

According to Regulation (EC) No. 1907/2006 (REACH), Annex II



## PRODUCT SAFETY DATA SHEET

### LOXICOM ORAL SUSPENSION 1.5mg/ml

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

- |     |                         |  |
|-----|-------------------------|--|
| 1.1 | Product identifier      | Loxicom Oral Suspension 1.5mg/ml   |
| 1.2 | Relevant identified use | Oral suspension for dogs. Used for alleviation and pain in both acute and chronic musculoskeletal disorders in dogs.   |
| 1.3 | Details of supplier     | Norbrook, Inc.<br>9733 Loiret Blvd<br>Lenexa, KS 66219<br>Phone: 913 599 5777<br>Fax: 913 599 5766   |
| 1.4 | Details of Manufacturer | 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 |
| 1.5 | Emergency Telephone No. | +44 (0) 28 3026 4435   |

#### 2. HAZARDS IDENTIFICATION

##### 2.1 Classification of the substance or mixture


Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.  
Not a hazardous substance or mixture according to EU Directives 67/548/EEC or 1999/45/EC

##### 2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

##### 2.3 Other hazards - none

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient name	%w/v	CAS No.	EC No.	Symbol	Classification (according to REACH)
Meloxicam	0.15	71125-38-7			H302, H360, H412, R61, R25, R52/53,

### 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

##### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

- Inhalation : Remove patient to fresh air, keep warm and at rest. If any signs or symptoms occur or persist seek medical advice.
- Skin Contact : Remove and wash contaminated clothing immediately. Wash affected area thoroughly with soap and water. If the patient feels unwell seek medical advice.
- Eyes Contact : Rinse affected eye with clean running water, or eyewash solution, for at least 15 minutes holding eyelids well apart. Rinse entire surface and do not allow run-off to contaminate unaffected eye. Seek medical attention.
- Ingestion : Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling (see Section 2.2) and/or in Section 11

### 5. FIRE FIGHTING MEASURES

#### 5.1 Extinguishing media

##### Suitable 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.

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

No data available.

#### 5.3 Advice for fire-fighters

Wear self contained breathing apparatus for fire fighting if necessary.

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**6. ACCIDENTAL RELEASE MEASURES**

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- 6.1 Personal precautions**  
Wear suitable personal protective equipment. Ensure area is well ventilated.
- 6.2 Environmental precautions**  
Do not let product enter drains.
- 6.3 Method for clean-up**  
Absorb small spills on spill pillows, sand, sawdust or other suitable absorbing material. Keep in suitable, closed containers for disposal.

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**7. HANDLING AND STORAGE**

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- 7.1 Precautions for safe 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.

**Conditions for safe storage**

Store in closed containers in a cool, dry, well-ventilated area, between 68°-77°F (20-25°C). Excursions permitted between 59°-86°F (15-30°C).

Keep out of reach of children.

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

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- 8.1 Control parameters**  
Contains no substances with occupational exposure limit values.
- 8.2 Appropriate engineering controls**  
Handle in accordance with good industrial hygiene and safety practice. Wash hands with soap and water after handling.
- 8.3 Personal protective equipment**  
Not generally required when handling containers.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

a) Appearance	Liquid (viscous suspension) 1.5mg/ml
b) Color	Yellowish
c) Odor	No data available.
d) pH	No data available
e) Melting point	No data available
f) Freezing point	No data available
g) Boiling point	No data available
h) Flash point	No data available (not flammable)
i) Flammability Limit-upper	Not applicable
j) Flammability Limit-lower	Not applicable
k) Evaporation rate	No data available
l) Vapor pressure	No data available
m) Vapor density (air=1)	No data available
n) Specific gravity	No data available
o) Solubility	No data available
p) Partition coefficient (n-octanol/water)	No data available
q) Auto-ignition temperature	No data available
r) Decomposition temperature	No data available

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available.

### 10.2 Chemical stability

Stable under normal temperatures and pressures.

### 10.3 Possibility of hazardous reactions

No data available.

### 10.4 Conditions to avoid

None known.

### 10.5 Incompatible materials

None known.

### 10.6 Hazardous decomposition products

Unidentified organic and inorganic compounds and oxides of nitrogen and carbon may be produced in the event of a fire.

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**11. TOXICOLOGICAL INFORMATION**

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**11.1 Information on toxicological effects****Exposure Effects (Acute)****Acute toxicity**

No data available

**Skin corrosion/irritation**

No data available

**Serious eye damage/eye irritation**

No data available

**Respiratory or skin sensitisation**

No data available

**Germ cell mutagenicity**

No data available

**Carcinogenicity**

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Reproductive toxicity**

No data available

**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

No data available **Aspiration hazard**

**Additional Information**

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

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**12. ECOLOGICAL INFORMATION**

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**12.1 Toxicity**

Data on the ecological implications for the product mixture is not yet available.

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

#### Product

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

### 14.1 UN number

ADR/RID:                      IMDG:                      IATA:

### 14.2 UN proper shipping name

ADR/RID:                      Not dangerous goods

IMDG:                         Not dangerous goods

IATA:                         Not dangerous goods

### 14.3 Transport hazard class (es)

ADR/RID:                      IMDG:                      IATA:

### 14.4 Packaging group

ADR/RID: -                      IMDG: -                      IATA: -

### 14.5 Environmental hazards

ADR/RID: no                      IMDG: no                      IATA: no

### 14.6 Special precautions for user

No data available.

## 15. REGULATORY INFORMATION

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available.

### 15.2 Chemical Safety Assessment

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

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**16. OTHER INFORMATION**

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**Full text of H-Statements referred to under Section 3**

H301 : Toxic if swallowed.  
H360 : May damage fertility or the unborn child.  
H412 : Harmful to aquatic life with long lasting effects.

**Full text of (R) Risk phrases referred to under Section 3**

R25 : Toxic if swallowed.  
R61 : May cause harm to the unborn child.  
R52/53 : Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

ANADA : 200-497

For Animal Treatment Only

ML : 2000/01

Revision Date : 02/04/2015  
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Suppliers' data sheets and various chemicals and pharmaceuticals databases were used to compile this sheet.

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