

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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

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.

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

Actual concentration is withheld as a trade secret

SECTION 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.
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 : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and : May cause an allergic skin reaction.
Suspected of damaging fertility. Suspected of damaging the

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

delayed	:	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.

SECTION 5. FIRE-FIGHTING 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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. 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
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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.

SECTION 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 vapors.
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 labeled 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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Gonadorelin	34973-08-5	TWA	0.2 µg/m ³ (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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 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: > 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 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

Gonadorelin:

|| Remarks : No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

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 sensitization

Skin sensitization

|| May cause an allergic skin reaction.

Respiratory sensitization

|| Not classified based on available information.

Components:

Benzyl alcohol:

|| Test Type : Human repeat insult patch test (HRIPT)
|| Routes of exposure : Skin contact
|| Species : Humans
|| Result : positive

|| Assessment : Probability or evidence of low to moderate skin sensitization 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: >= 2 µg/kg
Result: Effects on fetal development.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Subcutaneous

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

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

Reproductive toxicity - Assessment : 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 : 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

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

SECTION 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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version 6.0 Revision Date: 09/28/2024 SDS Number: 613544-00019 Date of last issue: 12/08/2023
Date of first issue: 04/27/2016

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water 7732-18-5
Benzyl alcohol 100-51-6

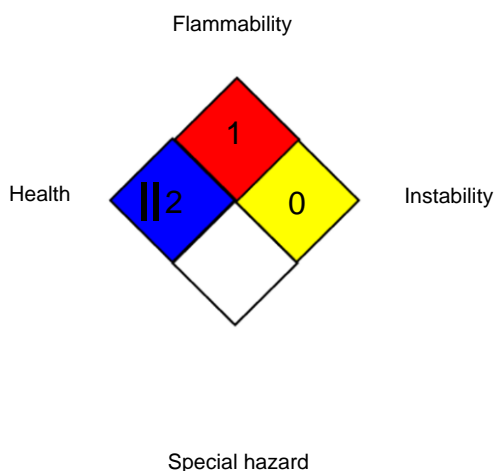
The ingredients of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA : 8-hr TWA

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date : 09/28/2024

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

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.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Gonadorelin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/08/2023
6.0	09/28/2024	613544-00019	Date of first issue: 04/27/2016

US / Z8