

Safety Data Sheet

#90038432 · Full 16-section SDS

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

PRODUCT	CAS NUMBER	FORMULA	VERSION	REVISION DATE
Amlodipine Besylate USP CRS	111470- 99-6	C20H25ClN2O5 · C6H5SO3H	10	17 Jul 2026

SECTION 1

Identification

Product name	Amlodipine besylate
CAS number	111470-99-6
Chemical formula	C20H25ClN2O5 · C6H5SO3H
Molecular weight	567.05
SMILES	CCOC(=O)C1=C(NC(=C(C1C2=CC=CC=C2Cl)C(=O)OC)C)COCCN.C1=CC=C(C=C1)S(=O)(=O)O
EC / EINECS number	601-097-8
Recommended use & restrictions	<i>Not applicable</i>
Emergency telephone	0344 892 0111 — National Poisons Information Service (NPIS) (United Kingdom — for healthcare professionals (via TOXBASE))

SECTION 2

Hazard identification

**DANGER**

CODE	HAZARD STATEMENT
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H335	May cause respiratory irritation
H361d	Suspected of damaging fertility. 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
USH01	May form combustible dust concentrations in air
CODE	PRECAUTIONARY STATEMENT
P261	Avoid breathing dust/fume/gas/mist/vapours/spray
P263	Avoid contact during pregnancy/while nursing
P273	Avoid release to the environment
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P305+P351+P338	IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing
Other hazards (e.g. PBT / vPvB, not classified)	None known

SECTION 3

Composition / information on ingredients

Purity / concentration	100 %
Impurities / stabilising additives	None

SECTION 4

First-aid measures

Inhalation	Remove person to fresh air and keep comfortable for breathing. In case of persistent throat irritation or coughing: seek medical attention.
Skin contact	Take off immediately all contaminated clothing. Rinse skin with water/shower. Contact a physician if discomfort continues.
Eye contact	Rinse with water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Get medical attention if any discomfort continues.
Ingestion	After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.
Symptoms / effects & medical attention	The most important known symptoms and effects are described in the labelling (see section 11)

SECTION 5

Fire-fighting measures

Suitable extinguishing media	Alcohol-resistant foam, carbon dioxide, dry powder or water fog. Water spray
Unsuitable extinguishing media	None known
Special hazards	Carbon oxides Nitrogen oxides (NO _x) Sulfur oxides Hydrogen chloride gas Combustible. Development of hazardous combustion gases or vapours possible in the event of fire.
Advice for firefighters	In the event of fire, wear self-contained breathing apparatus. Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system

SECTION 6

Accidental release measures

Personal precautions & PPE	Avoid breathing dust/fume/gas/mist/vapours/spray. Provide adequate ventilation. For personal protection, see section 8.
Environmental precautions	Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.
Containment & clean-up methods	Absorb spillage with a suitable absorbent material.

For specific precautions, see Section 8 and Section 13.

SECTION 7

Handling & storage

Storage temperature	Ambient
Precautions for safe handling	Wear protective clothing, gloves, eye and face protection. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray.
Conditions for safe storage (incompatibilities)	Store at ambient temperature. Store in a dry place. Store in a closed container.

SECTION 8

Exposure controls / personal protection

Occupational exposure limits (OEL / WEL)	<i>No data available</i>
DNEC/PNEC data	<i>No data available</i>
Eye / face protection	Safety glasses Wear eye/face protection as recommended. All eye/face protection should comply with EN ISO 16321-1:2022.
Skin / hand protection	Nitrile gloves Thickness: 0.11mm. Breakthrough time: 480mins.
Respiratory protection	Full-face respirator Keep self-contained breathing apparatus readily available for emergency use. Provide adequate ventilation. If ventilation is insufficient, suitable respiratory protection must be provided. Respiratory equipment: Reusable Air-Purifying Respirator (APR). Filter type: ABEK. Standard: EN 14387.

SECTION 9

Physical & chemical properties

Density (g/mL) *Not applicable*

Flash point *Not applicable*

Acidity Neutral
DERIVED FROM: LITERATURE

Appearance / physical state Solid
DERIVED FROM: LITERATURE

Colour Off-white
DERIVED FROM: LITERATURE

Odour Odourless
DERIVED FROM: LITERATURE

Melting / freezing point -
DERIVED FROM: LITERATURE

Boiling point -
DERIVED FROM: LITERATURE

Solubility (water) *No data available*

pH -
DERIVED FROM: LITERATURE

Vapour pressure -
DERIVED FROM: LITERATURE

Partition coefficient (log Pow) -
DERIVED FROM: LITERATURE

Auto-ignition / decomposition temp -
DERIVED FROM: LITERATURE

SECTION 10

Stability & reactivity

Chemical stability / reactivity Stable under the prescribed storage conditions

Conditions to avoid Excessive heat.

Incompatible materials Strong oxidising agents

Hazardous decomposition products See section 5

SECTION 11

Toxicological information

Acute toxicity (LD50 / LC50)	LD50 Oral - Rat - 393 mg/kg Ref: Oyo Yakuri. Pharmacometrics., 42(177), 1991
Skin corrosion / irritation	Causes skin irritation
Eye corrosion / irritation	Causes serious eye damage
Respiratory / skin sensitisation	<i>No data available</i>
Carcinogenicity	Suspected of damaging fertility; Suspected of damaging the unborn child
Mutagenicity	<i>Not applicable</i>
Reproductive toxicity	<i>Not applicable</i>
STOT (single / repeated exposure)	Single exposure: May cause respiratory irritation
Aspiration hazard	<i>No data available</i>
Endocrine disruptors	<i>No data available</i>

SECTION 12

Ecological information

Aquatic toxicity	<i>No data available</i>
Persistence & degradability	<i>No data available</i>
Bioaccumulative potential	<i>No data available</i>
Mobility in soil	<i>No data available</i>
PBT / vPvB assessment	<i>No data available</i>

SECTION 13

Disposal considerations

Waste treatment / disposal methods	Dispose of in accordance with local/national regulations
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SECTION 14

Transport information

UN number	UN3077
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Class	9
Packing group	III
Transport category	3
Tunnel code	-
Packing instruction (ADR)	P002
Packing instruction (IMDG)	P002
Environmental hazards	Yes.
Special precautions for user	None



SECTION 15

Regulatory information

REACH code	Y110
UFI code	<i>Not applicable</i>
ECHA notification	<i>Not applicable</i>
Chemical safety assessment carried out?	<i>Not applicable</i>

SECTION 16

Other information

Revision notes / other information	<i>Not applicable</i>
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