

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

SECTION 1. IDENTIFICATION

Product name : Embutramide / Mebezonium / Tetracaine Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 the Hazardous Products Regulations

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 2 (Nervous system, muscle)
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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.
H371 May cause damage to organs (Nervous system, muscle).

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.
P260 Do not breathe mist or vapors.
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 and face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of soap and water. Call a doctor if you feel unwell.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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 + P311 IF exposed or concerned: Call a doctor.
P337 + P313 If eye irritation persists: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
N,N-	Formic acid	68-12-2	>= 30 - < 60 *

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

Dimethylformamide	dimethylamide		
Embutramide	No data available	15687-14-6	$\geq 10 - < 30$ *
Mebezonium iodide	No data available	7681-78-9	$\geq 5 - < 10$ *
tetracaine hydrochloride	No data available	136-47-0	$\geq 0.1 - < 1$ *

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed, in contact with skin or if inhaled.
Causes serious eye irritation.
May cause drowsiness or dizziness.
May damage the unborn child.
May cause damage to organs.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

- 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 products : Carbon oxides
Nitrogen oxides (NOx)
- 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 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 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/vapors/mists with a water spray jet.
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 certain local or national requirements.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

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.
- 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 (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylformamide	68-12-2	TWA	10 ppm 30 mg/m ³	CA AB OEL
		TWA	5 ppm	CA BC OEL
		TWAEV	10 ppm 30 mg/m ³	CA QC OEL
Embutramide	15687-14-6	TWA	5 ppm	ACGIH
		TWA	10 µg/m ³ (OEB 3)	Internal
		STEL	30 µg/m ³	Internal

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

		Wipe limit	100 µg/100 cm ²	Internal
Mebezonium iodide	7681-78-9	TWA	1 µg/m ³ (OEB 4)	Internal
		STEL	3 µg/m ³ (OEB 4)	Internal
		Wipe limit	10 µg/100 cm ²	Internal
tetracaine hydrochloride	136-47-0	TWA	5 µg/m ³ (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	Sam- pling time	Permissible concentra- tion	Basis
N,N-Dimethylformamide	68-12-2	Total N- Methylforma mide	Urine	End of shift (As soon as possible after exposure ceases)	30 mg/l	ACGIH BEI
		N-Acetyl-S- (N- methylcarba moyl) cysteine	Urine	End of shift at end of work- week	30 mg/l	ACGIH 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. 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 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : 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

Other information

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

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 reactions	:	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 products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

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

TDL_o (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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

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 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
Result : negative

tetracaine hydrochloride:

Routes of exposure : Dermal
Result : Sensitizer

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version: 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

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 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 (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

Carcinogenicity

Not classified based on available information.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

Components:

N,N-Dimethylformamide:

Species : Rat
Application Route : inhalation (vapor)
Exposure time : 2 Years
Method : OECD Test Guideline 451
Result : negative

Species : Mouse
Application Route : inhalation (vapor)
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 fetal development : Test Type: Embryo-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 - 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

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.
May cause damage to organs (Nervous system, muscle).

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
LOAEL : 0.3 mg/l
Application Route : inhalation (vapor)
Exposure time : 2 y

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

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 : EC50 (Daphnia magna (Water flea)): 13,100 mg/l
aquatic invertebrates : Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): > 1,000
plants : mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): > 1,000
mg/l
Exposure time: 72 h

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 1,500 mg/l
aquatic invertebrates (Chron- : Exposure time: 21 d
ic toxicity)

Embutramide:

Toxicity to fish : LC50 : 21 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version 4.3 Revision Date: 08/27/2024 SDS Number: 1714262-00022 Date of last issue: 09/30/2023
Date of first issue: 05/25/2017

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWA EV : Time-weighted average exposure value

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Embutramide / Mebezonium / Tetracaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
4.3	08/27/2024	1714262-00022	Date of first issue: 05/25/2017

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; 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

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 Agency, <http://echa.europa.eu/>

Revision Date : 08/27/2024
Date format : mm/dd/yyyy

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.

CA / Z8