

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Section 1: Identification

Product name : Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification**GHS Classification**

Flammable liquids : Category 4

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Acute toxicity (Dermal) : Category 4

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 1

Specific target organ toxicity - single exposure : Category 2 (Nervous system, muscle)

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 1

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

GHS label elements

Hazard pictograms



Signal word

: Danger

Hazard statements

: H227 Combustible liquid.
H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.
H371 May cause damage to organs (Nervous system, muscle).
H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements

Prevention:

P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/ doctor if you feel unwell.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version 9.0 Revision Date: 14.04.2025 SDS Number: 1714274-00024 Date of last issue: 04.12.2024
Date of first issue: 25.05.2017

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N-Dimethylformamide	68-12-2	≥ 50 -< 70
Embutramide	15687-14-6	≥ 20 -< 25
Mebezonium iodide	7681-78-9	≥ 1 -< 10
tetracaine hydrochloride	136-47-0	≥ 0.1 -< 1

Section 4: First-aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed, in contact with skin or if inhaled.
Causes serious eye irritation.
May cause drowsiness or dizziness.
May damage the unborn child.
May cause damage to organs.
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version 9.0	Revision Date: 14.04.2025	SDS Number: 1714274-00024	Date of last issue: 04.12.2024 Date of first issue: 25.05.2017
----------------	------------------------------	------------------------------	---

Notes to physician : when the potential for exposure exists (see section 8).
: 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 : High volume water jet

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)

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 : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Use personal protective equipment.
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 : Non-sparking tools should be used.
Soak up with inert absorbent material.

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
9.0	14.04.2025	1714274-00024	04.12.2024
			Date of first issue: 25.05.2017

Suppress (knock down) gases/vapours/mists with a water spray jet.
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.

Section 7: Handling and storage

- | | | |
|-----------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
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 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. |
| Conditions for safe storage | : | Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations. |

Embutramide / Mebezonium / Tetracaine For- mulation

Version 9.0 Revision Date: 14.04.2025 SDS Number: 1714274-00024 Date of last issue: 04.12.2024
Date of first issue: 25.05.2017

Materials to avoid : Keep away from heat and sources of ignition.
Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylformamide	68-12-2	WES-TWA	5 ppm 15 mg/m3	NZ OEL
	Further information: Skin absorption			
		TWA	5 ppm	ACGIH
Embutramide	15687-14-6	TWA	10 µg/m3 (OEB 3)	Internal
		STEL	30 µg/m3	Internal
		Wipe limit	100 µg/100 cm ²	Internal
Mebezonium iodide	7681-78-9	TWA	1 µg/m3 (OEB 4)	Internal
		STEL	3 µg/m3 (OEB 4)	Internal
		Wipe limit	10 µg/100 cm ²	Internal
tetracaine hydrochloride	136-47-0	TWA	5 µg/m3 (OEB 4)	Internal
	Further information: DSEN, Skin			
		Wipe limit	50 µg/100 cm ²	Internal

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N,N-Dimethylformamide	68-12-2	Total N-Methylformamide	Urine	End of shift (As soon as possible after exposure ceases)	30 mg/l	ACGIH BEI
		N-Acetyl-S-(N-methylcarbamoyl) cysteine	Urine	End of shift at end of work-week	30 mg/l	ACGIH BEI

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

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

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.

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

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

- | | | |
|--------------------------|---|--|
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Combined particulates, ammonia/amines and organic vapour type |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection. |
| 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

- | | | |
|-----------------|---|-------------------|
| Appearance | : | liquid |
| Colour | : | No data available |
| Odour | : | No data available |
| Odour Threshold | : | No data available |

Embutramide / Mebezonium / Tetracaine Formulation

Version 9.0	Revision Date: 14.04.2025	SDS Number: 1714274-00024	Date of last issue: 04.12.2024 Date of first issue: 25.05.2017
----------------	------------------------------	------------------------------	---

pH	:	5 - 6
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	81 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition 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	:	Not applicable
Particle characteristics Particle size	:	Not applicable

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Combustible liquid. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Harmful if swallowed, in contact with skin or if inhaled.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 567.4 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 19.41 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 1,942 mg/kg Method: Calculation method

Components:**N,N-Dimethylformamide:**

Acute oral toxicity	:	Acute toxicity estimate: 500 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.
Acute inhalation toxicity	:	Acute toxicity estimate: 11 mg/l Exposure time: 4 h Test atmosphere: vapour Method: Expert judgement Remarks: Based on national or regional regulation.

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

|| Acute dermal toxicity :**||** Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.**Embutramide:****||** Acute oral toxicity : LD50 (Rat): 1,550 mg/kg**||** Acute toxicity (other routes of administration) : LD50 (Dog): 31 mg/kg
Application Route: IntravenousTDLo (Dog): 15.5 mg/kg
Application Route: Intravenous
Symptoms: narcosisLD50 (Horse): 20 mg/kg
Application Route: IntravenousLD50 (sheep): 80 mg/kg
Application Route: IntravenousLD50 (Pig): 100 mg/kg
Application Route: Intravenous**Mebezonium iodide:****||** Acute oral toxicity : LD50 (Rat, female): 200 - 300 mg/kg**||** Acute toxicity (other routes of administration) : LC50 (Dog): 15 mg/kg
Application Route: Intravenous**tetracaine hydrochloride:****||** Acute toxicity (other routes of administration) : LD50 (Rat): 6 mg/kg
Application Route: IntravenousLD50 (Mouse): 6 mg/kg
Application Route: Intravenous**Skin corrosion/irritation**

Not classified based on available information.

Components:**N,N-Dimethylformamide:****||** Species : Rabbit
|| Result : No skin irritation

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**N,N-Dimethylformamide:**

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**N,N-Dimethylformamide:**

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Result	: negative

tetracaine hydrochloride:

Exposure routes	: Dermal
Result	: Sensitiser

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**N,N-Dimethylformamide:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
	Test Type: DNA damage and repair, unscheduled DNA syn- thesis in mammalian cells (in vitro) Result: negative

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: inhalation (vapour) Result: negative Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Intraperitoneal injection Result: negative
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tetracaine hydrochloride:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Result: equivocal
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Rat Result: negative

Carcinogenicity

Not classified based on available information.

Components:**N,N-Dimethylformamide:**

Species	: Rat
Application Route	: inhalation (vapour)
Exposure time	: 2 Years
Method	: OECD Test Guideline 451
Result	: negative

Species	: Mouse
Application Route	: inhalation (vapour)
Exposure time	: 18 Months
Method	: OECD Test Guideline 451
Result	: negative

Reproductive toxicity

May damage the unborn child.

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Components:**N,N-Dimethylformamide:**

- | | | |
|------------------------------------|---|--|
| Effects on fertility | : | Test Type: Two-generation study |
| | | Species: Mouse |
| | | Application Route: Ingestion |
| | | Result: negative |
| | | Test Type: One-generation reproduction toxicity study |
| | | Species: Rat |
| | | Application Route: Skin contact |
| | | Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development |
| | | Species: Rabbit |
| | | Application Route: inhalation (vapour) |
| | | Method: OECD Test Guideline 414 |
| | | Result: positive |
| | | Test Type: Embryo-foetal development |
| | | Species: Rabbit |
| | | Application Route: Skin contact |
| | | Method: OECD Test Guideline 414 |
| | | Result: positive |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on development, based on animal experiments. |

tetracaine hydrochloride:

- | | | |
|-------------------------------|---|---|
| Effects on fertility | : | Test Type: Fertility |
| | | Species: Rat, male and female |
| | | Application Route: Subcutaneous |
| | | Fertility: NOAEL: 7.5 mg/kg body weight |
| | | Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Development |
| | | Species: Rat |
| | | Application Route: Subcutaneous |
| | | Developmental Toxicity: NOAEL: 5 mg/kg body weight |
| | | Result: No teratogenic effects |
| | | Test Type: Development |
| | | Species: Rabbit |
| | | Application Route: Subcutaneous |
| | | Developmental Toxicity: NOAEL: 10 mg/kg body weight |
| | | Result: No teratogenic effects |

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

STOT - single exposure

May cause drowsiness or dizziness.

May cause damage to organs (Nervous system, muscle).

Components:**Embutramide:**

Assessment	:	May cause drowsiness or dizziness.
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Mebezonium iodide:

Target Organs	:	Nervous system, muscle
Assessment	:	May cause damage to organs.

tetracaine hydrochloride:

Target Organs	:	Central nervous system, Cardio-vascular system
Assessment	:	Causes damage to organs.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:**N,N-Dimethylformamide:**

Assessment	:	Causes damage to organs through prolonged or repeated exposure.
Remarks	:	Based on national or regional regulation.

Repeated dose toxicity**Components:****N,N-Dimethylformamide:**

Species	:	Rat
NOAEL	:	238 mg/kg
LOAEL	:	475 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days

Species	:	Rat
NOAEL	:	0.08 mg/l
LOAEL	:	0.3 mg/l
Application Route	:	inhalation (vapour)
Exposure time	:	2 yr

Aspiration toxicity

Not classified based on available information.

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Experience with human exposure**Components:****Embutramide:**

Inhalation	: Target Organs: Central nervous system Symptoms: Drowsiness, Central nervous system depression, muscle weakness, Shortness of breath
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Mebezonium iodide:

Inhalation	: Symptoms: Weakness, Fatigue, Breathing difficulties
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tetracaine hydrochloride:

Inhalation	: Target Organs: Cardio-vascular system Target Organs: Central nervous system Symptoms: Central nervous system depression, Dizziness, Headache, hypotension, Vomiting
Skin contact	: Symptoms: Redness, pruritis

Section 12: Ecological information**Ecotoxicity****Components:****N,N-Dimethylformamide:**

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 7,100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 13,100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 1,500 mg/l Exposure time: 21 d

Embutramide:

Toxicity to fish	: LC50 : 21 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 24 h

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

Persistence and degradability**Components:****N,N-Dimethylformamide:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 21 d
Method: OECD Test Guideline 301E

Bioaccumulative potential**Components:****N,N-Dimethylformamide:**

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 0.3 - 1.2
Method: OECD Test Guideline 305C

Partition coefficient: n-octanol/water : log Pow: -0.93
Remarks: Calculation

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.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

Section 14: Transport information**International Regulations**

UNRTDG

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

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

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**NZS 5433**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 14.04.2025

Further informationSources 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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

**Embutramide / Mebezonium / Tetracaine For-
mulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
9.0	14.04.2025	1714274-00024	Date of first issue: 25.05.2017

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 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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