Safety Data Sheet

Release 1.0

 Revision
 10/17/2019

 Date of issue
 04/24/2022



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1 Identification of the substance

1.1 Product identifier

Identification of the

substance

Ganirelix acetate

Additional identification N-Acetyl-3-(2-naphthalenyl)-D-alanyl-4-chloro-D-phenylalanyl-3-(3-pyridinyl)-D-

alanyl-L-seryl-L-tyrosyl-N6-[bis(ethylamino)methylene]-D-lysyl-L-leucyl-N6-[bis

(ethylamino)methylene]-L-lysyl-L-prolyl-D-alaninamide

Cataloge Number FG23647

REACH No. A registration number is not available for this substance as the substance or its

uses are exempted from registration or the annual tonnage does not require a

registration.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses basic Intermediates

Restriction on use not for food or drug use, for laboratory use only

1.3 Details of the supplier of the safty data sheet

Company Carbosynth Ltd

8&9 Old Station Business Park

COMPTON RG20 6NE

Phone +44 1635 578444

Mail customerservice@biosynth-carbosynth.com

1.4 Emergency telephone number

Phone 24hr/7days: +44 118 338 8269

2 Hazards identification

2.1 Classification of the substance or mixturet

Physical Hazards

not classified

Health Hazards

Skin irritation (Category 2), H315 Eye irritation (Category 2), H319

Specific target organ toxicity, single exposure (Category 3), H335

Enviromental Hazards

not classified

2.2 Label elements

Symbol

GHS07 exclamation mark

Pictogram



Signal Word

Warning Warning

Hazard Statement

H315 Causes skin irritation.

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

Precautionary Statement

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302 IF ON SKIN:

P352 Wash with plenty of soap and water.

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| P304 | IF INHALED: |
|------|--|
| P340 | Remove casualty to fresh air and keep at rest inaposition comfortable for breathing. |
| P305 | IF IN EYES: |
| P351 | Rinse cautiously with water for several minutes. |
| P338 | Remove contact lenses, if present and easy to do.Continue rinsing. |

3 Composition/information on ingredients

Substance related information

Substance name Ganirelix acetate

Synonyms N-Acetyl-3-(2-naphthalenyl)-D-alanyl-4-chloro-D-phenylalanyl-3-(3-pyridinyl)-D-

alanyl-L-seryl-L-tyrosyl-N6-[bis(ethylamino)methylene]-D-lysyl-L-leucyl-N6-[bis

(ethylamino)methylene]-L-lysyl-L-prolyl-D-alaninamide

Cas No. [129311-55-3] Formula C₈₄H₁₂₁ClN₁₈O₁₇

4 First aid measures

4.1 Description of first aid measures

First Aid: Eye

Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult an ophthalmologist.

First Aid: Skin

Wash immediately with plenty of water and soap for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothes before reuse. Call a physician.

First Aid: Ingestion

Wash out mouth with water provided person is conscious. Call a physician.

4.2 Most important symptoms and effects, both acute and delayed

Hints for Physician: Symptoms

See Section 11 for additional information on health hazards

4.3 Indication of any immediate medical attention and special treatment needed

First Aid: Inhalation

Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration. Call a physician.

Hints for Physician: Treatment

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing Media

Suitable

foam, dry extinguishing powder, carbon dioxide (CO2), water spray jet

5.2 Special hazards arising from the substance or mixturet

Wear a self-contained breathing apparatus and chemical protective clothing.

Hazards During Fire-Fighting

toxic fumes

5.3 Fire-Fighting/Further Advice

Do not inhale explosion and combustion gases. Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Move undamaged containers from immediate hazard area if it can be done safely.

6 Accidental release measures

6.1 Personal Precautions, potective equipment and emergency procedures

Wear breathing apparatus if exposed to vapours/dusts/aerosols. Provide adequate ventilation.

6.2 Environmental Precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains. Ensure all waste water is collected and treated via a waste water treatment plant.

6.3 Methods and material for containment and cleaning up

not available

6.4 Further Accidental Release Measures

Collect in closed and suitable containers for disposal. Clear contaminated areas thoroughly. Ventilate affected area.

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7 Handling and storage

7.1 Precautions for safe handling

Handling advice

Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid prolonged or repeated exposure. Remove contaminated clothing and wash before reuse. Wash thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature

store at <-15°C

Storage Requirements

Warm to Room Temperature before use. Keep away from incompatible substances. Keep container tightly closed when not in use.

7.3 Specific end use(s)

8 Exposure controles/personal protection

8.1 Exposure limit values

Does not contain any substances with occupational exposure limits.

8.2 Exposure controles

Industrial Hygiene

Mechanical exhaust required. Safety shower and eye shower.

8.3 Personal Protective Equipment

Respiratory Protection

Wear NIOSH/MSHA or European Standard EN 149 approved respirator.

Hand Protection

Wear compatible chemical-resistant gloves to prevent skin exposure.

Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA.

Body Protection

Wear compatible chemical-resistant gloves and clothing to prevent skin exposure.

Advice on Safe Handling

Wash contaminated clothing before reuse. Wear appropriate protective clothing to prevent exposure.

9 Physical and chemical properties

9.1 Information on basic Physical and chemical color properties

Color

white

Form

powder

9.2 Other information

Molar Mass

1,690.42 g/mol

10 Stability and reactivity

10.1 Reactivity

No Data Available

10.2 Chemical stability

No Data Available

10.3 Possibility of hazardous reaction

No Data Available

10.4 Conditions to Avoid (SDS)

incompatible materials

10.5 Incompatible materials

strong oxidizers

10.6 Hazardous decomposition products

nitrogen oxides (NOx), carbon dioxide (CO2), hydrogen chloride (HCI), carbon monoxide

11 Toxicological information

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11.1 Information on toxicological effects

Other Relevant Toxicity Information

We are not aware of any toxicology data.

12 Ecological Information

12.1 Toxicity

| Acute toxicity versus | Test Type | Species | Method | Exposure Time | Value in standard unit mg/l |
|--|-------------------|-------------------|-------------------|----------------------|-----------------------------|
| Fishing | No data available | No data available | No data available | No data available | No data available |
| Acute toxicity in aquatic | Test Type | Species | Method | Exposure Time | Value in standard unit mg/l |
| plants | No data available | No data available | No data available | No data available | No data available |
| Acute toxicity versus Daphnia and others aquatic | Test Type | Species | Method | Exposure Time | Value in standard unit mg/l |
| invertebrates | No data available | No data available | No data available | No data available | No data available |

12.2 Persistence and degradablity

Remarks : no data available

12.3 Bioaccumulative potential
Remarks : no data available

12.4 Mobility in soil no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

no data available

13 Disposal considerations

Advice on Disposal and Packaging

Advice on Disposal

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and Exhaust air. Dispose of waste according to laws applicable.

Advice on Packaging not available

14 Transport information

| | Road Transport(ADR/GGVS) | Air Transport(IATA) |
|---|--------------------------|---------------------|
| 14.1 UN number | Not Dangerous Goods | Not Dangerous Goods |
| 14.2 UN proper shipping name | Not Dangerous Goods | Not Dangerous Goods |
| 14.3 Transport hazard class(es) | Not Dangerous Goods | Not Dangerous Goods |
| 14.4 Packing group | Not Dangerous Goods | Not Dangerous Goods |
| 14.5 Enviromental hazard class (es) | Not Dangerous Goods | Not Dangerous Goods |
| 14.6 Special precautions for user | Not applicable | Not applicable |
| 14.7 Transport in bulk according to Annex 11 of MARPOL and the IBC code | Not applicable | Not applicable |

15 Other regulations

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixturet

not available

| Component | Anney XIV - Substances | REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances | REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC) |
|-------------------|------------------------|--|---|
| Ganirelix acetate | | | |

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15.2 Chemical safty assessment

No chemical safety assessment has been carried out.

16 Additional information

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