

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

Revision date 24-Oct-2023

Revision Number 1

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

| 1.1. Product identifier |
|-------------------------|
|-------------------------|

| Product Code(s) | MM0095.06-0025 |
|-----------------|--|
| Product Name | 5-Methoxy-2-[[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulphanyl]-1H-benzimidazole (Ufiprazole) |
| 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

| 1.2. Relevant identified uses of the substance or mixture and uses advised against | | |
|--|-----------------|--|
| Molecular weight | 329.42 | |
| Formula | C17 H19 N3 O2 S | |
| Pure substance/mixture | Substance | |
| CAS No. | 73590-85-9 | |
| EC No (EU Index No) | 615-997-3 | |

| 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



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E-mail address

sds-request@lgcgroup.com

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]

| Skin sensitisation | Category 1 - (H317) |
|--------------------------|---------------------|
| Chronic aquatic toxicity | Category 4 - (H413) |



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2.2. Label elements

Contains 5-Methoxy-2-[[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulphanyl]-1H-benzimidazole (Ufiprazole)



Signal word Warning

Hazard statements

H317 - May cause an allergic skin reaction H413 - May cause long lasting harmful effects to aquatic life

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

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P280 - Wear protective gloves

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P362 + P364 - Take off contaminated clothing and wash it before reuse

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.

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 |
| 5-Methoxy-2-[[(4-methoxy-3,5-dimethylpyridin-2- | - | - |
| yl)methyl]sulphanyl]-1H-benzimidazole | | |
| (Ufiprazole) | | |

SECTION 3: Composition/information on ingredients

3.1 Substances



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| | | | | | 0 | | |
|-----------------------|----------|--------------------|-----------|--------------------------|---------------|----------|-------------|
| Chemical name | Weight-% | REACH registration | EC NO (EU | Classification according | Specific | M-Factor | M-Factor |
| | | number | Index No) | to Regulation (EC) No. | concentration | | (long-term) |
| | | | , | 1272/2008 [CLP] | limit (SCL) | | × 3 / |
| 5-Methoxy-2-[[(4-me | 100 | - | 615-997-3 | Skin Sens. 1 (H317) | | | |
| thoxy-3,5-dimethylp | | | | Aquatic Chronic 4 | | | |
| yridin-2-yl)methyl]su | | | | (H413) | | | |
| [lphanyl]-1H-benzimi | | | | | | | |
| dazole (Ufiprazole) | | | | | | | |
| 73590-85-9 | | | | | | | |

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. | |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor. | |
| Skin contact | Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor. | |
| Ingestion | Rinse mouth. | |
| 4.2. Most important symptoms and effects, both acute and delayed | | |
| Symptoms | Itching. Rashes. Hives. | |
| 4.3. Indication of any immediate medical attention and special treatment needed | | |
| Note to doctors | May cause sensitisation in susceptible persons. Treat symptomatically. | |
| | | |



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| 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 | Product is or contains a sensitiser. May cause sensitisation by skin contact. | |
| 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 | Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. | |
|---|--|--|
| For emergency responders | Use personal protection recommended in Section 8. | |
| 6.2. Environmental precautions | | |
| Environmental precautions | See Section 12 for additional Ecological Information. | |
| 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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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. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. 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, inc | luding any incompatibilities |
| Storage Conditions | 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. Keep containers tightly closed in a dry, cool and well-ventilated place. |
| 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



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Derived No Effect Level (DNEL)No information available.Predicted No Effect ConcentrationNo information available.(PNEC)No

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

 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 nitrile rubber gloves. Wear suitable gloves.

| Gloves | | | |
|---------------------------------|---|-----------------|--------------------|
| Duration of contact | PPE - Glove material | Glove thickness | Break through time |
| | Wear protective nitrile | 0.15 mm | |
| | rubber gloves | | |
| Skin and body protection | Wear suitable protective 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

9.1. Information on basic physical and chemical properties

| Physical state Appearance Colour | Solid Crystalline white to light brown | |
|---|---|--------------------------------|
| Odour Odour threshold | No information available. No information available | |
| <u>Property</u> Melting point / freezing point | <u>Values</u> 120 - 124 °C | Remarks • Method None known |



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| Initial boiling point and boiling rang | eNo data available | None known |
|--|----------------------------------|--------------------------|
| Flammability | No data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive | No data available | |
| limits | | |
| Lower flammability or explosive | No data available | |
| 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, Methanol, slightly soluble | |
| 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 | 329.42 | |
| Molecular formula | C17 H19 N3 O2 S | |

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.



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

10.3. Possibility of hazardous reactions

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 None known based on information supplied.

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. | |
|--|---|--|
| Eye contact | Specific test data for the substance or mixture is not available. | |
| Skin contact | May cause sensitisation by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). | |
| Ingestion | Specific test data for the substance or mixture is not available. | |
| Symptoms related to the physical, chemical and toxicological characteristics | | |
| Symptoms | Itching. Rashes. Hives. | |

Numerical measures of toxicity

No information available



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Acute toxicity

| Delayed and immediate effects as well as chronic effects from short and long-term exposure | | |
|--|---|--|
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | No information available. | |
| Respiratory or skin sensitisation | May cause an allergic skin reaction. | |
| Germ cell mutagenicity | No information available. | |
| Carcinogenicity | No information available. | |
| Reproductive toxicity | No information available. | |
| STOT - single exposure | No information available. | |
| STOT - repeated exposure | No information available. | |
| 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



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| Other adverse effects | No information available. | |
|--|---|--|
| SECTION 12: Ecological in | nformation | |
| <u>12.1. Toxicity</u> | | |
| Ecotoxicity | May cause long lasting harmful effects to aquatic life. | |
| 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 | No information available. | |
| 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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SECTION 14: Transport information

| IATA 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions | Not regulated Not regulated Not regulated Not regulated Not applicable None |
|--|---|
| IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments | Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available |
| RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions | Not regulated Not regulated Not regulated Not regulated Not applicable None |
| ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions | Not regulated Not regulated Not regulated Not regulated Not applicable None |

SECTION 15: Regulatory information



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

National regulations

Germany Water hazard class (WGK)

slightly hazardous to water (WGK 1)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003. No. 169. item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

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



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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. |
| Contact supplier for inventory compliance status |
| |

Legend:

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
 Australian Inventory of Chemical Substances

15.2. Chemical safety assessment



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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

H317 - May cause an allergic skin reaction

H413 - May cause long lasting harmful effects to aquatic life

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

| TŴĂ | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
|---------|-----------------------------|------|----------------------------------|
| Ceiling | Maximum limit value | Sk* | 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 |
| 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)



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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

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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