



## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Revision date: 17/02/2025 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 : Oxytocin for NMR identification

Chemical name : Oxytocin monoacetate

EC-No. : 228-347-5 CAS-No. : 6233-83-6 Product code : 202200222

#### 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
Acute toxicity (inhal.), Category 3 H331
Respiratory sensitisation, Category 1 H334
Skin sensitisation, Category 1 H317
Reproductive toxicity, Category 1B H360D

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

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

Toxic if swallowed. Toxic if inhaled. May damage the unborn child. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :





GHS06

GHS08

Signal word (CLP) : Danger

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Hazard statements (CLP) : H301+H331 - Toxic if swallowed or if inhaled.

H317 - May cause an allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H360D - May damage the unborn child.

Precautionary statements (CLP) P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P261 - Avoid breathing 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.

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

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P284 - Wear respiratory protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.

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

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P311 - Call a POISON CENTER or doctor.

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

P330 - Rinse mouth.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

P362+P364 - Take off contaminated clothing and wash it before reuse.

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

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]
Oxytocin monoacetate	CAS-No.: 6233-83-6 EC-No.: 228-347-5	≤ 100	Acute Tox. 3 (Oral), H301 (ATE=100 mg/kg bodyweight) Acute Tox. 3 (Inhalation), H331 (ATE=0.5 mg/l/4h) Resp. Sens. 1, H334 Skin Sens. 1, H317 Repr. 1B, H360D

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

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#### **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 : Immediately call a POISON CENTER/doctor. Remove person to fresh air and keep

comfortable for breathing. Allow the victim to rest. If experiencing respiratory symptoms:

Call a poison center or a doctor.

First-aid measures after skin contact : Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms

persist, call a physician.

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

Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/effects after skin contact : May cause an allergic skin reaction.

#### 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.

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#### 6.4. Reference to other sections

See Section 13 for disposal information.

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

#### 7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.

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 : Not available
Molecular mass : 1067 g/mol
Odour : Not available
Odour threshold : Not available
Melting point : Not available

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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 рΗ : Not available pH solution Not available : Not applicable Viscosity, kinematic Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Not available Vapour pressure Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not applicable : Not available Particle size

#### 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)

Acute toxicity (inhalation) : Toxic if inhaled.

## Oxytocin monoacetate (6233-83-6)

LD50 oral rat 50 – 300 mg/kg

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

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

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Germ cell mutagenicity : Not classified (Lack of data)
Carcinogenicity : Not classified (Lack of data)
Reproductive toxicity : May damage the unborn child.
STOT-single exposure : Not classified (Lack of data)
STOT-repeated exposure : Not classified (Lack of data)

Aspiration hazard : Not classified (Technical impossibility to obtain the 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)

Hazardous to the aquatic environment, long-term

(chronic)

: Not classified (Lack of data): Not classified (Lack of data)

## 12.2. Persistence and degradability

## Oxytocin monoacetate (6233-83-6)

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	Not applicable
14.2. UN proper shipping name		
TOXIC SOLID, ORGANIC, N.O.S.	TOXIC SOLID, ORGANIC, N.O.S.	Not applicable

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ADR	IMDG	IATA
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	Not applicable
14.3. Transport hazard class(es)		
6.1	6.1	Not applicable
6	6	Not applicable
14.4. Packing group		
III	III	Not applicable
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	Not applicable
No supplementary information available	1	

## 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 IBC special provisions (IMDG) : B3 Tank instructions (IMDG) T1 Tank special provisions (IMDG) : TP33

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Stowage category (IMDG) : A

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

#### Air transport

Not applicable

#### 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
	Supersedes version of	Added
	Revision date	Added
1.1	EC-No.	Added
1.1	CAS-No.	Added
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
2.3	Other information	Added

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
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
4.2	Symptoms/effects	Removed
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Modified
4.2	Symptoms/effects after inhalation	Modified
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
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	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	Modified
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	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	Odour	Removed

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Indication of changes		
Section	Changed item	Comments
9	Molecular mass	Added
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
12.1	Ecology - general	Removed
13.1	Product/Packaging disposal recommendations	Removed
13.1	Regional waste regulation	Removed

Full text of H- and EUH-statements:	
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D	May damage the unborn child.
Repr. 1B	Reproductive toxicity, Category 1B
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

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