

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	27.08.2024	9373264-00009	Date of first issue: 27.08.2021

#### **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- stance/Mixture	:	Veterinary product						
Recommended restrictions on use	:	Not applicable						
1.3 Details of the supplier of th	e saf	ety data sheet						
Company	:	MSD Walton Manor, Walton MK7 7AJ Milton Keynes - United Kingdom						
Telephone	:	+1-908-740-4000						
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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Acute toxicity, Category 4
Acute toxicity, Category 4
Acute toxicity, Category 4
Eye irritation, Category 2
Reproductive toxicity, Category 1B
Specific target organ toxicity - single ex-
posure, Category 3

H302: Harmful if swallowed.
H332: Harmful if inhaled.
H312: Harmful in contact with skin.
H319: Causes serious eye irritation.
H360D: May damage the unborn child.
H336: May cause drowsiness or dizziness.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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Hazar	rd pictograms	:		
Signa	l word	:	Danger	•
Hazar	rd statements	:	H319 Ca H336 M	H332 Harmful if swallowed, in contact with kin or if inhaled. auses serious eye irritation. ay cause drowsiness or dizziness. ay damage the unborn child.
Preca	utionary statements	:	P280 W	btain special instructions before use. /ear protective gloves/ protective clothing/ eye rotection/ face protection.
			P302 + P352 + te	- P312 IF ON SKIN: Wash with plenty of wa- r. Call a POISON CENTER/ doctor if you feel well.
			P304 + P340 + ai	
			P308 + P313	IF exposed or concerned: Get medical advice/ tention.
			P337 + P313	If eye irritation persists: Get medical advice/ tention.
	rdous components wh Dimethylformamide	ich m	nust be listed on	the label:

N,N-Dimethylformamide Embutramide Mebezonium iodide EUH208 Contains tetracaine hydrochloride. May produce an allergic reaction.

#### 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.

Vapours may form explosive mixture with air.

### **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

#### Components

Chemica	CAS-No. EC-No.	Classification	Concentration (% w/w)
	Index-No.		

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		Registration	number	
N,N-E	Dimethylformamide	68-12-2 200-679-5 616-001-00-2	Flam. Liq. 3; H226 Acute Tox. 4; H332	>= 50 - < 70
Embu	utramide	15687-14-6 239-780-4	Acute Tox. 4; H302 STOT SE 3; H336 Aquatic Chronic 3; H412	>= 20 - < 25
Mebe	zonium iodide	7681-78-9 231-676-7	Acute Tox. 3; H301 STOT SE 2; H371 (Nervous system, muscle)	>= 1 - < 10
tetrac	aine hydrochloride	136-47-0 205-248-5	Skin Sens. 1B; H317 STOT SE 1; H370 (Central nervous system, Cardio- vascular system)	>= 0.1 - < 1

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.
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.



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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 a	nd e	ffects, both acut	e and delayed		
Risks	5	:	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.		
	ation of any immediate tment	mec :		d special treatment needed ically and supportively.		
SECTIO	N 5: Firefighting mea	sure	es			
5.1 Exting	guishing media					
Suita	ble extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide ( Dry chemical			
Unsu medi	uitable extinguishing a	:	High volume wat	er jet		
5.2 Speci	al hazards arising from	the	substance or m	ixture		
	ific hazards during fire-	:	Do not use a soli fire. Flash back possi Vapours may for	d water stream as it may scatter and spread ble over considerable distance. m explosive mixtures with air. bustion products may be a hazard to health.		
Haza ucts	ardous combustion prod-	:	Carbon oxides Nitrogen oxides (	(NOx)		
5.3 Advic	e for firefighters					
Spec	cial protective equipment refighters	:		e, wear self-contained breathing apparatus. tective equipment.		
Spec ods	ific extinguishing meth-	:	cumstances and Use water spray	g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do		



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		Evacuate area.				
SECTION	N 6: Accidental rele	ase measures				
6.1 Perso	nal precautions, prot	ective equipment an	d emergency procedures			
Perso	onal precautions	Use personal p Follow safe hai	urces of ignition. rotective equipment. ndling advice (see section 7) and personal pro- ent recommendations (see section 8).			
6.2 Enviro	onmental precautions	6				
Envir	onmental precautions	Prevent further Prevent spread barriers). Retain and disp If spillage enter	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. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060).			
6.3 Metho	ods and material for c	ontainment and clea	ning up			
	ods for cleaning up	<ul> <li>Non-sparking to Soak up with in Suppress (know spray jet.</li> <li>For large spills, ment to keep m be pumped, sto Clean up remai bent.</li> <li>Local or nationa posal of this ma employed in the mine which reg Sections 13 an</li> </ul>	pools should be used. pert absorbent material. ck down) gases/vapours/mists with a water provide dyking or other appropriate contain- haterial from spreading. If dyked material can per recovered material in appropriate container. ining materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- julations are applicable. d 15 of this SDS provide information regarding 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.

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Hygiene measures		:	<ul> <li>Do not swallow.</li> <li>Do not get in eyes.</li> <li>Wash skin thoroughly after handling.</li> <li>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</li> <li>Keep container tightly closed.</li> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</li> <li>Take precautionary measures against static discharges.</li> <li>Do not eat, drink or smoke when using this product.</li> <li>Take care to prevent spills, waste and minimize release to the environment.</li> <li>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.</li> <li>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.</li> </ul>				
7.2	Conditi	ons for safe storage,	inc	luding any incom	patibilities		
	•	ements for storage and containers	:	tightly closed. Ke accordance with	labelled containers. Store locked up. Keep ep in a cool, well-ventilated place. Store in the particular national regulations. Keep nd sources of ignition.		
Advice on common storage : Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases					agents stances and mixtures		
7.3	Specifi	c end use(s)					
	-	c use(s)	:	No data available			

### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
N,N- Dimethylforma- mide	68-12-2	TWA	5 ppm 15 mg/m3	GB EH40

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			hose for which	absorbed through the skin. The there are concerns that dermal					
			STEL	10 ppm 30 mg/m3	GB EH40				
		Further information: Can be absorbed through the skin. The assigned sub- stances are those for which there are concerns that dermal absorption will lead to systemic toxicity.							
			STEL	10 ppm 30 mg/m3	2009/161/EU				
		Further infor		es the possibility of significant up	otake through the				
			TWA	5 ppm 15 mg/m3	2009/161/EL				
		Further information: Identifies the possibility of significant uptake through the skin, Indicative							
			TWA	5 ppm 15 mg/m3	2004/37/EC				
		Further infor	Further information: Skin, Carcinogens or mutagens						
			STEL	10 ppm 30 mg/m3	2004/37/EC				
		Further infor							
Embut	ramide	15687-14-6	TWA	10 µg/m3 (OEB 3)	Internal				
			STEL	30 µg/m3	Internal				
			Wipe limit	100 µg/100 cm <sup>2</sup>	Internal				
Mebez dide	onium io-	7681-78-9	TWA	1 μg/m3 (OEB 4)	Internal				
			STEL	3 µg/m3 (OEB 4)	Internal				
			Wipe limit	10 µg/100 cm2	Internal				
tetraca chlorid	aine hydro- le	136-47-0	TŴA	5 μg/m3 (OEB 4)	Internal				
		Further infor	mation: DSEN,	Skin					
			Wipe limit	50 μg/100 cm <sup>2</sup>	Internal				

### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health ef- fects	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)

Substance name	Environmental Compartment	Value
N,N-Dimethylformamide	Sewage treatment plant	44 mg/l

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		Fresh water so	ediment	111 mg/kg dry weight (d.w.)
		Marine sedime	ent	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 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 BS 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

Appearance Colour Odour Odour Threshold	: liquid : No data av : No data av : No data av	ailable
рН	: 5-6	



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	Melting point/freezing point		:	No data available	)
	Initial boiling point and boiling range Flash point		:	No data available	9
			:	81 °C	
	Evapor	ation rate	:	No data available	)
	Flamm	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	)
	Vapou	rpressure	:	No data available	)
	Relativ	e vapour density	:	No data available	
	Relativ	e density	:	No data available	
	Density	/	:	No data available	)
		ter solubility n coefficient: n-	:	soluble No data available	
		inition temperature	:	No data available	)
	Decom	position temperature	:	No data available	)
	Viscosi Visc	ity cosity, kinematic	:	No data available	
	Explos	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
9.2	Other ir	nformation			
	Flamm	ability (liquids)	:	Not applicable	
	Molecu	ılar weight	:	Not applicable	
	Particle size		:	Not applicable	



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### **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
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#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

_			
Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact	
Acute toxicity			

#### 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
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II				
Acute	inhalation toxicity	:	Exposure time: Test atmosphere Method: Expert	e: vapour
Acute	dermal toxicity	:	Method: Expert	stimate: 1,100 mg/kg judgement d on national or regional regulation.
Embu	ıtramide:			
Acute	oral toxicity	:	LD50 (Rat): 1,5	50 mg/kg
	toxicity (other routes of histration)	:	LD50 (Dog): 31 Application Rou	
			TDLo (Dog): 15 Application Rou Symptoms: nar	te: Intravenous
			LD50 (Horse): 2 Application Rou	
			LD50 (sheep): 8 Application Rou	
			LD50 (Pig): 100 Application Rou	
Mebe	zonium iodide:			
	oral toxicity	:	LD50 (Rat, fem	ale): 200 - 300 mg/kg
	toxicity (other routes of histration)	:	LC50 (Dog): 15 Application Rou	
tetrac	aine hydrochloride:			
Acute	toxicity (other routes of histration)	:	LD50 (Rat): 6 n Application Rou	
			LD50 (Mouse): Application Rou	

### Skin corrosion/irritation

Not classified based on available information.



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	<u>ponents:</u> Dimethylformamide:		Rabbit	
Resu		:	No skin irritation	
	ous eye damage/eye in ses serious eye irritation		on	
<u>Com</u>	ponents:			
N,N-	Dimethylformamide:			
Spec Resu		:	Rabbit Irritation to eyes,	reversing within 21 days
Resp	piratory or skin sensiti	satio	on	
_	sensitisation	lable	information.	
-	<b>biratory sensitisation</b> classified based on avai	lable	information.	
Com	ponents:			
N,N-	Dimethylformamide:			
	Type	:	Local lymph node Skin contact	e assay (LLNA)
Spec	osure routes cies	:	Mouse	
Resu	ılt	:	negative	
tetra	caine hydrochloride:			
	sure routes	:	Dermal Sensitiser	
Gern	n cell mutagenicity			
Not c	classified based on avai	lable	information.	
<u>Com</u>	ponents:			
	Dimethylformamide:			
Geno	otoxicity in vitro	:	Test Type: Bacter Result: negative	rial reverse mutation assay (AMES)
			Test Type: In vitro Result: negative	o mammalian cell gene mutation test
			Test Type: Chron Result: negative	nosome aberration test in vitro
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			e: DNA damage and repair, unscheduled DNA syn- mammalian cells (in vitro) negative
Gend	otoxicity in vivo	cytogene Species:	on Route: Intraperitoneal injection
		Species:	on Route: inhalation (vapour)
		Species:	on Route: Intraperitoneal injection
tetra	caine hydrochloride:		
	otoxicity in vitro	: Test Typ Result: n	e: Bacterial reverse mutation assay (AMES) negative
		Test Typ Result: e	e: Chromosomal aberration equivocal
Geno	otoxicity in vivo	: Test Typ Species: Result: n	
Carc	inogenicity		
Not c	lassified based on avai	able informatio	on.
<u>Com</u>	ponents:		
	Dimethylformamide:	_	
Spec Appli	ies cation Route	: Rat : inhalatior	n (vapour)
Expo	sure time	: 2 Years	
Meth Resu		: OECD Te : negative	est Guideline 451
Spec		: Mouse	
	cation Route sure time	: inhalatior : 18 Month	n (vapour) bs
Meth	od	: OECD Te	est Guideline 451
Resu	llt	: negative	

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-	oductive toxicity lamage the unborn ch	ild.	
Comp	oonents:		
	Dimethylformamide: s on fertility	: Test Type: Two Species: Mous Application Ro Result: negativ	ute: Ingestion
		Species: Rat	e-generation reproduction toxicity study ute: Skin contact e
Effect ment	s on foetal develop-	Species: Rabbi Application Ro	ute: inhalation (vapour) PTest Guideline 414
		Species: Rabbi Application Ro	ute: Skin contact • Test Guideline 414
Repro sessn	oductive toxicity - As- nent	: Clear evidence animal experim	of adverse effects on development, based or ents.
tetrac	aine hydrochloride:		
Effect	s on fertility	Application Rou	nale and female ute: Subcutaneous L: 7.5 mg/kg body weight
Effect ment	s on foetal develop-		ute: Subcutaneous Toxicity: NOAEL: 5 mg/kg body weight
			t ute: Subcutaneous Toxicity: NOAEL: 10 mg/kg body weight

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STOT	- single exposure			
May ca	ause drowsiness or diz	zine	SS.	
Compo	onents:			
Embut	ramide:			
Assess	sment	:	May cause drows	siness or dizziness.
Mebez	onium iodide:			
Target Assess	Organs sment	:	Nervous system, May cause dama	
tetraca	aine hydrochloride:			
Target Assess	Organs sment	:	Central nervous s Causes damage	system, Cardio-vascular system to organs.
	- repeated exposure	able	information.	
Repea	ted dose toxicity			
Compo	onents:			
N,N-Di	methylformamide:			
Specie NOAEL LOAEL Applica Exposu	L - ation Route	:	Rat 238 mg/kg 475 mg/kg Ingestion 28 Days	
Specie NOAEI LOAEL Applica Exposu	L - ation Route		Rat 0.08 mg/l 0.3 mg/l inhalation (vapou 2 yr	r)
-	tion toxicity ssified based on avail	able	information.	
Experi	ence with human exp	posi	ure	
Compo	onents:			
Embut	ramide:			
Inhalat	ion	:	Symptoms: Drow	Central nervous system siness, Central nervous system depression, s, Shortness of breath
Mebez	onium iodide:			
Inhalat	ion	:	Symptoms: Weak	ness, Fatigue, Breathing difficulties
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tetrad	caine hydrochloride:	:	
Inhala	ation	Target Organs: Symptoms: Ce	Cardio-vascular system Central nervous system ntral nervous system depression, Dizziness, otension, Vomiting
Skin (	contact	: Symptoms: Re	dness, 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 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: 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
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l 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 %



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			Exposure time: 2 Method: OECD T	1 d est Guideline 301E
12.3 Bio	accumulative potential			
Cor	nponents:			
N,N	-Dimethylformamide:			
Bioa	accumulation	:		s carpio (Carp) factor (BCF): 0.3 - 1.2 est Guideline 305C
	tition coefficient: n- anol/water	:	: log Pow: -0.93 Remarks: Calculation	
12.4 Mo	bility in soil			
No	data available			
12.5 Res	sults of PBT and vPvB a	sse	ssment	
<u>Pro</u>	duct:			
Ass	essment	:	to be either persis	hixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6 Oth	er adverse effects			
Pro	duct:			
End tial	ocrine disrupting poten-	:	ered to have end	ixture does not contain components consid- ocrine disrupting properties for environment REACH Article 57(f).
SECTIC	N 13: Disposal consid	der	ations	
13.1 Wa	ste treatment methods			
Pro	duct	:	According to the	ordance with local regulations. European Waste Catalogue, Waste Codes pecific, 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	<ul> <li>Empty containers should be taken to an approved waste han- dling site for recycling or disposal.</li> <li>Empty containers retain residue and can be dangerous.</li> </ul>
	Do not pressurize, cut, weld, braze, solder, drill, grind, or ex- pose 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.



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### **SECTION 14: Transport information**

#### 14.1 UN 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	
	ΙΑΤΑ	:	Not regulated as a dangerous good	
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	
	ΙΑΤΑ	:	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	
	ΙΑΤΑ	:	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				

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

# **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Remarks : Not applicable for product as supplied.



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#### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
UK REACH List of restrictions (Annex 17) UK REACH List of restrictions (Annex 17)		Number on list 72: 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 condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	N,N-Dimethylformamide
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation Control of Major Accident Hazards Regulations 2015 (CO	: DMA	Not applicable H)
Not applicable		

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

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



### Embutramide / Mebezonium / Tetracaine Formulation

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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.
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Full text of H-Statements	
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H226:H301:H302:H312:H317:H319:H336:H360D:H370:H371:H412:	Flammable liquid and vapour. Toxic if swallowed. Harmful if swallowed. Harmful in contact with skin. May cause an allergic skin reaction. Causes serious eye irritation. Harmful if inhaled. May cause drowsiness or dizziness. May damage the unborn child. Causes damage to organs. May cause damage to organs. Harmful to aquatic life with long lasting effects.
Full text of other abbreviations	5
Acute Tox.:Aquatic Chronic:Eye Irrit.:Flam. Liq.:Repr.:Skin Sens.:STOT SE:2004/37/EC:	Acute toxicity Long-term (chronic) aquatic hazard Eye irritation Flammable liquids Reproductive toxicity Skin sensitisation Specific target organ toxicity - single exposure 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
GB EH40       :         2004/37/EC / STEL       :         2004/37/EC / TWA       :         2009/161/EU / TWA       :         2009/161/EU / STEL       :         GB EH40 / TWA       :         GB EH40 / STEL       :	UK. EH40 WEL - Workplace Exposure Limits Short term exposure limit Long term exposure limit Limit Value - eight hours Short term exposure limit Long-term exposure limit (8-hour TWA reference period) Short-term exposure limit (15-minute reference period)

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 Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-



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tion (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 - Emergencv 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	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
Sheet	cy, http://echa.europa.eu/

Classification of the I	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

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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



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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.

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