

Carbamazepine

Safety Data Sheet

431621

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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

1.1. Product identifier

Product form : Substance
 Substance name : Carbamazepine
 IUPAC name : 5-Carbomoyl-5H-dibenz (b,f) azepine
 EC-No. : 206-062-7
 CAS-No. : 298-46-4
 Product code : 431621
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
 Industrial/Professional use : For professional use only
 spec
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31 (0) 23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31 (0) 23-5319093 (M-F 09:00-17:00)
 +31 (0) 6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

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
 Respiratory sensitisation, Category 1 H334

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Skin sensitisation, Category 1

H317

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display extra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

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

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330 - Rinse mouth.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P313 - If experiencing respiratory symptoms: Get medical advice/attention.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Carbamazepine	(CAS-No.) 298-46-4 (EC-No.) 206-062-7	100	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures**4.1. Description of first aid measures**

First-aid measures general	: If possible show this sheet, if not available show packaging or label.
First-aid measures after inhalation	: Allow affected person to breathe fresh air If not breathing, give artificial respiration Call a POISON CENTER/doctor.
First-aid measures after skin contact	: Remove contaminated clothing and shoes Wash skin with mild soap and water If irritation persists, consult a doctor.
First-aid measures after eye contact	: Rinse immediately with plenty of water Immediately call a POISON CENTER/doctor.
First-aid measures after ingestion	: Rinse mouth. Seek medical advice.

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

Symptoms/effects	: Dizziness, headaches, nausea Fatigue.
Symptoms/effects after skin contact	: Skin irritation, dermatitis and sensitisation.

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	: Water spray dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂).
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Nitrogen oxides Carbon oxides (CO, CO ₂).
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5.3. Advice for firefighters

Protection during firefighting	: Wear self-contained breathing apparatus, rubber boots and thick rubber gloves.
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SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

General measures	: Ensure adequate ventilation.
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6.1.1. For non-emergency personnel

Protective equipment	: Use the personal protective equipment as indicated in chapter 8.
Emergency procedures	: Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

No additional information available

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6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Sweeping or shovelling without dust for disposal.
Methods for cleaning up : Hose down area with water.

6.4. Reference to other sections

See Heading 8. See Heading 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures. Ensure adequate ventilation.
Reduce/avoid exposure and/or contact.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Store in a well-ventilated place. Keep container tightly closed.
Storage conditions : Protect from light.
Incompatible products : Strong oxidizing agent.
Incompatible materials : Moisture. Water.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry. Laboratory chemicals.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Dust/aerosol mask with filter type P3. Gloves.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

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Dustmask with filtertype P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 189 - 193 °C
Freezing point	: No data available
Boiling point	: 411 °C
Flash point	: 202.4 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.266 g/cm ³
Solubility	: Soluble in methanol Soluble in methylene chloride.
Log Pow	: 3.67
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

None under normal conditions.

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10.4. Conditions to avoid

High temperature

Keep away from open flames, hot surfaces and sources of ignition.

10.5. Incompatible materials

Oxidizing agents.

10.6. Hazardous decomposition products

In case of fire refer to chapter 5.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Harmful if swallowed.

Carbamazepine (298-46-4)	
LD50 oral rat	1957
LD50 oral	529 mouse

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified

Carcinogenicity : IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity : This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Carbamazepine (298-46-4)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

Carbamazepine (298-46-4)	
Log Pow	3.67
Bioaccumulative potential	Low bioaccumulation potential. Based on the coefficient n-octanol / water (log Pow) a concentration in organisms not to be expected.

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12.4. Mobility in soil

Carbamazepine (298-46-4)	
Ecology - soil	There are no available data for a classification.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

HP Code : HP6 - "Acute Toxicity:" waste which can cause acute toxic effects following oral or dermal administration, or inhalation exposure.
HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Not applicable	Not applicable
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Not applicable

- Air transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Carbamazepine is not on the REACH Candidate List

Carbamazepine is not on the REACH Annex XIV List

15.1.2. National regulations

no additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
LD50	Median lethal dose
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Data sources : Supplier.

Training advice : Provide good information, instruction and training for the users.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SDS EU (REACH Annex II) ducheфа nieuwe logo

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.