UK REACH Regulations SI 2019/758



Serum Gonadotrophin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.3	28.09.2024	9374237-00008	Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifier Trade name	:	Serum Gonadotrophin Formulation
1.2	Relevant identified uses of th	ie s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture		Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	saf	ety data sheet
	Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom
	Telephone	:	+1-908-740-4000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Reproductive toxicity, Category 1B

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms



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Hazar	d statements	:	H360Fd		damage fertility. Suspected of damaging the n child.
Preca	utionary statements	:	Prevention P201 P280	Obtai Wear	n special instructions before use. protective gloves/ protective clothing/ eye ction/ face protection.
			Response:		
			P308 + P31	I3 IF attent	exposed or concerned: Get medical advice/ ion.
			Storage: P405	Store	locked up.

Hazardous components which must be listed on the label:

Gonadotropin, pregnant mare serum

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Gonadotropin, pregnant mare serum	9002-70-4 232-663-9	Repr. 1B; H360Fd specific concentra- tion limit Repr. 1B; H360Fd >= 0.01 % Repr. 1B; H360Fd >= 0.01 %	>= 30 - < 50

For explanation of abbreviations see section 16.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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SECTION 4: First aid measures

4.1 Description of 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.		
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).		
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.		
4.2 Most important symptoms an	nd e	effects, both acute and delayed		
Risks	:	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.		
4.3 Indication of any immediate r	neo	dical attention and special treatment needed		
Treatment	:	Treat symptomatically and supportively.		
SECTION 5: Firefighting meas	sur	es		

5.1 Extinguishing media		
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing	:	None known.



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media					
5.2 Specia	I hazards arising from	the	e substance or mi	xture	
		:	Avoid generating dust; fine dust dispersed in air in sufficient 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.		
Hazar ucts	Hazardous combustion prod- ucts		Carbon oxides Metal oxides Oxides of phosph	orus	
5.3 Advice	for firefighters				
•	Special protective equipment for firefighters			e, wear self-contained breathing apparatus. tective equipment.	
Specif ods	ic extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. ged containers from fire area if it is safe to do	

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		

Environmental precautions	 Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ-
	If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for 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.
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			d 15 of this SDS provide information regarding national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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. 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
Hygiene measures	 environment. 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.
7.2 Conditions for safe storage, in	ncluding any incompatibilities
Requirements for storage areas and containers	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types:

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7.3 Specific end use(s)

Specific use(s)

: No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

dust of any kind

10 mg/m3 Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40

4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Gonadotropin, pregnant mare serum	9002-70-4	TWA	4 μg/m3 (OEB 4)	Internal
		Wipe limit	40 μg/100 cm2	Internal

8.2 Exposure controls

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

Eye/face 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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. 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.



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Resp	iratory protection	contaminated c If adequate loca sure assessme ommended guid	e degowning techniques to remove potentially lothing. al exhaust ventilation is not available or expo- nt demonstrates exposures outside the rec- delines, use respiratory protection. uld conform to BS EN 143
Fi	lter type	: Particulates typ	

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance Colour Odour Odour Threshold	:	powder white No data available No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling	:	No data available
range Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han- dling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature	::	No data available Not applicable No data available
Decomposition temperature	:	No data available
Viscosity		

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Viscosity, kinem	atic : Not applicat	le
Explosive propertie	s : Not explosiv	e
Oxidizing properties	: The substan	ce or mixture is not classified as oxidizing.
9.2 Other information Flammability (liquid Molecular weight Particle size	s) : No data ava : No data ava : No data ava	ilable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	: May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents.
10.4 Conditions to avoid	
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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 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

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 - 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:

Species	:	Rat
NOAEL	:	1.5 mg/kg

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Annlia	ation Route		Oral	
	sure time	:	3 Days	
Symp		:	No adverse effe	cts
Speci	es	:	Rat	
LÖAE	L	:	10 mg/kg	
	ation Route	:	Oral	
•	sure time	:	14 Days	
Targe	t Organs	:	Reproductive or	gans
Aspir	ation toxicity			
Not cl	assified based on ava	ailable	information.	
Expe	rience with human e	xposı	ıre	
<u>Comp</u>	oonents:			
Gona	dotropin, pregnant i	nare s	serum:	
Inhala	ition	:		dache, Fatigue, mood swings, altered mental , Allergic reactions, Effects on fertility
Skin o	contact	:		roduce an allergic reaction.
Inges	tion	:	Remarks: May b	e harmful if swallowed.

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-	:	This substance/mixture does not contain components consid-
tial		ered to have endocrine disrupting properties for environment
		according to UK REACH Article 57(f).



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SECTION 13: Disposal considerations

13.1 Waste treatment methods	
Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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.

SECTION 14: Transport information

14.1 UN number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.2 UN proper shipping name		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.3 Transport hazard class(es)		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good



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IATA (Cargo) : Not regulated as a da IATA (Passenger) : Not regulated as a da		5 5			
14.5 Environmental hazards Not regulated as a dangerous good					
14.6 Special precautions for user Not applicable					
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Remarks : Not applicable for product as supplied.					

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-	:	Not applicable
ain) Regulation (EC) on substances that deplete the ozone laver	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable
Control of Major Accident Hazards Regulations 2015 (CC Not applicable	OMA	\H)

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.



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SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H360Fd

May damage fertility. Suspected of damaging the unborn child.

Full text of other abbreviations

Repr.	:	Reproductive toxicity
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/



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H360Fd

Classification of the mixture:

Repr. 1B

Classification procedure:

Calculation method

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.

GB / EN