

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: AMLODIPINE BESILATE
Chemical name	: 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-3-ethoxycarbonyl-5-methoxycarbonyl-6-methyl-1,4-dihydropyridine benzenesulfonate
IUPAC name	: 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-3-ethoxycarbonyl-5-methoxycarbonyl-6-methyl-1,4-dihydropyridine benzenesulfonate
CAS-No.	: 111470-99-6
Product code	: 70450
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₂₀ H ₂₅ ClN ₂ O ₅ .C ₆ H ₆ O ₃ S
Synonyms	: Amlodipine benzenesulfonate ; Amlodipine besylate ; 3,5-Pyridinedicarboxylic acid,2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)- 1,4-dihydro-6-methyl-,3-ethyl 5-methyl ester,monobenzenesulfonate
Other means of identification	: SMILES: CCOC(=O)C1=C(COCCN)NC(C)=C(C1C1=CC=CC=C1Cl)C(=O)OC (Amlodipine free base)

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API,Professional use,Industrial use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: A long-acting dihydropyridine calcium channel blocker. It is effective in the treatment of angina pectoris and hypertension.
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Supplier**

MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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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 (inhal.), Category 4	H332
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 1	H318
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. Harmful if inhaled. Harmful if swallowed. Toxic to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H302+H332 - Harmful if swallowed or if inhaled.

H315 - Causes skin irritation.

H318 - Causes serious eye damage.

H335 - May cause respiratory irritation.

H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P261 - Avoid breathing spray, fume, dust, mist, vapours.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear eye protection, protective gloves, face protection, protective clothing.

P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P330 - Rinse mouth.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 - 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.

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

P273 - Avoid release to the environment.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
AMLODIPINE BESILATE	CAS-No.: 111470-99-6	100

3.2. Mixtures

Not applicable

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
First-aid measures after skin contact	: Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. Specific treatment (see supplemental first aid instruction on this label).
First-aid measures after eye contact	: Get medical advice/attention. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects	: If you feel unwell, seek medical advice.
Symptoms/effects after inhalation	: Harmful if inhaled. May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye damage.
Symptoms/effects after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Collect spillage.
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Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray. Use only outdoors or in a well-ventilated area.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Provide local exhaust or general room ventilation. Comply with applicable regulations.
Storage conditions	: Store in a well-ventilated place. Store at room temperature. Keep away from ignition sources. Keep only in the original container in a cool, well ventilated place away from : Keep container tightly closed.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Breathing equipment. Dust extraction (suction). Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Safety glasses. Dust/aerosol mask with filter type P3. Avoid all unnecessary exposure.

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Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Polyvinylalcohol (PVA), Natural rubber, Polyvinylchloride (PVC), Latex, Vinyl	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection		
Device	Filter type	Standard
Dust mask	Type P3	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 203 °C
Freezing point	: Not available
Boiling point	: 527 °C [at 760 mmHg]
Flammability	: Not available
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: > 65 °F
Auto-ignition temperature	: Not applicable

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Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 75.9 mg/l [Amlodipine free base]
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 1.9 [Amlodipine free base predicted using ALOGPS]
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1.227 g/cm ³
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	: 150 mJ
Additional information	: Dust Cloud minimum Flammability Temperature : 480 °C. Layer Minimum flammability Temperature : Melt. Explosivity Pmax : 7.7 bar-g. Minimum Explosive Concentration : 20 g/m ³ . Explosion Severity Factor Kmax (bar.m/s) : 181 bar.m/s. Explosion Class : St1

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under use and storage conditions as recommended in section 7.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7. Not established.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Nitrogen oxides. Toxic gases. fume. Carbon monoxide. Carbon dioxide.

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Harmful if inhaled.

AMLODIPINE BESILATE (111470-99-6)	
LD50 oral rat	393 mg/kg
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if inhaled,Harmful if swallowed.
Other information	: Likely routes of exposure: inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water	: Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects.

AMLODIPINE BESILATE (111470-99-6)	
EC50 - Crustacea [1]	3.2 ppm
EC50 72h - Algae [1]	5.6 mg/l

12.2. Persistence and degradability

AMLODIPINE BESILATE (111470-99-6)	
Persistence and degradability	May cause long-term adverse effects in the environment.

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12.3. Bioaccumulative potential

AMLODIPINE BESILATE (111470-99-6)

Partition coefficient n-octanol/water (Log Pow)	1.9 [Amlodipine free base predicted using ALOGPS]
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : UN 3077
UN-No. (IMDG) : UN 3077
UN-No. (IATA) : UN 3077
UN-No. (ADN) : UN 3077
UN-No. (RID) : UN 3077

14.2. UN proper shipping name

Proper Shipping Name (ADR) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IMDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IATA) : Environmentally hazardous substance, solid, n.o.s.
Proper Shipping Name (ADN) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (RID) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description (ADR) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((Amlodipine Besilate)), 9, III, (E)
Transport document description (IMDG) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((Amlodipine Besilate)), 9, III, MARINE POLLUTANT
Transport document description (IATA) : UN 3077 Environmentally hazardous substance, solid, n.o.s. ((Amlodipine Besilate)), 9, III
Transport document description (ADN) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((Amlodipine Besilate)), 9, III
Transport document description (RID) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ((Amlodipine Besilate)), 9, III

AMLODIPINE BESILATE

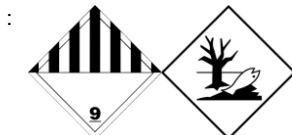
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14.3. Transport hazard class(es)

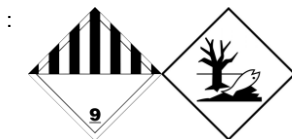
ADR

Transport hazard class(es) (ADR) : 9
Danger labels (ADR) : 9



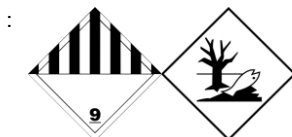
IMDG

Transport hazard class(es) (IMDG) : 9
Danger labels (IMDG) : 9



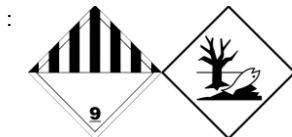
IATA

Transport hazard class(es) (IATA) : 9
Danger labels (IATA) : 9



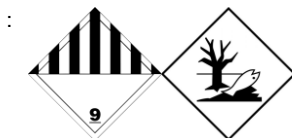
ADN

Transport hazard class(es) (ADN) : 9
Danger labels (ADN) : 9



RID

Transport hazard class(es) (RID) : 9
Danger labels (RID) : 9



14.4. Packing group

Packing group (ADR) : III
Packing group (IMDG) : III
Packing group (IATA) : III
Packing group (ADN) : III
Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : Yes
Marine pollutant : Yes
Other information : No supplementary information available

14.6. Special precautions for user


Overland transport

Classification code (ADR) : M7

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Special provisions (ADR)	: 274, 335, 601, 375
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
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

Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002, LP02
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1, BK1, BK2, BK3
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

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

Inland waterway transport

Classification code (ADN)	: M7
Special provisions (ADN)	: 274, 335, 375, 601
Limited quantities (ADN)	: 5 kg
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T* B**
Equipment required (ADN)	: PP, A
Number of blue cones/lights (ADN)	: 0

Rail transport

Classification code (RID)	: M7
Special provisions (RID)	: 274, 335, 375, 601

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Limited quantities (RID)	: 5kg
Excepted quantities (RID)	: E1
Packing instructions (RID)	: P002, IBC08, LP02, R001
Special packing provisions (RID)	: PP12, B3
Mixed packing provisions (RID)	: MP10
Portable tank and bulk container instructions (RID)	: T1, BK1, BK2
Portable tank and bulk container special provisions (RID)	: TP33
Tank codes for RID tanks (RID)	: SGAV, LGBV
Transport category (RID)	: 3
Special provisions for carriage – Packages (RID)	: W13
Special provisions for carriage – Bulk (RID)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (RID)	: CW13, CW31
Colis express (express parcels) (RID)	: CE11
Hazard identification number (RID)	: 90

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed

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SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed
Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 11/13 - Solids

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
BCF	Bioconcentration factor
IARC	International Agency for Research on Cancer
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
EC50	Median effective concentration
IATA	International Air Transport Association
DSD	Dangerous Substances Directive 67/548/EEC
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
NOAEL	No-Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

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.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2

AMLODIPINE BESILATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H411	Toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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.