according to the Globally Harmonized System



Gonadorelin Formulation

Revision Date: Date of last issue: 08.12.2023 Version SDS Number: 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name Gonadorelin Formulation

FERTAGYL SYNTHETIC GONADOTROPHIN RELEASING Other means of identification

HORMONE (37210)

Manufacturer or supplier's details

Company MSD

Briahnager - Off Pune Nagar Road Address

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

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

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

Skin sensitisation : Category 1

Category 2 Reproductive toxicity

repeated exposure (Oral)

Specific target organ toxicity - : Category 1 (Endocrine system)

GHS label elements

Hazard pictograms

Signal word Danger

azard statements H317 May cause an allergic skin reaction.

H361fd Suspected of damaging fertility. Suspected of damag-

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

ing the unborn child.

H372 Causes damage to organs (Endocrine system) through

prolonged or repeated exposure if swallowed.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe mist or vapours.

P264 Wash hands 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. P318 IF exposed or concerned, get medical advice.

P333 + P317 If skin irritation or rash occurs: Get medical help. 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.

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 - < 5 |
| 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.

according to the Globally Harmonized System



Gonadorelin Formulation

Revision Date: Version SDS Number: Date of last issue: 08.12.2023 28.09.2024 641765-00017 Date of first issue: 27.04.2016 6.0

Thoroughly clean shoes before reuse.

Flush eyes with water as a precaution. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed

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 if swallowed.

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

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

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, protec: : tive 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 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

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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 absorbent.

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

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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.

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

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 ² | Internal |

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

Minimize workplace exposure concentrations.

Personal protective equipment

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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 : Organic vapour type

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.

Eye protection : Wear the following personal protective equipment:

Safety glasses

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

sistance data and an assessment of the local exposure poten-

tiai.

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.

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

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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

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.

Passibility of bazardous rose : Con react with strong exidizing agents.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition : No hazardous decomposition products are known.

products

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

Ingestion Eye contact

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

Acute toxicity

Not classified based on available information.

Product:

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

Method: Calculation method

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

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

Gonadorelin:

Remarks : No data available

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 the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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 the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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 (Endocrine system) through prolonged or repeated exposure if swallowed.

Components:

Gonadorelin:

Target Organs : Endocrine system

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

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 : Intramuscular
Exposure time : 15 Days

Remarks : No significant adverse effects were reported

Species : Rat

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

Remarks : No significant adverse effects were reported

Species : Dog

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

Remarks : No significant adverse effects were reported

Species : Dog

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

Remarks : No significant adverse effects were reported

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Gonadorelin:

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

acne, liver function change, bronchospasm, anaphylaxis

according to the Globally Harmonized System



Gonadorelin Formulation

Revision Date: Date of last issue: 08.12.2023 Version SDS Number: 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : 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

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

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

octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

according to the Globally Harmonized System



Gonadorelin Formulation

Revision Date: Version SDS Number: Date of last issue: 08.12.2023 28.09.2024 641765-00017 Date of first issue: 27.04.2016 6.0

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 regulated as a dangerous good

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

Revision Date 28.09.2024

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 dd.mm.yyyy

according to the Globally Harmonized System



Gonadorelin Formulation

Version Revision Date: SDS Number: Date of last issue: 08.12.2023 6.0 28.09.2024 641765-00017 Date of first issue: 27.04.2016

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IN / EN