

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form : Mixture  
Name : Tilmodil  
Product code : TILM-300

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Use of the substance/mixture : solution for injection containing tilmicosin  
Use in veterinary medicine.

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet**

Name EMDOKA bvba  
John Lijsenstraat 16  
2321 Hoogstraten - Belgium  
Telephone +32 (0)3 315 04 26  
Fax +32 (0)3 605 86 23  
E-mail mail@emdoka.be

**Inquiry office**

IFZ Ingenieurbüro und Consulting GmbH  
Telephone: +49 30 / 2904897-10  
E-mail asi@ifz-berlin.de

**1.4. Emergency telephone number**

Emergency number United Kingdom +44 870 600 626 / 0870 600 6266

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4 H302  
Acute toxicity (inhalation: dust, mist) Category 4 H332  
Serious eye damage/eye irritation, Category 2 H319  
Respiratory sensitisation, Category 1 H334  
Skin sensitisation, Category 1 H317  
Specific target organ toxicity — Repeated exposure, Category 2 H373  
Hazardous to the aquatic environment — Chronic Hazard, Category 1 H410

Full text of H statements : see section 16

**Adverse physicochemical, human health and environmental effects**

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazardous ingredients :

Tilmicosin

Hazard statements (CLP) :

H302+H332 - Harmful if swallowed or if inhaled  
H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation.  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H373 - May cause damage to organs (heart) through prolonged or repeated exposure.  
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) :

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P312 - Call a POISON CENTRE or doctor if you feel unwell.  
P314 - Get medical advice/attention if you feel unwell.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P391 - Collect spillage.

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

| Name   | Product identifier                          | %       | Classification according to Regulation (EC) No. 1272/2008 [CLP]   |
|--|---|---------|---|
| Tilmicosin   | (CAS-No.) 108050-54-0<br>(EC-No.) 639-676-2 | 30 - 50 | Acute Tox. 4 (Oral), H302<br>Acute Tox. 4 (Inhalation), H332<br>Eye Irrit. 2, H319<br>Resp. Sens. 1, H334<br>Skin Sens. 1, H317<br>STOT RE 2, H373<br>Aquatic Chronic 1, H410 |
| propylene glycol<br>substance with national workplace exposure limit(s) (GB) | (CAS-No.) 57-55-6                           | 30 - 50 | Not classified  |

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general :

Protection is needed for the First Aider. Move out of dangerous area.

First-aid measures after inhalation :

Remove person to fresh air and keep comfortable for breathing. Lay the affected person down and keep him still; If unconscious, place the person in the recovery position. Call a physician immediately. Allow affected person to breathe fresh air. Respiratory arrest: artificial respiration or oxygen.

First-aid measures after skin contact :

After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Wash skin with plenty of water. Call a physician immediately.

First-aid measures after eye contact :

Rinse with plenty of water immediately, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth out with water. Drink plenty of water. Do not induce vomiting. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Irritation of mucous membranes. Cough.

Symptoms/effects after skin contact : May cause an allergic skin reaction. Causes skin irritation.

Symptoms/effects after eye contact : Eye irritation.

Symptoms/effects after ingestion : May cause irritation to the digestive tract.

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

Eye wash.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to the environment.

Unsuitable extinguishing media : High volume water jet.

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

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>). nitrogen oxides (NO<sub>x</sub>).

#### 5.3. Advice for firefighters

No additional information available

### SECTION 6: Accidental release measures

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

General measures : Wear personal protective equipment.

##### 6.1.1. For non-emergency personnel

No additional information available

##### 6.1.2. For emergency responders

No additional information available

#### 6.2. Environmental precautions

May not end up in waste water or open waters. Seal discharge point, if possible without danger.

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

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Take up mechanically and collect in suitable container for disposal.

#### 6.4. Reference to other sections

See section 8. For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Hygiene measures : Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product.

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

Storage conditions : Store in a dry place. Store in a closed container.

Information on mixed storage : Keep away from food, drink and animal food stuffs.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

| propylene glycol (57-55-6) |                              |  |
|----------------------------|------------------------------|--|
| United Kingdom             | Local name                   | Propane-1,2-diol   |
| United Kingdom             | WEL TWA (mg/m <sup>3</sup> ) | 10 mg/m <sup>3</sup> particulates<br>474 mg/m <sup>3</sup> total vapour and particulates |
| United Kingdom             | WEL TWA (ppm)                | 150 ppm total vapour and particulates  |
| United Kingdom             | Regulatory reference         | EH40/2005 (Third edition, 2018). HSE   |

**8.2. Exposure controls****Personal protective equipment:**

Gloves. Safety glasses.

**Personal protective equipment symbol(s):****SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

|  |                     |
|--|---------------------|
| Physical state                             | : Liquid            |
| Colour                                     | : No data available |
| Odour                                      | : No data available |
| Odour threshold                            | : No data available |
| pH   | : 6                 |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point                              | : No data available |
| Freezing point                             | : No data available |
| Boiling point                              | : No data available |
| Flash point                                | : No data available |
| Auto-ignition temperature                  | : No data available |
| Decomposition temperature                  | : No data available |
| Flammability (solid, gas)                  | : No data available |
| Vapour pressure                            | : No data available |
| Relative vapour density at 20 °C           | : No data available |
| Relative density                           | : No data available |
| Solubility                                 | : No data available |
| Log Pow                                    | : No data available |
| Viscosity, kinematic                       | : No data available |
| Viscosity, dynamic                         | : No data available |
| Explosive properties                       | : No data available |
| Oxidising properties                       | : No data available |
| Explosive limits                           | : No data available |

**9.2. Other information**

No additional information available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

The product is non-reactive under normal conditions of use, storage and transport.

**10.2. Chemical stability**

Stable under proper storage and handling.

**10.3. Possibility of hazardous reactions**

None known.

**10.4. Conditions to avoid**

None known.

**10.5. Incompatible materials**

None known.

**10.6. Hazardous decomposition products**

None known.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

|                                   |   |
|-----------------------------------|---|
| Acute toxicity (oral)             | : Harmful if swallowed.   |
| Acute toxicity (dermal)           | : Not classified  |
| Acute toxicity (inhalation)       | : Harmful if inhaled.   |
| ATE CLP (oral)                    | 1000 mg/kg bodyweight   |
| ATE CLP (dust,mist)               | 3 mg/l/4h   |
| Skin corrosion/irritation         | : Not classified<br>pH: 6   |
| Serious eye damage/irritation     | : Causes serious eye irritation.<br>pH: 6   |
| Respiratory or skin sensitisation | : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. |
| Germ cell mutagenicity            | : Not classified  |
| Carcinogenicity                   | : Not classified  |
| Reproductive toxicity             | : Not classified  |
| STOT-single exposure              | : Not classified  |
| STOT-repeated exposure            | : May cause damage to organs (heart) through prolonged or repeated exposure.                                      |
| Aspiration hazard                 | : Not classified  |

**SECTION 12: Ecological information****12.1. Toxicity**

|                          |   |
|--------------------------|---|
| Acute aquatic toxicity   | : Not classified  |
| Chronic aquatic toxicity | : Very toxic to aquatic life with long lasting effects. |

**phosphoric acid ... %, orthophosphoric acid ... % (7664-38-2)**

|             |          |
|-------------|----------|
| LC50 fish 1 | 138 mg/l |
|-------------|----------|

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

No additional information available

**12.4. Mobility in soil**

No additional information available

**12.5. Results of PBT and vPvB assessment**

No additional information available

**12.6. Other adverse effects**

No additional information available






**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Regional legislation (waste) : Disposal must be done according to official regulations.

**SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR   | IMDG  | IATA  | ADN   | RID   |
|---|---|---|---|---|
| <b>14.1. UN number</b>                              |   |   |   |   |
| 3082  | 3082  | 3082  | 3082  | 3082  |
| <b>14.2. UN proper shipping name</b>                |   |   |   |   |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | Environmentally hazardous substance, liquid, n.o.s. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. |

| ADR  | IMDG   | IATA  | ADN  | RID   |
|--|--|---|--|---|
| <b>Transport document description</b>  |  |   |  |   |
| UN 3082<br>ENVIRONMENTALLY<br>HAZARDOUS<br>SUBSTANCE, LIQUID,<br>N.O.S., 9, III, (-) | UN 3082<br>ENVIRONMENTALLY<br>HAZARDOUS<br>SUBSTANCE, LIQUID,<br>N.O.S., 9, III, MARINE<br>POLLUTANT | UN 3082 Environmentally<br>hazardous substance,<br>liquid, n.o.s., 9, III         | UN 3082<br>ENVIRONMENTALLY<br>HAZARDOUS<br>SUBSTANCE, LIQUID,<br>N.O.S., 9, III    | UN 3082<br>ENVIRONMENTALLY<br>HAZARDOUS<br>SUBSTANCE, LIQUID,<br>N.O.S., 9, III     |
| <b>14.3. Transport hazard class(es)</b>  |  |   |  |   |
| 9  | 9  | 9   | 9  | 9   |
|      |                     |  |  |  |
| <b>14.4. Packing group</b>   |  |   |  |   |
| III  | III  | III   | III  | III   |
| <b>14.5. Environmental hazards</b>   |  |   |  |   |
| Dangerous for the<br>environment : Yes   | Dangerous for the<br>environment : Yes<br>Marine pollutant : Yes                                     | Dangerous for the<br>environment : Yes  | Dangerous for the<br>environment : Yes   | Dangerous for the<br>environment : Yes  |
| No supplementary information available   |  |   |  |   |

**14.6. Special precautions for user**
**- Overland transport**

|   |                           |
|---|---------------------------|
| Classification code (ADR)   | : M6                      |
| Special provisions (ADR)  | : 274, 335, 375, 601      |
| Limited quantities (ADR)  | : 5I                      |
| Excepted quantities (ADR)   | : E1                      |
| Packing instructions (ADR)  | : P001, IBC03, LP01, R001 |
| Special packing provisions (ADR)  | : PP1                     |
| Mixed packing provisions (ADR)  | : MP19                    |
| Portable tank and bulk container instructions (ADR)                     | : T4                      |
| Portable tank and bulk container special provisions (ADR)               | : TP1, TP29               |
| Tank code (ADR)   | : LGBV                    |
| Vehicle for tank carriage   | : AT                      |
| Transport category (ADR)  | : 3                       |
| Special provisions for carriage - Packages (ADR)                        | : V12                     |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13                    |
| Hazard identification number (Kemler No.)                               | : 90                      |
| Orange plates   | :                         |



|                               |       |
|-------------------------------|-------|
| Tunnel restriction code (ADR) | : -   |
| EAC code                      | : •3Z |

**- Transport by sea**

|                                   |                 |
|-----------------------------------|-----------------|
| Special provisions (IMDG)         | : 274, 335, 969 |
| Limited quantities (IMDG)         | : 5 L           |
| Excepted quantities (IMDG)        | : E1            |
| Packing instructions (IMDG)       | : LP01, P001    |
| Special packing provisions (IMDG) | : PP1           |
| IBC packing instructions (IMDG)   | : IBC03         |

|                                |             |
|--------------------------------|-------------|
| Tank instructions (IMDG)       | : T4        |
| Tank special provisions (IMDG) | : TP2, TP29 |
| EmS-No. (Fire)                 | : F-A       |
| EmS-No. (Spillage)             | : S-F       |
| Stowage category (IMDG)        | : A         |

**- Air transport**

|  |                   |
|--|-------------------|
| PCA Excepted quantities (IATA)               | : E1              |
| PCA Limited quantities (IATA)                | : Y964            |
| PCA limited quantity max net quantity (IATA) | : 30kgG           |
| PCA packing instructions (IATA)              | : 964             |
| PCA max net quantity (IATA)                  | : 450L            |
| CAO packing instructions (IATA)              | : 964             |
| CAO max net quantity (IATA)                  | : 450L            |
| Special provisions (IATA)                    | : A97, A158, A197 |
| ERG code (IATA)                              | : 9L              |

**- Inland waterway transport**

|                                   |                      |
|-----------------------------------|----------------------|
| Classification code (ADN)         | : M6                 |
| Special provisions (ADN)          | : 274, 335, 375, 601 |
| Limited quantities (ADN)          | : 5 L                |
| Excepted quantities (ADN)         | : E1                 |
| Carriage permitted (ADN)          | : T                  |
| Equipment required (ADN)          | : PP                 |
| Number of blue cones/lights (ADN) | : 0                  |

**- Rail transport**

|   |                           |
|---|---------------------------|
| Classification code (RID)   | : M6                      |
| Special provisions (RID)  | : 274, 335, 375, 601      |
| Excepted quantities (RID)   | : E1                      |
| Packing instructions (RID)  | : P001, IBC03, LP01, R001 |
| Special packing provisions (RID)  | : PP1                     |
| Mixed packing provisions (RID)  | : MP19                    |
| Portable tank and bulk container instructions (RID)                     | : T4                      |
| Portable tank and bulk container special provisions (RID)               | : TP1, TP29               |
| Tank codes for RID tanks (RID)  | : LGBV                    |
| Transport category (RID)  | : 3                       |
| Special provisions for carriage – Packages (RID)                        | : W12                     |
| Special provisions for carriage - Loading, unloading and handling (RID) | : CW13, CW31              |
| Colis express (express parcels) (RID)                                   | : CE8                     |
| Hazard identification number (RID)                                      | : 90                      |

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

Contains no REACH substances with Annex XVII restrictions  
Contains no substance on the REACH candidate list  
Contains no REACH Annex XIV substances

**15.1.2. National regulations**

No additional information available

**15.2. Chemical safety assessment**

No additional information available

**SECTION 16: Other information**

Full text of H- and EUH-statements:

|                                     |  |
|-------------------------------------|--|
| Acute Tox. 4 (Inhalation)           | Acute toxicity (inhal.), Category 4  |
| Acute Tox. 4 (Inhalation:dust,mist) | Acute toxicity (inhalation:dust,mist) Category 4                           |
| Acute Tox. 4 (Oral)                 | Acute toxicity (oral), Category 4  |
| Aquatic Chronic 1                   | Hazardous to the aquatic environment — Chronic Hazard, Category 1          |
| Eye Irrit. 2                        | Serious eye damage/eye irritation, Category 2                              |
| Resp. Sens. 1                       | Respiratory sensitisation, Category 1                                      |
| Skin Sens. 1                        | Skin sensitisation, Category 1   |
| STOT RE 2                           | Specific target organ toxicity — Repeated exposure, Category 2             |
| H302                                | Harmful if swallowed.  |
| H317                                | May cause an allergic skin reaction  |
| H319                                | Causes serious eye irritation.   |
| H332                                | Harmful if inhaled.  |
| H334                                | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H373                                | May cause damage to organs through prolonged or repeated exposure.         |
| H410                                | Very toxic to aquatic life with long lasting effects.                      |

Other information :

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.