SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Embutramide / Mebezonium / Tetracaine Formulation

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

1.1 Product identifier
Trade name : Embutramide / Mebezonium / Tetracaine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : 908-740-4000
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4 H302: Harmful if swallowed.
Acute toxicity, Category 4 H332: Harmful if inhaled.
Acute toxicity, Category 4 H312: Harmful in contact with skin.
Eye irritation, Category 2 H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 3 H336: May cause drowsiness or dizziness.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H302 + H312 + H332 Harmful if swallowed, in contact with
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- 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.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:
- N,N-Dimethylformamide
- Embutramide
- Mebezonium iodide
- Tetracaine hydrochloride

Additional Labelling:
- EUH208 Contains Tetracaine hydrochloride. May produce an allergic reaction. Restricted to professional users.

2.3 Other hazards
Vapours may form explosive mixture with air.

**SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>Flam. Liq. 3; H226 Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td></td>
<td>200-679-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>616-001-00-X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embutramide</td>
<td>15687-14-6</td>
<td>Acute Tox. 4; H302 STOT SE 3; H336 Aquatic Chronic 3;</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td>239-780-4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
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 produce an allergic reaction.
SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Embutramide / Mebezonium / Tetracaine Formulation

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
</tbody>
</table>

| Unsuitable extinguishing media | High volume water jet |

5.2 Special hazards arising from the substance or mixture

<table>
<thead>
<tr>
<th>Specific hazards during firefighting</th>
<th>Do not use a solid water stream as it may scatter and spread fire.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flash back possible over considerable distance.</td>
</tr>
<tr>
<td></td>
<td>Vapours may form explosive mixtures with air.</td>
</tr>
<tr>
<td></td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
<th>Carbon oxides</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nitrogen oxides (NOx)</td>
</tr>
<tr>
<td></td>
<td>Ammonia</td>
</tr>
</tbody>
</table>

5.3 Advice for firefighters

<table>
<thead>
<tr>
<th>Special protective equipment for firefighters</th>
<th>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific extinguishing methods</td>
<td>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.</td>
</tr>
</tbody>
</table>

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

<table>
<thead>
<tr>
<th>Personal precautions</th>
<th>Remove all sources of ignition.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td></td>
<td>Follow safe handling advice and personal protective equipment recommendations.</td>
</tr>
</tbody>
</table>

6.2 Environmental precautions

<table>
<thead>
<tr>
<th>Environmental precautions</th>
<th>Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil</th>
</tr>
</thead>
</table>
barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 vapours or spray mist.
Do not swallow.
Do not get in eyes.
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 and sources of ignition.
Take precautionary measures against static discharges.
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>TWA</td>
<td>5 ppm</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>10 ppm</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>10 ppm</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further information: Identifies the possibility of significant uptake through the skin, Indicative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embutramide</td>
<td>15687-14-6</td>
<td>TWA</td>
<td>10 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(OEB 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>30 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Mebezonium iodide</td>
<td>7681-78-9</td>
<td>TWA</td>
<td>1 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(OEB 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Tetracaine hydrochloride</td>
<td>136-47-0</td>
<td>TWA</td>
<td>10 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(OEB 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further information: DSEN, Skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
# Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>30 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>30 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>3.31 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>26.3 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0.446 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>5.9 mg/cm²</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>30 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>15 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>30 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.98 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>15.8 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0.267 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>3.550 mg/cm²</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>1.98 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>5.94 mg/kg bw/day</td>
<td></td>
</tr>
</tbody>
</table>

# Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>Fresh water</td>
<td>30 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>123 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>115.18 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>11.52 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>56.97 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**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**

<table>
<thead>
<tr>
<th>Protection Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye protection</strong></td>
<td>Wear safety glasses with side shields or goggles.</td>
</tr>
<tr>
<td></td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td></td>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td><strong>Hand protection</strong></td>
<td>Material: Chemical-resistant gloves</td>
</tr>
<tr>
<td></td>
<td>Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.</td>
</tr>
<tr>
<td><strong>Skin and body protection</strong></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
<tr>
<td><strong>Respiratory protection</strong></td>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td></td>
<td>Equipment should conform to BS EN 14387</td>
</tr>
<tr>
<td><strong>Filter type</strong></td>
<td>Combined particulates and ammonia/amines type (K-P)</td>
</tr>
</tbody>
</table>

### SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5 - 6</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>81 °C</td>
</tr>
</tbody>
</table>
Embutramide / Mebezonium / Tetracaine Formulation

Evaporation rate : No data available
Flammability (solid, gas) : 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.

9.2 Other information
Flammability (liquids) : Not applicable
Molecular weight : Not applicable
Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Combustible liquid.
Vapours may form explosive mixture with air.
10.4 Conditions to avoid

Conditions to avoid: Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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: 1,549 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: LC50 (Rat): > 5.85 mg/l
Exposure time: 4 h
Test atmosphere: vapour

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): LD50 (Dog): 31 mg/kg
administration)  

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  
Application Route: Intravenous  

**Tetracaine hydrochloride:**  
Acute oral toxicity : LD50 (Mouse): 300 mg/kg  
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
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: 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 (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: equivocal

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: inhalation (vapour)
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.

**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
Embutramide / Mebezonium / Tetracaine Formulation

Version 4.7  Revision Date: 23.03.2020  SDS Number: 1714388-00013  Date of last issue: 14.02.2020  Date of first issue: 25.05.2017

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

12.1 Toxicity

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
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

12.2 Persistence and degradability

Components:

N,N-Dimethylformamide:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 21 d
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Embutramide / Mebezonium / Tetracaine Formulation

Version 4.7
Revision Date: 23.03.2020
SDS Number: 1714388-00013
Date of last issue: 14.02.2020
Date of first issue: 25.05.2017

Method: OECD Test Guideline 301E

12.3 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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Embutramide / Mebezonium / Tetracaine Formulation**

**Version** 4.7  
**Revision Date:** 23.03.2020  
**SDS Number:** 1714388-00013  
**Date of last issue:** 14.02.2020  
**Date of first issue:** 25.05.2017

### 14.5 Environmental hazards
Not regulated as a dangerous good

### 14.6 Special precautions for user
Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

### SECTION 15: Regulatory information

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

**REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):**
Conditions of restriction for the following entries should be considered:
- Number on list 3
- N,N-Dimethylformamide (Number on list 72, 30)

**REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59):**
- N,N-Dimethylformamide

**REACH - List of substances subject to authorisation (Annex XIV):**
- Not applicable

**Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:**
- Not applicable

**Regulation (EU) 2019/1021 on persistent organic pollutants (recast):**
- Not applicable

**Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:**
- Not applicable

- Not applicable

**Other regulations:**
- Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
- Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

#### 15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Embutramide / Mebezonium / Tetracaine Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.7</td>
<td>23.03.2020</td>
<td>1714388-00013</td>
<td>14.02.2020</td>
<td>25.05.2017</td>
</tr>
</tbody>
</table>

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- **H226**: Flammable liquid and vapour.
- **H301**: Toxic if swallowed.
- **H302**: Harmful if swallowed.
- **H312**: Harmful in contact with skin.
- **H317**: May cause an allergic skin reaction.
- **H319**: Causes serious eye irritation.
- **H332**: Harmful if inhaled.
- **H336**: May cause drowsiness or dizziness.
- **H360D**: May damage the unborn child.
- **H370**: Causes damage to organs.
- **H371**: May cause damage to organs.
- **H412**: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

- **Acute Tox.**: Acute toxicity
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Irrit.**: Eye irritation
- **Flam. Liq.**: Flammable liquids
- **Repr.**: Reproductive toxicity
- **Skin Sens.**: Skin sensitisation
- **STOT SE**: Specific target organ toxicity - single exposure
- **GB EH40**: UK. EH40 WEL - Workplace Exposure Limits
  - **2009/161/EU / TWA**: Limit Value - eight hours
  - **2009/161/EU / STEL**: Short term exposure limit
  - **GB EH40 / TWA**: Long-term exposure limit (8-hour TWA reference period)
  - **GB EH40 / STEL**: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Organisa-
Further information


Classification of the mixture:

| Acute Tox. 4   | H302          | Classification procedure: Calculation method |
| Acute Tox. 4   | H332          | Calculation method               |
| Acute Tox. 4   | H312          | Calculation method               |
| Eye Irrit. 2   | H319          | Calculation method               |
| Repr. 1B       | H360D         | Calculation method               |
| STOT SE 3      | H336          | Calculation method               |

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.