

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 7.1

Revision Date 20.06.2023

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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 : Carbamazepine (100 mg)

Product Number : 1093001

Brand : US Pharmacopeia

REACH No. : 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.

CAS-No. : 298-46-4

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

Identified uses : Laboratory chemicals, Manufacture of substances

### 1.3

### 1.4 Emergency telephone

Emergency Phone # : 000 800 1007 141 (CHEMTREC)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 4), H302

Respiratory sensitization (Category 1), H334

Skin sensitization (Sub-category 1A), H317

Reproductive toxicity (Category 1A), H360FD

Specific target organ toxicity - single exposure (Category 3), Central nervous system, H336

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 2.2 Label elements

### Labelling according Regulation (EC) No 1272/2008

#### Pictogram

|                                |                                                                               |
|--------------------------------|-------------------------------------------------------------------------------|
| Signal Word                    | Danger                                                                        |
| Hazard statement(s)            |                                                                               |
| H302                           | Harmful if swallowed.                                                         |
| H317                           | May cause an allergic skin reaction.                                          |
| H334                           | May cause allergy or asthma symptoms or breathing difficulties if inhaled.    |
| H336                           | May cause drowsiness or dizziness.                                            |
| H360FD                         | May damage fertility. May damage the unborn child.                            |
| Precautionary statement(s)     |                                                                               |
| P202                           | Do not handle until all safety precautions have been read and understood.     |
| P261                           | Avoid breathing dust.                                                         |
| P280                           | Wear protective gloves/ protective clothing/ eye protection/ face protection. |
| P301 + P312                    | IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.                |
| P302 + P352                    | IF ON SKIN: Wash with plenty of water.                                        |
| P308 + P313                    | IF exposed or concerned: Get medical advice/ attention.                       |
| Supplemental Hazard Statements | none                                                                          |

### Reduced Labeling ( $\leq 125$ ml)

#### Pictogram

|                                |                                                                               |
|--------------------------------|-------------------------------------------------------------------------------|
| Signal Word                    | Danger                                                                        |
| Hazard statement(s)            |                                                                               |
| H334                           | May cause allergy or asthma symptoms or breathing difficulties if inhaled.    |
| H317                           | May cause an allergic skin reaction.                                          |
| H360FD                         | May damage fertility. May damage the unborn child.                            |
| Precautionary statement(s)     |                                                                               |
| P202                           | Do not handle until all safety precautions have been read and understood.     |
| P261                           | Avoid breathing dust.                                                         |
| P280                           | Wear protective gloves/ protective clothing/ eye protection/ face protection. |
| P302 + P352                    | IF ON SKIN: Wash with plenty of water.                                        |
| P308 + P313                    | IF exposed or concerned: Get medical advice/ attention.                       |
| Supplemental Hazard Statements | none                                                                          |

### 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.

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.

Caution: Physiologically highly active, therapeutically usable substance. The substance must be handled with the care required for hazardous materials.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Formula : C<sub>15</sub>H<sub>12</sub>N<sub>2</sub>O  
Molecular weight : 236,27 g/mol  
CAS-No. : 298-46-4  
EC-No. : 206-062-7

| Component            |           | Classification                                                                                  | Concentration |
|----------------------|-----------|-------------------------------------------------------------------------------------------------|---------------|
| <b>Carbamazepine</b> |           |                                                                                                 |               |
| CAS-No.              | 298-46-4  | Acute Tox. 4; Resp. Sens. 1; Skin Sens. 1A; Repr. 1A; STOT SE 3; H302, H334, H317, H360FD, H336 | <= 100 %      |
| EC-No.               | 206-062-7 |                                                                                                 |               |

For the full text of the H-Statements mentioned in this Section, see Section 16.

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## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

#### General advice

First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.

#### If inhaled

After inhalation: fresh air. Call in physician.

#### In case of skin contact

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

**In case of eye contact**

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

**If swallowed**

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

**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

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**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing media**

Water Foam Carbon dioxide (CO<sub>2</sub>) Dry powder

**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 (NO<sub>x</sub>)

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

**5.3 Advice for firefighters**

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

**5.4 Further information**

Suppress (knock down) gases/vapors/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. Avoid substance contact. Ensure adequate ventilation. 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 carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

## 6.4 Reference to other sections

For disposal see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Work under hood. Do not inhale substance/mixture.

#### Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

For precautions see section 2.2.

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

#### Storage conditions

Tightly closed. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorized persons.

#### Storage class

Storage class (TRGS 510): 6.1C: Combustible, acute toxic Cat.3 / toxic compounds or compounds which causing chronic effects

### 7.3 Specific end use(s)

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

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## 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 EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

##### Full contact

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

### **Body Protection**

protective clothing

### **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 P3

The entrepreneur 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.

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## **SECTION 9: Physical and chemical properties**

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

- |                                                 |                                                                                  |
|-------------------------------------------------|----------------------------------------------------------------------------------|
| a) Physical state                               | solid                                                                            |
| b) Color                                        | white                                                                            |
| c) Odor                                         | No data available                                                                |
| d) Melting point/freezing point                 | Melting point/range: 191 - 192 °C                                                |
| 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                                  | Not applicable                                                                   |
| 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: n-octanol/water       | No data available                                                                |
| o) Vapor pressure                               | No data available                                                                |

- |                             |                   |
|-----------------------------|-------------------|
| p) Density                  | No data available |
| Relative density            | No data available |
| q) Relative vapor density   | No data available |
| r) Particle characteristics | No data available |
|                             |                   |
| s) Explosive properties     | No data available |
| t) Oxidizing properties     | none              |

## 9.2 Other safety information

No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

### 10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

### 10.3 Possibility of hazardous reactions

Violent reactions possible with:  
Strong oxidizing agents

### 10.4 Conditions to avoid

no information available

### 10.5 Incompatible materials

No data available

### 10.6 Hazardous decomposition products

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - 1.957 mg/kg

Remarks: Behavioral: Altered sleep time (including change in righting reflex).  
(RTECS)

Acute toxicity estimate Oral - 1.957 mg/kg  
(ATE value derived from LD50/LC50 value)

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**

May cause sensitization by skin contact.

May cause allergic respiratory and skin reactions

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

No data available

**Reproductive toxicity**

May damage the unborn child. Positive evidence from human epidemiological studies.

May damage fertility. Positive evidence from human epidemiological studies.

**Specific target organ toxicity - single exposure**

May cause drowsiness or dizziness.

**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.

anemia

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

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**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

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## 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.

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## 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.

**Other regulations**

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

**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 H-Statements referred to under sections 2 and 3.**

|        |                                                                            |
|--------|----------------------------------------------------------------------------|
| H302   | Harmful if swallowed.                                                      |
| H317   | May cause an allergic skin reaction.                                       |
| H334   | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H336   | Harmful if swallowed.                                                      |
| H360FD | May cause an allergic skin reaction.                                       |

**Relevant changes since previous version**

2. Hazards identification

CHEMIKART

## 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 above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. 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](http://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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