



## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Revision date: 26/06/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form : Substance

Substance name : Atracurium besilate Chemical name : Atracurium besilate

: 264-743-4 EC-No. CAS-No. : 64228-81-5 Product code : 201600078

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development

> Technical testing and analysis For professional use only

Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare

EDQM, Council of Europe 7, Allée Kastner, CS30026 F 67081 Strasbourg

France

T +33(0)388412035, F +33(0)388412771

sds@edqm.eu, www.edqm.eu

## 1.4. Emergency telephone number

**Emergency number** : +33(0)390215608

## **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 3 H301 Specific target organ toxicity - Single exposure, Category 2

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

#### Adverse physicochemical, human health and environmental effects

Toxic if swallowed. May cause damage to organs.

## 2.2. Label elements

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

Hazard pictograms (CLP)





GHS06

GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) H301 - Toxic if swallowed.

> H371 - May cause damage to organs (nervous system). P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

Precautionary statements (CLP)

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

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

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P330 - Rinse mouth. P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP)





GHS06

GHS08

#### 2.3. Other hazards

Other information : Active substance (in pharmaceutical products).

Warning - substance not yet tested completely.

## **SECTION 3: Composition/information on ingredients**

#### 3.1. Substances

Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Atracurium besilate	CAS-No.: 64228-81-5 EC-No.: 264-743-4	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) STOT SE 2, H371

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

#### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If

the person feels unwell : Get medical advice/attention.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water,

followed by warm water rinse.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking

or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth

to an unconscious person. Immediately call a POISON CENTER/doctor.

## 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: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.

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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 : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other

toxic gases. Toxic fumes may be released.

#### 5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

#### **SECTION 6: Accidental release measures**

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

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

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

#### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

## 6.4. Reference to other sections

See Section 13 for disposal information.

## **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and

direct sunlight.

Packaging materials : Keep in original containers.

## 7.3. Specific end use(s)

No additional information available

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

No additional information available

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#### 8.2. Exposure controls

#### Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

#### Eye and face protection

#### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

#### Skin protection

#### Skin and body protection:

Wear suitable protective clothing. Laboratory use: Lab coat. (EN 13034)

## Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

#### **Respiratory protection**

#### Respiratory protection:

In case of dust formation use respirator with filter: P3

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour : white. almost white.

Appearance Powder. Molecular mass 1243 g/mol Not available Odour Odour threshold Not available · 85 - 90 °C Melting point : Not available Freezing point Boiling point : Not available Flammability : Not available Lower explosion limit : Not applicable Upper explosion limit : Not applicable : Not applicable Flash point Auto-ignition temperature : Not applicable Decomposition temperature : Not available рΗ : Not available pH solution : Not available

Solubility : Water: 33.3 - 100 g/l Partition coefficient n-octanol/water (Log Kow) : Not available : Not available Vapour pressure : Not available Vapour pressure at 50°C Density : Not available : Not available Relative density Relative vapour density at 20°C Not applicable : Not available Particle size

## 9.2. Other information

Viscosity, kinematic

No additional information available

: Not applicable

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## **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

No additional information available

## **SECTION 11: Toxicological information**

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

Acute toxicity (oral) : Toxic if swallowed.

Acute toxicity (dermal) : Not classified (Lack of data; Ingestion is not considered a potential route of exposure)
Acute toxicity (inhalation) : Not classified (Lack of data; Ingestion is not considered a potential route of exposure)

Atracurium besilate (64228-81-5)

LD50 oral rat > 50 – ≤ 300 mg/kg (estimated value)

Skin corrosion/irritation : Not classified (Lack of data)
Serious eye damage/irritation : Not classified (Lack of data)

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)

Germ cell mutagenicity : Not classified (Lack of data)
Carcinogenicity : Not classified (Lack of data)
Reproductive toxicity : Not classified (Lack of data)

STOT-single exposure : May cause damage to organs (nervous system).

STOT-repeated exposure : Not classified (Lack of data)
Aspiration hazard : Not classified (Lack of data)

#### 11.2. Information on other hazards

No additional information available

## **SECTION 12: Ecological information**

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term : Not classified (Lack of data)

(acute)

Hazardous to the aquatic environment, long-term : Not classified (Lack of data)

(chronic)

## 12.2. Persistence and degradability

Atracurium besilate (64228-81-5)	
Persistence and degradability	Not rapidly degradable

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## 12.3. Bioaccumulative potential

No additional information available

## 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

No additional information available

## 12.7. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

No additional information available

## **SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
UN 2811	UN 2811	UN 2811
14.2. UN proper shipping name		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
Transport document description		
UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III, (E)	UN 2811 TOXIC SOLID, ORGANIC, N.O.S., 6.1, III	UN 2811 Toxic solid, organic, n.o.s., 6.1, III
14.3. Transport hazard class(es)		
6.1	6.1	6.1
6	6	6
14.4. Packing group		
III	III	Ш
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	Dangerous for the environment: No

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#### 14.6. Special precautions for user

#### **Overland transport**

Classification code (ADR) : T2
Special provisions (ADR) : 274, 614
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1

Packing instructions (ADR) : P002, IBC08, LP02, R001

Special packing provisions (ADR) : B3
Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1
Portable tank and bulk container special provisions : TP33

(ADR)

Tank code (ADR) : SGAH, L4BH Tank special provisions (ADR) : TU15, TE19

Vehicle for tank carriage : AT Transport category (ADR) : 2

Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7 Special provisions for carriage - Loading, unloading : CV13, CV28

and handling (ADR)

Special provisions for carriage - Operation (ADR) : S9 Hazard identification number (Kemler No.) : 60

Orange plates :

60 2811

Tunnel restriction code (ADR) : E

#### Transport by sea

Special provisions (IMDG) : 223, 274 Limited quantities (IMDG) : 5 kg Excepted quantities (IMDG) : E1 Packing instructions (IMDG) : P002 IBC packing instructions (IMDG) : IBC08 : B3 IBC special provisions (IMDG) Tank instructions (IMDG) : T1 : TP33 Tank special provisions (IMDG) Stowage category (IMDG) : A

Properties and observations (IMDG) : Toxic if swallowed, by skin contact or by inhalation.

#### Air transport

PCA Excepted quantities (IATA) : E1 PCA Limited quantities (IATA) : Y645 PCA limited quantity max net quantity (IATA) 10kg PCA packing instructions (IATA) 670 PCA max net quantity (IATA) 100kg CAO packing instructions (IATA) 677 CAO max net quantity (IATA) 200kg Special provisions (IATA) A3, A5 ERG code (IATA) 6L

#### 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

#### **EU-Regulations**

#### **REACH Annex XVII (Restriction List)**

Not listed on REACH Annex XVII

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#### **REACH Annex XIV (Authorisation List)**

Not listed on REACH Annex XIV (Authorisation List)

#### **REACH Candidate List (SVHC)**

Not listed on the REACH Candidate List

## Ozone Regulation (1005/2009)

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

#### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

#### **Explosives Precursors Regulation (EU 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 (EC 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)

#### 15.2. Chemical safety assessment

No additional information available

## **SECTION 16: Other information**

#### Indication of changes:

Classification of the substance or mixture.

ndication of changes		
Section	Changed item	Comments
	UN-No. (RID)	Added
	Number of blue cones/lights (ADN)	Added
	Equipment required (ADN)	Added
	Carriage permitted (ADN)	Added
	Excepted quantities (ADN)	Added
	Limited quantities (ADN)	Added
	Danger labels (ADN)	Added
	Classification code (ADN)	Added
	Proper Shipping Name (RID)	Added
	Hazard identification number (RID)	Added
	Colis express (express parcels) (RID)	Added
	Special provisions for carriage - Loading, unloading and handling (RID)	Added
	Special provisions for carriage – Bulk (RID)	Added
	Transport category (RID)	Added
	Special provisions for RID tanks (RID)	Added
	Tank codes for RID tanks (RID)	Added
	Portable tank and bulk container special provisions (RID)	Added
	Portable tank and bulk container instructions (RID)	Added

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Indication of changes		
Section	Changed item	Comments
	Mixed packing provisions (RID)	Added
	Special packing provisions (RID)	Added
	Packing instructions (RID)	Added
	Excepted quantities (RID)	Added
	Limited quantities (RID)	Added
	Special provisions (RID)	Added
	Packing group (RID)	Added
	Classification code (RID)	Added
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.1	Name	Modified
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Precautionary statements (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.1	First-aid measures after skin contact	Modified
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added

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Indication of changes		
Section	Changed item	Comments
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Emergency procedures	Added
6.1	Protective equipment	Added
6.1	General measures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Removed
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Storage conditions	Modified
7.3	Specific end uses	Removed
8.2	Eye protection	Modified
8.2	Hand protection	Modified
8.2	Skin and body protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Respiratory protection	Modified
9	Odour	Removed
9	Colour	Added
9	Molecular mass	Added
9	Melting point	Added
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
12.1	Ecology - general	Removed
13.1	Product/Packaging disposal recommendations	Removed
13.1	Regional waste regulation	Removed
14.1	UN-No. (ADN)	Added
14.2	Proper Shipping Name (ADN)	Added
14.3	Danger labels (RID)	Added
14.4	Packing group (ADN)	Added

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Indication of changes		
Section	Changed item	Comments
14.6	Special provisions (ADN)	Added

Full text of H- and EUH-statements:	
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.
H371	May cause damage to organs (nervous system).
STOT SE 2	Specific target organ toxicity – Single exposure, Category 2

Safety Data Sheet (SDS), EU

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