



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Comfortan® (Solution for Injection 10mg/ml)
Synonyms:	Semfortan [IT, SE]
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Used for: <ul style="list-style-type: none"> • Analgesia in dogs and cats. • Premedication for general anaesthesia or neuroleptanalgesia in dogs and cats in combination with a neuroleptic drug.
Uses advised against:	<ul style="list-style-type: none"> • Do not use in known cases of hypersensitivity to the active substance or to any of the excipients. • People with known hypersensitivity to methadone should avoid contact with the veterinary medicinal product. • Methadone has the potential to cause stillbirths. Pregnant women are advised not to handle the product. • Do not use in animals with advanced respiratory failure. • Do not use in animals with severe liver and renal dysfunction.
1.3 Details of the supplier of the substance or mixture	
Registered company name (UK):	Eurovet Animal Health BV
Address:	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Fax:	+31 (0) 497 544 302
Email:	Not available
1.4 Emergency Telephone Numbers	
	+31 (0) 497 544 300 Office Hours.8.30-17.00

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes.	
DSD Classification (EU):	Not Available
DPD Classification (EU):	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU):	H373 - Specific target organ toxicity - repeated exposure Category 2 H412 - Chronic Aquatic Hazard Category 3
2.2 Label Elements	
Signal Word:	WARNING
Hazard statement(s):	
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful to aquatic life with long lasting effects.
Precautionary Statement(s) Prevention:	
P273	Avoid release to the environment.
Precautionary Statement(s) Response:	
P314	Get medical advice/attention if you feel unwell.
Precautionary Statement(s) Storage:	
Not Applicable	
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.
2.3 Other Hazard Information	
Ingestion may produce health damage*. May produce discomfort of the eyes, respiratory tract and skin*. REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	

SECTION 3: INFORMATION ON THE INGREDIENTS
3.1 Substances
See section below for composition of mixtures

3.2 Mixtures			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 125-56-4 2. 214-140-7 3. Not Available 4. Not Available	1	Methadone Hydrochloride (active)	Acute Toxicity (Oral) Category 3, Specific target organ toxicity - repeated exposure Category 2, Acute Aquatic Hazard Category 1, Chronic Aquatic Hazard Category 1; H301, H373, H410 ¹
1. 99-76-3 2. 202-785-7 3. Not Available 4. 01-2119463264-40-xxxx 01-2120065912-54-xxxx	0.1	Methyl Paraben	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Chronic Aquatic Hazard Category 2; H315, H319, H335, H411 ¹
1. 94-13-3 2. 202-307-7 3. Not Available 4. 01-2119969462-29-XXXX	0.02	Propyl Paraben	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Chronic Aquatic Hazard Category 2; H315, H319, H335, H411 ¹
N/a	Proprietary	Other ingredients	N/a
Legend:	1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I		
SECTION 4: FIRST AID MEASURES			
4.1 Description of first aid measures			
Eye contact:	Accidental spillage on the eyes should be washed off immediately with large amounts of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.		
Skin contact:	Wear impermeable gloves when handling the product to avoid skin contact. Accidental spillage on the skin should be washed off immediately with large amounts of water. Removed contaminated clothes. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.		

Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	If swallowed, do NOT induce vomiting. Seek medical advice immediately and show the package leaflet or the label to the medical practitioner.
Self-injection:	In the case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician but DO NOT DRIVE as sedation may occur.
4.2 Most important symptoms and effects, both acute and delayed	
See Section 11	
4.3 Indication of immediate medical attention and special treatment needed ADVICE TO MEDICAL PRACTITIONERS: Methadone is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs controlled ventilation should be installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.	
SECTION 5: FIRE FIGHTING MEASURES	
5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area .
Unsuitable:	There is no restriction on the type of extinguisher which may be used.
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility:	None known.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn. Irritating and highly toxic gases may be generated from thermal decomposition or combustion.



SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
See section 8	
6.2 Environmental Precautions	
See section 12	
6.3 Methods and material for containment and cleaning up	
Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Collect spillage and place into a suitable disposal container.
Major Spills:	Moderate hazard. Alert Fire Brigade and tell them location and nature of the hazard. Wear breathing apparatus plus protective gloves. Clear area of personnel and move upwind.
SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Avoid skin, eye and mouth contact, and wear impermeable gloves when handling the product. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Stored in glass vials with rubber stopper and aluminium cap, filled with 5 ml, 10 ml, 20 ml, 25 ml, 30 ml and 50 ml. 1 vial in a cardboard box. Store in the original package in order to protect from light.
Storage incompatibility:	Note: Special security requirements may be applicable by law. Store locked up
7.3 Specific end uses	
See section 1.2	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL (EU)

Not Available

PREDICTED NO EFFECT LEVEL - PNEC (EU)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:

Source	Ingredient	Material Name	TWA	STEL	Peak	Notes
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Not Available

EMERGENCY LIMITS:

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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Not Available

Ingredient	Original IDLH	Revised IDLH
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Not Available

8.2 Exposure controls

Appropriate engineering controls: The basic types of engineering controls are:
 Process controls which involve changing the way a job activity or process is done to reduce the particular risk.

Personal protection:



Eye and face protection: Safety glasses with side shields / chemical goggles

Skin protection: See hand protection below

Hands/ feet protection: Wear impermeable gloves when handling the product.

Body protection: Wear appropriate clothing

Other protection: No special equipment needed when handling small quantities

Thermal hazards: Not applicable

Respiratory protection: Not applicable

8.3 Environmental exposure controls	
See Section 12	
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES	
9.1 Information on basic physical and chemical properties	
<p>Appearance: Comfortan®: A clear colourless to pale yellow solution. Methadone hydrochloride: white or almost white crystalline powder</p> <p>Container: Vials of uncoloured glass type I filled with 5ml, 10ml, 20ml, 25ml, 30ml and 50ml</p> <p>Physical state: Liquid</p> <p>Odour: Not available</p> <p>Odour Threshold: Not available</p> <p>pH (as supplied): Not available</p> <p>Melting point / freezing point (degrees C): Methadone hydrochloride melting point: 233-236°C</p> <p>Initial boiling point and boiling range: Not available</p> <p>Flash Point: Not applicable</p> <p>Evaporation rate: Not available</p> <p>Flammability: Not available</p> <p>Upper/lower flammability or explosive limits: Not available</p> <p>Vapour pressure: Not available</p> <p>Relative Density (at degrees C): Not available</p> <p>Solubility in water and solvents (mg/l): Methadone hydrochloride soluble in water, freely soluble in alcohol</p> <p style="text-align: right;">Vapour density: Not available</p> <p>Auto ignition temperature (degrees C): Not available</p> <p>Decomposition temperature (degrees C): Not available</p> <p>Viscosity: (degrees C): Not available</p> <p>Explosive properties: Not available</p> <p>Oxidising properties: Not available</p> <p>Partition Coefficient: Not available</p> <p>Molecular weight: Methadone hydrochloride: 345.9</p> <p>Taste: Not available</p> <p>Surface tension: Not available</p> <p>Volative component: Not available</p> <p>Gas group: Not available</p> <p>pH as a solution: Not available</p> <p>VOC g/L: Not available</p>	
9.2 Other information	
Not Available	
10: REACTIVITY AND STABILITY	
10.1 Reactivity:	See Section 7
10.2 Chemical stability:	See Section 7
10.3 Possibility of hazardous reactions:	See Section 7
10.4 Conditions to avoid:	See Section 7.

10.5 Incompatible materials:	See section 7.	
10.6 Hazardous decomposition:	See Section 5.	
SECTION 11: TOXICOLOGICAL INFORMATION		
Inhalation:	May cause respiratory tract irritation.	
Ingestion:	Toxic if swallowed. May cause gastrointestinal irritation with nausea, vomiting, gastrointestinal irritation, drowsiness and confusion.	
Skin contact:	Methadone can cause respiratory depression following spillage onto the skin.	
Eye contact:	Contact may cause transient eye irritation.	
Self-injection:	Methadone can cause respiratory depression following accidental self-injection.	
Chronic:	Methadone is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma.	
Comfortan®:	Acute toxicity	Irritation
	Not Available	Not Available
Methadone Hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD50: 95 mg/kgd ²	Not available
Methyl Paraben:	Acute toxicity	Irritation
	Oral (rat) LD50: 2100 mg/kg ²	Not available
Propyl Paraben:	Acute toxicity	Irritation
	Oral (mouse) LD50: 6332 mg/kg ²	Not Available
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances		
Skin corrosion/ irritation:	Not Available	
Serious eye damage/ irritation:	Not Available	
Respiratory or skin sensitization:	Not Available	



Germ cell mutagenicity:
Not Available
Carcinogenicity:
Not Available
Reproductive toxicity:
Methadone has the potential to cause stillbirths. Pregnant women are advised not to handle the product.
STOT – single exposure:
This substance may cause respiratory irritation in some people. The reaction to this irritation can lead to further damage to the lungs.
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Name	Endpoint	Test duration (hr)	Species	Value	Source
Methadone hydrochloride	N/a	N/a	N/a	N.a	N/a
Methyl Paraben	EC ₅₀	48	Crustacea	41.1mg/L	2
Methyl Paraben	NOEC	504	Crustacea	0.2mg/L	1
Propyl Paraben	LC ₅₀	96	Fish	6.4mg/L	1
Propyl Paraben	NOEC	96	Fish	3.4mg/L	1

DO NOT discharge into sewer or waterways.

Legend:

1. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 2. US EPA, Ecotox database - Aquatic Toxicity Data

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Methadone hydrochloride	HIGH	HIGH
Methyl Paraben	LOW	LOW
Propyl Paraben	LOW	LOW

12.3 Bioaccumulative potential



Ingredient	Bioaccumulative Potential
Methadone Hydrochloride	MEDIUM (LogKOW = 4.1665)
Methyl Paraben	LOW (LogKOW = 1.96)
Propyl Paraben	LOW (LogKOW = 3.04)
12.4 Mobility in Soil	
Ingredient	Mobility
Methadone Hydrochloride	LOW (KOC = 72790)
Methyl Paraben	LOW (KOC = 125.6)
Propyl Paraben	LOW (KOC = 427.2)
12.5 Results of PBT and vPvB assessment Not Available	
12.6 Other adverse effects Not Available	
SECTION 13: DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	
Product / packaging disposal:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.</p> <p>Do not let the wash water run into the drain.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available



SECTION 14: TRANSPORT INFORMATION		
Labels required:		
Marine pollutant:	NO	
Hazchem:	Not Applicable	
Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Limited quantity	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	

14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
	EMS Number	N/a
	Special provisions	N/a

14.6 Special precautions for user	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
SECTION 15: REGULATORY INFORMATION		
15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture		

METHADONE HYDROCHLORIDE (125-56-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Customs of Chemicals ECICS (English)
- European Union - The European Inventory of Existing Chemical Commodities (EINECS) (English)

METHYL PARABEN (99-76-3)
<ul style="list-style-type: none"> • EU European Chemicals Agency (ECHA) - Community Progressive Action Plan (CoRAP) List of Substances • European Union Confederation of Trade Unions (EVV) Priority List for REACH License • European Customs of Chemicals ECICS (English) • European Union - European inventory of existing chemical commodities (EINECS)

PROPYL PARABEN (94-13-3)
<ul style="list-style-type: none"> • EU European Chemicals Agency (ECHA) - Community Progressive Action Plan (CoRAP) List of Substances • European Customs of Chemicals ECICS (English) • European Union - European inventory of existing chemical raw materials (EINECS) (English)
This Safety Data Sheet is in accordance with the following EU legislation and its adaptations as applicable: 98/24 / EC, 92/85 / EC, 94/33 / EC, 91/689 / EEC, 1999/13 / EC

15.2 Chemical Safety Assessment			
ECHA SUMMARY			
Ingredient	CAS Number	Index Number	ECHA Dossier
Methadone Hydrochloride	125-56-4	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 2	GHS06, Dgr	H300
1	Acute Tox. 3	GHS06, Dgr	H301
Ingredient	CAS Number	Index Number	ECHA Dossier
Methyl paraben	99-76-3	Not Available	01-2119463264-40-XXXX 01-2120065912-54-XXXX
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	GHS07; Wng	H315; H319; H335
Ingredient	CAS Number	Index Number	ECHA Dossier
Propyl paraben	94-13-3	Not Available	01-2119969462-29-XXXX



Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	GHS07; Wng	H315; H319; H335
Harmonization Code 1 = The most prevalent classification.			

National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (Methadone Hydrochloride)
Canada - NDSL	N (Methadone hydrochloride, methyl paraben, Propyl paraben,)
China - IECSC	N (Methadone Hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Methadone hydrochloride, methyl paraben, Propyl paraben)
Korea - KECI	N (Methadone Hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Methadone Hydrochloride)
USA - TSCA	N (Methadone Hydrochloride)
Legend:	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

SECTION 16: OTHER INFORMATIONN

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

Full text Risk and Hazard codes:

H300	Fatal if swallowed.
H301	Toxic if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Name	CAS Number
Methadone hydrochloride	125-56-4, 1095-90-5

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices



Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

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