

# Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

---

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Embutramide / Mebezonium / Tetracaine Formulation

### Manufacturer or supplier's details

Company name of supplier : MSD  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 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



---

## SECTION 2. HAZARDS 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 2A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity - single exposure : Category 2 (Nervous system, muscle)  
Specific target organ toxicity - single exposure : Category 3

### 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.

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

H336 May cause drowsiness or dizziness.  
H360D May damage the unborn child.  
H371 May cause damage to organs (Nervous system, muscle).

### Precautionary Statements :

#### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P260 Do not breathe mist or vapors.  
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 or doctor/ physician if you feel unwell. Rinse mouth.  
P302 + P352 + P312 IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/ physician if you feel unwell.  
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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.  
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

Vapors 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 / Mebezonium / Tetracaine Formulation


Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
 Date of first issue: 25.05.2017

|                          |            |             |
|--------------------------|------------|-------------|
| Embutramide              | 15687-14-6 | >= 20 -< 30 |
| Mebezonium iodide        | 7681-78-9  | >= 5 -< 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.
- 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.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 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.  
 Vapors may form explosive mixtures with air.  
 Exposure to combustion products may be a hazard to health.
-  Hazardous combustion prod- : Carbon oxides

## Embutramide / Mebezonium / Tetracaine Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

|  |   |
|--|---|
| ucts   | Nitrogen oxides (NO <sub>x</sub> )  |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

|   |   |
|---|---|
| Personal precautions, protective equipment and emergency procedures | : Remove all sources of ignition.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Do not get in eyes. |

## Embutramide / Mebezonium / Tetracaine For- mulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

- 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 labeled 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  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components                      | CAS-No.    | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis             |
|---------------------------------|------------|-------------------------------|--|-------------------|
| N,N-Dimethylformamide           | 68-12-2    | VLE-PPT                       | 10 ppm   | NOM-010-STPS-2014 |
|                                 |            | TWA                           | 5 ppm  | ACGIH             |
| Embutramide                     | 15687-14-6 | TWA                           | 10 µg/m <sup>3</sup> (OEB 3)                   | Internal          |
|                                 |            | STEL                          | 30 µg/m <sup>3</sup>                           | Internal          |
|                                 |            | Wipe limit                    | 100 µg/100 cm <sup>2</sup>                     | Internal          |
| Mebezonium iodide               | 7681-78-9  | TWA                           | 1 µg/m <sup>3</sup> (OEB 4)                    | Internal          |
|                                 |            | STEL                          | 3 µg/m <sup>3</sup> (OEB 4)                    | Internal          |
| tetracaine hydrochloride        | 136-47-0   | TWA                           | 5 µg/m <sup>3</sup> (OEB 4)                    | Internal          |
| Further information: DSEN, Skin |            |                               |  |                   |
|                                 |            | Wipe limit                    | 50 µg/100 cm <sup>2</sup>                      | Internal          |

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

### Biological occupational exposure limits

| Components            | CAS-No. | Control parameters                     | Biological specimen | Sampling time  | Permissible concentration | Basis     |
|-----------------------|---------|--|---------------------|--|---------------------------|-----------|
| N,N-Dimethylformamide | 68-12-2 | N-methylformamide                      | Urine               | End of shift   | 15 mg/l                   | MX BEI    |
|                       |         | N-Acetyl-S-(N-methylcarbonyl) cysteine | Urine               | Prior to the last shift of the work week                 | 40 mg/l                   | MX BEI    |
|                       |         | Total N-Methylformamide                | Urine               | End of shift (As soon as possible after exposure ceases) | 30 mg/l                   | ACGIH BEI |
|                       |         | N-Acetyl-S-(N-methylcarbonyl) cysteine | Urine               | End of shift at end of work-week                         | 30 mg/l                   | ACGIH 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 vapor 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

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

---

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

Color : No data available

Odor : No data available

Odor 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

Vapor pressure : No data available

Relative vapor 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

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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

---

|                           |   |  |
|---------------------------|---|--|
| Autoignition 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 size             | : | Not applicable   |

---

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | Not classified as a reactivity hazard.  |
| Chemical stability                 | : | Stable under normal conditions.   |
| Possibility of hazardous reactions | : | Combustible liquid.<br>Vapors may form explosive mixture with air.<br>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****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<br>Method: Calculation method  |
| Acute inhalation toxicity | : | Acute toxicity estimate: 19.41 mg/l<br>Exposure time: 4 h<br>Test atmosphere: vapor<br>Method: Calculation method |
| Acute dermal toxicity     | : | Acute toxicity estimate: 1,942 mg/kg<br>Method: Calculation method  |

---



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

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

---

**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: vapor  
Method: Expert judgment  
Remarks: Based on national or regional regulation.

Acute dermal toxicity :  
Acute toxicity estimate: 1,100 mg/kg  
Method: Expert judgment  
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: Intravenous

TDL<sub>0</sub> (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.

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
 Date of first issue: 25.05.2017

### 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 |

#### **Respiratory or skin sensitization**

##### **Skin sensitization**

Not classified based on available information.

##### **Respiratory sensitization**

Not classified based on available information.

### Components:

#### **N,N-Dimethylformamide:**

|                    |                                 |
|--------------------|---------------------------------|
| Test Type          | : Local lymph node assay (LLNA) |
| Routes of exposure | : Skin contact                  |
| Species            | : Mouse                         |
| Result             | : negative                      |

#### **tetracaine hydrochloride:**

|                    |              |
|--------------------|--------------|
| Routes of exposure | : Dermal     |
| Result             | : Sensitizer |

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **N,N-Dimethylformamide:**

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

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

Genotoxicity in vivo : Result: negative

: 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 (vapor)  
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Application Route: Intraperitoneal injection  
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 (vapor)  
Exposure time : 2 Years  
Method : OECD Test Guideline 451  
Result : negative

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

### Reproductive toxicity

May damage the unborn child.

### Components:

#### **N,N-Dimethylformamide:**

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
 Date of first issue: 25.05.2017

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

### tetracaine hydrochloride:

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

### STOT-single exposure

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

### Components:

#### Embutramide:

Assessment : May cause drowsiness or dizziness.

## Embutramide / Mebezonium / Tetracaine Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

---

### 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.

### 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 (vapor) |
| Exposure time     | : | 2 y                |

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Embutramide:**

|            |   |  |
|------------|---|--|
| Inhalation | : | Target Organs: Central nervous system<br>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<br>Target Organs: Central nervous system<br>Symptoms: Central nervous system depression, Dizziness, Headache, hypotension, Vomiting |
| Skin contact | : | Symptoms: Redness, pruritis   |

## Embutramide / Mebezonium / Tetracaine Formulation

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **N,N-Dimethylformamide:**

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

##### **Embutramide:**

|                            |   |
|----------------------------|---|
| Toxicity to fish           | : LC50 : 21 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203  |
| Toxicity to microorganisms | : EC50: > 1,000 mg/l<br>Exposure time: 24 h<br>Test Type: Respiration inhibition of activated sludge<br>Method: OECD Test Guideline 209 |

#### Persistence and degradability

##### Components:

##### **N,N-Dimethylformamide:**

|                  |  |
|------------------|--|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 100 %<br>Exposure time: 21 d<br>Method: OECD Test Guideline 301E |
|------------------|--|

#### Bioaccumulative potential

##### Components:

##### **N,N-Dimethylformamide:**

|                 |   |
|-----------------|---|
| Bioaccumulation | : Species: Cyprinus carpio (Carp)<br>Bioconcentration factor (BCF): 0.3 - 1.2 |
|-----------------|---|

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

Version 5.0      Revision Date: 04.04.2023      SDS Number: 1714272-00019      Date of last issue: 20.01.2023  
Date of first issue: 25.05.2017

---

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 : 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.

---

**SECTION 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 Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****NOM-002-SCT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

---

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Not applicable

## Embutramide / Mebezonium / Tetracaine Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

essential chemical products and machinery for producing capsules, tablets and pills.

### The ingredients of this product are reported in the following inventories:

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

## SECTION 16. OTHER INFORMATION

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 04.04.2023 |
| Date format   | : | dd.mm.yyyy |

### Full text of other abbreviations

|                                 |   |   |
|---------------------------------|---|---|
| ACGIH                           | : | USA. ACGIH Threshold Limit Values (TLV)   |
| ACGIH BEI                       | : | ACGIH - Biological Exposure Indices (BEI)   |
| MX BEI                          | : | Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents             |
| NOM-010-STPS-2014               | : | Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits |
| ACGIH / TWA                     | : | 8-hour, time-weighted average   |
| NOM-010-STPS-2014 / VLE-<br>PPT | : | Time weighted average limit value   |

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; KECl - 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



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

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 20.01.2023  |
| 5.0     | 04.04.2023     | 1714272-00019 | Date of first issue: 25.05.2017 |

---

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

Sources of key data used to compile the Material 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.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8