

According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

## 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Product code : GP5216  
Product name : Linagliptin  
CAS number : 668270-12-0  
Physical form : solid, substance  
REACH : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

PC21: Laboratory chemicals.

### 1.3 Details of the supplier of the safety data sheet

|              |                               |           |  |
|--------------|-------------------------------|-----------|--|
| Company name | : Glenthams Life Sciences Ltd | Telephone | : +44 (0) 1225 667 798                                       |
|              | Unit 5 Leafield Way           | Fax       | : +44 (0) 2033 978 909                                       |
|              | Corsham SN13 9SW              | Email     | : <a href="mailto:info@glenthams.com">info@glenthams.com</a> |
|              | United Kingdom                | Web       | : <a href="http://www.glenthams.com">www.glenthams.com</a>   |

### 1.4 Emergency telephone number

Emergency telephone : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT) number

## 2. Hazards identification

### 2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

|      |             |
|------|-------------|
| H315 | Skin Irr. 2 |
| H319 | Eye Irr. 2A |
| H335 | STOT SE 3   |
| H336 | STOT SE 3   |

### 2.2 Label elements

Label elements under CLP according to (EC) 1272/2008

#### Pictograms



GHS07

#### Signal words

Warning

#### Hazard statements

|      |                                   |
|------|-----------------------------------|
| H315 | Causes skin irritation            |
| H319 | Causes serious eye irritation     |
| H335 | May cause respiratory irritation  |
| H336 | May cause drowsiness or dizziness |

#### Precautionary statements

|                |  |
|----------------|--|
| P261           | Avoid breathing dust/fume/gas/mist/vapors/spray.   |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. |
| P264           | Do not breathe fume.   |

### 2.3 Other hazards

#### PBT

This substance is not identified as a PBT substance.

## 3.0 Composition/information on ingredients

### 3.1 Substances

| Name        | Identifier                                       | %     | Classification   |
|-------------|--|-------|--|
| Linagliptin | CAS: 668270-12-0<br>EC:<br>REACH: Not applicable | 98.0% | H315, Skin Irr. 2<br>H319, Eye Irr. 2A<br>H335, STOT SE 3<br>H336, STOT SE 3 |

#### 4. First aid measures

##### 4.1 Description of first aid measures

|              |  |
|--------------|--|
| Skin contact | Consult a doctor. Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water. |
| Eye contact  | Consult a doctor. Bathe the eye with running water for 15 minutes.   |
| Ingestion    | Consult a doctor. Wash out mouth with water.   |
| Inhalation   | Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor.   |

##### 4.2 Most important symptoms and effects, both acute and delayed

|                             |  |
|-----------------------------|--|
| Skin contact                | There may be irritation and redness at the site of contact.  |
| Eye contact                 | The eyes may water profusely. There may be irritation and redness.   |
| Ingestion                   | There may be soreness and redness of the mouth and throat.   |
| Inhalation                  | Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest. |
| Delayed / immediate effects | Immediate effects can be expected after short-term exposure.   |

##### 4.3 Indication of any immediate medical attention and special treatment needed

###### Immediate / special treatment

Eye bathing equipment should be available on the premises.

#### 5. Fire-fighting measures

##### 5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used.

##### 5.2 Special hazards arising from the substance or mixture

###### Exposure hazards

In combustion emits toxic fumes.

##### 5.3 Advice for fire-fighters

Wear protective clothing to prevent contact with skin and eyes. Wear self-contained breathing apparatus.

#### 6. Accidental release measures

##### 6.1 Personal precautions, protective equipment and emergency procedures

###### Personal precautions

Do not create dust. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

##### 6.2 Environmental precautions

Do not discharge into drains or rivers.

##### 6.3 Methods and material for containment and cleaning up

###### Clean-up procedures

Transfer to a closable, labelled salvage container for disposal by an appropriate method.

##### 6.4 Reference to other sections

Refer to section 8 of SDS.

## 7. Handling and storage

### 7.1 Precautions for safe handling

#### Handling requirements

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is sufficient ventilation of the area.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Storage conditions

Avoid contact with water or humidity. Keep container tightly closed. Store in cool, well ventilated area.

### 7.3 Specific end use(s)

No data available.

## 8. Exposure controls/personal protection

### 8.1 Control parameters

#### Workplace exposure limits

No workplace exposure limit control parameters set

### 8.2 Exposure controls

|                        |   |
|------------------------|---|
| Engineering measures   | Ensure there is sufficient ventilation of the area.   |
| Respiratory protection | Respiratory protective device with particle filter. Self- contained breathing apparatus must be available in case of emergency. |
| Hand protection        | Protective gloves.  |
| Eye protection         | Ensure eye bath is to hand. Safety glasses.   |
| Skin protection        | Protective clothing.  |

## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|   |                    |
|---|--------------------|
| Physical state                                    | Solid              |
| Colour  | White              |
| Odour   | No data available. |
| Melting point/Freezing point                      | 202 °C             |
| Boiling point/initial boiling point/boiling range | No data available. |
| Flammability                                      | No data available. |
| Lower/Upper explosion limit                       | No data available. |
| Flash Point                                       | No data available. |
| Auto-ignition temperature                         | No data available. |
| Decomposition temperature                         | No data available. |
| pH  | No data available. |
| Kinematic viscosity                               | No data available. |
| Solubility  | No data available. |
| Partition coefficient n-octanol/water             | No data available. |
| Vapour pressure                                   | No data available. |
| Density/relative density                          | No data available. |
| Relative vapour pressure                          | No data available. |
| Particle characteristics                          | No data available. |

### 9.2 Other information

No data available.

## 10. Stability and reactivity

### 10.1 Reactivity

Stable under recommended transport or storage conditions.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

#### Hazardous reactions

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

### 10.4 Conditions to avoid

Heat.

### 10.5 Incompatible materials

#### Materials to avoid

Strong acids. Strong oxidising agents.

## 11. Toxicological information

### 11.1 Information on toxicological effects

#### a) Acute toxicity

No data available.

#### b) Skin corrosion/irritation

Skin corrosion/irritation (Category 2)

#### c) Serious eye damage/irritation

Serious eye damage/eye irritation (Category 2A)

#### d) Respiratory or skin sensitisation

No data available.

#### e) Germ cell mutagenicity

No data available.

#### f) Carcinogenicity

No data available.

#### g) Reproductive toxicity

No data available.

#### h) STOT-single exposure

Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3)

#### i) STOT-repeated exposure

No data available.

#### j) Aspiration hazard

No data available.

### 11.2 Symptoms / routes of exposure

|                             |  |
|-----------------------------|--|
| Skin contact                | There may be irritation and redness at the site of contact.  |
| Eye contact                 | The eyes may water profusely. There may be irritation and redness.   |
| Ingestion                   | There may be soreness and redness of the mouth and throat.   |
| Inhalation                  | Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest. |
| Delayed / immediate effects | Immediate effects can be expected after short-term exposure.   |
| Other information           | No data available.   |

## 12. Ecological information

### 12.1 Toxicity

No data available.

### 12.2 Persistence and degradability

Biodegradable.

### 12.3 Bioaccumulative potential

No bioaccumulation potential.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

This substance is not identified as a PBT substance.

### 12.6 Endocrine disrupting properties

This substance is not identified as having endocrine disrupting properties

### 12.7 Other adverse effects

No data available.

## 13. Disposal considerations

### 13.1 Waste treatment methods

#### Disposal operations

Transfer to a suitable container and arrange for collection by specialised disposal company.

#### NB

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

## 14. Transport information

This product does not require a classification for transport.

## 15. Regulatory information

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

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

#### Authorisations/Restrictions

Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation: No data available.

Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances: No data available.

Regulation (EC) 1005/2009 on substances that deplete the ozone layer: No data available.

Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No 2019/1021: No data available.

### 15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

## 16. Other information

### H-Statement Full Texts

H315 Causes skin irritation  
H319 Causes serious eye irritation  
H335 May cause respiratory irritation  
H336 May cause drowsiness or dizziness

### Abbreviations Full Texts

ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
ADR European Agreement concerning the International Carriage of Dangerous Goods by Road  
ALARP As low as is reasonably practicable  
CAS Chemical Abstracts Service  
CLP Classification, Labelling and Packaging Regulations  
COSHH Control of Substances Hazardous to Health  
EC Number European Community Number

|         |  |
|---------|--|
| EC50    | Effective Concentration 50%  |
| EILINCS | European List of Notified Chemical Substances                                |
| EINECS  | European Inventory of Existing Commercial Chemical Substances                |
| GHS     | Globally Harmonised System   |
| HSE     | Health & Safety Executive UK   |
| IATA    | International Air Transport Association                                      |
| IM      | Intramuscular  |
| IMDG    | The International Maritime Dangerous Goods Code                              |
| IP      | Intraperitoneal  |
| IV      | Intravascular  |
| LD50    | Lethal Dose 50%  |
| LOEC    | Lowest Observable Effective Concentration                                    |
| LTEL    | Long Term Exposure Limit   |
| NOEC    | No Observable Effective Concentration  |
| OECD    | Organisation for Economic Cooperations and Development                       |
| PBT     | Persistent Bioaccumulative Toxic   |
| PPE     | Personal Protective Equipment  |
| REACH   | Registration, Evaluation, Authorisation and Restriction of Chemicals         |
| RID     | Regulations Concerning the International Carriage of Dangerous Goods by Rail |
| SC      | Subcutaneous   |
| SDS     | Safety Data Sheet  |
| STEL    | Short Term Exposure Limit  |
| VOC     | Volatile Organic Compounds   |
| vPvB    | Very Persistent and Very Bioaccumulative                                     |
| WEL     | Workplace Exposure Limits  |

**This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.**

Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.