SAFETY DATA SHEETS

This SDS packet was issued with item:

078412881

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078345132 078777637 078777645 078918381





Printing date 07/12/2016 Reviewed on 07/12/2016

1 Identification

· Product identifier

· Trade name: Gonadorelin Diacetate Tetrahydrate CYSTORELIN®

· Item number: 828301-828304

• CAS Number: 52699-48-6

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Merial, Inc.

3239 Satellite Blvd.

Duluth, Ga. 30096-4640

1-888-MERIAL 1 (1-888-637-4251)

· Emergency telephone number:

Spill Information:

CHEMTREC® 1-800-424-9300

CHEMTREC® International 1+703-527-3887

International calls 011+703-527-3887

Reverse charges.

2 Hazard(s) identification

· Classification of the substance or mixture



Acute Tox. 4 H302 Harmful if swallowed.

- · Label elements
- · GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labeling:

Gonadorelin Diacetate Tetrahydrate

· Hazard statements

H302 Harmful if swallowed.

· Precautionary statements

P264 Wash thoroughly after handling.

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

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

TIC

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Trade name: Gonadorelin Diacetate Tetrahydrate **CYSTORELIN®**

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 1Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1Fire = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description

52699-48-6 Gonadorelin Diacetate Tetrahydrate

4 First-aid measures

- · Description of first aid measures
- · General information:

Do not leave affected persons unattended if individual is exposed to large quantities of product. *Involve doctor immediately.*

- · After inhalation: Not an expected route of entry.
- · After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation occurs, consult a doctor.

· After eye contact:

Rinse opened eye for a minimum of 15 minutes under running water. Get medical attention immediately.

- · After swallowing: Immediately call a doctor.
- · After self injection
- · Most important symptoms and effects, both acute and delayed

Allergic reactions to inhaled dust. Hormonal disturbances. Abdominal pain, nausea, headaches and menorrhagia.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use appropriate media for underlying fire.
- · Special hazards arising from the substance or mixture May emit toxic fumes when exposed to fire.

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- · Advice for firefighters
- · Protective equipment:

Fire fighters should wear self-contained breathing apparatus and full protective equipment.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures
- Keep people at a distance and stay upwind.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· Reference to other sections No dangerous substances are released.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Keep containers tightly sealed.

Store in cool, dry place in tightly closed containers.

Handle with care. Avoid jolting and impact.

Avoid breathing mists.

Protect from freezing.

- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store only in the original container.

Protect from light.

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

Store in the dark.

Store in a cool, dry, well ventilated place.

- · Recommended storage temperature: 2-8 °C
- \cdot *Specific end use*(s) *No further relevant information available.*

8 Exposure controls/personal protection

- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Do not eat, drink, smoke or inhale.

Do not store food in the working area.

- · Breathing equipment: Use approved NIOSH mist filter and full face mask.
- · Protection of hands: Chemical resistant gloves

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· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Safety goggles.

· Body protection: Use protective apron and/or outer garment.

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Liquid Color: Clear

· Odor: Characteristic

· Change in condition

Melting point/Melting range: Undetermined. *Boiling point/Boiling range:* 94 °C (201 °F)

• Flash point: Not applicable.

· Danger of explosion: Product does not present an explosion hazard.

· Specific gravity: 1.007 g/cm³ (8.403 lbs/gal)

· Solubility in / Miscibility with

Water: Fully miscible.

• Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: Oxidizing materials
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

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Oral | *LD50* | >600 mg/kg (rat)

HS

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- · Primary irritant effect:
- · on the skin: No irritating effect known.
- · on the eye: No irritating effect known.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

The substance is not subject to classification.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

Substance is not listed.

· NTP (National Toxicology Program)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not known to be hazardous to water.
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation: Incinerate at an EPA approved incinerator facility.
- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport information	
· UN-Number	None
· UN proper shipping name	None
· Transport hazard class(es)	
· DOT, ADR, IMDG, IATA · Class	Non regulated

US-

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· Packing group	None
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	c II of Not applicable.

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · SARA
- · Section 355 (extremely hazardous substances):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not listed.

- · CA Proposition 65
- · Chemicals known to cause cancer:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

- · Carcinogenesis potential categories
- · EPA (Environmental Protection Agency)

Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

· MAK (German Maximum Workplace Concentration)

Substance is not listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

Substance is not listed.

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS07
- · Signal word Warning
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· Hazard statements

H302 Harmful if swallowed.

· Precautionary statements

P264 Wash thoroughly after handling.

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

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This material safety data sheet is provided for information purposes only. As per WHMIS regulations, SDS are not required for products regulated by the Canadian Food and Drug Act (such as drugs) or the Pest Control Products Act (such as disinfectants), or for products not regulated by Health Canada (such as veterinary vaccines).

- · Contact: MSDS Coordinator, msds@merial.com
- · Date of preparation / last revision 07/12/2016 / -
- · Abbreviations and acronyms:

Acute Tox. 4: Acute toxicity, Hazard Category 4

US