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Safety data sheet according to 1907/2006/EC, Article 31

628900

Revision: 29.11.2011 Printing date: 07.07.2016

01 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- Trade name: (Des-Gly¹o,D-Leu^e,Pro-NHEt^e)-LHRH acetate salt Leuprolide
- · Article number:

new: 4033014 old: H-4060

- CAS Number: 74381-53-6
- · Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the preparation Laboratory chemicals
 Biochemicals
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Bachem AG Hauptstrasse 144 CH-4416 Bubendorf Switzerland E-mail msds@bachem.com

E-mail msds@bachem.cd Tel +41 58 595 2021 Fax +41 58 595 2040

· Further information obtainable from:

Department: Marketing

Emergency telephone number:
 +41 44 251 51 51 (Tox Info Suisse)

02 Hazards identification

- · Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008



GHS08

Repr. 1A - H360 May damage fertility or the unborn child.

- Label elements
- Labelling according to Regulation (EC) No 1272/2008



GHS08

Signal word

Danger

Hazard statements

H360 May damage fertility or the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P281 Use personal protective equipment as required.

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

P405 Store locked up.

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

· Other hazards

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(Contd. of page 1)

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

Not applicable.

03 Composition/information on ingredients

· Chemical characterization: Substances

CAS No. Description

74381-53-6 (Des-Gly¹º,D-Leu⁶,Pro-NHEt⁹)-LHRH

- Identification number(s)
- · EC number:
- -DTECS No

 RTECS Number: OH6390000

04 First aid measures

· After inhalation:

Supply fresh air; consult doctor in case of complaints.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek immediate medical advice.

· After eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing:

Call a doctor immediately.

- Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

05 Firefighting measures

- · Suitable extinguishing agents:
 - CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · Special hazards arising from the substance or mixture

No further relevant information available.

- · Advice for firefighters
- Protective equipment:

No special measures required.

06 Accidental release measures

 Personal precautions, protective equipment and emergency procedures Avoid formation of dust.

Use respiratory protective device against the effects of fumes/dust/ aerosol.

Wear protective clothing.

• Environmental precautions:

Suppress gases/fumes/haze with water spray.

Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

GB



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07 Handling and storage

- · Handling:
- · Precautions for safe handling

Open and handle receptacle with care.

Prevent formation of dust.

· Information about fire - and explosion protection:

Keep respiratory protective device available.

- · Storage:
- · Requirements to be met by storerooms and receptacles:

No special requirements.

· Information about storage in one common storage facility:

Store away from foodstuffs.

• Further information about storage conditions:

Store in dry conditions.

Recommended storage temperature:

-20 +/- 5 °C

Specific end use(s)

No further relevant information available.

08 Exposure controls/personal protection

· Ingredients with limit values that require monitoring at the workplace:

CAS No. Designation of material

Not required.

· Additional information:

The lists valid during the making were used as basis.

- · Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Protective gloves

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

• 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 glasses

09 Physical and chemical properties

General Information

Appearance:

Form:

Colour:

White

Odourless

Odour threshold:

Molecular Weight

Lyophilisate

White

Odourless

Not determined.

1.209,4200 g/mol

Change in condition

Boiling point/Boiling range: Undetermined.

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	(Contd. of pag
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	
Decomposition temperature:	Not determined.
Self-igniting:	Not determined.
Danger of explosion:	Not determined.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Solubility in / Miscibility with	
water:	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Other information	No further relevant information available.

10 Stability and reactivity

- 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:
 - No further relevant information available.
- Hazardous decomposition products:
 No dangerous decomposition products known.

11 Toxicological information

- · Acute toxicity:
 - No further relevant information available.
- LD/LC50 values relevant for classification:

74381-53-6 (Des-Gly¹, D-Leu, Pro-NHEt)-LHRH

Oral, LD50: > 5000 mg/kg (rat)

Oral, LD50: > 5000 mg/kg (mouse)

- · Primary irritant effect:
- · on the skin:
 - No further relevant information available.
- on the eye:
 - No further relevant information available.
- · Sensitization:
 - No sensitizing effects known.

12 Ecological information

- · Acquatic toxicity:
 - No further relevant information available.
- · Persistence and degradability
 - No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential
 - No further relevant information available.
- · Mobility in soil

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No further relevant information available.

- · Additional ecological information:
- General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 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
- Waste disposal key: 18 02 05
- · Uncleaned packaging:
- · Recommendation:

Disposal must be made according to official regulations.

14 Transport information

ADR/RID class: IMDG Class: ICAO/IATA Class: -

- · Environmental hazards:
 - Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

15 Regulatory information

- · National regulations:
- · Waterhazard class:
- Water hazard class 1 (Self-assessment): slightly hazardous for water.
- 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.

- · Department issuing MSDS:
 - Department: Marketing
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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PRODUCT: (Des-Gly¹º,D-Leu⁴,Pro-NHEt⁴)-LHRH acetate salt

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

RTECS: Registry of Toxic Effects of Chemical Substances

WGK: Wassergefährdungsklasse

vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.

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