

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 16-Sep-2024

Revision Number 1.01

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product Code(s) TRC-D281985-50MG

Product Name 3-Desamino-2,3-dehydro Sitagliptin

Form Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

| EC No (EU Index No) | - | |
|--|---|--|
| CAS No. | 1253056-18-6 | |
| Pure substance/mixture | Substance | |
| Formula | C ₁₆ H ₁₂ F ₆ N ₄ O | |
| Molecular weight | 390.29 | |
| 1.2. Relevant identified uses of the substance or mixture and uses advised against | | |

| Recommended use | Laboratory use |
|----------------------|--------------------------|
| Uses advised against | No information available |

1.3. Details of the supplier of the safety data sheet

Supplier

LGC Limited Queens Road Teddington Middlesex TW11 0LY UNITED KINGDOM :+44 (0) 20 8943 7000 Fax :+44 (0) 20 8943 2767 eMail : gb@lgcstandards.com

Web : www.lgcstandards.com

For further information, please contact

E-mail address

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This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

1.4. Emergency telephone number

Emergency Telephone

For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire Exposure, or Accident Call CHEMTREC: USA & Canada 1-800-424-9300 Rest of the world +1 703-741-3877

| Emergency Telephone - §45 - (EC)1272/2008 | | |
|---|--------------------------|--|
| Europe | 112 | |
| Austria | No information available | |
| Bulgaria | | |
| Croatia | | |
| Cyprus | | |
| Czech Republic | | |
| Denmark | | |
| France | | |
| Hungary | | |
| Ireland | | |
| Italy | | |
| Lithuania | | |
| Luxembourg | | |
| Netherlands | | |
| Norway | | |
| Portugal | | |
| Romania | | |
| Slovakia | | |
| Slovenia | | |
| Spain | | |
| Sweden | | |
| Switzerland | | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

| Acute toxicity - Oral | Category 4 - (H302) |
|--|---------------------|
| Skin corrosion/irritation | Category 2 - (H315) |
| Serious eye damage/eye irritation | Category 2 - (H319) |
| Specific target organ toxicity — repeated exposure | Category 2 - (H373) |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

2.2. Label elements

Contains 3-Desamino-2,3-dehydro Sitagliptin



Warning

Hazard statements

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

- P280 Wear protective gloves and eye/face protection
- P337 + P313 If eye irritation persists: Get medical advice/attention
- P501 Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

| Chemical name | EU - REACH (1907/2006) - Article 59(1) | EU - REACH (1907/2006) - Endocrine |
|------------------------------------|--|------------------------------------|
| | - Candidate List of Substances of Very | Disruptor Assessment List of |
| | High Concern (SVHC) for Authorisation | Substances |
| 3-Desamino-2,3-dehydro Sitagliptin | - | - |

SECTION 3: Composition/information on ingredients

3.1 Substances



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| Chemical name | Weight-% | REACH registration number | · · · | Classification according to Regulation (EC) No. | | M-Factor | M-Factor (long-term) |
|--------------------|----------|------------------------------|---------|---|-------------|----------|-------------------------|
| | | | , , , , | 1272/2008 [CLP] | limit (SCL) | | (|
| 3-Desamino-2,3-deh | 100 | - | - | Acute Tox. 4 (H302) | | | |
| ydro Sitagliptin | | | | Skin Irrit. 2 (H315) | | | |
| 1253056-18-6 | | | | Eye Irrit. 2 (H319) | | | |
| | | | | STOT RE 2 (H373) | | | |
| ydro Sitagliptin | 100 | - | - | Acute Tox. 4 (H302) Skin Irrit. 2 (H315) | | | |

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

| General advice | Show this safety data sheet to the doctor in attendance. | |
|---|--|--|
| Inhalation | Remove to fresh air. Get medical attention immediately if symptoms occur. | |
| Eye contact | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists. | |
| Skin contact | Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. | |
| Ingestion | Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor. | |
| Self-protection of the first aider | Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8). | |
| 4.2. Most important symptoms and effects, both acute and delayed | | |
| Symptoms | May cause redness and tearing of the eyes. Burning sensation. | |
| 4.3. Indication of any immediate medical attention and special treatment needed | | |
| Note to doctors | Treat symptomatically. | |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| SECTION 5: Firefighting measures 5.1. Extinguishing media | | |
|--|---|--|
| Suitable Extinguishing Media | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. | |
| Large Fire | CAUTION: Use of water spray when fighting fire may be inefficient. | |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. | |
| 5.2. Special hazards arising from the substance or mixture | | |
| Specific hazards arising from the chemical | No information available. | |
| 5.3. Advice for firefighters | | |
| Special protective equipment and precautions for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. | |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| Personal precautions | Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. | |
|---|--|--|
| Other information | Refer to protective measures listed in Sections 7 and 8. | |
| For emergency responders | Use personal protection recommended in Section 8. | |
| 6.2. Environmental precautions | | |
| Environmental precautions | Prevent further leakage or spillage if safe to do so. | |
| 6.3. Methods and material for containment and cleaning up | | |
| Methods for containment | Prevent further leakage or spillage if safe to do so. | |
| Methods for cleaning up | Take up mechanically, placing in appropriate containers for disposal. | |
| Prevention of secondary hazards | Clean contaminated objects and areas thoroughly observing environmental regulations. | |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| Advice on safe handling | Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. |
|--|--|
| General hygiene considerations | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. |
| 7.2. Conditions for safe storage, incl | luding any incompatibilities |
| Storage Conditions | Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. |
| 7.3. Specific end use(s) | |

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) No information available.



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

Predicted No Effect Concentration No information available. (PNEC)

8.2. Exposure controls

Personal protective equipment

| Eye/face protection | Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields. |
|---------------------------------|---|
| Hand protection | The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective Viton™ gloves. Wear suitable gloves. Impervious gloves. |
| Skin and body protection | Wear suitable protective clothing. Long sleeved clothing. |
| Respiratory protection | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. |
| General hygiene considerations | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. |
| Environmental exposure controls | Do not allow into any sewer, on the ground or into any body of water. |

SECTION 9: Physical and chemical properties

| Physical state | Solid | |
|--|----------------------------|------------------|
| Appearance | Viscous Solid | |
| Colour | colourless to light yellow | |
| Odour | No information available. | |
| Odour threshold | No information available | |
| Property | Values | Remarks • Method |
| Melting point / freezing point | No data available | None known |
| Initial boiling point and boiling rang | geNo data available | None known |
| Flammability | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | No data available | |
| Lower flammability or explosive | No data available | |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| limits | | |
|----------------------------|--------------------------|--------------------------|
| Flash point | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | | None known |
| pH | No data available | None known |
| pH (as aqueous solution) | No data available | No information available |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Water solubility | No data available | None known |
| Solubility(ies) | DMSO, slightly soluble | None known |
| Partition coefficient | No data available | None known |
| Vapour pressure | No data available | None known |
| Relative density | No data available | None known |
| Bulk density | No data available | |
| Liquid Density | No data available | |
| Relative vapour density | No data available | None known |
| Particle characteristics | | |
| Particle Size | No information available | |
| Particle Size Distribution | No information available | |
| 9.2. Other information | | |
| Molecular weight | 390.29 | |
| Molecular formula | C 16H 12F 6N 4O | |

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity

No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

| Inhalation | Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. |
|--------------|---|
| Eye contact | Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain. |
| Skin contact | Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components). |
| Ingestion | Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components). |

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity No information available

Acute toxicity



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| Delayed and immediate effects as well as chronic effects from short and long-term exposure | | |
|--|--|--|
| Skin corrosion/irritation | Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation. | |
| Serious eye damage/eye irritation | Classification based on data available for ingredients. Causes serious eye irritation. | |
| Respiratory or skin sensitisation | No information available. | |
| Germ cell mutagenicity | No information available. | |
| Carcinogenicity | No information available. | |
| Reproductive toxicity | No information available. | |
| STOT - single exposure | No information available. | |
| STOT - repeated exposure | May cause damage to organs through prolonged or repeated exposure. | |
| Aspiration hazard | No information available. | |
| 11.2. Information on other hazards | | |
| 11.2.1. Endocrine disrupting properties | | |
| Endocrine disrupting properties | No information available. | |
| 11.2.2. Other information | | |
| Other adverse effects | No information available. | |

SECTION 12: Ecological information



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| <u>12.1. Toxicity</u> | | |
|--|---|--|
| Ecotoxicity | The environmental impact of this | product has not been fully investigated. |
| | | |
| 12.2. Persistence and degradability | | |
| Persistence and degradability | No information available. | |
| 12.3. Bioaccumulative potential | | |
| Bioaccumulation | No information available. | |
| 12.4. Mobility in soil | | |
| Mobility in soil | No information available. | |
| 12.5. Results of PBT and vPvB assessment | | |
| PBT and vPvB assessment | This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB). | |
| Chemical | name | PBT and vPvB assessment |

Chemical name PBT and vPvB assessment 3-Desamino-2,3-dehydro Sitagliptin The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| Waste from residues/unused products | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
|--|---|
| Contaminated packaging | Do not reuse empty containers. |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

SECTION 14: Transport information

| IA. | TΑ |
|-----|----|
| | |

| 14.1 UN number or ID number | Not regulated |
|---|---------------------------------------|
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | · · · · · · · · · · · · · · · · · · · |
| Special Provisions | None |
| opoolari romonomo | |
| IMDG | |
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Marine pollutant | Not applicable |
| • | Not applicable |
| 14.6 Special precautions for user Special Provisions | None No information available |
| - | No information available |
| 14.7 Maritime transport in bulk | NO INICITIATION AVAILABLE |
| according to IMO instruments | |
| BID | |
| <u>RID</u> | Net regulated |
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None |
| | |
| ADR | |
| 14.1 UN number or ID number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing group | Not regulated |
| 14.5 Environmental hazards | Not applicable |
| 14.6 Special precautions for user | |
| Special Provisions | None |
| | |

SECTION 15: Regulatory information

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



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

Water hazard class (WGK) slightly hazardous to water (WGK 1)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors Not applicable

Persistent Organic Pollutants Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

| International Inventories TSCA | LGC has not confirmed that the chemical substances in this product are on the TSCA Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided |
|-----------------------------------|---|
| | at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the |
| | requirements that apply to its use of this product. |
| DSL/NDSL | Contact supplier for inventory compliance status |
| EINECS/ELINCS | Contact supplier for inventory compliance status |
| ENCS | Contact supplier for inventory compliance status |
| IECSC | Contact supplier for inventory compliance status |
| KECI | Contact supplier for inventory compliance status |
| PICCS | Contact supplier for inventory compliance status |
| AIIC | Contact supplier for inventory compliance status |
| Legend: | |



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Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H373 - May cause damage to organs through prolonged or repeated exposure

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

| TWA | TWA (time-weighted average) | STEL |
|---------|-----------------------------|------|
| Ceiling | Maximum limit value | Sk* |

STEL (Short Term Exposure Limit) Skin designation

| Classification procedure | |
|---|--------------------|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used |
| Acute oral toxicity | Calculation method |
| Acute dermal toxicity | Calculation method |
| Acute inhalation toxicity - gas | Calculation method |
| Acute inhalation toxicity - Vapour | Calculation method |
| Acute inhalation toxicity - dust/mist | Calculation method |
| Skin corrosion/irritation | Calculation method |
| Serious eye damage/eye irritation | Calculation method |
| Respiratory sensitisation | Calculation method |
| Skin sensitisation | Calculation method |
| Mutagenicity | Calculation method |
| Carcinogenicity | Calculation method |



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 16-Sep-2024

Revision Number 1.01

TRC-D281985-50MG - 3-Desamino-2,3-dehydro Sitagliptin

| Reproductive toxicity | Calculation method |
|--------------------------|--------------------|
| STOT - single exposure | Calculation method |
| STOT - repeated exposure | Calculation method |
| Acute aquatic toxicity | Calculation method |
| Chronic aquatic toxicity | Calculation method |
| Aspiration hazard | Calculation method |
| Ozone | Calculation method |

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme Organisation for Economic Co-operation and Development Screening Information Data Set World Health Organization

Revision date 16-Sep-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet