# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 6.3
Revision Date 26.05.2025
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GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

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

### 1.1 Product identifiers

| | | |
|---|---|---|
| Product name | : | Nateglinide impurity B |
| Product Number | : | Y0001441 |
| Brand | : | Sigma-Aldrich |
| 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. |
| CAS-No. | : | 105816-05-5 |

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

| | | |
|---|---|---|
| Identified uses | : | Laboratory chemicals, Manufacture of substances |

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

| | | |
|---|---|---|
| Company | : | Merck Life Science Sp. z o.o<br>Pastelowa 8<br>PL-60-198 POZNAN |
| Telephone | : | +48 61 8290-100 |
| Fax | : | +48 61 8290-120 |
| E-mail address | : | TechnicalService@merckgroup.com |

### 1.4 Emergency telephone number

| | | |
|---|---|---|
| Emergency Phone # | : | +(48)-223988029 (CHEMTREC) 112<br>(numer alarmowy) |

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

### 2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



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Ecological information:
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Toxicological information:
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

| | | |
|---|---|---|
| Formula | : | C19H27NO3 |
| Molecular weight | : | 317,42 g/mol |
| CAS-No. | : | 105816-05-5 |

No components need to be disclosed according to the applicable regulations.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

**If inhaled**
After inhalation: fresh air.

**In case of skin contact**
In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

**In case of eye contact**
After eye contact: rinse out with plenty of water. Remove contact lenses.

**If swallowed**
After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

### 4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

### 4.3 Indication of any immediate medical attention and special treatment needed
No data available

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Unsuitable extinguishing media**
For this substance/mixture no limitations of extinguishing agents are given.

### 5.2 Special hazards arising from the substance or mixture
Carbon oxides
Nitrogen oxides (NOx)

### 5.3 Advice for firefighters
In the event of fire, wear self-contained breathing apparatus.

### 5.4 Further information
Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.



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## SECTION 6: Accidental release measures

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

Advice for non-emergency personnel: Avoid inhalation of dusts. Evacuate the danger area, observe emergency procedures, consult an expert.
For personal protection see section 8.

### 6.2 Environmental precautions

Do not let product enter drains.

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

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

### 6.4 Reference to other sections

For disposal see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

For precautions see section 2.2.

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

**Storage conditions**
Tightly closed. Dry.
**Storage stability**Recommended storage temperature
2 - 8 °C
**Storage class**
Storage class (TRGS 510): 11: Combustible Solids

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

**Ingredients with workplace control parameters**

### 8.2 Exposure controls

**Personal protective equipment**

**Eye/face protection**
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

**Skin protection**
This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN 16523-1 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Full contact



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Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® L

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: 480 min
Material tested:KCL 741 Dermatril® L

**Respiratory protection**
required when dusts are generated.
Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.
Recommended Filter type: Filter type P1

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

**Control of environmental exposure**
Do not let product enter drains.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| a) | Physical state | solid |
| b) | Color | No data available |
| c) | Odor | No data available |
| d) | Melting point/freezing point | No data available |
| e) | Initial boiling point and boiling range | No data available |
| f) | Flammability (solid, gas) | No data available |
| g) | Upper/lower flammability or explosive limits | No data available |
| h) | Flash point | No data available |
| i) | Autoignition temperature | No data available |
| j) | Decomposition temperature | No data available |
| k) | pH | No data available |
| l) | Viscosity | Viscosity, kinematic: No data available<br>Viscosity, dynamic: No data available |
| m) | Water solubility | No data available |
| n) | Partition coefficient: | No data available |



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| | | |
|---|---|---|
| | n-octanol/water | |
| o) | Vapor pressure | No data available |
| p) | Density | No data available |
| | Relative density | No data available |
| q) | Relative vapour density | No data available |
| r) | Particle characteristics | No data available |
| s) | Explosive properties | No data available |
| t) | Oxidizing properties | No data available |

**9.2 Other safety information**
No data available

## SECTION 10: Stability and reactivity

**10.1 Reactivity**
No data available

**10.2 Chemical stability**
The product is chemically stable under standard ambient conditions (room temperature) .

**10.3 Possibility of hazardous reactions**
No data available

**10.4 Conditions to avoid**
no information available

**10.5 Incompatible materials**
Strong oxidizing agents

**10.6 Hazardous decomposition products**
In the event of fire: see section 5

## SECTION 11: Toxicological information

**11.1 Information on toxicological effects**

**Acute toxicity**
Oral: No data available
Inhalation: No data available
Dermal: No data available

**Skin corrosion/irritation**
No data available

**Serious eye damage/eye irritation**
No data available

**Respiratory or skin sensitization**
No data available

**Germ cell mutagenicity**
No data available

**Carcinogenicity**



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No data available

**Reproductive toxicity**
No data available

**Specific target organ toxicity - single exposure**
No data available

**Specific target organ toxicity - repeated exposure**
No data available

**Aspiration hazard**
No data available

### 11.2 Additional Information

**Endocrine disrupting properties**

**Product:**

| | |
|---|---|
| Assessment | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

## SECTION 12: Ecological information

### 12.1 Toxicity
No data available

### 12.2 Persistence and degradability
No data available

### 12.3 Bioaccumulative potential
No data available

### 12.4 Mobility in soil
No data available

### 12.5 Results of PBT and vPvB assessment
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties
**Product:**

| | | |
|---|---|---|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |

### 12.7 Other adverse effects
No data available



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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

No data available

## SECTION 14: Transport information

### 14.1 UN number

ADR/RID: - IMDG: - IATA: -

### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

### 14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

### 14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

### 14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

### 14.6 Special precautions for user

No data available

**Further information**

Not classified as dangerous in the meaning of transport regulations.

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

Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

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

### 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out



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## SECTION 16: Other information

### Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

The information is believed to be correct but is not exhaustive and will be used solely as a guideline, which is based on current knowledge of the chemical substance or mixture and is applicable to appropriate safety precautions for the product. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

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