

## Oxytocin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/12/04
8.0	2025/04/14	3447252-00015	Date of first issue: 2018/09/26

## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxytocin Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

**GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Oxytocin, monoacetate (salt)	6233-83-6	$\geq 0.0002$ - $< 0.0025$	-

## 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.

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In case of eye contact	: Get medical attention if symptoms occur. Flush eyes with water as a precaution.
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.

**5. FIREFIGHTING MEASURES**

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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 firefighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

**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.

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Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

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## 7. HANDLING AND STORAGE

### Handling

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

Avoidance of contact : Oxidizing agents

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
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.

### Storage

Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.

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

Packaging material : Unsuitable material: None known.

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Oxytocin, monoacetate (salt)	6233-83-6	STEL	50 ng/m3 (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 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.

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Use appropriate degowning techniques to remove potentially contaminated clothing.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	No data available

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Density	:	No data available
Relative vapour density	:	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

**10. STABILITY AND REACTIVITY**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

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

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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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

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  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

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

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: NOAEL: 1 mg/kg body weight  
Result: No effects on foetal 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.

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## 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
		Target Organs: Gastrointestinal tract Symptoms: Nausea, Vomiting

## 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



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**Persistence and degradability**

No data available

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

Partition coefficient: n-octanol/water	: log Pow: 6.27
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**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

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**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues	: Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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.

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Environmentally hazardous	: no

**IATA-DGR**

UN/ID No.	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Packing instruction (cargo aircraft)	: Not applicable
Packing instruction (passenger aircraft)	: Not applicable

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**IMDG-Code**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**Special precautions for user**

Not applicable

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**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

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**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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**The components of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

**16. OTHER INFORMATION****Further information**

Sources of key data used to compile the 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.

Date format : yyyy/mm/dd

**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 - 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; KECI - 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 Recom-

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mendations 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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