SAFETY DATA SHEET

Embutramide / Mebezonium / Tetracaine Formulation

Section 1: Identification

Product name: Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
         Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 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: Hazard identification

GHS Classification

Flammable liquids: Flam. Liq.4
Acute toxicity (Oral): Acute Tox.4
Acute toxicity (Inhalation): Acute Tox.4
Acute toxicity (Dermal): Acute Tox.4
Serious eye damage/eye irritation: 2A
Reproductive toxicity: Repr.1B
Specific target organ toxicity - single exposure: STOT SE3

GHS label elements

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.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
- P261 Avoid breathing mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- P281 Use personal protective equipment as required.

**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 + P313 IF exposed or concerned: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P363 Wash contaminated clothing before reuse.

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

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>
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. Vapours 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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: 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 barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 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.

Conditions for safe storage: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

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

**Section 8: Exposure controls/personal protection**

**Components with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>WES-TWA</td>
<td>10 ppm</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin absorption</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>5 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Embutramide</td>
<td>15687-14-6</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</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 (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>3 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Tetracaine hydrochloride</td>
<td>136-47-0</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</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></td>
<td></td>
<td></td>
<td>Further information: DSEN, Skin</td>
<td></td>
</tr>
</tbody>
</table>
Biological occupational exposure limits

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

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 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 face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance : liquid
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Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: 5 - 6
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: 81 °C
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: soluble
Partition coefficient: n-octanol/water: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Embutramide / Mebezonium / Tetracaine Formulation

**Section 10: Stability and reactivity**

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reactions**: Combustible liquid. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

**Conditions to avoid**: Heat, flames and sparks.

**Incompatible materials**: Oxidizing agents

**Hazardous decomposition products**: No hazardous decomposition products are known.

**Section 11: Toxicological information**

**Exposure routes**: Inhalation, Skin contact, Ingestion, Eye contact

**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 administration) : LD50 (Dog): 31 mg/kg
Application Route: Intravenous

TDLo (Dog): 15.5 mg/kg
Application Route: Intravenous
Symptoms: narcotics

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

N,N-Dimethylformamide:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: 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
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Version 2.11  Revision Date: 23.03.2020  SDS Number: 1714274-00013  Date of last issue: 14.02.2020  Date of first issue: 25.05.2017

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
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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:
Toxicity to algae/aquatic plants:

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

Embutramide:
Toxicity to fish:
Toxicity to microorganisms:

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.

National Regulations

- **NZS 5433:** Not regulated as a dangerous good

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median
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.