



CONSEIL DE L'EUROPI

Ergometrine

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Ergometrine
CAS-No.	: 60-79-7
Product code	: 201600350
Synonyms	: Ergometrine, salts, hydrates, isomers and impurities where applicable

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category Use of the substance/mixture Function or use category	 The product is intended for research, analysis and scientific education. For professional use only Laboratory chemicals
1.2.2. Uses advised against	
Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal

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 <u>sds@edqm.eu</u> - <u>www.edqm.eu</u>

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 (inhal.), Category 3 H331 Reproductive toxicity, Category 1B H360 Specific target organ toxicity – Repeated exposure, Category 1 H372 Full text of H- and EUH-statements: see section 16 H372

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

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)	: H331 - Toxic if inhaled.
	H360 - May damage fertility or the unborn child.
	H372 - Causes damage to organs through prolonged or repeated exposure.
Precautionary statements (CLP)	: P202 - Do not handle until all safety precautions have been read and understood.
,	P308+P313 - IF exposed or concerned: Get medical advice/attention.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

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Hazard pictograms (CLP)



2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ergometrine	CAS-No.: 60-79-7	≤ 100	Acute Tox. 3 (Inhalation), H331 (ATE=0.5 mg/l/4h) Repr. 1B, H360 STOT RE 1, H372

3.2. Mixtures

Not applicable

4.1. Description of first aid measures	
First-aid measures after inhalation	: Move to fresh air. Allow affected person to breathe fresh air.
First-aid measures after skin contact	: Wipe off as much as possible (using a clean, soft, absorbent material). Wash with plenty o water/
First-aid measures after eye contact	: Rinse with water while holding the eyes wide open.
First-aid measures after ingestion	: Rinse mouth. Immediately call a POISON CENTER/doctor. Specific medical surveillance. Prolonged medical observation may be indicated.
4.2. Most important symptoms and e	ffects, both acute and delayed
Symptoms/effects	: Nervous system disorders. Reproductive system and breast disorders. Skin and subcutaneous tissue disorders. Delayed adverse effects possible.
Symptoms/effects after inhalation	: Insufficient data available.
Symptoms/effects after skin contact	: Insufficient data available.
Symptoms/effects after eye contact	: Insufficient data available.
Symptoms/effects after ingestion	: Symptoms may include dizziness, headache, nausea and loss of coordination.

Get medical advice/attention. If possible show this sheet, if not available show packaging or label. Active substance. Pharmaceutical.

SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable extinguishing media	: Extinguishing blanket.	
5.2. Special hazards arising from the substance or mixture		
Fire hazard	: See Heading 2.2.	

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5.3. Advice for firefighters	
Firefighting instructions	: Use extinguishing media appropriate for surrounding fire.

SECTION 6: Accidental release measu	res
6.1. Personal precautions, protective equip	ment and emergency procedures
General measures	: Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapours/spray.
6.1.1. For non-emergency personnel	
Emergency procedures	: Wear suitable protective clothing, gloves and eye or face protection.
6.1.2. For emergency responders	
No additional information available	
6.2. Environmental precautions	
No additional information available	
6.3. Methods and material for containment	and cleaning up
Methods for cleaning up	: Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with : Sodium hypochlorite solution.
6.4. Reference to other sections	

No additional information available

SECTION 7: Handling and storag	e
7.1. Precautions for safe handling	
Additional hazards when processed	: The attention of the user is drawn to the risks possibly incurred by using the product for any other purpose than that for which it was intended.
Precautions for safe handling	: Material should be handled with caution. Avoid any direct contact with the product. Material should be handled in a laboratory hood whenever possible.
Hygiene measures	: Handle in accordance with good industrial hygiene and safety procedures.
7.2. Conditions for safe storage, incl	uding any incompatibilities
Technical measures Storage conditions	Comply with applicable regulations.Store locked up.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

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8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Use only in a exhaust booth with integrated air filter. High efficiency particulate air filter (HEPA filter).

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection: Safety glasses. DIN EN 166

8.2.2.2. Skin protection

Skin and body protection:

Use chemically protective clothing. DIN EN 13034

Hand protection:

Chemically resistant protective gloves. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Dust production: dust mask with filter type P3. DIN EN 140 & 149. Liquid product : Aerosol mask. Wear breathing apparatus if exposed to vapours/dusts/aerosols

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	
Physical state	: Solid
Colour	: Not available
Appearance	: Powder.
Odour	: Not applicable.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
рН	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 10 – 33.3 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

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Particle	size
I allicie	3120

: Not available

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

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

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

	11.1. Information on haza	ard classes as defined in Reg	Julation (EC) No 1272/2008
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Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Toxic if inhaled.
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: May damage fertility or the unborn child.
Additional information	: Pregnancy, puerperium and perinatal conditions
	Possible premature birth
STOT-single exposure	: Not classified (Conclusive but not sufficient for classification)
STOT-repeated exposure	: Causes damage to organs through prolonged or repeated exposure.
Additional information	: Vascular disorders
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information		
12.1. Toxicity		
Ecology - general: Hazardous waste. Use suitable disposal containers.Hazardous to the aquatic environment, short-term (acute): Not classifiedHazardous to the aquatic environment, long-term (chronic): Not classified		
12.2. Persistence and degradability		
No additional information available		
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			
Regional legislation (waste) Product/Packaging disposal recommendations	 Dispose in a safe manner in accordance with local/national regulations. Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point. 		

ADR	IMDG	ΙΑΤΑ		
14.1. UN number or ID number				
UN 1544	UN 1544	UN 1544		
14.2. UN proper shipping name				
ALKALOIDS, SOLID, N.O.S.	ALKALOIDS, SOLID, N.O.S.	Alkaloids, solid, n.o.s.		
Transport document description				
UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, III, (E)	UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, III	UN 1544 Alkaloids, solid, n.o.s., 6.1, III		
14.3. Transport hazard class(es)				
6.1	6.1	6.1		

SECTION 14: Transport information

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ADR	IMDG	ΙΑΤΑ
6	6	6
14.4. Packing group		
Ш	III	Ш
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No
No supplementary information available		
14.6. Special precautions for user		
Overland transport Classification code (ADR) Special provisions (ADR) Limited quantities (ADR) Excepted quantities (ADR) Packing instructions (ADR) Special packing provisions (ADR) Mixed packing provisions (ADR) Portable tank and bulk container instructions (ADR) Portable tank and bulk container special provisions (ADR) Tank code (ADR) Tank code (ADR) Tank special provisions (ADR) Vehicle for tank carriage Transport category (ADR) Special provisions for carriage - Bulk (ADR) Special provisions for carriage - Loading, unloading and handling (ADR) Special provisions for carriage - Operation (ADR) Hazard identification number (Kemler No.) Orange plates	 : TP33 : SGAH, L4BH : TU15, TE19 : AT : 2 : VC1, VC2, AP7 	
Tunnel restriction code (ADR) Transport by sea Special provisions (IMDG) Limited quantities (IMDG) Excepted quantities (IMDG) Packing instructions (IMDG) IBC packing instructions (IMDG) IBC special provisions (IMDG) Tank instructions (IMDG) Tank special provisions (IMDG) EmS-No. (Fire) EmS-No. (Spillage) Stowage category (IMDG) Properties and observations (IMDG)	 E 43, 223, 274 5 kg E1 P002, LP02 IBC08 B3 T1 TP33 F-A S-A A A wide range of toxic solids, generally of vecontact or by inhalation. 	egetable origin. Toxic if swallowed, by skin
Air transport PCA Excepted quantities (IATA) PCA Limited quantities (IATA)	: E1 : Y645	

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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, A4, A6, A801
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

15.1.1. 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

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (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 (273/2004)

Contains 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)

Name	CN designation	CAS-No.	CN code	Category	Threshold	Annex
Ergometrine		60-79-7	2939 61 00	Category 1		Annex I

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Regulatory information.

Full text of H- and EUH-statements:	
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3

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Full text of H- and EUH-statements:		
H331	Toxic if inhaled.	
H360	May damage fertility or the unborn child.	
H372	Causes damage to organs through prolonged or repeated exposure.	
Repr. 1B	Reproductive toxicity, Category 1B	
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1	

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. 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 article.