

# Pimozide impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 03/01/2023 Revision date: 26/03/2025 Supersedes version of: 03/01/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Pimozide impurity D  
Chemical name : 1-[1-[4,4-bis(4-fluorophenyl)butyl]-1,2,3,6-tetrahydropyridin-4-yl]-1,3-dihydro-2H-benzimidazol-2-one  
Product code : 202300004

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

##### Relevant identified uses

Use of the substance/mixture : Scientific research and development  
Technical testing and analysis  
For professional use only  
Function or use category : Laboratory chemicals

##### Uses advised against

Restrictions on use : Not for food, drug or home use

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

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

### 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  
Reproductive toxicity, Category 2 H361  
Specific target organ toxicity – Single exposure, Category 3, H336  
Narcosis  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Suspected of damaging fertility or the unborn child. May cause drowsiness or dizziness.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.  
H336 - May cause drowsiness or dizziness.  
H361 - Suspected of damaging fertility or the unborn child.

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Precautionary statements (CLP) :

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P271 - Use only outdoors or in a well-ventilated area.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.
- P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- P312 - Call a POISON CENTRE or doctor if you feel unwell.
- P330 - Rinse mouth.
- P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
- P405 - Store locked up.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS08

### 2.3. Other hazards

Other information : Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

| Name  | Product identifier | %     | Classification according to Regulation (EC) No. 1272/2008 [CLP]               |
|---|--------------------|-------|---|
| 1-[1-[4,4-bis(4-fluorophenyl)butyl]-1,2,3,6-tetrahydropyridin-4-yl]-1,3-dihydro-2H-benzimidazol-2-one | -                  | ≤ 100 | Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg)<br>Repr. 2, H361<br>STOT SE 3, H336 |

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

No additional information available

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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- |                                |   |
|--------------------------------|---|
| Suitable extinguishing media   | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream.  |

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

- |  |  |
|--|--|
| Hazardous decomposition products in case of fire | : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released. |
|--|--|

### 5.3. Advice for firefighters

- |                                |  |
|--------------------------------|--|
| Firefighting instructions      | : Prevent fire fighting water from entering the environment.   |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

## SECTION 6: Accidental release measures

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

- |                  |   |
|------------------|---|
| General measures | : Avoid contact with skin, eyes and clothing. |
|------------------|---|

#### For non-emergency personnel

- |                      |                                   |
|----------------------|-----------------------------------|
| Emergency procedures | : Evacuate unnecessary personnel. |
|----------------------|-----------------------------------|

#### For emergency responders

- |                      |   |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

- |                         |   |
|-------------------------|---|
| For containment         | : Absorb with an inert material and place in an appropriate waste disposal container.     |
| Methods for cleaning up | : Clean contaminated surfaces with an excess of water. Clean with the help of detergents. |

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- |                                   |  |
|-----------------------------------|--|
| Additional hazards when processed | : Do not expose pregnant or breastfeeding women.   |
| Precautions for safe handling     | : Avoid all unnecessary exposure. Ensure good ventilation of the work station.   |
| Hygiene measures                  | : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work. |

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

- |                     |   |
|---------------------|---|
| Storage conditions  | : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight. |
| Packaging materials | : Keep in original containers.  |

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### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

##### Skin protection

##### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

##### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

##### Respiratory protection

##### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|   |                  |
|---|------------------|
| Physical state                                  | : Solid          |
| Colour  | : Not available  |
| Molecular mass                                  | : 459.53 g/mol   |
| Odour   | : Not available  |
| Odour threshold                                 | : Not available  |
| Melting point                                   | : Not available  |
| Freezing point                                  | : Not available  |
| Boiling point                                   | : Not available  |
| Flammability                                    | : Not available  |
| Lower explosion limit                           | : Not applicable |
| Upper explosion limit                           | : Not applicable |
| Flash point                                     | : Not applicable |
| Auto-ignition temperature                       | : Not applicable |
| Decomposition temperature                       | : Not available  |
| pH  | : Not available  |
| pH solution                                     | : Not available  |
| Viscosity, kinematic                            | : Not applicable |
| Solubility                                      | : Not available  |
| Partition coefficient n-octanol/water (Log Kow) | : Not available  |
| Vapour pressure                                 | : Not available  |
| Vapour pressure at 50°C                         | : Not available  |
| Density   | : Not available  |
| Relative density                                | : Not available  |
| Relative vapour density at 20°C                 | : Not applicable |
| Particle size                                   | : Not available  |

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### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

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

|                             |                                 |
|-----------------------------|---------------------------------|
| Acute toxicity (oral)       | : Harmful if swallowed.         |
| Acute toxicity (dermal)     | : Not classified (Lack of data) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |

| 1-[1-[4,4-bis(4-fluorophenyl)butyl]-1,2,3,6-tetrahydropyridin-4-yl]-1,3-dihydro-2H-benzimidazol-2-one |   |
|---|---|
| LD50 oral rat   | > 300 – ≤ 2000 mg/kg (estimated value)  |
| Skin corrosion/irritation   | : Not classified (Lack of data)   |
| Serious eye damage/irritation   | : Not classified (Lack of data)   |
| Respiratory or skin sensitisation   | : Not classified (Lack of data)   |
| Germ cell mutagenicity  | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity   | : Not classified (Inconclusive data)  |
| Reproductive toxicity   | : Suspected of damaging fertility or the unborn child.                              |
| STOT-single exposure  | : May cause drowsiness or dizziness.  |
| STOT-repeated exposure  | : Not classified (Inconclusive data)  |
| Aspiration hazard   | : Not classified (Lack of data)   |

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

|   |                                 |
|---|---------------------------------|
| Hazardous to the aquatic environment, short-term (acute)  | : Not classified (Lack of data) |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified (Lack of data) |

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### 12.2. Persistence and degradability

#### 1-[1-[4,4-bis(4-fluorophenyl)butyl]-1,2,3,6-tetrahydropyridin-4-yl]-1,3-dihydro-2H-benzimidazol-2-one

|                               |                        |
|-------------------------------|------------------------|
| Persistence and degradability | Not rapidly degradable |
|-------------------------------|------------------------|

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR                                     | IMDG           | IATA           |
|---|----------------|----------------|
| <b>14.1. UN number or ID number</b>     |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.2. UN proper shipping name</b>    |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.3. Transport hazard class(es)</b> |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.4. Packing group</b>              |                |                |
| Not applicable                          | Not applicable | Not applicable |
| <b>14.5. Environmental hazards</b>      |                |                |
| Not applicable                          | Not applicable | Not applicable |
| No supplementary information available  |                |                |

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

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### Air transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes

| Section | Changed item          | Comments     |
|---------|-----------------------|--------------|
|         | Supersedes version of | <b>Added</b> |
|         | Revision date         | <b>Added</b> |

### Full text of H- and EUH-statements:

|                     |  |
|---------------------|--|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4                                      |
| H302                | Harmful if swallowed.  |
| H336                | May cause drowsiness or dizziness.                                     |
| H361                | Suspected of damaging fertility or the unborn child.                   |
| Repr. 2             | Reproductive toxicity, Category 2                                      |
| STOT SE 3           | Specific target organ toxicity – Single exposure, Category 3, Narcosis |

Safety Data Sheet (SDS), EU

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