according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Vers 8.0	sion	Revision Date: 28.09.2024	-	S Number: 7988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016			
1. P	1. PRODUCT AND COMPANY IDENTIFICATION							
	Produc	t name	:	Human Gonadot lation	ropin Chorionic / Serum Gonadotropin Formu-			
	Other r	neans of identification	:		TION OF SERUM GONADOTROPHIN (400 IONIC GONADOTROPHIN (200 I.U.) (37234)			
	Manufa	acturer or supplier's c	letai	ils				
	Compa	iny	:	MSD				
	Addres	S	:	Briahnager - Off Wagholi - Pune -	Pune Nagar Road India 412 207			
	Teleph	one	:	+1-908-740-4000)			
	Emerge	ency telephone number	r:	+1-908-423-6000)			
	E-mail	address	:	EHSDATASTEW	/ARD@msd.com			
	Recom	mended use of the cl	nem	ical and restriction	ons on use			
		mended use tions on use	:	Veterinary produ Not applicable	ct			

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 1A
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Ovary)
GHS label elements Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H360Fd May damage fertility. Suspected of damaging the un-

born child.

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version 8.0	Revision Date: 28.09.2024	SDS Number: 657988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016
			s damage to organs (Ovary) through prolonged or osure if swallowed.
Preca	autionary statements	P260 Do not P264 Wash h P270 Do not	ands thoroughly after handling. eat, drink or smoke when using this product. rotective gloves/ protective clothing/ eye protec-
		Response: P318 IF expo	sed or concerned, get medical advice.
		Storage: P405 Store Ic	ocked up.
		Disposal: P501 Dispose disposal plan	e of contents/ container to an approved waste t.

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	>= 1 - < 5
Gonadotropin, chorionic	9002-61-3	>= 1 - < 5

4. FIRST AID MEASURES

:	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, remove to fresh air.
	Get medical attention.
:	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.
•	If in eyes, rinse well with water.
•	Get medical attention if irritation develops and persists.
	:





Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Vers 8.0	ion	Revision Date: 28.09.2024		9S Number: 7988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016	
		nportant symptoms ects, both acute and	:	Get medical atten Rinse mouth thoro May damage fertil child. Causes damage t exposure if swallo Contact with dust	bughly with water. ity. Suspected of damaging the unborn o organs through prolonged or repeated	
	Protection of first-aiders Notes to physician		:	First Aid responde and use the recon when the potentia	ith the eyes can lead to mechanical irritation. Inders should pay attention to self-protection, commended personal protective equipment initial for exposure exists (see section 8). atically and supportively.	
5. FI	REFIGH	TING MEASURES				
	Suitable	e extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical		
	Unsuita media	able extinguishing	:	None known.		
	Specific fighting	c 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.	
	Hazard ucts	ous combustion prod-	:	Carbon oxides Nitrogen oxides (N Sulphur oxides Metal oxides Oxides of phosph		
	Specific ods	c extinguishing meth-	:	cumstances and t Use water spray to	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 firefi	protective equipment ighters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.	

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :	Use personal protective equipment.
tive equipment and emer-	Follow safe handling advice (see section 7) and personal pro-
gency procedures	tective equipment recommendations (see section 8).

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Vers 8.0	ion	Revision Date: 28.09.2024		9S Number: 7988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016
	Environmental precautions		:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages
		ls and materials for ment 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. H/		IG AND STORAGE			
	Technic	cal measures	:	causing an explos	precautions, such as electrical grounding
	Local/T	otal ventilation	:		tion is unavailable, use with local exhaust
	Advice	on safe handling	:	Do not get on skir Do not breathe du Do not swallow. Avoid contact with Wash skin thoroug Handle in accorda practice, based or sessment Keep container tig Minimize dust ger Keep container cle Keep away from h Take precautiona Do not eat, drink o Take care to prev	ist. n eyes. ghly after handling. ance with good industrial hygiene and safety n the results of the workplace exposure as-
	Conditio	ons for safe storage	:	Store locked up. Keep tightly close	
	Materia	ls to avoid	:		ce with the particular national regulations. the following product types: igents

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

SDS Number:

657988-00021

Version Revision Date: 8.0 28.09.2024 Date of last issue: 22.02.2024 Date of first issue: 03.05.2016

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Ī	Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
			exposure)	concentration	
	Gonadotropin, pregnant mare serum	9002-70-4	TWA	4 µg/m3 (OEB 4)	Internal
			Wipe limit	40 µg/100 cm2	Internal
	Gonadotropin, chorionic	9002-61-3	TWA	OEB 4 (3 µg/m3)	Internal
			Wipe limit	25 µg/100 cm ²	Internal

Engineering measures	:	Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are de- signed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If sufficient ventilation is unavailable, use with local exhaust ventilation.
Personal protective equipme	ent	
Respiratory protection	:	If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection.
Filter type Hand protection	:	Particulates type
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance 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.
Eye protection	:	Wear the following personal protective equipment: Safety goggles
Skin and body protection	:	Select appropriate protective clothing based on chemical re- sistance data and an assessment of the local exposure poten- tial. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
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.

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date: 28.09.2024	SDS Number:	Dat
8.0		657988-00021	Dat

Date of last issue: 22.02.2024 Date of first issue: 03.05.2016

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
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	:	No data available
Partition coefficient: n- octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	Not applicable

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version 8.0	Revision Date: 28.09.2024	SDS Number: 657988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016
Explo	osive properties	: Not explosive	
Oxidi	zing properties	: The substance	e or mixture is not classified as oxidizing.
Mole	cular weight	: No data avail	able
	cle characteristics cle size	: No data avail	able

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

Acute toxicity

Not classified based on available information.

Components:

Gonadotropin, pregnant mare serum:

I	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

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date:
8.0	28.09.2024

SDS Number: 657988-00021 Date of last issue: 22.02.2024 Date of first issue: 03.05.2016

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.

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:

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 22.02.2024
8.0	28.09.2024	657988-00021	Date of first issue: 03.05.2016

Carcinogenicity - Assess- : No data available ment

Reproductive toxicity

May damage fertility. Suspected of damaging the unborn child.

Components:

Gonadotropin, pregnant mare serum:

Gonadoli opin, pregnant ma		
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.
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 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 develop- ment	:	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 - As- sessment	:	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.

according to the Globally Harmonized System



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date:	SDS Number:
8.0	28.09.2024	657988-00021

Date of last issue: 22.02.2024 Date of first issue: 03.05.2016

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Ovary) through prolonged or repeated exposure if swallowed.

Components:

Gonadotropin, chorionic:

- J J		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.

Experience with human exposure

Components:

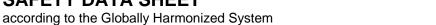
Gonadotropin, pregnant mare serum:

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, Head- ache, mental depression, Irritability, restlessness, Fatigue

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available





Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version 8.0	Revision Date: 28.09.2024	SDS Number: 657988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016			
Persistence and degradability						
No da	No data available					
Bioaccumulative potential						

Bioaccumulative potential No data available

Mobility in soil No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal m	nethods
------------	---------

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.

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



Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version 8.0	Revision Date: 28.09.2024		DS Number: 57988-00021	Date of last issue: 22.02.2024 Date of first issue: 03.05.2016
Rev	vision Date	:	28.09.2024	
Further information Sources of key data used to compile the Safety Data		:	Internal technical data, data from raw material SDSs, OEC eChem Portal search results and European Chemicals Age	
She	eet		cy, http://echa.eu	ropa.eu/

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

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 - 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 SAFETY DATA SHEET according to the Globally Harmonized System



22.02.2024 03.05.2016

Human Gonadotropin Chorionic / Serum Gonadotropin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.0	28.09.2024	657988-00021	Date of first issue:

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