

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

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

· 1.1 Product identifier

· **Product name: Amlodipine Besilate**

· **Part number:** CAT 1221

· **CAS Number:**

111470-99-6

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

No further relevant information available.

· **Application of the substance / the mixture** Reference material for laboratory use only

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

British Pharmacopoeia Commission

MHRA

10 South Colonnade

Canary Wharf

London E14 4PU

United Kingdom

Tel : +44 (0)20 3080 6561

eMail: bpcrs@mhra.gsi.gov.uk

· **Further information obtainable from:** eMail: bpcrs@mhra.gsi.gov.uk

· **1.4 Emergency telephone number:** +44 (0) 20 3080 6561 (Monday - Friday: 8am - 5pm)

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Repr. 2 H361d Suspected of damaging the unborn child.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS09 environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

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

· **Hazard pictograms**



GHS07



GHS08



GHS09

· **Signal word** Warning

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 1)

· Hazard statements*H302 Harmful if swallowed.**H315 Causes skin irritation.**H319 Causes serious eye irritation.**H361d Suspected of damaging the unborn child.**H373 May cause damage to organs through prolonged or repeated exposure.**H411 Toxic to aquatic life with long lasting effects.***· Precautionary statements***P260 Do not breathe dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.**P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P405 Store locked up.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.1 Chemical characterisation: Substances****· CAS No. Description***111470-99-6 Amlodipine Besylate***· Identification number(s) None****· RTECS:** *US7967700***· Additional information:** *For the wording of the listed hazard phrases refer to section 16.***SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:***Immediately remove any clothing soiled by the product.**Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.***· After inhalation:** *Supply fresh air; consult doctor in case of complaints.***· After skin contact:***Immediately wash with water and soap and rinse thoroughly.**If skin irritation continues, consult a doctor.***· After eye contact:***Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.***· After swallowing:***Rinse mouth. Do not induce vomiting.**Seek medical treatment.***· 4.2 Most important symptoms and effects, both acute and delayed** *No further relevant information available.***· 4.3 Indication of any immediate medical attention and special treatment needed***No further relevant information available.*

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(Contd. on page 3)

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

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 2)

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:**
Mouth respiratory protective device.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Avoid formation of dust.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/extraction at the workplace.
Store in cool, dry place in tightly closed receptacles.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Lists used were valid at the time of SDS preparation.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 3)

- **8.2 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.
 Store protective clothing separately.
 Avoid contact with the eyes and skin.*
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**
*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 protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374*



Protective gloves

- **Material of gloves** *Fluorocarbon rubber (Viton)*
- **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

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

| | |
|-------------------------|------------------------|
| Form: | <i>Solid</i> |
| Colour: | <i>Off white</i> |
| Odour: | <i>Odourless</i> |
| Odour threshold: | <i>Not determined.</i> |
- **pH-value:** *Not applicable.*
- **Change in condition**

| | |
|---|------------------------|
| Melting point/freezing point: | <i>199-201 °C</i> |
| Initial boiling point and boiling range: | <i>Not determined.</i> |
- **Flash point:** *Not applicable.*
- **Flammability (solid, gas):** *Not determined.*
- **Ignition temperature:** *Not determined*
- **Decomposition temperature:** *Not determined.*

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 4)

| | |
|--|--|
| · Auto-ignition temperature: | <i>Not determined.</i> |
| · Explosive properties: | <i>Not determined.</i> |
| · Explosion limits: Lower: Upper: | <i>Not determined.</i> <i>Not determined.</i> |
| · Vapour pressure: | <i>Not applicable.</i> |
| · Density: · Relative density · Vapour density · Evaporation rate | <i>Not determined.</i> <i>Not determined.</i> <i>Not applicable.</i> <i>Not applicable.</i> |
| · Solubility in / Miscibility with water: | <i>Chloroform, Ethanol, Methanol Soluble.</i> |
| · Partition coefficient: n-octanol/water: | <i>2.76 logP</i> |
| · Viscosity: Dynamic: Kinematic: | <i>Not applicable.</i> <i>Not applicable.</i> |
| · 9.2 Other information | <i>No further relevant information available.</i> |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *Stable under normal conditions.*
- **10.2 Chemical stability** *Stable under normal conditions.*
- **Thermal decomposition / conditions to be avoided:**
Formation of toxic gases is possible during heating or in case of fire.
- **10.3 Possibility of hazardous reactions** *No dangerous reactions known.*
- **10.4 Conditions to avoid**
Heat.
Light.
Sources of ignition
- **10.5 Incompatible materials:** *Strong oxidizing agents.*
- **10.6 Hazardous decomposition products:**
Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

| | | |
|------|-------------------------|-----------------|
| Oral | LD50 | 393 mg/kg (rat) |
| | LD 50 (Intraperitoneal) | 42 mg/kg (rat) |

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

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 04.07.2018

Version number 1

Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 5)

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 2
- **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**
Suspected of damaging the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

| | |
|-----------|--------------------|
| LC50/48 | 2.7 mg/l (fish) |
| EC50/48 h | 9.9 mg/l (daphnia) |
| EC50/72h | 5.6 mg/l (Algae) |

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

GB

(Contd. on page 7)

Safety data sheet

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Product name: Amlodipine Besilate

(Contd. from page 6)

SECTION 14: Transport information

| | |
|---|--|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, IMDG, IATA · ADR · IMDG · IATA | <p>UN3077</p> <p>3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amlodipine Besylate)</p> <p>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amlodipine Besylate), MARINE POLLUTANT</p> <p>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Amlodipine Besylate)</p> |
|---|--|

· **14.3 Transport hazard class(es)**

· **ADR, IMDG, IATA**



| | |
|--|--|
| <ul style="list-style-type: none"> · Class · Label | <p>9 Miscellaneous dangerous substances and articles.</p> <p>9</p> |
|--|--|

· **14.4 Packing group**

· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

· **Marine pollutant:**

Symbol (fish and tree)

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Danger code (Kemler):**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

· **Stowage Code**

SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

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

Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 g

Maximum net quantity per outer packaging: 1000 g

· **Transport category**

2

· **Tunnel restriction code**

E

· **UN "Model Regulation":**

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (AMLODIPINE BESYLATE), 9, III

Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 04.07.2018

Product name: Amlodipine Besilate

(Contd. from page 7)

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

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

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Repr. 2: Reproductive toxicity – Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

- **Data compared to the previous version altered.** All sections have been updated.