



SAFETY DATA SHEET

(REACH regulation no. 1907/2006 and 453/2010)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product name: Torphadine 10 mg/ml solution for injection

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

Use: Analgesic/sedative veterinary medicinal product

1.3 Details of the supplier of the safety data sheet

Registered company name: Le Vet Beheer B.V.

Address: Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Telephone: +31-(0)348-565858.

Fax: +31-(0)348-565454

info@levetpharma.com

www.levetpharma.com

1.4 Emergency telephone number:**+31-(0)6-10203326**

SECTION 2: HAZARDS IDENTIFICATION

Appearance:**Classification of the Substance or Mixture****GHS – Classification**

Reproductive Toxicity: Category 1B

Reproductive Toxicity: Effects on or via lactation

EU Classification:

EU Indication of danger: Not classified

Label Elements**Signal Word:** Danger

Hazard Statements: H302 – Harmful if swallowed
 H360 – May damage fertility or the unborn child
 H362 – May cause harm to breast-fed children

Precautionary Statements: P201 – Obtain special instructions before use
 P202 – Do not handle until all safety precautions have been read and understood
 P280 – Wear protective gloves/protective clothing/eye protection/face protection
 P260 – Do not breathe dust/fume/gas/mist/vapors/spray
 P264 – Wash hands thoroughly after handling
 P270 – Do not eat, drink or smoke when using this product
 P263 – Avoid contact during pregnancy/while nursing
 P308 + P313 – IF exposed or concerned: Get medical attention/advice
 P501 – Dispose of contents/container in accordance with all local and national regulations

**Other Hazards****Short Term:** May be harmful if swallowed.

Long Term:	Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.
Known Clinical Effects:	Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdosage may also lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

No substances fulfill the criteria set forth in annex II section A of the REACH regulation (EC) no. 1907/2006

3.2 Mixtures**Composition:**

Ingredient	CAS-no.	Quantity
Butorphanol tartrate	58786-99-5	10.0 mg/ml
Benzethonium chloride	121-54-0	0.1 mg/ml
Citric acid, anhydrous	77-92-9	Classified
Sodium citrate, dihydrate	6132-04-3	Classified
Sodium chloride	7647-14-5	Classified
Water for injections	7789-20-0	ad 1 ml

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most important Symptoms and Effects, Both Acute and Delayed**Symptoms and Effects**

of Exposure:	For information on potential signs and symptoms of exposure, See section 2 – Hazards Identification and/or Section 11 – Toxicological Information.
---------------------	--

Medical Conditions

Aggravated by Exposure:	None known
--------------------------------	------------

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:	None
----------------------------	------

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special hazards arising from the substance or mixture

Hazardous Combustion

Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire/Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for firefighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning up

Measures for Cleaning /

Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration

for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, including any Incompatibilities

Storage Conditions: Store as directed by product packaging

Specific end use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters**Occupational****Exposure Limits:** No data available.**Exposure controls****Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate, unless the process generates dust, mist or fumes.**Personal Protective****Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.**Eyes:** Wear safety glasses or goggles if eye contact is possible.**Skin:** Impervious, disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: Odourless
Colour: Colourless
Molecular formula: Mixture
Molecular weight: Mixture

Solvent Solubility: Not applicable
Water Solubility: Not applicable
pH: 3.0 – 5.5
Melting/Freezing Point: No data available
Boiling Point (°C): No data available
Partition Coefficient: No data available
Evaporation Rate: No data available
Vapor Pressure: No data available
Vapor Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid): No data available
Flammability (Solids): No data available
Flash Point (Liquid): No data available
Upper Explosive Limits (Liquid): No data available
Lower Explosive Limits (Liquid): No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity

No data available

Name: TORPHADINE 10 MG/ML SOLUTION FOR INJECTION**Chemical stability**

Stable under normal conditions of use.

Possibility of hazardous reactions

No data available

Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products

No data available

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact , skin contact.

Acute Toxicity: (Species, Route, End Point, Dose)**Butorphanol tartrate**

Rat	Oral	LD ₅₀	315 mg/kg
-----	------	------------------	-----------

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Butorphanol tartrate**

Reproductive & Fertility	Rat	Oral	2.5 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Oral	Dose not specified	NOAEL	Not teratogenic
Reproductive & Fertility	Rat	S.C.	1 mg/kg/day	LOAEL	Fetal mortality

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Butorphanol tartrate**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Unscheduled DNA Synthesis	Human fibroblast cells	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**Butorphanol tartrate**

2 Year(s)	Rat	Oral	60 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	60 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation, unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15: REGULATORY INFORMATION

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

Particular provisions: Veterinary medicinal product, under the scope of 2001/82/EC as amended

Chemical safety assessment: No data available

SECTION 16: OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Toxic to Reproduction: Category 2

Xn - Harmful

R22 - Harmful if swallowed.

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.