

According to EC Regulation 1907/2006 (REACH)



## PRODUCT SAFETY DATA SHEET

### OPTI-MAG 3 BOLUS

#### 1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

|              |   |
|--------------|---|
| Product Name | Opti-MAG 3 Bolus  |
| Supplier     | Norbrook Laboratories Ltd,<br>Station Works, Newry, Co.Down,<br>N.Ireland, BT35 6JP.<br>Telephone No. +44 (0) 28 3026 4435<br>Fax No. +44 (0) 28 3026 1721<br>E-Mail: enquiries@norbrook.co.uk.<br>Emergency Telephone +44 (0) 28 3026 4435 |

#### 2. HAZARDS IDENTIFICATION

|                               |   |   |
|-------------------------------|---|---|
| Physical and Chemical Hazards | : | Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC |
| Environmental Hazards         | : | None known  |
| Adverse Human Health Effects  | : | There are no known adverse effects of exposure to Opti-MAG 3 Bolus.                 |

#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

|                       |   |                            |
|-----------------------|---|----------------------------|
| Substance/Preparation | : | Preparation                |
| Active Ingredients    | : | Magnesium                  |
| Description           | : | Maintains magnesium intake |

#### 4. FIRST AID MEASURES

|              |   |   |
|--------------|---|---|
| Inhalation   | : | Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.   |
| Skin Contact | : | Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.                                      |
| Eyes Contact | : | Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. |
| Ingestion    | : | Do not induce vomiting. Seek medical attention.   |

#### 5. FIRE FIGHTING MEASURES

|                             |  |
|-----------------------------|--|
| Extinguishing media:        | Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. |
| Fire and explosion hazards: | None.  |



**6. ACCIDENTAL RELEASE MEASURES**

|                            |   |   |
|----------------------------|---|---|
| Personal Precautions       | : | Provide good ventilation. Prevent skin and eye contact.                                   |
| Environmental Precautions: |   | Keep away from drains, surface-water, ground-water and soil.                              |
| Method for Clean-up        | : | Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material. |

**7. HANDLING AND STORAGE**

|          |   |  |
|----------|---|--|
| Handling | : | Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.   |
| Storage  | : | Store in closed containers in a cool, dry, well-ventilated area, below 25°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.<br><br>Keep container closed when not in use. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children. |

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Component - Occupational Exposure Standard

Magnesium

Not Established

|                      |   |   |
|----------------------|---|---|
| Protective Equipment | : | Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product. |
|----------------------|---|---|

**9. PHYSICAL AND CHEMICAL PROPERTIES**

|        |   |                              |
|--------|---|------------------------------|
| Form   | : | Moulded metal cylinder bolus |
| Colour | : | Silver                       |
| Odour  | : | None.                        |

**10. STABILITY AND REACTIVITY**

|                     |   |   |
|---------------------|---|---|
| Stability           | : | Stable under normal temperatures and pressures. |
| Conditions to avoid | : | None known                                      |
| Materials to avoid  | : | None known                                      |

**11. TOXICOLOGICAL INFORMATION**

Exposure Effects ( Acute )

|              |   |   |
|--------------|---|---|
| Eye Contact  | : | Direct contact with eyes may cause irritation.                |
| Skin Contact | : | Prolonged contact with Opti-MAG 3 Bolus may cause irritation. |
| Inhalation   | : | None known.   |
| Ingestion    | : | None known.   |

**12. ECOLOGICAL INFORMATION**



According to Regulation (EC) No.1907/2006



## PRODUCT SAFETY DATA SHEET

### PARAFEND 2.265% ORAL SUSPENSION

#### 1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY / UNDERTAKING

|              |   |
|--------------|---|
| Product Name | Parafend 2.265% Oral Suspension   |
| Supplier     | Norbrook Laboratories (Ireland) Ltd,<br>Rossmore Industrial Estate,<br>Clones Road, Monaghan.<br>Republic of Ireland<br>Telephone No. +353 (0) 47 81180<br>Fax No. +353 (0) 47 81187<br>E-Mail: roienquiries@norbrook.co.uk.<br>Emergency Telephone +353 (0) 47 81180 |

#### 2. HAZARDS IDENTIFICATION

|                               |   |  |
|-------------------------------|---|--|
| Physical and Chemical Hazards | : | Not classified as dangerous under EEC Directives 67/548/EEC, 88/379/EEC or 99/45/EC. |
| Environmental Hazards         | : | None known   |
| Adverse Human Health Effects  | : | There are no known adverse effects of exposure to Parafend 2.265%.                   |

#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

|                       |   |                                      |
|-----------------------|---|--------------------------------------|
| Substance/Preparation | : | Preparation                          |
| Active Ingredients    | : | Oxfendazole                          |
| Description           | : | Anthelmintic ( Chemical Group 1-BZ ) |
| Chemical Family       | : | Benzimidazole                        |

#### 4. FIRST AID MEASURES

|              |   |   |
|--------------|---|---|
| Inhalation   | : | Remove to fresh air. If any signs or symptoms occur or persist seek medical advice.   |
| Skin Contact | : | Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse.                                      |
| Eyes Contact | : | Immediately flush eyes with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. |
| Ingestion    | : | Do not induce vomiting. Seek medical attention.   |

#### 5. FIRE FIGHTING MEASURES

|                      |   |
|----------------------|---|
| Extinguishing media: | Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours. |
|----------------------|---|



Fire and explosion hazards: None.

## 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Provide good ventilation. Prevent skin and eye contact.  
Environmental Precautions : Keep away from drains, surface-water, ground-water and soil.  
Method for Clean-up : Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material.

## 7. HANDLING AND STORAGE

Handling : Avoid contact with eyes, skin or clothing. Do not breathe vapours or mist. Do not ingest. Do not smoke or eat while handling the product. Wash thoroughly after handling. The containers should be stored in their original boxes when not in use.  
Storage : Store in closed containers in a cool, dry, well-ventilated area, below 25°C and away from oxidisers, heat, sparks and open flame. Protect containers from physical damage and light.  
Keep container closed when not in use. Before opening large containers, release any pressure build-up by loosening closure slowly. Do not transfer contents to unlabelled containers. Use only with adequate ventilation. Keep out of reach of children.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Component - Occupational Exposure Standard

Oxfendazole

Not Established

For pure oxfendazole :

LD50 ( Oral, mouse ) 6400 mg/kg

LD50 ( Oral, rat ) 6400 mg/kg

Protective Equipment : Wear vinyl, nitrile or rubber gloves, a waterproof bib-apron and suitable eye protection when applying the product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Form : Aqueous suspension  
Colour : Off-white  
Odour : None.

## 10. STABILITY AND REACTIVITY

Stability : Stable under normal temperatures and pressures.  
Conditions to avoid : None known  
Materials to avoid : None known

## 11. TOXICOLOGICAL INFORMATION

Exposure Effects ( Acute )





|              |   |   |
|--------------|---|---|
| Eye Contact  | : | Direct contact of the solution with eyes can cause irritation.  |
| Skin Contact | : | Prolonged or repeated contact with Parafend 2.265% Oral Suspension may cause irritation and/or drying and cracking of the skin. |
| Inhalation   | : | None known.   |
| Ingestion    | : | Oral toxicity of the Parafend 2.265% Oral Suspension is low.  |

## Exposure Effects ( Chronic )

Unknown for the product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Both its mutagenicity and its teratogenicity are not known.

**12. ECOLOGICAL INFORMATION**

Data on the ecological implications for Parafend 2.265% Oral Suspension is not yet available.

**13. DISPOSAL CONSIDERATIONS**

|                  |   |  |
|------------------|---|--|
| Product/Residues | : | Do not discharge the product material into surface or waste water. For disposal, use an incinerator licensed for chemical waste. |
| Package          | : | Dispose of waste containers using regular disposal methods in accordance with local and national environmental regulations.      |

**14. TRANSPORT INFORMATION**

Land, Sea & Air Transport

ADR/RID, IMO/IMDG, IATA/ICAO, UN No. : Not applicable

**15. REGULATORY INFORMATION**

|                       |   |                                  |
|-----------------------|---|----------------------------------|
| Labelling Information | : | None                             |
| Safety phrases        | : | S2 Keep out of reach of children |
|                       | : | S7 Keep container tightly closed |

**16. OTHER INFORMATION**

|                  |                           |
|------------------|---------------------------|
| VPA : 10999/59/1 | For Animal Treatment Only |
| ML : 2000/01     |                           |
| Revision Date    | : 03/08/12                |
| Revision No      | : 07                      |
| Printing Date    | : 02/01/2013              |

Suppliers data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.



The information contained in this PSDS is believed to be accurate and represents the best information available at the time of preparation. However Norbrook Laboratories (Ireland) Limited makes no warranty, express or implied, with respect to such information and assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes, and Norbrook Laboratories (Ireland) Limited will not be held liable for any damage resulting from the handling of or contact with the above product.





**Norbrook Laboratories Ltd – Solantel**

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

- 1.1 Product identifier:** Norbrook Laboratories Ltd - Closantel Drench For Sheep - VM 02000/4402  
Res : 94627
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: Veterinary Pharmaceutical Product  
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**  
Norbrook Laboratories Ltd  
Cambane Industrial Estate  
BT35 6QQ Newry - Northern Ireland  
Phone.: +44 (0)28 3026 4435 -  
Fax: +44 (0)28 3026 5060  
<http://www.norbrook.com>
- 1.4 Emergency telephone number:** +44 (0)28 3026 4435

**SECTION 2: HAZARDS IDENTIFICATION**

- 2.1 Classification of the substance or mixture:**  
**CLP Regulation (EC) n° 1272/2008:**  
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**  
This mixture is regulated under the Veterinary Medicines Directive and will be labelled accordingly  
**CLP Regulation (EC) n° 1272/2008:**  
None
- 2.3 Other hazards:**  
Non-applicable

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

- 3.1 Substance:**  
Non-applicable
- 3.2 Mixture:**  
**Chemical description:** Oral Solution  
**Components:**  
In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

| Identification        | Chemical name/Classification                     | Concentration      |
|-----------------------|--|--------------------|
| CAS: 61438-64-0       | <b>Closantel Sodium Dihydrate</b>                | <b>Proprietary</b> |
| EC: 262-794-7         |  |                    |
| Index: Non-applicable |  |                    |
| REACH: Non-applicable |  |                    |
|                       | Regulation 1272/2008 Acute Tox. 3: H301 - Danger |                    |

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

**SECTION 4: FIRST AID MEASURES**

- 4.1 Description of first aid measures:**  
The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.
- By inhalation:**  
This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.
- By skin contact:**

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#### SECTION 4: FIRST AID MEASURES (continued)

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

**By eye contact:**

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

**By ingestion/aspiration:**

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

**4.2 Most important symptoms and effects, both acute and delayed:**

Acute and delayed effects are indicated in sections 2 and 11.

**4.3 Indication of any immediate medical attention and special treatment needed:**

Non-applicable

#### SECTION 5: FIREFIGHTING MEASURES

**5.1 Extinguishing media:**

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

**5.2 Special hazards arising from the substance or mixture:**

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

**5.3 Advice for firefighters:**

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

**Additional provisions:**

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

**6.1 Personal precautions, protective equipment and emergency procedures:**

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

**6.2 Environmental precautions:**

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

**6.3 Methods and material for containment and cleaning up:**

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

**6.4 Reference to other sections:**

See sections 8 and 13.

#### SECTION 7: HANDLING AND STORAGE

**7.1 Precautions for safe handling:**

A.- Precautions for safe manipulation





**SECTION 7: HANDLING AND STORAGE (continued)**

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

**B.- Technical recommendations for the prevention of fires and explosions**

Product is non-flammable under normal conditions of storage, manipulation and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

**C.- Technical recommendations to prevent ergonomic and toxicological risks**

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

**D.- Technical recommendations to prevent environmental risks**

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

**7.2 Conditions for safe storage, including any incompatibilities:**

**A.- Technical measures for storage**

Maximum Temp.: 30 °C

**B.- General conditions for storage**

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

**7.3 Specific end use(s):**

For the treatment and prevention of chronic and subacute fasciolosis (due to Fasciola hepatica).

For the treatment and prevention of Oestrus ovis (Sheep Nasal Bot Fly).

For the treatment and prevention of inhibited, L4 and adult stages of Haemonchus contortus (Barber Pole Worm) including benzimidazole resistant strains.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the work environment

There are no occupational exposure limits for the substances contained in the product

**DNEL (Workers):**

Non-applicable

**DNEL (General population):**

Non-applicable

**PNEC:**

Non-applicable

**8.2 Exposure controls:**

**A.- General security and hygiene measures in the work place**



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

**B.- Respiratory protection**

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

**C.- Specific protection for the hands**



| Pictogram  | PPE                                   | Labelling   | CEN Standard | Remarks   |
|--|---------------------------------------|---|--------------|---|
| <br>Mandatory hand protection | Protective gloves against minor risks |  |              | Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374. |

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

D.- Ocular and facial protection



| Pictogram  | PPE                                     | Labelling   | CEN Standard                    | Remarks   |
|--|---|---|---------------------------------|---|
| <br>Mandatory face protection | Panoramic glasses against liquid splash |  | EN 166:2001<br>EN ISO 4007:2012 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Bodily protection

| Pictogram | PPE                  | Labelling   | CEN Standard      | Remarks |
|-----------|----------------------|---|-------------------|---------|
|           | Work clothing        |  |                   |         |
|           | Anti-slip work shoes |  | EN ISO 20347:2012 |         |

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

| Emergency measure   | Standards                      | Emergency measure  | Standards                     |
|---|--------------------------------|--|-------------------------------|
| <br>Emergency shower | ANSI Z358-1<br>ISO 3864-1:2002 | <br>Eyewash stations | DIN 12 899<br>ISO 3864-1:2002 |

**Environmental exposure controls:**

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

**Volatile organic compounds:**

With regard to Directive 2010/75/EU, this product has the following characteristics:

|                           |                             |
|---------------------------|-----------------------------|
| V.O.C. (Supply):          | 0 % weight                  |
| V.O.C. density at 20 °C:  | 0 kg/m <sup>3</sup> (0 g/L) |
| Average carbon number:    | Non-applicable              |
| Average molecular weight: | Non-applicable              |

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties:**

For complete information see the product datasheet.

**Appearance:**

|                          |               |
|--------------------------|---------------|
| Physical state at 20 °C: | Liquid        |
| Appearance:              | Not available |
| Color:                   | Not available |
| Odor:                    | Not available |

**Volatility:**

|  |                   |
|--|-------------------|
| Boiling point at atmospheric pressure: | 112 °C            |
| Vapour pressure at 20 °C:              | 2193 Pa           |
| Vapour pressure at 50 °C:              | 11557 Pa (12 kPa) |
| Evaporation rate at 20 °C:             | Non-applicable *  |

\*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

**Product description:**

|  |                        |
|--|------------------------|
| Density at 20 °C:                            | 1037 kg/m <sup>3</sup> |
| Relative density at 20 °C:                   | 1.037                  |
| Dynamic viscosity at 20 °C:                  | Non-applicable *       |
| Kinematic viscosity at 20 °C:                | Non-applicable *       |
| Kinematic viscosity at 40 °C:                | Non-applicable *       |
| Concentration:                               | Non-applicable *       |
| pH:  | Non-applicable *       |
| Vapour density at 20 °C:                     | Non-applicable *       |
| Partition coefficient n-octanol/water 20 °C: | Non-applicable *       |
| Solubility in water at 20 °C:                | Non-applicable *       |
| Solubility properties:                       | Non-applicable *       |
| Decomposition temperature:                   | Non-applicable *       |
| Melting point/freezing point:                | Non-applicable *       |
| Explosive properties:                        | Non-applicable *       |
| Oxidising properties:                        | Non-applicable *       |

**Flammability:**

|                           |                        |
|---------------------------|------------------------|
| Flash Point:              | Non Flammable (>60 °C) |
| Autoignition temperature: | 421 °C                 |
| Lower flammability limit: | Non-applicable *       |
| Upper flammability limit: | Non-applicable *       |

**9.2 Other information:**

|                           |                  |
|---------------------------|------------------|
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index:         | Non-applicable * |

\*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

**10.1 Reactivity:**

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

**10.2 Chemical stability:**

Chemically stable under the conditions of storage, handling and use.

**10.3 Possibility of hazardous reactions:**

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

**10.4 Conditions to avoid:**

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight       | Humidity       |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable     | Not applicable   | Not applicable          | Not applicable | Not applicable |

**10.5 Incompatible materials:**

| Acids              | Water          | Combustive materials | Combustible materials | Others                        |
|--------------------|----------------|----------------------|-----------------------|-------------------------------|
| Avoid strong acids | Not applicable | Avoid direct impact  | Not applicable        | Avoid alkalis or strong bases |

**10.6 Hazardous decomposition products:**

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO<sub>2</sub>), carbon monoxide and other organic compounds.



## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

#### Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

#### A.- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

#### Other information:

Non-applicable

#### Specific toxicology information on the substances:

| Identification             | Acute toxicity |             | Genus |
|----------------------------|----------------|-------------|-------|
|                            | LD50 oral      | LD50 dermal |       |
| Closantel Sodium Dihydrate | 262 mg/kg      | >2000 mg/kg | Rat   |
| CAS: 61438-64-0            |                |             |       |
| EC: 262-794-7              | Non-applicable |             |       |

## SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

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**SECTION 12: ECOLOGICAL INFORMATION (continued)**

**12.1 Toxicity:**

Not available

**12.2 Persistence and degradability:**

Not available

**12.3 Bioaccumulative potential:**

Not available

**12.4 Mobility in soil:**

Not available

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

Non-applicable

**12.6 Other adverse effects:**

Not described

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods:**

| Code     | Description   | Waste class - (Regulation (EU) No 1357/2014) |
|----------|---|--|
| 16 03 06 | Organic wastes other than those mentioned in 16 03 05 | Non dangerous                                |

**Type of waste (Regulation (EU) No 1357/2014):**

Non-applicable

**Waste management (disposal and evaluation):**

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

**Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

**SECTION 14: TRANSPORT INFORMATION**

**Transport of dangerous goods by land:**

With regard to ADR 2015 and RID 2015:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- Tunnel restriction code: Non-applicable
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

**Transport of dangerous goods by sea:**

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## SECTION 14: TRANSPORT INFORMATION (continued)

With regard to IMDG 37-14:

|   |                |
|---|----------------|
| <b>14.1 UN number:</b>  | Non-applicable |
| <b>14.2 UN proper shipping name:</b>  | Non-applicable |
| <b>14.3 Transport hazard class(es):</b>   | Non-applicable |
| Labels:   | Non-applicable |
| <b>14.4 Packing group:</b>  | Non-applicable |
| <b>14.5 Dangerous for the environment:</b>                                      | No             |
| <b>14.6 Special precautions for user</b>  |                |
| Special regulations:  | Non-applicable |
| EmS Codes:  |                |
| Physico-Chemical properties:  | see section 9  |
| Limited quantities:   | Non-applicable |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:</b> | Non-applicable |

### Transport of dangerous goods by air:

With regard to IATA/ICAO 2015:

|   |                |
|---|----------------|
| <b>14.1 UN number:</b>  | Non-applicable |
| <b>14.2 UN proper shipping name:</b>  | Non-applicable |
| <b>14.3 Transport hazard class(es):</b>   | Non-applicable |
| Labels:   | Non-applicable |
| <b>14.4 Packing group:</b>  | Non-applicable |
| <b>14.5 Dangerous for the environment:</b>                                      | No             |
| <b>14.6 Special precautions for user</b>  |                |
| Physico-Chemical properties:  | see section 9  |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:</b> | Non-applicable |

## SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

**Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ....):**

Non-applicable

#### Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

#### Other legislation:

The product could be affected by sectorial legislation

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

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SECTION 15: REGULATORY INFORMATION (continued)

**15.2 Chemical safety assessment:**

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

**Legislation related to safety data sheets:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

**Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:**

Non-applicable

**Texts of the legislative phrases mentioned in section 3:**

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

**CLP Regulation (EC) n° 1272/2008:**

Acute Tox. 3: H301 - Toxic if swallowed

**Classification procedure:**

Non-applicable

**Advice related to training:**

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

**Principal bibliographical sources:**

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

**Abbreviations and acronyms:**

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -

