

### Printing date 12/05/2007

Reviewed on 12/05/2007

### **1** Identification of substance

· Product details

• Trade name: <u>Gonadorelin Diacetate Tetrahydrate</u> CYSTORELIN®

- · Item number: 828301-828304
- Manufacturer/Supplier: Merial Limited
  3239 Satellite Blvd.
  Duluth, Ga. 30096-4640
  1-888-MERIAL 1 (1-888-637-4251)
  Emergency information: Spill Information: CHEMTREC® 1-800-424-9300

CHEMTREC® International 1+703-527-3887 International calls 011+703-527-3887 Reverse charges.

## 2 Composition/Data on components

- · Chemical characterization:
- · CAS No. Description
- 52699-48-6 Gonadorelin Diacetate Tetrahydrate

### **3 Hazards identification**

- · Hazard description: Not applicable.
- · Classification system:
- · NFPA ratings (scale 0 4)



· HMIS-ratings (scale 0 - 4)



## 4 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.

Printing date 12/05/2007

Reviewed on 12/05/2007

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

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

• Information for doctor.

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

## 5 Fire fighting measures

- · Suitable extinguishing agents: Use appropriate media for underlying fire.
- Special hazards caused by the material, its products of combustion or resulting gases: May emit toxic fumes when exposed to fire.
- **Protective equipment:**

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

### 6 Accidental release measures

- · Person-related safety precautions: Keep people at a distance and stay upwind.
- Measures for environmental protection: No special measures required.
- *Measures for cleaning/collecting:* Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- · Additional information: No dangerous substances are released.

## 7 Handling and storage

· Handling:

- · Information 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.

- · 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

8 Exposure controls and personal protection

· 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.

USA

Printing date 12/05/2007

Reviewed on 12/05/2007

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

- · 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
- · 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:



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

#### 9 Physical and chemical properties · General Information 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: $1.007 \text{ g/cm}^3$ · Solubility in / Miscibility with Fully miscible. Water:

# **10 Stability and reactivity**

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Materials to be avoided: Oxidizing materials

- · Dangerous reactions No dangerous reactions known.
- · Dangerous products of decomposition: No dangerous decomposition products known.

# **11 Toxicological information**

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

52699-48-6 Gonadorelin Diacetate Tetrahydrate

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

Printing date 12/05/2007

Reviewed on 12/05/2007

### Trade name: Gonadorelin Diacetate Tetrahydrate CYSTORELIN®

- 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.

# **12** Ecological information

· General notes: Not known to be hazardous to water.

# **13 Disposal considerations**

· Product:

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

# 14 Transport information

- DOT regulations:
- Hazard class: Non regulated
- Land transport ADR/RID (cross-border): • ADR/RID class: Non regulated
- Maritime transport IMDG:
- **MDG Class:** Non regulated
- Marine pollutant: No
- Air transport ICAO-TI and IATA-DGR:
- · ICAO/IATA Class: Non regulated

# **15 Regulations**

## · 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.

Printing date 12/05/2007

Reviewed on 12/05/2007

### Trade name: Gonadorelin Diacetate Tetrahydrate CYSTORELIN®

Su	ibstance is not listed.
Cl	hemicals known to cause reproductive toxicity for males:
Su	ibstance is not listed.
Cl	hemicals known to cause developmental toxicity:
Su	ibstance is not listed.
С	arcinogenesis potential categories
El	PA (Environmental Protection Agency)
Su	ibstance is not listed.
IA	RC (International Agency for Research on Cancer)
Su	ibstance is not listed.
N	TP (National Toxicology Program)
Su	ibstance is not listed.
Tl	LV (Threshold Limit Value established by ACGIH)
Su	ibstance is not listed.
M	AK (German Maximum Workplace Concentration)
Su	ubstance is not listed.
N	IOSH-Ca (National Institute for Occupational Safety and Health)
Su	ibstance is not listed.
0	SHA-Ca (Occupational Safety & Health Administration)
	ibstance is not listed.

The substance is not subject to classification according to the sources of literature known to us. Observe the general safety regulations when handling chemicals.

## **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.

· Contact: MSDS Coordinator, msds@merial.com