SAFETY DATA SHEET

Embutramide / Mebezonium / Tetracaine Formulation

Version 6.1  Revision Date: 2021/08/27  SDS Number: 1714270-00016  Date of last issue: 2021/04/09  Date of first issue: 2017/05/25

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Embutramide / Mebezonium / Tetracaine Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Flammable liquids : Category 4
Acute toxicity (Oral) : Category 4
Acute toxicity (Inhalation) : Category 4
Acute toxicity (Dermal) : Category 4
Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3

GHS label elements
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.
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.
- **P261** Avoid breathing mist or vapours.
- **P264** Wash skin thoroughly after handling.
- **P270** Do not eat, drink or smoke when using this product.
- **P271** Use only outdoors or in a well-ventilated area.
- **P280** Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- **P301 + P330 IF SWALLOWED:** Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
- **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.
- **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.
- **P362 + P364** Take off contaminated clothing and wash it before reuse.

**Storage:**
- **P405** Store locked up.

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

**Other hazards which do not result in classification**
- Important symptoms and outlines of the emergency assumed:
- Vapours may form explosive mixture with air.

---

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:**
- Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
</table>

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### SAFETY DATA SHEET

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<table>
<thead>
<tr>
<th>N,N-Dimethylformamide</th>
<th>68-12-2</th>
<th>56.67</th>
<th>2-680</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embutramide</td>
<td>15687-14-6</td>
<td>&gt;= 20 - &lt; 25</td>
<td></td>
</tr>
<tr>
<td>Mebezonomium iodide</td>
<td>7681-78-9</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Tetracaine hydrochloride</td>
<td>136-47-0</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td></td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**General advice**  
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

- **If inhaled**  
  - If inhaled, remove to fresh air.
  - If not breathing, give artificial respiration.
  - If breathing is difficult, give oxygen.
  - Get medical attention.

- **In case of skin contact**  
  - In case of contact, immediately flush skin with plenty of water.
  - Remove contaminated clothing and shoes.
  - Get medical attention.
  - Wash clothing before reuse.
  - Thoroughly clean shoes before reuse.

- **In case of eye contact**  
  - In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
  - If easy to do, remove contact lens, if worn.
  - Get medical attention.

- **If swallowed**  
  - If swallowed, DO NOT induce vomiting.
  - Get medical attention.
  - Rinse mouth thoroughly with water.
  - Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed**  
Harmful if swallowed, in contact with skin or if inhaled.  
Causes serious eye irritation.  
May cause drowsiness or dizziness.  
May damage the unborn child.

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

**Notes to physician**  
Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- **Suitable extinguishing media**  
  - Water spray  
  - Alcohol-resistant foam  
  - Carbon dioxide (CO2)  
  - Dry chemical

- **Unsuitable extinguishing media**  
  - High volume water jet

- **Specific hazards during 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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

7. HANDLING AND STORAGE

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 mist or vapours.
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.

Avoidance of contact:
- Oxidizing agents

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.

Storage:
- 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:
  - Oxidizing solids
  - Oxidizing liquids

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment:

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>68-12-2</td>
<td>ACL</td>
<td>10 ppm / JP OEL ISHL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M</td>
<td>10 ppm / 30 mg/m3 / JP OEL JSOH</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Group 2: Substances presumed to cause reproductive toxicity in humans, Skin absorption, Group 2B: pos-
Embutramide / Mebezonium / Tetracaine Formulation

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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-Methylformamide</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>30 mg/l</td>
<td>ACGIH BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N-Acetyl-S-(N-methylcarbamoyl) cysteine</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>30 mg/l</td>
<td>ACGIH BEI</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**: 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
### 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
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<tr>
<td>Odour</td>
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<tr>
<td>Odour Threshold</td>
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</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
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<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
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<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
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<td>Lower explosion limit and upper explosion limit / flammability limit</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>pH</td>
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<td>Evaporation rate</td>
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<tr>
<td>Auto-ignition temperature</td>
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<td>Viscosity</td>
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<td>Viscosity, kinematic</td>
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<td>Solubility (ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
<td>Soluble</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

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

Conditions to avoid: Heat, flames and sparks.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

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

Product:

Acute oral toxicity: Acute toxicity estimate: 1,549 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: 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
Repellent 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

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

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
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

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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.
14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR
UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code
UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Type 3 petroleum, Water soluble liquid, (4000 litre), Hazardous rank III

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>27</td>
</tr>
</tbody>
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Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health

Chemical name
N,N-Dimethylformamide

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>299</td>
<td>&gt;=50 - &lt;60</td>
</tr>
<tr>
<td>Iodine compounds</td>
<td>606</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>N,N-Dimethylformamide</td>
<td>299</td>
</tr>
<tr>
<td>Iodine and its compounds</td>
<td>606</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
</table>
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| N,N-dimethylformamide | 232 | 57 |

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Y)
Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
JP OEL ISHL : Japan. Administrative Control Levels
ACGIH / TWA : 8-hour, time-weighted average
JP OEL ISHL / ACL : Administrative Control level
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean
SAFETY DATA SHEET

Embutramide / Mebezonium / Tetracaine Formulation

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<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
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<td>1714270-00016</td>
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AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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

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.

JP / EN