

Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Embutramide / Mebezonium / Tetracaine Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

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@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

Flammable liquids : Category 4

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Acute toxicity (Dermal) : Category 4

Serious eye damage/eye

irritation

Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity

- single exposure

Category 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.

H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness.



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth. P302 + P352 + P312 IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/ physician if you feel unwell.

P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

Vapors may form explosive mixture with air.

SECTION 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 -< 30



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

Mebezonium iodide	7681-78-9	>= 5 -< 10
tetracaine hydrochloride	136-47-0	>= 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, 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 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

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- : Carbon oxides



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

ucts 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

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.

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.



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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 (Form of exposure)	Control parameters / Permissible concentration	Basis
N,N-Dimethylformamide	68-12-2	VLE-PPT	10 ppm	NOM-010- STPS-2014
		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



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

		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 ²	Internal	

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
N,N-Dimethylformamide	68-12-2	N- methylforma mide	Urine	End of shift	15 mg/l	MX BEI
		N-Acetyl-S- (N- methylcarba moyl) cysteine	Urine	Prior to the last shift of the work week	40 mg/l	MX BEI
		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.



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Autoignition temperature

: No data available

nperature : 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

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.

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



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

LD50 (sheep): 80 mg/kg Application Route: Intravenous

LD50 (Pig): 100 mg/kg

Application Route: Intravenous

Mebezonium iodide:

Acute oral toxicity : LD50 (Rat, female): 200 - 300 mg/kg

Acute toxicity (other routes of:

administration)

LC50 (Dog): 15 mg/kg

Application Route: Intravenous

tetracaine hydrochloride:



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

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



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

Carcinogenicity

Not classified based on available information.

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)



Embutramide / Mebezonium / Tetracaine Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 5.2
 27.08.2024
 1714272-00021
 Date of first issue: 25.05.2017

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 - 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 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



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

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:



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

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



Embutramide / Mebezonium / Tetracaine Formulation

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

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

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

NOM-002-SCT

Not regulated as a dangerous good



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

: 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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental

Health - Biological exposure indices for workers occupational-

ly exposed to chemical agents

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

the Work Environment - Identification, Assessment and Con-

trol - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average NOM-010-STPS-2014 / VLE- : Time weighted average limit value

PPT

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 Con-



Embutramide / Mebezonium / Tetracaine Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 5.2 27.08.2024 1714272-00021 Date of first issue: 25.05.2017

centration 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

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/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8