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SECTION 1. IDENTIFICATION

Product name : Gonadorelin Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : One Merck Drive

Whitehouse Station - New Jersey - USA 08889

Telephone : 908-423-1000

Telefax : 908-735-1496

Emergency telephone : 908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated

exposure (Oral)

Category 1 (Endocrine system)

GHS label elements

Hazard pictograms

Signal Word : Danger

Hazard Statements : 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.



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

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

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

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

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

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

Suspected of damaging fertility. Suspected of damaging the

unborn child.



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delayed 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.

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING 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-

nds

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 fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective

equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.

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



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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 : Avoid inhalation of vapor or mist.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety

practice.

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 Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Benzyl alcohol	100-51-6	TWA	10 ppm	US WEEL
Gonadorelin	34973-08-5	TWA	0.2 μg/m³	Merck
		Wipe limit	2 μg/100 cm ²	Merck

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

Minimize workplace exposure concentrations.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where



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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 : Ensure that eye flushing systems and safety showers are

located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

Odor : No information 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



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Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit : No data available

Lower explosion 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

Explosive properties : Not explosive

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

Molecular weight : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.



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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

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Ingredients:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Gonadorelin:

Acute oral toxicity : 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.

Ingredients:

Benzyl alcohol:

Species: Rabbit

Method: OECD Test Guideline 404

Result: No skin irritation

Gonadorelin:

Remarks: No data available



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Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

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

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Benzyl alcohol:

Test Type: Maximization Test Routes of exposure: Skin contact

Species: Guinea pig

Method: OECD Test Guideline 406

Result: negative

Assessment: Does not cause skin sensitization.

Gonadorelin:

Remarks: No data available

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Benzyl alcohol:

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

Method: OECD Test Guideline 471

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)



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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.

Ingredients:

Benzyl alcohol:

Species: Mouse

Application Route: Ingestion Exposure time: 103 weeks

Method: OECD Test Guideline 453

Result: negative

Gonadorelin:

Species: Mouse Exposure time: 2 Years

Result: positive

Remarks: 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 ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

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.

Reproductive toxicity

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

Ingredients:

Benzyl alcohol:

Effects on fetal development : Species: Mouse

Application Route: Ingestion

Result: negative



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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.

Test Type: Fertility/early embryonic development

Species: Rat, male

Application Route: Subcutaneous

Fertility: 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

Developmental Toxicity: LOAEL: > 20 µg/kg

Result: Effects on fetal 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

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.

Ingredients:

Gonadorelin:

Target Organs: Endocrine system

Assessment: Causes damage to organs through prolonged or repeated exposure.



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Repeated dose toxicity

Ingredients:

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 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 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

Ingredients:

Gonadorelin:

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

acne, liver function change, bronchospasm, anaphylaxis

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Benzyl alcohol:



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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 : 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

Method: OECD Test Guideline 211

Persistence and degradability

Ingredients:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

Bioaccumulative potential

Ingredients:

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.

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.



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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

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Ingredients	CAS-No.	Component RQ Calculated product RQ	
		(lbs)	(lbs)
Acetic acid	64-19-7	5000	*

^{*:} Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 311/312 Hazards : Chronic Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting

requirements of SARA Title III, Section 302.

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

California Prop. 65 This product does not contain any chemicals known to the

State of California to cause cancer, birth, or any other

reproductive defects.

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

AICS not determined

DSL not determined



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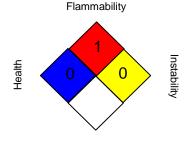
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IECSC not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



Special hazard.

HMIS III:



0 = not significant, 1 = Slight,

2 = Moderate, 3 = High

4 = Extreme, * = Chronic

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; 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



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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; 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 Agen-

cy, http://echa.europa.eu/

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

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