SAFETY DATA SHEET

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.2 Revision Date: 02.10.2020 SDS Number: 1714263-00014 Date of last issue: 23.03.2020 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: MSD
Address: Rua Coronel Bento Soares, 530 Cruzeiro - Sao Paulo - Brazil CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Flammable liquids: Category 4
Acute toxicity (Oral): Category 4
Acute toxicity (Inhalation): Category 4
Acute toxicity (Dermal): Category 4
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - single exposure: Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H227 Combustible liquid. H302 + H312 + H332 Harmful if swallowed, in contact with skin
Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
- No smoking.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- 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.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Other hazards which do not result in classification:
- Vapors may form explosive mixture with air.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
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<tbody>
<tr>
<td><strong>Chemical name</strong></td>
<td><strong>CAS-No.</strong></td>
</tr>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
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<tr>
<td>Embutramide</td>
<td>15687-14-6</td>
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</table>
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Embutramide / Mebezonium / Tetracaine Formulation

<table>
<thead>
<tr>
<th>Mebezonium iodide</th>
<th>Category 3</th>
<th>Acute toxicity (Oral), Category 3 Specific target organ toxicity - single exposure (Nervous system, muscle), Category 2</th>
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<table>
<thead>
<tr>
<th>Tetracaine hydrochloride</th>
<th>Category 3</th>
<th>Acute toxicity (Oral), Category 3 Skin sensitization, Sub-category 1B Specific target organ toxicity - single exposure (Central nervous system, Cardiovascular system), Category 1</th>
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<td>&gt;= 0.1 - &lt; 1</td>
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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.

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 (CO2)
Dry chemical

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: 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 products: Carbon oxides
Nitrogen oxides (NOx)
Ammonia

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 fire-fighters: 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.
Suppress (knock down) gases/vapors/mists with a water spray jet.
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.
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...
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 vapors. 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.


Materials to avoid: Do not store with the following product types: Strong oxidizing agents 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 | LT | 8 ppm  
24 mg/m³ | BR OEL  
Further information: Degree of harmfulness: medium  
TWA | 5 ppm | ACGIH  
Embutramide  
Mebezonium iodide  
Tetracaine hydrochloride  
Further information: DSEN, Skin  
TWA | 10 µg/m³ (OEB 3) | Internal  
STEL | 1 µg/m³ (OEB 4) | Internal  
Wipe limit | 3 µg/m³ (OEB 4) | Internal  
Wipe limit | 100 µg/100 cm² | Internal  
**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 and ammonia/amines type

- **Hand protection**: Chemical-resistant gloves
  - **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.
  - **Remarks**: 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.
  - **Remarks**: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
  - **Remarks**: 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
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: Vapors 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

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: 1.200 mg/kg
  - Method: Calculation method

- **Acute inhalation toxicity**
  - Acute toxicity estimate: 19.41 mg/l
  - Exposure time: 4 h
  - Test atmosphere: vapor
  - 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**
  - LC50 (Rat): > 5.85 mg/l
  - Exposure time: 4 h
  - Test atmosphere: vapor

- **Acute dermal toxicity**
  - LD50 (Rat): > 3.160 mg/kg
  - Method: OECD Test Guideline 402

**Embutramide:**
- **Acute oral toxicity**
  - LD50 (Rat): 1.550 mg/kg

- **Acute toxicity (other routes of administration)**
  - LD50 (Dog): 31 mg/kg
  - Application Route: Intravenous
  - TDLo (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
Tetracaine hydrochloride:
Acute oral toxicity: LD50 (Mouse): 300 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 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

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)
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  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:
Effects on fertility:
- Test Type: Two-generation study
- Species: Mouse
- Application Route: Ingestion
- Result: equivocal

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rabbit
- Application Route: Inhalation (vapor)
- 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 fetal 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.

Repeated dose toxicity

Components:

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

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

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: EC50 (Desmodesmus subspicatus (green algae)): > 1.000 mg/l
Exposure time: 72 h
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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
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: -1.01

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.

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**

**ANTT**
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

**International Regulations**

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
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SECTION 16. OTHER INFORMATION

**Further information**

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<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<td>4.2</td>
<td>02.10.2020</td>
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**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACGIH</td>
<td>USA, ACGIH Threshold Limit Values (TLV)</td>
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<tr>
<td>ACGIH BEI</td>
<td>ACGIH - Biological Exposure Indices (BEI)</td>
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<tr>
<td>BR BEI</td>
<td>Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents</td>
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<tr>
<td>BR OEL</td>
<td>Brazil. NR 15 - Unhealthy activities and operations</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>BR OEL / LT</td>
<td>Up to 48 hours /week</td>
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</table>

All abbreviations are represented as follows:

- ACGIH - USA, American Conference of Governmental Industrial Hygienists
- ACGIH BEI - ACGIH - Biological Exposure Indices
- BR BEI - Brazil, National Institute ofOccupational Health, Biological Exposure Indices
- BR OEL - Brazil, National Institute ofOccupational Health, Occupational Exposure Limit
- ACGIH / TWA - 8-hour, time-weighted average
- BR OEL / LT - Up to 48 hours /week

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.

BR / Z8