according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Embutramide / Mebezonium / Tetracaine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed. Acute toxicity, Category 4 H332: Harmful if inhaled.

Acute toxicity, Category 4

H312: Harmful in contact with skin.

Eye irritation, Category 2

Reproductive toxicity, Category 1B

Specific target organ toxicity - single ex
H319: Causes serious eye irritation.

H360D: May damage the unborn child.

H336: May cause drowsiness or dizziness.

posure, Category 3

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms





Signal word

Hazard statements 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.

Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

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

attention.

Hazardous components which must be listed on the label:

N.N-Dimethylformamide

Embutramide

Mebezonium iodide

EUH208

Contains tetracaine hydrochloride. May produce an allergic reaction.

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
N,N-Dimethylformamide	68-12-2	Flam. Liq. 3; H226	>= 50 - < 70
	200-679-5	Acute Tox. 4; H332	
	616-001-00-X	Acute Tox. 4; H312	
		Eye Irrit. 2; H319	
		Repr. 1B; H360D	
		Acute toxicity esti-	
		mate	
		Acute inhalation	
		toxicity (vapour): 11	
		mg/l	
		Acute dermal toxici-	
		ty: 1.100 mg/kg	
Embutramide	15687-14-6	Acute Tox. 4; H302	>= 20 - < 25
	239-780-4	STOT SE 3; H336	
		Aquatic Chronic 3;	
		H412	
Mebezonium iodide	7681-78-9	Acute Tox. 3; H301	>= 1 - < 10
	231-676-7	STOT SE 2; H371	
		(Nervous system,	
		muscle)	
tetracaine hydrochloride	136-47-0	Skin Sens. 1B;	>= 0,1 - < 1
 	205-248-5	H317	
		STOT SE 1; H370	
		(Central nervous	
		system, Cardio-	
		vascular system)	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : 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 produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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5.2 Special hazards arising from the substance or mixture

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 prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment:

for firefighters

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

Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Remove all sources of ignition.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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 absor-

bent.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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 as-

sessment

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 contami-

nated 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep

away from heat and sources of ignition.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

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Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form	Control parameters	Basis	
		of exposure)			
N,N-	68-12-2	TWA	6 mg/m3	FOR-2011-	
Dimethylforma- mide				12-06-1358	
	Further inforn	Further information: Substances considered to be reprotoxic, Chemicals that			
	can be absorbed through the skin.				
		STEL	10 ppm	FOR-2011-	
			30 mg/m3	12-06-1358	
	Further inform	Further information: Substances considered to be reprotoxic, Chemicals that			
	can be absorbed through the skin.				
		STEL	10 ppm	2009/161/EU	
			30 mg/m3		
		Further information: Identifies the possibility of significant uptake through the			
	skin, Indicativ		T =	0000/404/511	
		TWA	5 ppm	2009/161/EU	
			15 mg/m3		
	Further information: Identifies the possibility of significant uptake through the skin, Indicative				
	,	TWA	5 ppm	2004/37/EC	
			15 mg/m3		
	Further information: Skin, Carcinogens or mutagens				
		STEL	10 ppm	2004/37/EC	
			30 mg/m3		
	Further inform	nation: Skin, Carcino	gens or mutagens		
	15687-14-6	TWA	10 μg/m3 (OEB 3)	Internal	
		STEL	30 μg/m3	Internal	
		Wipe limit	100 μg/100 cm ²	Internal	
Mebezonium io- dide	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 hydro- chloride	136-47-0	TWA	5 μg/m3 (OEB 4)	Internal	
	Further inforn	nation: DSEN, Skin			

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Wipe limit 50 μg/100 cm² Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
N,N- Dimethylformamide	Workers	Inhalation	Long-term systemic effects	6 mg/m3
	Workers	Skin contact	Long-term systemic effects	1,1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,1 mg/m3
	Consumers	Ingestion	Long-term systemic effects	0,16 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
N,N-Dimethylformamide	Sewage treatment plant	44 mg/l
	Fresh water sediment	111 mg/kg dry
		weight (d.w.)
	Marine sediment	11,1 mg/kg dry
		weight (d.w.)

8.2 Exposure controls

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

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387

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

type (AK-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

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

Flash point : 81 °C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 5-6

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : soluble

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Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Combustible liquid.

Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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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: 1.590 mg/kg

Method: Calculation method

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

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

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

Method: Calculation method

Components:

N,N-Dimethylformamide:

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

Acute inhalation toxicity :

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

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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 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

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Result : negative

tetracaine hydrochloride:

Exposure routes : Dermal Result : Sensitiser

Germ cell mutagenicity

Not classified based on available information.

Components:

N,N-Dimethylformamide:

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

Result: negative

Test Type: 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 (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

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Result: negative

Carcinogenicity

Not classified based on available information.

Components:

N,N-Dimethylformamide:

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 2 Years

Method : OECD Test Guideline 451

Result : negative

Species : Mouse

Application Route : inhalation (vapour)

Exposure time : 18 Months

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

N,N-Dimethylformamide:

Effects on fertility : Test Type: Two-generation study

Species: Mouse

Application Route: Ingestion

Result: negative

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

Result: negative

Effects on foetal develop-

ment

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 - As-

sessment

: Clear evidence of adverse effects on development, based on

animal experiments.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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tetracaine hydrochloride:

Effects on fertility : Test Type: Fertility

Species: Rat, male and female Application Route: Subcutaneous Fertility: NOAEL: 7,5 mg/kg body weight

Result: No effects on fertility

Effects on foetal develop-

ment

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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 Species
 : Rat

 NOAEL
 : 0,08 mg/l

 LOAEL
 : 0,3 mg/l

Application Route : inhalation (vapour)

Exposure time : 2 yr

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

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

12.1 Toxicity

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Method: OECD Test Guideline 202

Toxicity to algae/aquatic ErC50 (Desmodesmus subspicatus (green algae)): > 1.000

plants

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: 1.500 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Embutramide:

Toxicity to fish : LC50:21 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

EC50 : > 1.000 mg/lToxicity to microorganisms

Exposure time: 24 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

12.2 Persistence and degradability

Components:

N,N-Dimethylformamide:

Biodegradability Result: Readily biodegradable.

Biodegradation: 100 % Exposure time: 21 d

Method: OECD Test Guideline 301E

12.3 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-

: log Pow: -0,93 octanol/water Remarks: Calculation

12.4 Mobility in soil

No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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

14.1 UN number or ID number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 30: N,N-Dimethylformamide

Number on list 72: N,N-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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II

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Dimethylformamide

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Number on list 76: N,N-Dimethylformamide

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

N,N-Dimethylformamide

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation (Annex XIV)

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

Not applicableNot applicable

Not applicable

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : 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 H-Statements

H226 : Flammable liquid and vapour.

H301 : Toxic if swallowed. H302 : Harmful if swallowed.

H312 : Harmful in contact with skin. H317 : May cause an allergic skin reaction.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H336
H360D
H370
H371
May cause drowsiness or dizziness.
May damage the unborn child.
Causes damage to organs.
May cause damage to organs.

H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation

STOT SE : Specific target organ toxicity - single exposure

2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers

from the risks related to exposure to carcinogens or mutagens

at work

2009/161/EU : Europe. COMMISSION DIRECTIVE 2009/161/EU establishing

a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending

Commission Directive 2000/39/EC

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

2004/37/EC / STEL : Short term exposure limit 2004/37/EC / TWA : Long term exposure limit 2009/161/EU / TWA : Limit Value - eight hours 2009/161/EU / STEL : Short term exposure limit FOR-2011-12-06-1358 / : Long term exposure limit

TWA

FOR-2011-12-06-1358 / : Short term exposure limit

STEL

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/

Classification of the mixture:

Classification procedure:

Acute Tox. 4	H302	Calculation method
Acute Tox. 4	H332	Calculation method
Acute Tox. 4	H312	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 1B	H360D	Calculation method
STOT SE 3	H336	Calculation method

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

NO / EN