

SAFETY DATA SHEET



Gonadorelin Formulation

Version
6.0

Revision Date:
2024/09/28

SDS Number:
613535-00017

Date of last issue: 2023/12/08
Date of first issue: 2016/04/27

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gonadorelin Formulation
Other means of identification : FERTAGYL SYNTHETIC GONADOTROPHIN RELEASING HORMONE (37210)

Manufacturer or supplier's details

Company : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

||| Skin sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Endocrine system)

GHS label elements

||| Hazard pictograms : 
Signal word : Danger
Hazard statements : H317 May cause an allergic skin reaction.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H372 Causes damage to organs (Endocrine system) through prolonged or repeated exposure if swallowed.

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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 protection/ 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 advice/ 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.

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 -< 1

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice 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.

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In case of eye contact	Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. 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 if swallowed.
Most important symptoms and effects, both acute and delayed	
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 (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances 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 emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment.

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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 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 determine 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 assessment

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 parame- ters / Permissible concentration	Basis
Gonadorelin	34973-08-5	TWA	0.2 µg/m ³ (OEB)	Internal

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			5) Wipe limit	2 µg/100 cm ²	Internal
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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 exposure assessment demonstrates exposures outside the recommended 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 resistance data and an assessment of the local exposure potential.
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

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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
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.

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tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 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 inhalation 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

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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

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

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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
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 humans. Based on data from similar materials

Reproductive toxicity

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

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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 development	: Test Type: Embryo-foetal development Species: Mouse Application Route: Ingestion Result: negative

Gonadorelin:

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 development	: 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

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

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 Assessment**

: Endocrine system
: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Benzyl alcohol:****Species**
NOAEL
Application Route
Exposure time
Method

: Rat
: 1.072 mg/l
: inhalation (dust/mist/fume)
: 28 Days
: OECD Test Guideline 412

Gonadorelin:**Species**
NOAEL
Application Route
Exposure time
Remarks

: Rat
: 0.12 mg/kg
: Intramuscular
: 15 Days
: No significant adverse effects were reported

Species
NOAEL
Application Route
Exposure time
Remarks

: Rat
: 0.072 mg/kg
: Intravenous
: 15 Days
: No significant adverse effects were reported

Species
NOAEL
Application Route
Exposure time
Remarks

: Dog
: 0.12 mg/kg
: Intramuscular
: 15 Days
: No significant adverse effects were reported

Species

: Dog

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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
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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 (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 51 mg/l Exposure time: 21 d Method: OECD Test Guideline 211

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 - 96 % Exposure time: 14 d
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II

Bioaccumulative potential**Components:****Benzyl alcohol:**

Partition coefficient: n-octanol/water : log Pow: 1.05

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION**International Regulations****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 aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable

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Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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; KECL - 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

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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.

ID / EN