

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 3447208-00015 Date of last issue: 04.12.2024 Date of first issue: 26.09.2018

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### SECTION 1. IDENTIFICATION

Product identifier : Oxytocin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530  
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

#### Other hazards which do not result in classification

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Oxytocin, monoacetate (salt)	6233-83-6	Acute Tox. (Oral), 4 Repr., 1A Aquatic Chronic, 4	>= 0,0003 -< 0,0025

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### SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact

: Flush eyes with water as a precaution.

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 3447208-00015	Date of last issue: 04.12.2024 Date of first issue: 26.09.2018
----------------	------------------------------	------------------------------	---

If swallowed	Get medical attention if irritation develops and persists. : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
Notes to physician	: Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: No hazardous combustion products are known
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Soak up with inert absorbent material. For large spills, provide diking or other appropriate

# SAFETY DATA SHEET



## Oxytocin Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
3447208-00015

Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.

Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

Hygiene measures : When using do not eat, drink or smoke.

Hygiene measures : Wash contaminated clothing before re-use.

Hygiene measures : The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Materials to avoid : Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Materials to avoid : Strong oxidizing agents

Materials to avoid : Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Oxytocin, monoacetate (salt)	6233-83-6	STEL	50 ng/m <sup>3</sup> (OEB 5)	Internal
		Wipe limit	500 ng/100 cm <sup>2</sup>	Internal

Engineering measures : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 3447208-00015	Date of last issue: 04.12.2024 Date of first issue: 26.09.2018
----------------	------------------------------	------------------------------	---

risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

### Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally required.
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: liquid
Color	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 3447208-00015      Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

---

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.

**Oxytocin Formulation**

Version 3.0      Revision Date: 14.04.2025      SDS Number: 3447208-00015      Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

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tions  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****Oxytocin, monoacetate (salt):**

Acute oral toxicity	: LD50 (Mouse): > 514 mg/kg
	LD50 (Rat): > 21 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Mouse): > 514 mg/kg Application Route: Subcutaneous
	LD50 (Mouse): 5,8 mg/kg Application Route: Intravenous
	LD50 (Rat): > 21 mg/kg Application Route: Subcutaneous
	LD50 (Rat): 2,3 mg/kg Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Oxytocin, monoacetate (salt):**

Genotoxicity in vitro	: Test Type: Chromosomal aberration Test system: Human lymphocytes
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**Oxytocin Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
3447208-00015Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Oxytocin, monoacetate (salt):**

Effects on fetal development	:	Test Type: Development Species: Rat Application Route: Subcutaneous Developmental Toxicity: NOAEL: 1 mg/kg body weight Result: No effects on fetal development.
Reproductive toxicity - Assessment	:	May damage the unborn child.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Oxytocin, monoacetate (salt):**

Species	:	Rat
LOAEL	:	5 µg/kg
Application Route	:	Subcutaneous
Exposure time	:	5 Days
Target Organs	:	Endocrine system

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Oxytocin, monoacetate (salt):**

Inhalation	:	Target Organs: Central nervous system Symptoms: behavioral abnormalities Target Organs: Cardio-vascular system Symptoms: Increased heart rate, May cause cardiac arrhythmia., hypotension, tachycardia, flushing Target Organs: Gastrointestinal tract Symptoms: Nausea, Vomiting
Ingestion	:	Target Organs: Central nervous system Symptoms: behavioral abnormalities Target Organs: Cardio-vascular system Symptoms: Increased heart rate, May cause cardiac arrhythmia., hypotension, tachycardia, flushing

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 3447208-00015 Date of last issue: 04.12.2024 Date of first issue: 26.09.2018

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mia., hypotension, tachycardia, flushing  
Target Organs: Gastrointestinal tract  
Symptoms: Nausea, Vomiting

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### Oxytocin, monoacetate (salt):

#### Ecotoxicology Assessment

|||  
Acute aquatic toxicity : Toxic effects cannot be excluded

|||  
Chronic aquatic toxicity : Toxic effects cannot be excluded

#### Persistence and degradability

No data available

#### Bioaccumulative potential

#### Components:

##### Oxytocin, monoacetate (salt):

|||  
Partition coefficient: n-octanol/water : log Pow: 6,27

#### Mobility in soil

No data available

#### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

# SAFETY DATA SHEET



## Oxytocin Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 3447208-00015      Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### ANTT

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - : Not applicable  
(LINACH)

Brazil. List of chemicals controlled by the Federal Police : Not applicable

### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

# SAFETY DATA SHEET



## Oxytocin Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
3447208-00015

Date of last issue: 04.12.2024  
Date of first issue: 26.09.2018

- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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