



Complying to 91/155/EC, 93/112/EC

# Product Safety Data Sheet

## Torphasol 10mg/ml Injection

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### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	Torphasol 10mg/ml Injection
Product Code	XVD 129
Supplier	Animalcare Ltd, Common Road, Dunnington, York, YO19 5RU. Telephone No. +44 (0) 1904 487687 Fax No. +44 (0) 1904 487611 E-Mail: animalcare@animalcare.co.uk. Emergency Telephone +44 (0) 1904 487687 (daytime)

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### 2. HAZARDS IDENTIFICATION

Under normal conditions and use it is unlikely to cause any health hazards. The preparation may be hazardous in case of accidental eye or skin contact, inhalation, ingestion or self-injection.

#### Acute health effects

Eye/Skin:	May cause irritation/allergic reaction
Ingestion/Self-injection/Inhalation:	Respiratory depression, sedation, drowsiness, nausea, visual disturbances and dizziness may occur

#### Chronic health effects

Potential organ system affected is the Central Nervous System. Signs and symptoms that may appear after chronic exposure are similar to those that may occur after acute exposure.

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### 3. COMPOSITION / INFORMATION ON COMPONENTS

Ingredients	CAS-No.
Butorphanol Tartrate	58786-99-5
Chlorocresol	59-50-7
Sodium Chloride	7647-14-5
Sodium Citrate	68-04-2
Citric Acid Monohydrate	5949-29-1
Water for Injections	7732-18-5

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### 4. FIRST AID MEASURES

<b>Skin contact:</b>	In case of accidental skin contact, flush skin with plenty of water and wash thoroughly with soap and water. If irritation appears, seek medical attention.
<b>Eye contact:</b>	Rinse thoroughly immediately with plenty of water for at least 15 minutes. Seek medical attention.
<b>Ingestion:</b>	Seek medical advice immediately and show the package leaflet or the label to the physician. Treatment: symptomatic.
<b>Inhalation:</b>	If breathing is difficult, administer oxygen and seek medical attention immediately. If necessary provide artificial respiration. Treatment: symptomatic.

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### 5. FIRE FIGHTING MEASURES

- Flammable properties:** Non-flammable. Not expected to present a fire hazard.
- Suitable extinguishing media:** Water mist, foam
- Extinguishing media which must not be used for safety reasons:**  
None known.
- Special protective equipment for fire fighters:**  
Self-contained breathing apparatus and full fire-fighting suits.
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### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions:** Use appropriate personal protective equipment during clean-up to minimize exposure (see section 8).
- Environmental precautions:** Prevent material from entering sewers or waterways. Any unused products should be disposed of in accordance with national requirements.
- Methods for cleaning up:** Wear suitable protective clothing and equipment. Mop up the liquid and place absorbent materials in a container suitable for chemical waste. Thoroughly wash area with detergent and water. Dispose wash and rinse water in accordance with national regulations.
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### 7. HANDLING AND STORAGE

- Handling:** Avoid eye and skin contact. Do not ingest. Avoid procedure that will generate aerosols and use with adequate ventilation.
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**Storage:** Keep out of the reach and sight of children. Keep the container tightly closed in original cardboard box.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The usual precautionary measures for dealing with chemicals should be observed. No eating or drinking when handling the product. Wash hands before break and end of work. Handle material under adequate ventilation.

**Respiratory protection:** recommended if the room is not well ventilated and if there is a risk of exposure to high vapour concentrations.

**Skin protection:** recommended (gloves, lab coat)

**Eye protection:** recommended (splash goggles)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:** liquid (solution for injection)

**Colour:** clear, colourless

**Odour:** slight characteristic odour

**pH:** 3.5-5.5

**Boiling point/range:** not applicable

**Melting point/ range:** not applicable

**Flammability:** non-flammable

**Relative density:** 1.006-1.016

**Solubility:** water soluble

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### 10. STABILITY AND REACTIVITY

- Stability:** The product is stable under normal conditions.
- Reactivity:** The product is not expected to present any reactivity concerns.
- Decomposition products:** Carbon monoxide, carbon dioxide, nitrogen oxide under fire conditions.
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### 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity - butorphanol tartrate

- Acute intravenous toxicity: LD50 (mice): 32 mg/kg BW  
LD50 (rat): 20 mg/kg BW
- Acute oral toxicity: LD50 (rat): > 100 mg/kg BW
- Acute subcutaneous toxicity: LD50 (mice): 300 mg/kg BW  
LD50 (rat): 620 mg/kg BW

#### Repeat dose toxicity - butorphanol tartrate

- 3-month toxicity study (rat): NOEL <0.5 mg/kg BW
- 3-month toxicity study (dog): LOEL 0.1-0.5 mg/kg BW/day
- 6-month toxicity study (monkey): NOEL >1.5 mg/kg BW/day

#### Skin toxicity

Butorphanol tartrate - LD50 dermal (rabbits): 622-852 mg/kg BW

Since butorphanol tartrate is classified as harmful substance for the skin, irritation after skin contact with the product is not excluded.

#### Eye toxicity

Butorphanol tartrate is considered as irritating for eyes. However, no specific eye effects are known after ocular exposure with the product, but direct contact with any foreign material may cause eye irritation.

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### **Carcinogenicity**

No evidence of carcinogenicity of butorphanol tartrate.

### **Mutagenicity**

Butorphanol tartrate is not genotoxic in standard battery of genetic toxicological tests.

### **Toxicity for Reproduction**

No known human teratogenic effect of butorphanol tartrate. Reproduction studies in mice, rats and rabbits during organogenesis did not reveal any teratogenic potential to butorphanol tartrate.

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## **12. ECOLOGICAL INFORMATION**

No known significant effects or critical hazards. The product does not contain any hazardous ingredients. However the product should be handled in a manner to prevent spills or release to the environment.

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## **13. DISPOSAL CONSIDERATIONS**

Any unused product or waste materials derived from the products should be disposed of by incineration at an approved/permited incinerator, in accordance with local requirements.

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## **14. TRANSPORT INFORMATION**

The product is not classified as hazardous goods in terms of RID/ADR (Carriage of dangerous goods by rail (RID) and by road (ADR)), IMDG (Carriage of dangerous goods by water) and ICAO-TI/IATA-DGR (Carriage of dangerous goods by air).



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### 15. REGULATORY INFORMATION

**Symbol:** No symbol required.  
**R-phrases:** Not regulated.  
**S-phrases:** Not regulated.

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### 16. OTHER INFORMATION

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use.

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