according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2024/09/28 613532-00018 Date of first issue: 2016/04/27 6.0

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Gonadorelin Formulation Product name

FERTAGYL SYNTHETIC GONADOTROPHIN RELEASING Other means of identification

**HORMONE (37210)** 

Manufacturer or supplier's details

Company MSD

No. 485 Jing Tai Road Address

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

Veterinary product Recommended use Restrictions on use Not applicable

### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

**Appearance** liquid

No data available Colour Odour No data available

May cause an allergic skin reaction. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.

**GHS Classification** 

Skin sensitisation Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - : Category 1

repeated exposure

#### **GHS** label elements

according to GB/T 16483 and GB/T 17519



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Hazard pictograms :





Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H361fd Suspected of damaging fertility. Suspected of damag-

ing the unborn child.

H372 Causes damage to organs through prolonged or repeated

exposure.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

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

attention.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

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 cause an allergic skin reaction. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 -< 10
Gonadorelin	34973-08-5	>= 0.001 -< 0.1

#### 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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Most important symptoms : and effects, both acute and

delayed

Rinse mouth thoroughly with water.

May cause an allergic skin reaction.

Suspected of damaging fertility. Suspected of damaging the

unborn child.

Causes damage to organs through prolonged or repeated

exposure.

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.

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

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).

Environmental precautions : Av

Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

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

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

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.

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
Gonadorelin	34973-08-5	TWA	0.2 μg/m3 (OEB 5)	Internal
		Wipe limit	2 μg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations.

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 : Organic vapour type

Eye/face protection : Wear the following personal protective equipment:

Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Hand protection

according to GB/T 16483 and GB/T 17519



### **Gonadorelin Formulation**

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Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration and quantity of the hazardous substance 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.

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

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : No data available

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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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 : No data available

Relative vapour density : No data available

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : Not applicable

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- : Can react with strong oxidizing agents.

. USSIDII

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

according to GB/T 16483 and GB/T 17519



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### **Components:**

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Gonadorelin:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg

LD50 (Mouse): > 4,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Gonadorelin:

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

# **Components:**

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Gonadorelin:

Remarks : No data available

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Gonadorelin:

Remarks : No data available

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

### Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

. Application Route: Intraperitoneal injection

Result: negative

#### Gonadorelin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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Germ cell mutagenicity -

Assessment

: Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Gonadorelin:

Species : Mouse Exposure time : 2 Years

LOAEL : 2.4 mg/kg body weight

Result : positive

Remarks : Based on data from similar materials

Species : Rat Exposure time : 1 Years

LOAEL : 0.05 mg/kg body weight

Result : negative Remarks : Benign tumor(s)

The mechanism or mode of action may not be relevant in hu-

mans.

Based on data from similar materials

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:** 

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Gonadorelin:

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, female

Application Route: Subcutaneous Fertility: LOAEL: 50 µg/kg Result: Effects on fertility

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Rat, male

Application Route: Subcutaneous Fertility: LOAEL: 500 µg/kg Result: Effects on fertility

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Rabbit

Application Route: Subcutaneous Fertility: LOAEL: 1,000 μg/kg Result: Effects on fertility

Test Type: Fertility/early embryonic development

Species: Dog, male and female Application Route: Subcutaneous Fertility: LOAEL: 107 - 214 µg/kg

Result: Effects on fertility

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: >= 2 μg/kg Result: Effects on foetal development

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: > 20 μg/kg Result: Effects on foetal development

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and fertility, based on animal experiments.. Some evidence of

adverse effects on development, based on animal experi-

ments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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### **Components:**

#### Gonadorelin:

Target Organs Endocrine system

Assessment Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

#### **Components:**

### Benzyl alcohol:

Species Rat NOAEL 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

#### Gonadorelin:

Species Rat

NOAEL 0.12 mg/kg : Application Route Exposure time Intramuscular 15 Days

Remarks : No significant adverse effects were reported

Species : Rat

NOAEL
Application Route
Exposure time : 0.072 mg/kg : Intravenous : 15 Days

: No significant adverse effects were reported Remarks

Species Dog

NOAEL : 0.12 mg/kg Application Route
Exposure time : Intramuscular : 15 Days

Remarks : No significant adverse effects were reported

Species Dog

0.072 mg/kg NOAEL NOAEL Application Route Intravenous Exposure time 15 Days

: No significant adverse effects were reported Remarks

# **Aspiration toxicity**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### **Experience with human exposure**

**Components:** 

Gonadorelin:

Ingestion : Symptoms: Nausea, Abdominal pain, Headache, Palpitation,

acne, liver function change, bronchospasm, anaphylaxis

#### 12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d

Mathed OFOR Teach

Method: OECD Test Guideline 211

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

Bioaccumulative potential

**Components:** 

Benzyl alcohol:

Partition coefficient: n- : log Pow: 1.05

according to GB/T 16483 and GB/T 17519



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### octanol/water

### 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.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

### International Regulations

#### **UNRTDG**

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

Environmentally hazardous no

### **IATA-DGR**

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

aircraft)

Packing instruction (passen-Not applicable

ger aircraft)

#### **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

according to GB/T 16483 and GB/T 17519



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### 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

### **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.

according to GB/T 16483 and GB/T 17519



### **Gonadorelin Formulation**

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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

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 Sub-

according to GB/T 16483 and GB/T 17519



# **Gonadorelin Formulation**

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stances 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