

# Material Safety Data Sheet

## Torphasol 10 mg/ml Solution for injection

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

#### 1.1 Product identification

**Product name(s):** Torphasol 10 mg/ml Solution for injection  
**Product code(s):** XVD129

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

**Relevant identified uses:** Veterinary medicinal product  
**Uses advised against:** Not for human use. Refer to the product information leaflet  
**Reasons why uses advised against:** Refer to the product information leaflet

#### 1.3 Details of the supplier of the safety data sheet

**Company name:** Animalcare Limited  
**Address:** 10 Great Northway  
York Business Park  
Nether Poppleton  
York  
YO26 6RB  
United Kingdom

#### 1.4 Emergency telephone number

**Daytime:** +44 (0) 1904 487687

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

**Classification according to Regulation (EC) 1272/2008** This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

#### 2.2 Label elements

**Labelling according to Regulation (EC) 1272/2008** This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

**Hazard pictograms:** Not applicable  
**Signal word:** Not applicable  
**Hazard statements:** Not applicable  
**Precautionary statements:** Not applicable  
**Supplemental information:** Not applicable

#### 2.3 Other hazards

**Hazard(s) not otherwise classified (HNOC)** None known

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Butorphanol tartrate	[58786-99-5]	1%
Benzethonium chloride	[121-54-0]	Proprietary
Sodium chloride	[7647-14-5]	Proprietary
Sodium citrate	[68-04-2]	Proprietary
Citric acid monohydrate	[5949-29-1]	Proprietary
Water for injections	[7732-18-5]	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	Rinse thoroughly immediately with plenty of water for at least 15 minutes. Seek medical attention
<b>Skin:</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>Ingestion:</b>	Seek medical advice immediately if large quantities are ingested 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

### 4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

### 4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment: Water, mist, foam
<b>Unsuitable extinguishing media:</b>	None known

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Not flammable or combustible
<b>Hazardous combustion products:</b>	Decomposition products may include the following materials: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> )

### 5.3 Advice for fire-fighters

<b>Special protective equipment for firefighters:</b>	Use personal protective equipment
<b>Further information:</b>	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**Advice for non-emergency personnel:** Refer to protective measures listed in sections 7 and 8

**Advice for emergency responders:** If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

### 6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### 6.3 Methods and material for containment and cleaning up

**Large spills:** 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

**Small spills:** Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water

### 6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

**Advice on safe handling:** Avoid procedure that will generate aerosols and use with adequate ventilation. Avoid eye and skin contact. Do not ingest.

**Hygiene measures:** None identified

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers:** Keep out of reach of children. Keep in the original packaging

**Storage temperature:** Not specified

**Further information on storage conditions:** Protect from direct incidence of light

### 7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. Data not known.

## 8.2 Exposure controls

**Engineering measures:** Good general ventilation should be sufficient to control worker exposure to airborne contaminants

### Individual protection measures:

**Hygiene measures:** Wash hands before break and end of work

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

**Skin/body protection:** recommended (lab coat)

**Hand protection:** recommended (gloves)

**Respiratory protection:** None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

**Environmental exposure controls:** Consider the provision of containment around storage vessels

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Colour:</b>	Clear, colourless
<b>Odour:</b>	Slight characteristic odour
<b>Odour threshold:</b>	No data available
<b>pH:</b>	3.5 – 5.5
<b>Density:</b>	1.004 – 1.014
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	Soluble
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available
<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	The substance or mixture is not classified as oxidizing

### 9.2 Other information

No data available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

### 10.2 Chemical stability

Stable under normal conditions

### 10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

#### 10.4 Conditions to avoid

Avoid contact with incompatible materials

#### 10.5 Incompatible materials

None Known

#### 10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute toxicity:</b>	Butorphanol tartrate LD <sub>50</sub> 32 mg/kg (Mice, IV) Butorphanol tartrate LD <sub>50</sub> 20 mg/kg (Rat, IV) Butorphanol tartrate LD <sub>50</sub> >100 mg/kg (Rat, oral) Butorphanol tartrate LD <sub>50</sub> 620 mg/kg (Rat, SC) Butorphanol tartrate LD <sub>50</sub> 300 mg/kg (Mice, SC)
<b>Chronic toxicity:</b>	Butorphanol tartrate NOEL <0.5 mg/kg/day (Rat, oral) Butorphanol tartrate LOEL 0.1-0.5 mg/kg/day (Dog, oral) Butorphanol tartrate NOEL >1.5 mg/kg/day (Monkey, oral)
<b>Skin irritation/sensitization:</b>	Butorphanol tartrate Skin corrosion LD <sub>50</sub> 622-852 mg/kg (Rabbit, dermal) Since butorphanol tartrate is classified as harmful substance for the skin, irritation after skin contact with the product is not excluded. 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
<b>Reproductive toxicity:</b>	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
<b>Carcinogenicity:</b>	No evidence of carcinogenicity of butorphanol tartrate
<b>Mutagenicity:</b>	Butorphanol tartrate is not genotoxic in standard battery of genetic toxicological tests

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

No data available

#### 12.2 Persistence and degradability

No data available

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

No data available

#### 12.6 Other adverse effects

No data available

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1 Waste treatment methods**

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

## **SECTION 14: TRANSPORT INFORMATION**

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

## **SECTION 15: REGULATORY INFORMATION**

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

This product has been authorised under the provisions of Directive 2001/82/EC

### **15.2 Chemical safety assessment**

For this product, a chemical safety assessment was not carried out

## **SECTION 16: OTHER INFORMATION**

For animal treatment only

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