

# Amlodipine besilate

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 21/04/2017 Revision date:

**900608**

Version: 1.0

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

### 1.1. Product identifier

Product form : Substance  
Substance name : Amlodipine besilate  
CAS-No. : 111470-99-6  
Product code : 900608  
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  
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 - F +31(0)23-5318027  
[farma@ducheffa.nl](mailto:farma@ducheffa.nl) - [www.duchefa-farma.com](http://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)

| Country        | Organisation/Company   | Address                         | Emergency number | Comment |
|----------------|--|---------------------------------|------------------|---------|
| United Kingdom | Guy's & St Thomas' Poisons Unit<br>Medical Toxicology Unit,<br>Centre Hospitalier Universitaire de Constantine | Avonley Road<br>SE14 5ER London | 0870 243 2241    |         |

## 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  
Acute toxicity (inhalation:dust,mist) Category 4 H332  
Serious eye damage/eye irritation, Category 1 H318  
Hazardous to the aquatic environment — Chronic Hazard, Category 2 H411

Full text of hazard classes and 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]**

Hazard pictograms (CLP)



GHS05

GHS07

GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302+H332 - Harmful if swallowed or if inhaled  
H318 - Causes serious eye damage  
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray  
P273 - Avoid release to the environment  
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician 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  
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing**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]  |
|---------------------|-----------------------|-----|--|
| Amlodipine besilate | (CAS-No.) 111470-99-6 | 100 | Acute Tox. 4 (Oral), H302<br>Acute Tox. 4<br>(Inhalation:dust,mist), H332<br>Eye Dam. 1, H318<br>Aquatic Chronic 2, H411 |

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 after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician.

First-aid measures after skin contact : Rinse with plenty of water.

- First-aid measures after eye contact : Seek medical attention immediately. Immediately flush eyes thoroughly with water for at least 15 minutes.
- First-aid measures after ingestion : Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

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

No additional information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Fire-fighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Foam. Carbon dioxide. Sand.
- Unsuitable extinguishing media : Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Toxic and irritating gases are released.

#### 5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.
- Other information : Avoid direct discharge into drains.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

- Protective equipment : Wear recommended personal protective equipment.
- Emergency procedures : Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. Avoid raising dust.

#### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection".

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Avoid raising dust and aerosols.
- Hygiene measures : Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety practice.

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

- Storage conditions : Protect from light. Keep container tightly closed.

Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

No additional information available

## 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.

#### Hand protection:

Wear gloves to EN374 to protect against skin effects from powders

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

Dustmask with filtertype P2

## SECTION 9: Physical and chemical properties

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

|  |                       |
|--|-----------------------|
| Physical state                             | : Solid               |
| Molecular mass                             | : 567.1 g/mol         |
| Colour                                     | : White to off-white. |
| Odour                                      | : Characteristic.     |
| Odour threshold                            | : No data available   |
| pH   | : No data available   |
| Relative evaporation rate (butylacetate=1) | : No data available   |
| Melting point                              | : 203 °C              |
| Freezing point                             | : No data available   |
| Boiling point                              | : 527 °C              |
| Flash point                                | : No data available   |
| 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   |

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|                      |  |
|----------------------|--|
| Density              | : 1.227 g/cm <sup>3</sup>                |
| Solubility           | : Soluble in methanol.<br>Water: 76 mg/l |
| Log Pow              | : 1.9                                    |
| 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 additional information available

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

Direct sunlight.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed. Inhalation:dust,mist: Harmful if inhaled.

| Amlodipine besilate (111470-99-6) |           |
|-----------------------------------|-----------|
| LD50 oral rat                     | 393 mg/kg |

|                                   |                              |
|-----------------------------------|------------------------------|
| Skin corrosion/irritation         | : Not classified             |
| Serious eye damage/irritation     | : Causes serious eye damage. |
| Respiratory or skin sensitisation | : Not classified             |
| Germ cell mutagenicity            | : Not classified             |
| Carcinogenicity                   | : Not classified             |
| Reproductive toxicity             | : Not classified             |
| STOT-single exposure              | : Not classified             |
| STOT-repeated exposure            | : Not classified             |
| Aspiration hazard                 | : Not classified             |

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

| Amlodipine besilate (111470-99-6) |          |
|-----------------------------------|----------|
| EC50 Daphnia 1                    | 3.2 ppm  |
| EC50 72h algae (1)                | 5.6 mg/l |

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

| Amlodipine besilate (111470-99-6) |     |
|-----------------------------------|-----|
| Log Pow                           | 1.9 |

**12.4. Mobility in soil**

No additional information available

**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) : Disposal must be done according to official regulations.

**SECTION 14: Transport information**

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

| ADR  | IATA   |
|--|--|
| <b>14.1. UN number</b>   |  |
| 3077   | 3077   |
| <b>14.2. UN proper shipping name</b>   |  |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.                                 | Environmentally hazardous substance, solid, n.o.s.                                   |
| <b>14.3. Transport hazard class(es)</b>  |  |
| 9  | 9  |
|  |  |
| <b>14.4. Packing group</b>   |  |
| III  | III  |
| <b>14.5. Environmental hazards</b>   |  |
| Dangerous for the environment : Yes  | Dangerous for the environment : Yes  |
| No supplementary information available   |  |

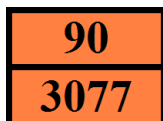
**14.6. Special precautions for user****- Overland transport**

|                            |                           |
|----------------------------|---------------------------|
| Classification code (ADR)  | : M7                      |
| Special provisions (ADR)   | : 274, 335, 601, 375      |
| Limited quantities (ADR)   | : 5kg                     |
| Excepted quantities (ADR)  | : E1                      |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |

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|   |                |
|---|----------------|
| Mixed packing provisions (ADR)  | : MP10         |
| Portable tank and bulk container instructions (ADR)                     | : T1, BK1, BK2 |
| Portable tank and bulk container special provisions (ADR)               | : TP33         |
| Tank code (ADR)   | : SGAV, LGBV   |
| Vehicle for tank carriage   | : AT           |
| Transport category (ADR)  | : 3            |
| Special provisions for carriage - Packages (ADR)                        | : V13          |
| Special provisions for carriage - Bulk (ADR)                            | : VC1, VC2     |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13         |
| Hazard identification number (Kemler No.)                               | : 90           |
| Orange plates   | :              |



|                               |      |
|-------------------------------|------|
| Tunnel restriction code (ADR) | : E  |
| EAC code                      | : 2Z |

### - Air transport

|  |                         |
|--|-------------------------|
| PCA Excepted quantities (IATA)               | : E1                    |
| PCA Limited quantities (IATA)                | : Y956                  |
| PCA limited quantity max net quantity (IATA) | : 30kgG                 |
| PCA packing instructions (IATA)              | : 956                   |
| PCA max net quantity (IATA)                  | : 400kg                 |
| CAO packing instructions (IATA)              | : 956                   |
| CAO max net quantity (IATA)                  | : 400kg                 |
| Special provisions (IATA)                    | : A97, A158, A179, A197 |
| ERG code (IATA)                              | : 9L                    |

### 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

Amlodipine besilate is not on the REACH Candidate List

Amlodipine besilate 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:

|       |   |
|-------|---|
| ADN   | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways   |
| ADR   | European Agreement concerning the International Carriage of Dangerous Goods by Road               |
| ATE   | Acute Toxicity Estimate   |
| CLP   | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008                       |
| RID   | Regulations concerning the International Carriage of Dangerous Goods by Rail                      |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG  | International Maritime Dangerous Goods  |
| LC50  | Median lethal concentration   |
| IATA  | International Air Transport Association   |

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

|  |   |
|--|---|
| Acute Tox. 4<br>(Inhalation:dust,mist) | Acute toxicity (inhalation:dust,mist) Category 4                  |
| Acute Tox. 4 (Oral)                    | Acute toxicity (oral), Category 4                                 |
| Aquatic Chronic 2                      | Hazardous to the aquatic environment — Chronic Hazard, Category 2 |
| Eye Dam. 1                             | Serious eye damage/eye irritation, Category 1                     |
| H302                                   | Harmful if swallowed  |
| H318                                   | Causes serious eye damage   |
| H332                                   | Harmful if inhaled  |
| H411                                   | Toxic to aquatic life with long lasting effects                   |

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*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*