

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Flammable liquid

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 2A


Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

GHS label elements

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
 Date of first issue: 25.05.2017

- 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.
- Precautionary statements : **Prevention:**
 P203 Obtain, read and follow all safety instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P261 Avoid breathing 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 + P317 + P330 IF SWALLOWED: Get medical help. Rinse mouth.
 P302 + P352 + P317 IF ON SKIN: Wash with plenty of water. Get medical help.
 P304 + P340 + P317 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P318 IF exposed or concerned, get medical advice.
 P337 + P317 If eye irritation persists: Get medical help.
 P362 + P364 Take off contaminated clothing and wash it before reuse.
- Storage:**
 P405 Store locked up.
- Disposal:**
 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

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	>= 5 - < 10
tetracaine hydrochloride	136-47-0	>= 0.1 - < 1

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.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING 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.

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

Exposure to combustion products may be a hazard to health.

- | | | |
|---|---|---|
| Hazardous combustion products | : | Carbon oxides
Nitrogen oxides (NOx) |
| 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. |

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.
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. |

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. |

Embutramide / Mebezonium / Tetracaine For- mulation

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

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.

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.
Keep away from heat and sources of ignition.

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

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	TWA	5 ppm	ACGIH
Embutramide	15687-14-6	TWA	10 µg/m ³ (OEB 3)	Internal
		STEL	30 µg/m ³	Internal
		Wipe limit	100 µg/100 cm ²	Internal
Mebezonium iodide	7681-78-9	TWA	1 µg/m ³ (OEB 4)	Internal
		STEL	3 µg/m ³ (OEB 4)	Internal
tetracaine hydrochloride	136-47-0	TWA	5 µg/m ³ (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-	Urine	End of	30 mg/l	ACGIH

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

	(N-methylcarbamoyl) cysteine		shift at end of work-week		BEI
--	------------------------------	--	---------------------------	--	-----

Engineering measures : 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : No data available

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

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

Odour	:	No data available
Odour Threshold	:	No data available
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

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

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	:	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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

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

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,224 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	:	LD50 (Rat): 3,010 mg/kg
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.
Acute dermal toxicity	:	Acute toxicity estimate: 1,100 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.

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

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

Embutramide:

Acute oral toxicity : LD50 (Rat): 1,550 mg/kg

Acute toxicity (other routes of administration) : LD50 (Dog): 31 mg/kg
Application Route: Intravenous

TDL₀ (Dog): 15.5 mg/kg
Application Route: Intravenous
Symptoms: narcosis

LD50 (Horse): 20 mg/kg
Application Route: Intravenous

LD50 (sheep): 80 mg/kg
Application Route: Intravenous

LD50 (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: Intravenous

LD50 (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

Serious eye damage/eye irritation

Causes serious eye irritation.

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

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

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

Version 4.1 Revision Date: 04.04.2023 SDS Number: 1714390-00019 Date of last issue: 20.01.2023
Date of first issue: 25.05.2017

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

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 synthesis in mammalian cells (in vitro)
Result: negative

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

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

Result: negative

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.

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

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

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

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Embutramide:

Assessment : May cause drowsiness or dizziness.

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

Not classified based on available information.

Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

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.

Experience with human exposure

Components:

Embutramide:

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

Mebezonium iodide:

Inhalation	:	Symptoms: Weakness, Fatigue, Breathing difficulties
------------	---	---

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

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	:	ErC50 (Desmodesmus subspicatus (green algae)): > 1,000
---------------------------	---	---

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.1	Revision Date: 04.04.2023	SDS Number: 1714390-00019	Date of last issue: 20.01.2023 Date of first issue: 25.05.2017
----------------	------------------------------	------------------------------	---

plants : 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: 1,500 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

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
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

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

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

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.
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.
-

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

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

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

16. OTHER INFORMATION

Revision Date : 04.04.2023

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/>

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

Version	Revision Date:	SDS Number:	Date of last issue: 20.01.2023
4.1	04.04.2023	1714390-00019	Date of first issue: 25.05.2017

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

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

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; TECl - 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.

IN / EN