

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Oxytocin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
1.15	28.09.2024	3468153-00016	Date of first issue: 26.09.2018

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

1.1	Product identifier		
	Trade name	:	Oxytocin Formulation
1.2	Relevant identified uses of t	he s	ubstance or mixture and uses advised against
	Use of the Sub- stance/Mixture	:	Veterinary product
	Recommended restrictions on use	:	Not applicable
1.3	Details of the supplier of the	safe	ety data sheet
	Company	:	MSD
			Kilsheelan
			Clonmel Tipperary, IE
	Telephone	:	353-51-601000
	E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.



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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. Classification		Concentration	
	EC-No.		(% w/w)	
	Index-No.			
	Registration number			
Oxytocin, monoacetate (salt)	6233-83-6	Acute Tox. 4; H302	>= 0.0002 - <	
	228-347-5	Repr. 1A; H360D	0.0025	
		Aquatic Chronic 4;		
		H413		

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders	:	No special precautions are necessary for first aid responders.
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. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

	Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
	Unsuitable extinguishing media	:	None known.
5.2	Special hazards arising from	the	e substance or mixture
	Specific hazards during fire- fighting	:	Exposure to combustion products may be a hazard to health.
	Hazardous combustion prod- ucts	:	No hazardous combustion products are known
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. Use personal protective equipment.
	Specific extinguishing meth-	:	Use extinguishing measures that are appropriate to local cir-

Use extinguishing measures that are appropriate to local cir-Specific extinguishing methcumstances and the surrounding environment. ods Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do SO. Evacuate area.

SECTION 6: Accidental release measures

6 1 D 4 - - 4 -4 .

6.1 Personal precautions, protec	tive	e equipment and emergency procedures
Personal precautions	:	Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8).
6.2 Environmental precautions		
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.

6.3 Methods and material for containment and cleaning up

:	Soak up with inert absorbent material.
	For large spills, provide dyking or other appropriate contain-
	ment to keep material from spreading. If dyked material can
	:

cannot be contained.

Local authorities should be advised if significant spillages

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		Clean up remain bent. Local or national posal of this mate employed in the mine which regul Sections 13 and	e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

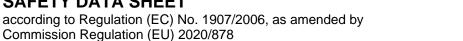
7.1 Precautions for safe handling	g		
Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.	
Local/Total ventilation	:	Use only with adequate ventilation.	
Advice on safe handling	:	Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment 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. When using do not eat, drink or smoke. Wash contami- nated 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.	
7.2 Conditions for safe storage,	inc	luding any incompatibilities	
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.	
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Gases	
7.3 Specific end use(s)			
Specific use(s)	:	No data available	

7.1 Precautions for safe handling

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits





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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis

		of exposure)		
Oxytocin, mono- acetate (salt)	6233-83-6	STEL	50 ng/m3 (OEB 5)	Internal
		Wipe limit	500 ng/100 cm ²	Internal

8.2 Exposure controls

Engineering measures

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

Eye/face 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	No personal respiratory protective equipment normally re- quired.

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

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	Initial boiling point and boiling range		:	No data available	9
	Flamm	ability (solid, gas)	:	Not applicable	
	Flamm	ability (liquids)	:	No data available	9
		explosion limit / Upper ability limit	:	No data available	2
		explosion limit / Lower ability limit	:	No data available	9
	Flash p	point	:	No data available	2
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	рН		:	No data available	9
	Viscos Viso	ity cosity, kinematic	:	No data available	9
	Solubil Wa	ity(ies) ter solubility	:	No data available	9
	Partitio octano	n coefficient: n- I/water	:	Not applicable	
	Vapou	r pressure	:	No data available	9
	Relativ	e density	:	No data available	9
	Density	ý	:	No data available	9
	Relativ	e vapour density	:	No data available	9
		e characteristics ticle size	:	Not applicable	
9.2	Other in Explos	nformation ives	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapoi	ration rate	:	No data available	9
	Molecu	ılar weight	:	No data available	9

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SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of	:	Inhalation
exposure		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

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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.

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

Reproductive toxicity - As- : May damage the unborn child.

sessment

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

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	Species:LOAEL:Application Route:Exposure time:Target Organs:			Rat 5 µg/kg Subcutaneous 5 Days Endocrine system			
	-	tion toxicity ssified based on availa	able	information.			
11.2	Inform	ation on other hazard	ds				
	Endoc	rine disrupting prope	rtie	S			
	Produ	<u>ct:</u>					
	Assessment :		The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.				
	Experi	ence with human exp	osi	ıre			
	Compo	onents:					
	Oxytoo	cin, monoacetate (sal	t):				
	Inhalat		:	Symptoms: behave Target Organs: C Symptoms: Increase mia., hypotension Target Organs: G Symptoms: Naus Target Organs: C Symptoms: behave Target Organs: C	entral nervous system vioral abnormalities ardio-vascular system ased heart rate, May cause cardiac arrhyth- astrointestinal tract ea, Vomiting entral nervous system vioral abnormalities ardio-vascular system ased heart rate, May cause cardiac arrhyth-		
				mia., hypotensior	n, tachycardia, flushing astrointestinal tract		

SECTION 12: Ecological information

12.1 Toxicity

Components:

Oxytocin, monoacetate (salt):

Ecotoxicology Assessment

Acute aquatic toxicity		Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Symptoms: Nausea, Vomiting

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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Oxytocin, monoacetate (salt):

Partition coefficient: n- : log Pow: 6.27 octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment

This substance/mixture contains no components considered : to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment The substance/mixture does not contain components consid-: ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

12.1 Wasta traatmant mathada

13.1 Waste treatment methods	
Product	 Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	 Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN

Not regulated as a dangerous good :

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		: Not regulated as a dangerous good	
ADR		5 5 5	
RID		: Not regulated as a dangerous good	
IMDG		: Not regulated as a dangerous good	
		: Not regulated as a dangerous good	
14.2 UN p	roper shipping nam		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	;	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.3 Trans	sport hazard class(e)	
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	ì	: Not regulated as a dangerous good	
ΙΑΤΑ		: Not regulated as a dangerous good	
14.4 Pack	ing group		
ADN		: Not regulated as a dangerous good	
ADR		: Not regulated as a dangerous good	
RID		: Not regulated as a dangerous good	
IMDG	ì	: Not regulated as a dangerous good	
ΙΑΤΑ	(Cargo)	: Not regulated as a dangerous good	
	(Passenger)	: Not regulated as a dangerous good	
14.5 Envii	ronmental hazards		
-	ial precautions for upplicable	er	
14.7 Marit	ime transport in bul	according to IMO instruments	
Rema	arks	: Not applicable for product as supplied.	

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on : Not applicable the market and use of certain dangerous substances,

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REACH	es and articles (Annex) I - Candidate List of Su In for Authorisation (Art	ubstances of Very High	:	Not applicable
Regulation (EC) on substances that deplete the ozone				Not applicable
layer Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)				Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals				Not applicable
REACH - List of substances subject to authorisation (Annex XIV)			:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parlian major-accident hazards involving dangerous substances. Not applicable				nt and of the Council on the control of

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	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 H-Statements

H360D :	Harmful if swallowed. May damage the unborn child. May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Aquatic Chronic :	Acute toxicity Long-term (chronic) aquatic hazard Reproductive toxicity
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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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 as-



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sociated with x% growth rate response; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

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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