

Page 1/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

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

· Product identifier

· Trade name: Phenobarbital, API

· Article number: 4920

· CAS Number:

50-06-6

· EC number:

200-007-0

- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

- · Uses advised against No relevant information available.
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

CAELO

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

GERMANY

· Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 3 H301 Toxic if swallowed.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Repr. 1A H360 May damage fertility or the unborn child.

- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)



Page 2/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

Trade name: Phenobarbital, API

(Contd. of page 1)

· Hazard pictograms



· Signal word Danger

· Hazard statements

H301 Toxic if swallowed.

H317 May cause an allergic skin reaction.

H360 May damage fertility or the unborn child.

· Precautionary statements

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

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

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Other hazards

· Results of PBT and vPvB assessment

PBT: Not applicable.vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Substances

· CAS No. Description 50-06-6 phenobarbital

Identification number(s)

EC number: 200-007-0

4 First aid measures

- · Description of first aid measures
- General information:

Immediately remove any clothing soiled by the product.

In case of irregular breathing or respiratory arrest provide artificial respiration.

· After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Do not induce vomiting; call for medical help immediately.

(Contd. on page 3)



Page 3/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

Trade name: Phenobarbital, API

(Contd. of page 2)

- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · Advice for firefighters
- Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.
- **Additional information**

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Avoid contact with the substance.

- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling Thorough dedusting.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: No further information
- · Storage class: TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
- Specific end use(s) No further relevant information available.

(Contd. on page 4)



Page 4/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

Trade name: Phenobarbital, API

(Contd. of page 3)

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

- · Respiratory protection: Dust protection mask.
- Protection of hands: Protective gloves
- Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

- Information on basic physical and chemical properties
- · General Information

· Appearance:

Form: Crystalline powder

Colour: White

Odour: CharacteristicOdour threshold: Not determined.pH-value: Not applicable.

· Change in condition

Melting point/freezing point: 174–178 °C Initial boiling point and boiling range: Undetermined.

• Flash point: Not applicable.

· Flammability (solid, gas): Product is not flammable.

Decomposition temperature: Not determined.Auto-ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

(Contd. on page 5)



Page 5/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

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(Contd. of page 4)

· Explosion limits:

Lower:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not applicable.

Density:
Not determined.
Relative density
Not determined.
Vapour density
Not applicable.
Evaporation rate
Not applicable.

· Solubility in / Miscibility with

water at 20 °C:

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not applicable. **Kinematic:** Not applicable.

• Other information No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- Acute toxicity

Toxic if swallowed.

· LD/LC50 values relevant for classification:

Oral LD50 162 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation

May cause an allergic skin reaction.

- · Additional toxicological information:
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity

May damage fertility or the unborn child.

(Contd. on page 6)



Page 6/7

Safety data sheet according to 1907/2006/EC, Article 31

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(Contd. of page 5)

- · STOT-single exposure Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

LC50 484 mg/L /96h (Fish)

- · Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- · Recommendation: Disposal must be made according to local regulations.

14 Transport information

· UN-Number

· ADR, IMDG, IATA UN2811

· UN proper shipping name

• ADR 2811 TOXIC SOLID, ORGANIC, N.O.S. (phenobarbital)
• IMDG TOXIC SOLID, ORGANIC, N.O.S. (phenobarbital)

· IATA Toxic solid, organic, n.o.s. (phenobarbital)

· Transport hazard class(es)

· ADR, IMDG, IATA

Class 6.1 Toxic substances.

· Label 6.1

· Packing group

· ADR

· Environmental hazards: Not applicable.

· Special precautions for user Warning: Toxic substances.

(Contd. on page 7)



Page 7/7

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 30.08.2021 Version number 2.00 Revision: 25.08.2021

Trade name: Phenobarbital, API

(Contd. of page 6)

· Hazard identification number (Kemler code): 60

Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

· Transport/Additional information:

· Limited quantities (LQ) 5 kg · Transport category 2 Tunnel restriction code Ε

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- · REGULATION (EC) No 1907/2006 ANNEX XVII Not listed
- · National regulations:
- · Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 6.1 C Combustible acutely toxic or chronic substances

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- · Reasons for alterations This version replaces all old versions.
- · Department issuing SDS: Quality Assurance department
- · Contact:

E-Mail: info@caelo.de Telefon: +49 2103 4994 0

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygjejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - Category 3

Skin Sens. 1: Skin sensitisation – Category 1 Repr. 1A: Reproductive toxicity – Category 1A