

# **Embutramide / Mebezonium / Tetracaine Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 27.08.2024 1714263-00022 Date of first issue: 25.05.2017

#### **SECTION 1. IDENTIFICATION**

Product identifier : Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

## **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification in accordance with ABNT NBR 14725 Standard

Flammable liquids : Category 4

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Acute toxicity (Dermal) : Category 4

Eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

single exposure

Category 3

#### GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :





Signal Word : Danger

Hazard Statements : H227 Combustible liquid.



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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:

P201 Obtain special instructions before use.

P210 Keep away from heat, hot surfaces, sparks, open flames

and other ignition sources. No smoking.

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 protec-

tion/ face protection.

Response:

P301 + P312 + 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/ at-

tention.

Storage:

P405 Store locked up.

### Other hazards which do not result in classification

Vapors may form explosive mixture with air.

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

Substance / Mixture : Mixture

#### Components

| Chemical name         | CAS-No.    | Classification  | Concentration (% w/w) |
|-----------------------|------------|---|-----------------------|
| N,N-Dimethylformamide | 68-12-2    | Flam. Liq., 3 Acute Tox. (Oral), 5 Acute Tox. (Inhalation), 4 Acute Tox. (Dermal), 4 Eye Irrit., 2A Repr., 1B | >= 50 -< 70           |
| Embutramide           | 15687-14-6 | Acute Tox. (Oral), 4<br>STOT SE, 3  | >= 20 -< 25           |



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|                          |           | Aquatic Acute, 3<br>Aquatic Chronic, 3  |             |
|--------------------------|-----------|---|-------------|
| Mebezonium iodide        | 7681-78-9 | Acute Tox. (Oral), 3<br>STOT SE, (Nervous<br>system, muscle), 2                           | >= 5 -< 10  |
| tetracaine hydrochloride | 136-47-0  | Skin Sens., 1B<br>STOT SE, (Central<br>nervous system, Car-<br>dio-vascular system),<br>1 | >= 0,1 -< 1 |

#### **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. Harmful if swallowed, in contact with skin or if inhaled.

Most important symptoms and effects, both acute and

delayed

Causes serious eye irritation.

May acres decreis account district

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



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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. Vapors may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Remove all sources of ignition.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions

Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapors/mists with a water spray

iet.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

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



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certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapors.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled 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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame-    | Basis |
|------------|---------|------------|--------------------|-------|
|            |         | (Form of   | ters / Permissible |       |



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|                          |                                 | exposure)  | concentration              |          |  |  |
|--------------------------|---------------------------------|--|----------------------------|----------|--|--|
| N,N-Dimethylformamide    | 68-12-2                         | LT   | 8 ppm                      | BR OEL   |  |  |
|                          |                                 |  | 24 mg/m <sup>3</sup>       |          |  |  |
|                          | Further inform                  | Further information: Degree of harmfulness: medium |                            |          |  |  |
|                          |                                 | 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 <sup>2</sup> | 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 cm2              | Internal |  |  |
| tetracaine hydrochloride | 136-47-0                        | TWA  | 5 μg/m3 (OEB 4)            | Internal |  |  |
|                          | Further information: DSEN, Skin |  |                            |          |  |  |
|                          |                                 | Wipe limit 50 μg/100 cm <sup>2</sup> Internal      |                            |          |  |  |

## **Biological occupational exposure limits**

| Components            | CAS-No. | Control parameters   | Biological specimen | Sam-<br>pling<br>time  | Permissible concentra-tion | Basis        |
|-----------------------|---------|--|---------------------|--|----------------------------|--------------|
| N,N-Dimethylformamide | 68-12-2 | N- methylforma mide total (sum of N- methylforma mide and N- (hidroxymet hyl)-N- methylforma mide) | Urine               | End of<br>workday  | 30 mg/l                    | BR BEI       |
|                       |         | N-Acetyl-S-<br>(N-<br>methylcarba<br>moyl)<br>cysteine   | Urine               | End of<br>workday<br>at end of<br>work-<br>week                            | 30 mg/l                    | BR BEI       |
|                       |         | Total N-<br>Methylforma<br>mide  | Urine               | End of<br>shift (As<br>soon as<br>possible<br>after<br>exposure<br>ceases) | 30 mg/l                    | ACGIH<br>BEI |
|                       |         | N-Acetyl-S-<br>(N-<br>methylcarba<br>moyl)<br>cysteine   | Urine               | End of<br>shift at<br>end of<br>work-<br>week                              | 30 mg/l                    | ACGIH<br>BEI |

**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.



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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.

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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 vapor

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 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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 5-6

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 81 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable



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Other information

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle characteristics

Particle size : Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Stable under normal conditions. Combustible liquid.

Vapors may form explosive mixture with air.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.



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products

**SECTION 11. TOXICOLOGICAL INFORMATION** 

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity** 

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

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1.224 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 19,41 mg/l

Exposure time: 4 h
Test atmosphere: vapor
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 1.942 mg/kg

Method: Calculation method

**Components:** 

N,N-Dimethylformamide:

Acute oral toxicity : LD50 (Rat): 3.010 mg/kg

Acute inhalation toxicity :

Acute toxicity estimate: 11 mg/l

Exposure time: 4 h
Test atmosphere: vapor
Method: Expert judgment

Remarks: Based on national or regional regulation.

Acute dermal toxicity :

Acute toxicity estimate: 1.100 mg/kg

Method: Expert judgment

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



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> 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 : LC50 (Dog): 15 mg/kg

administration)

Application Route: Intravenous

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

N,N-Dimethylformamide:

Test Type Local lymph node assay (LLNA)

Routes of exposure Skin contact Species Mouse



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Result : negative

tetracaine hydrochloride:

Routes of exposure : Dermal Result : Sensitizer

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

N,N-Dimethylformamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: 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 syn-

thesis 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 (vapor)

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



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#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### N,N-Dimethylformamide:

Species : Rat

Application Route : inhalation (vapor)

Exposure time : 2 Years

: OECD Test Guideline 451 Method

Result : negative

Species : Mouse

Application Route : inhalation (vapor)

Exposure time : 18 Months

: OECD Test Guideline 451 Method

Result : negative

#### Reproductive toxicity

May damage the unborn child.

#### **Components:**

#### N,N-Dimethylformamide:

: Test Type: Two-generation study Effects on fertility

Species: Mouse

Application Route: Ingestion

Result: negative

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

Test Type: Embryo-fetal development Effects on fetal development :

Species: Rabbit

Application Route: inhalation (vapor) Method: OECD Test Guideline 414

Result: positive

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Skin contact Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

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



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Fertility: NOAEL: 7,5 mg/kg body weight

Result: No effects on fertility.

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Result: No teratogenic effects.

Test Type: Development

Species: Rabbit

Application Route: Subcutaneous

Developmental Toxicity: NOAEL: 10 mg/kg body weight

Result: No teratogenic effects.

#### STOT-single exposure

May cause drowsiness or dizziness.

#### **Components:**

#### **Embutramide:**

Assessment : May cause drowsiness or dizziness.

#### Mebezonium iodide:

Target Organs : Nervous system, muscle
Assessment : May cause damage to organs.

#### tetracaine hydrochloride:

Target Organs : Central nervous system, Cardio-vascular system

Assessment : Causes damage to organs.

### STOT-repeated exposure

Not classified based on available information.

## Repeated dose toxicity

#### **Components:**

#### N,N-Dimethylformamide:

Species: RatNOAEL: 238 mg/kgLOAEL: 475 mg/kgApplication Route: IngestionExposure time: 28 Days

 Species
 : Rat

 NOAEL
 : 0,08 mg/l

 LOAEL
 : 0,3 mg/l

Application Route : inhalation (vapor)

Exposure time : 2 y



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**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

**Embutramide:** 

Inhalation : Target Organs: Central nervous system

Symptoms: Drowsiness, Central nervous system depression,

muscle weakness, Shortness of breath

Mebezonium iodide:

Inhalation : Symptoms: Weakness, Fatigue, Breathing difficulties

tetracaine hydrochloride:

Inhalation : Target Organs: Cardio-vascular system

Target Organs: Central nervous system

Symptoms: Central nervous system depression, Dizziness,

Headache, hypotension, Vomiting

Skin contact : Symptoms: Redness, pruritis

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

N,N-Dimethylformamide:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 7.100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 13.100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

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-

ic 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



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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

#### **SECTION 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. 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



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**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation** 

**ANTT** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

**SECTION 15. REGULATORY INFORMATION** 

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

mixture

National List of Carcinogenic Agents for Humans -

Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Police

Not applicable

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

**AICS** not determined

DSL not determined

**IECSC** not determined

**SECTION 16. OTHER INFORMATION** 

**Revision Date** 27.08.2024 Date format dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

**Data Sheet** 

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, 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.

Full text of other abbreviations

**ACGIH** USA, ACGIH Threshold Limit Values (TLV) ACGIH BEI ACGIH - Biological Exposure Indices (BEI)

BR BEI Brazil. NR7. Parameters for Biological Control of Occupational



# Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.0 27.08.2024 1714263-00022 Date of first issue: 25.05.2017

**Exposure to Some Chemical Agents** 

BR OEL : Brazil. NR 15 - Unhealthy activities and operations

ACGIH / TWA : 8-hour, time-weighted average

BR OEL / LT : Up to 48 hours /week

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 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

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**BR / Z8**