Cisatracurium besilate

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 14/05/2025 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	:	Cisatracurium besilate
Chemical name	:	Cisatracurium besilate
CAS-No.	:	96946-42-8
Product code	:	201600205

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	H371

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).
Precautionary statements (CLP)	:	P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash hands, forearms and face thoroughly after handling. 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]
Cisatracurium besilate	CAS-No.: 96946-42-8	≤ 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.
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

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. yellowish.
Appearance	:	Hygroscopic. Powder.
Molecular mass	:	1243 g/mol
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	89 – 106 °C
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	6.2 – 6.5 (10%, Aqueous solution)
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: 33.3 – 100 g/l
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not 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

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)

Cisatracurium besilate (96946-42-8)	
LD50 oral rat	> 50 – ≤ 300 mg/kg (estimated value)

Skin corrosion/irritation : Not classified (Lack of data)
pH: 6.2 – 6.5 (10%, Aqueous solution)
Serious eye damage/irritation : Not classified (Lack of data)
pH: 6.2 – 6.5 (10%, Aqueous solution)
Respiratory or skin sensitisation : Not classified (Lack of data)
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 (acute) : Not classified (Lack of data)
Hazardous to the aquatic environment, long–term (chronic) : Not classified (Lack of data)

12.2. Persistence and degradability

Cisatracurium besilate (96946-42-8)	
Persistence and degradability	Not rapidly degradable

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

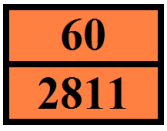
In accordance with ADR / IMDG / IATA

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
		
14.4. Packing group		
III	III	III

ADR	IMDG	IATA
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
No supplementary information available		

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 (ADR)	:	TP33
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 and handling (ADR)	:	CV13, CV28
Special provisions for carriage - Operation (ADR)	:	S9
Hazard identification number (Kemler No.)	:	60
Orange plates	:	
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
IBC special provisions (IMDG)	:	B3
Tank instructions (IMDG)	:	T1
Tank special provisions (IMDG)	:	TP33
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

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

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**

Indication of changes		
Section	**Changed item**	**Comments**
	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**
	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**
	ERG code (IATA)	**Added**
	Special provisions (IATA)	**Added**
	CAO max net quantity (IATA)	**Added**
	CAO packing instructions (IATA)	**Added**
	PCA max net quantity (IATA)	**Added**
	PCA packing instructions (IATA)	**Added**
	PCA limited quantity max net quantity (IATA)	**Added**
	PCA Limited quantities (IATA)	**Added**
	PCA Excepted quantities (IATA)	**Added**
	Danger labels (IATA)	**Added**
	Proper Shipping Name (IATA)	**Added**
	Properties and observations (IMDG)	**Added**
	Proper Shipping Name (IMDG)	**Added**
	Danger labels (IMDG)	**Added**
	EmS-No. (Spillage)	**Added**
	EmS-No. (Fire)	**Added**
	Limited quantities (IMDG)	**Added**
	Stowage category (IMDG)	**Added**
	Tank special provisions (IMDG)	**Added**
	Tank instructions (IMDG)	**Added**
	IBC special provisions (IMDG)	**Added**
	IBC packing instructions (IMDG)	**Added**
	Excepted quantities (IMDG)	**Added**
	Special provisions (IMDG)	**Added**

Indication of changes		
Section	**Changed item**	**Comments**
	Special provisions for carriage - Operation (ADR)	**Added**
	Special provisions for carriage - Loading, unloading and handling (ADR)	**Added**
	Special provisions for carriage - Bulk (ADR)	**Added**
	Tank special provisions (ADR)	**Added**
	Tank code (ADR)	**Added**
	Portable tank and bulk container special provisions (ADR)	**Added**
	Portable tank and bulk container instructions (ADR)	**Added**
	Mixed packing provisions (ADR)	**Added**
	Special packing provisions (ADR)	**Added**
	Packing instructions (ADR)	**Added**
	Vehicle for tank carriage	**Added**
	Supersedes version of	**Added**
	Revision date	**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	Hazard statements (CLP)	**Modified**
2.2	Signal word (CLP)	**Modified**
2.2	Hazard pictograms (CLP)	**Modified**
2.2	Precautionary statements (CLP)	**Modified**
2.3	Other information	**Added**
4.1	First-aid measures general	**Added**
4.1	First-aid measures after skin contact	**Modified**
4.1	First-aid measures after inhalation	**Added**
4.1	First-aid measures after ingestion	**Added**
4.1	First-aid measures after eye contact	**Modified**
5.1	Unsuitable extinguishing media	**Added**
5.1	Suitable extinguishing media	**Modified**

Indication of changes		
Section	**Changed item**	**Comments**
5.2	Hazardous decomposition products in case of fire	**Added**
5.2	Fire hazard	**Removed**
5.3	Protection during firefighting	**Added**
5.3	Firefighting instructions	**Modified**
6.1	Protective equipment	**Added**
6.1	Emergency procedures	**Modified**
6.1	General measures	**Added**
6.2	Environmental precautions	**Added**
6.3	For containment	**Added**
6.3	Methods for cleaning up	**Added**
6.4	Reference to other sections (8, 13)	**Added**
7.1	Precautions for safe handling	**Added**
7.1	Hygiene measures	**Added**
7.2	Storage conditions	**Added**
7.2	Packaging materials	**Added**
7.3	Specific end uses	**Removed**
8.2	Respiratory protection	**Added**
8.2	Hand protection	**Modified**
8.2	Eye protection	**Added**
8.2	Appropriate engineering controls	**Modified**
8.2	Skin and body protection	**Modified**
9	Colour	**Added**
9	Molecular mass	**Added**
9	Appearance	**Modified**
9	pH	**Added**
9	Melting point	**Added**
10.1	Reactivity	**Removed**
10.3	Possibility of hazardous reactions	**Removed**
10.5	Incompatible materials	**Removed**
10.6	Hazardous decomposition products	**Removed**
11.1	LD50 oral rat	**Added**
11.1	ATE CLP (oral)	**Added**
12.1	Ecology - general	**Removed**
14.1	UN-No. (ADN)	**Added**
14.1	UN-No. (IMDG)	**Added**
14.1	UN-No. (IATA)	**Added**
14.1	UN-No. (ADR)	**Added**

Indication of changes		
Section	**Changed item**	**Comments**
14.2	Proper Shipping Name (ADN)	**Added**
14.2	Proper Shipping Name (ADR)	**Added**
14.3	Danger labels (RID)	**Added**
14.3	Danger labels (ADR)	**Added**
14.3	Class (ADR)	**Added**
14.4	Packing group (ADN)	**Added**
14.4	Packing group (IATA)	**Added**
14.4	Packing group (IMDG)	**Added**
14.4	Packing group (ADR)	**Added**
14.6	Special provisions (ADN)	**Added**
14.6	Packing instructions (IMDG)	**Added**
14.6	Transport category (ADR)	**Added**
14.6	Special provisions (ADR)	**Added**
14.6	Excepted quantities (ADR)	**Added**
14.6	Limited quantities (ADR)	**Added**
14.6	Tunnel restriction code (ADR)	**Added**
14.6	Hazard identification number (Kemler No.)	**Added**
14.6	Classification code (ADR)	**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

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. 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.