
			LD50 (Rat): 50 Application Rot	0 mg/kg ute: Subcutaneous
-	corrosion/irritation			
	assified based on av	ailable	information.	
	oonents:			
Gona Rema	dotropin, pregnant	mare :	serum: No data availat	
Reilla	ΠNΟ	•	no uala avallal	סול
	us eye damage/eye assified based on av			
Comp	oonents:			

Remarks : No data available





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Resp	iratory or skin sensit	isation	
Skin	sensitisation		
Not c	lassified based on ava	ilable information.	
-	iratory sensitisation lassified based on ava	ilable information	
	ponents:	naple information.	
Rema	idotropin, pregnant n arks	: No data availa	ble
_			
	n cell mutagenicity		
	lassified based on ava	ilable information.	
	ponents:		
	adotropin, pregnant n otoxicity in vivo		togenetic assay
Geno		Species: Mous	se
		Application Ro Result: positiv	oute: Intraperitoneal injection
		Remarks: Not	classified due to data which are conclusive ficient for classification.
	inogenicity		
	lassified based on ava	ilable information.	
	ponents:		
Gona	dotropin, pregnant n	nare serum:	
Carci ment	nogenicity - Assess-	: No data availa	ble
-	oductive toxicity damage fertility. Suspe	ected of damaging the	unborn child.
Com	ponents:		
Gona	dotropin, pregnant n	nare serum:	
Effec	ts on fertility	: Test Type: Fer	rtility
			ute: Subcutaneous
		Fertility: LOAE Result: Effects	
		Remarks: May	cause adverse reproductive effects.
		Based on data	from similar materials
	ts on foetal develop-		r cause birth defects.
ment		Based on data	from similar materials





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Repro sessr	oductive toxicity - As- nent	anir	nal experime	of adverse effects on development, based or nts., Clear evidence of adverse effects on nd fertility, based on animal experiments.
	Γ - single exposure lassified based on avai	lable infor	mation.	
	F - repeated exposure			
	lassified based on avai	lable infor	nation.	
Repe	ated dose toxicity			
Com	ponents:			
Gona	dotropin, pregnant m	are serun	n:	
	EL cation Route sure time	: Ora : 3 Da	mg/kg I	rts
Expo		: Ora : 14 [ng/kg	jans
•	r ation toxicity lassified based on avai	lable infor	mation	
	rience with human ex			
-	ponents:			
Gona	dotropin, pregnant m	are serun	n:	
Inhala		: Syn	nptoms: Head	lache, Fatigue, mood swings, altered menta Allergic reactions, Effects on fertility
Skin	contact	: Ren	narks: May p	roduce an allergic reaction.

12. ECOLOGICAL INFORMATION

Ingestion

Ecotoxicity No data available Persistence and degradability No data available Bioaccumulative potential No data available

:

Remarks: May be harmful if swallowed.



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Mobil	ity in soil				
No da	ta available				
Other	adverse effects				
No da	ta available				
3. DISPO	SAL CONSIDERATION	NS			
Dispo	sal methods				
Waste	e from residues			of waste into sewer.	
Conta	minated packaging	: E c	 Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste hadling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. 		
4. TRANS	SPORT INFORMATION	I			
Intern	ational Regulations				
UNRT	DG				
UN nu			lot applicable		
	r shipping name		lot applicable		
Class	diary risk		lot applicable lot applicable		
	ng group		lot applicable		
Labels			lot applicable		
ΙΑΤΑ-	DGR				
UN/ID	No.	: N	lot applicable		
Prope	r shipping name		ot applicable		
Class			Not applicable		
	diary risk		Not applicable		
Labels	ng group s		Not applicable Not applicable		
	ng instruction (cargo		lot applicable		
	ng instruction (passen-	: N	lot applicable		
IMDG-	-Code				
UN nu			lot applicable		
	r shipping name		Not applicable		
Class	diary risk		lot applicable		
	ng group		Not applicable Not applicable		
Labels			lot applicable		
EmS (lot applicable		
Marin	e pollutant		lot applicable		



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Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered	:	Not applicable
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Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

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	:	2023/09/30
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/



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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 - 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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