according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Serum Gonadotrophin Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number: 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

# **Emergency Overview**

Appearance : powder Colour : white

Odour : No data available

May damage fertility. Suspected of damaging the unborn child.

**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:

P201 Obtain special instructions before use.

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

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.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

## Physical and chemical hazards

Not classified based on available information.

#### **Health hazards**

May damage fertility. Suspected of damaging the unborn child.

#### **Environmental hazards**

Not classified based on available information.

## 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.

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

and effects, both acute a delayed

b

child.

Contact with dust can cause mechanical irritation or drying of

May damage fertility. Suspected of damaging the unborn

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.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

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.

Hazardous combustion prod- :

ucts

Carbon oxides

Metal oxides

Oxides of phosphorus

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective 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).

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal 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

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 as-

sessment

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

environment.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / 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-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

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.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

eye flushing systems and safety showers close to the work-

ing 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

pH : 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

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

## 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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.

Oxidizing agents

Incompatible materials :

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Exposure routes : 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

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2024/09/28 5445445-00009 3.0 Date of first issue: 2020/02/20

Acute dermal toxicity : Remarks: No data available

administration)

Acute toxicity (other routes of : 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.

#### **Components:**

#### Gonadotropin, pregnant mare serum:

Genotoxicity in vivo : Test Type: Cytogenetic assay

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

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: RatNOAEL: 1.5 mg/kgApplication Route: OralExposure time: 3 Days

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

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.

#### 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.

#### 14. TRANSPORT INFORMATION

## International Regulations

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen:

ger aircraft)

Not applicable

**IMDG-Code** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable

Marine pollutant : no

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

Not applicable for product as supplied.

#### **National Regulations**

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Marine pollutant : no

Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

#### **National regulatory information**

Law on the Prevention and Control of Occupational Diseases

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

#### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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** 2024/09/28

**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/

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

Date format yyyy/mm/dd

according to GB/T 16483 and GB/T 17519



# **Serum Gonadotrophin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/09/28 5445445-00009 Date of first issue: 2020/02/20

#### 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

## **Disclaimer**

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.

CN / EN