# Safety Data Sheet

ISO/DIS 11014 / 29 CFR 1910.1200 / ANSI Z400.1

**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**
  - GHS07
  - 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.
Trade name: Gonadorelin Diacetate Tetrahydrate
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· Classification system:
  · NFPA ratings (scale 0 - 4)
    Health = 1
    Fire = 0
    Reactivity = 0

· HMIS-ratings (scale 0 - 4)

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FIRE</th>
<th>REACTIVITY</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>0</td>
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· 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.
Trade name: Gonadorelin Diacetate Tetrahydrate
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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
  - 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.

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:** Liquid
    - **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.

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### 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.

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### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
  - **LD/LC50 values that are relevant for classification:**
    - 52699-48-6 Gonadorelin Diacetate Tetrahydrate
      - **Oral LD50:** >600 mg/kg (rat)
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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
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· Packing group None
· Environmental hazards:
  · Marine pollutant: No
· Special precautions for user Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code 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
  · Hazard-determining components of labeling:
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Hazard statements

H302 Harmful if swallowed.

Precautionary statements

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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
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Abbreviations and acronyms:
Acute Tox. 4: Acute toxicity, Hazard Category 4