

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Emergency Overview

| | |
|------------|---------------------|
| Appearance | : liquid |
| Colour | : No data available |
| Odour | : No data available |

Combustible liquid. Harmful if swallowed, in contact with skin or if inhaled. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child.

GHS Classification

| | |
|-----------------------------------|---------------|
| Flammable liquids | : Category 4 |
| Acute toxicity (Oral) | : Category 4 |
| Acute toxicity (Inhalation) | : Category 4 |
| Acute toxicity (Dermal) | : Category 4 |
| Serious eye damage/eye irritation | : Category 2A |
| Reproductive toxicity | : Category 1B |
| Specific target organ toxicity - | : Category 3 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519




Embutramide / Mebezonium / Tetracaine For- mulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

single exposure

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. H336 May cause drowsiness or dizziness. H360D May damage the unborn child. |
| Precautionary statements | : | Prevention: P203 Obtain, read and follow all safety instructions before use. 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/ hearing protection. Response: P301 + P317 + P330 IF SWALLOWED: Get medical help. Rinse mouth. P302 + P352 + P317 IF ON SKIN: Wash with plenty of water. Get medical help. P304 + P340 + P317 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help. 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. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

Version 6.0 Revision Date: 2025/04/14 SDS Number: 1714239-00024 Date of last issue: 2024/12/04
Date of first issue: 2017/05/25

Physical and chemical hazards

Combustible liquid.

Health hazards

Harmful if swallowed. Harmful if inhaled. Harmful in contact with skin. Causes serious eye irritation. May damage the unborn child. May cause drowsiness or dizziness.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--------------------------|------------|-----------------------|
| N,N-Dimethylformamide | 68-12-2 | ≥ 50 - < 70 |
| Embutramide | 15687-14-6 | ≥ 20 - < 25 |
| Mebezonium iodide | 7681-78-9 | ≥ 1 - < 10 |
| tetracaine hydrochloride | 136-47-0 | ≥ 0.1 - < 1 |

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 : Harmful if swallowed, in contact with skin or if inhaled.
Causes serious eye irritation.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

| | | |
|----------------------------|---|---|
| delayed | | 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 (CO ₂) Dry chemical |
| Unsuitable extinguishing media | : | High volume water jet |
| Specific hazards during fire-fighting | : | Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides Nitrogen oxides (NO _x) |
| 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 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine For-mulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

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

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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

Version 6.0 Revision Date: 2025/04/14 SDS Number: 1714239-00024 Date of last issue: 2024/12/04
Date of first issue: 2017/05/25

Materials to avoid : Keep away from heat and sources of ignition.
: Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|--------------------------|--|----------------------------------|--|----------|
| N,N-Dimethylformamide | 68-12-2 | PC-TWA | 20 mg/m3 | CN OEL |
| | Further information: G2A - Probably carcinogenic to humans, Skin | | | |
| | | TWA | 5 ppm | ACGIH |
| Embutramide | 15687-14-6 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | | STEL | 30 µg/m3 | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |
| Mebezonium iodide | 7681-78-9 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | | STEL | 3 µg/m3 (OEB 4) | Internal |
| | | Wipe limit | 10 µg/100 cm ² | Internal |
| tetracaine hydrochloride | 136-47-0 | TWA | 5 µg/m3 (OEB 4) | Internal |
| | Further information: DSEN, Skin | | | |
| | | Wipe limit | 50 µg/100 cm ² | Internal |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|-----------------------|---------|---|---------------------|--|---------------------------|-----------|
| N,N-Dimethylformamide | 68-12-2 | N-methyl-carbonyl hemoglobin adduct | Blood | Any time after four months of continuous exposure | 135 nmol/g globine | CN BEI |
| | | Total N-Methylformamide | Urine | End of shift (As soon as possible after exposure ceases) | 30 mg/l | ACGIH BEI |
| | | N-Acetyl-S-(N-methylcarbamoyl) cysteine | Urine | End of shift at end of work-week | 30 mg/l | ACGIH BEI |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine For-mulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

Engineering measures : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates, ammonia/amines and organic vapour type

Eye/face 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 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.

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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---------------------|
| Appearance | : liquid |
| 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 |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

| | | |
|--|---|--|
| 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. |
| Molecular weight | : | Not applicable |
| Particle characteristics | : | |
| Particle size | : | Not applicable |

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. |

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: 1,224 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : | Acute toxicity estimate: 19.41 mg/l Exposure time: 4 h |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

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 :
Acute toxicity estimate: 11 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement
Remarks: Based on national or regional regulation.

Acute dermal toxicity :
Acute toxicity estimate: 1,100 mg/kg
Method: Expert judgement
Remarks: Based on national or regional regulation.

Embutramide:

Acute oral toxicity : LD50 (Rat): 1,550 mg/kg

Acute toxicity (other routes of administration) : LD50 (Dog): 31 mg/kg
Application Route: Intravenous

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

tetracaine hydrochloride:

| | |
|---|---|
| Acute toxicity (other routes of administration) | : LD50 (Rat): 6 mg/kg Application Route: Intravenous |
| | : LD50 (Mouse): 6 mg/kg Application Route: Intravenous |

Skin corrosion/irritation

Not classified based on available information.

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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

Components:

N,N-Dimethylformamide:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Chromosome aberration test in vitro Result: negative Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative |
| Genotoxicity in vivo | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: inhalation (vapour) Result: negative Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Mouse Application Route: Intraperitoneal injection Result: negative |

tetracaine hydrochloride:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosomal aberration Result: equivocal |
| Genotoxicity in vivo | : Test Type: Micronucleus test Species: Rat Result: negative |

Carcinogenicity

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

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: negative Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rabbit Application Route: inhalation (vapour) Method: OECD Test Guideline 414 Result: positive Test Type: Embryo-foetal development Species: Rabbit Application Route: Skin contact 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 |
|----------------------|---|

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

| | |
|-------------------------------|---|
| | 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 |

| | |
|---------|-------------|
| Species | : Rat |
| NOAEL | : 0.08 mg/l |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

| | |
|-------------------|-----------------------|
| LOAEL | : 0.3 mg/l |
| Application Route | : inhalation (vapour) |
| Exposure time | : 2 yr |

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 | : ErC50 (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 (Chron- | : NOEC (Daphnia magna (Water flea)): 1,500 mg/l Exposure time: 21 d |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: |
| 6.0 | 2025/04/14 | 1714239-00024 | 2024/12/04 |
| | | | Date of first issue: 2017/05/25 |

||ic toxicity)

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: -0.93 Remarks: Calculation |

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

| | | |
|------------------------|---|---|
| Waste from residues | : | Do not dispose of waste into sewer. 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. |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

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 |
| Environmentally hazardous | : no |

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 | : no |

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

| | |
|----------------------|------------------|
| UN number | : Not applicable |
| Proper shipping name | : Not applicable |
| Class | : Not applicable |
| Subsidiary risk | : Not applicable |
| Packing group | : Not applicable |

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

Labels : Not applicable
Marine pollutant : no

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218) : Not listed

Hazardous Chemicals for Priority Management under SAWS : Not listed

Catalogue of Specially Controlled Hazardous Chemicals : Not listed

List of Explosive Precursors : Not listed

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

List of Controlled Ozone Depleting Substances : Not listed

Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
CN BEI : China. Biological Occupational Exposure Indices
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Embutramide / Mebezonium / Tetracaine Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2024/12/04 |
| 6.0 | 2025/04/14 | 1714239-00024 | Date of first issue: 2017/05/25 |

centration; 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; TECL - 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

Disclaimer

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.

CN / EN