

# Material Safety Data Sheet

## Daxocox<sup>®</sup> tablets for dogs

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

#### 1.1 Product identification

Product name(s):	Daxocox 15 mg tablets for dogs Daxocox 30 mg tablets for dogs Daxocox 45 mg tablets for dogs Daxocox 70 mg tablets for dogs Daxocox 100 mg tablets for dogs
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#### 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:	Ecuphar NV
Address:	Legeweg 157-i Oostkamp 8020 Belgium

#### 1.4 Emergency telephone number

Daytime:	+32 (0) 50314269
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### 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.
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#### 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 classified
Signal word:	Not classified
Hazard statements:	Not classified
Precautionary statements:	Not classified
Supplemental information:	None available

#### 2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	The information contained in this datasheet refers to the naked product, unprotected from the primary packaging materials. This veterinary medicinal product can cause reactions in sensitised individuals. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
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Some NSAIDs may be harmful for the unborn child, especially during the third trimester of pregnancy. Pregnant women should administer this veterinary medicinal product with care.

Ingestion of this veterinary medicinal product may be harmful, especially for children, and prolonged pharmacological effects leading to e.g. gastrointestinal disorders may be observed. To avoid accidental ingestion.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Enflicoxib	[251442-94-1]	15, 30, 45, 70 or 100 mg/tablet
Silicified microcrystalline cellulose	[9004-34-6]	Proprietary
Crospovidone	[9003-39-8]	Proprietary
Copovidone	[25086-89-9]	Proprietary
Sodium stearyl fumarate	[4070-80-8]	Proprietary
Talc	[14807-96-6]	Proprietary
Iron oxide black (E172)	[12227-89-3]	Proprietary
Iron oxide yellow (E172)	[20344-49-4]	Proprietary
Iron oxide red (E172)	[90452-21-4]	Proprietary
Microcrystalline cellulose	[9004-34-6]	Proprietary
Dried flavour	N/A	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
<b>Skin:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately

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

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information

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

See patient package insert in shipping carton for complete information.

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Use carbon dioxide, dry chemical, or water spray
<b>Unsuitable extinguishing media:</b>	Not known

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

<b>Specific hazards during firefighting:</b>	During fire, gases hazardous to health may be formed. Fine particles (such as dust and mists) may fuel fires/explosions
<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>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire
<b>Further information:</b>	Use standard firefighting procedures and consider the hazards of other involved materials. Fire may produce toxic or corrosive gases. Vapours may ignite. Fine particles (such as mists) may fuel fires/explosions

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

<b>Advice for non-emergency personnel:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
<b>Advice for emergency responders:</b>	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

<b>Small spills:</b>	Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination
<b>Large spills:</b>	Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area 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

<b>Advice on safe handling:</b>	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation
<b>Hygiene measures:</b>	Wash thoroughly after handling

## 7.2 Conditions for safe storage, including any incompatibilities

<b>Requirements for storage areas and containers:</b>	Keep out of reach of children. Keep in the original packaging
<b>Storage temperature:</b>	Store between 15-30 °C
<b>Further information on storage conditions:</b>	Keep in a dry, cool and well-ventilated place

## 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.

At this time, none of the constituents have known exposure limits.

## 8.2 Exposure controls

<b>Engineering measures:</b>	Good general ventilation should be sufficient to control worker exposure to airborne contaminants
<b>Individual protection measures:</b>	
<b>Hygiene measures:</b>	Wash thoroughly after handling
<b>Eye/face protection:</b>	If contact is likely, safety glasses with side shields are recommended
<b>Skin/body protection:</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas
<b>Hand protection:</b>	Wear appropriate chemical resistant gloves. Suitable gloves can be recommended by the glove supplier
<b>Respiratory protection:</b>	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. Chemical respirator with organic vapor cartridge and full facepiece
<b>Environmental exposure controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Round convex tablet
<b>Colour:</b>	Brown
<b>Odour:</b>	Meat flavoured, characteristic
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	No data available
<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>	No data available

<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

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

### 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

Contact with incompatible materials. Keep away from heat, sparks, flame and all other sources of ignition. Protect from sunlight

### 10.5 Incompatible materials

Not known

### 10.6 Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Hydrogen fluoride. Carbon oxides. fluorine

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

<b>Acute toxicity:</b>	Enflicoxib LD <sub>50</sub> >2000 mg/kg (mouse, oral) Enflicoxib LD <sub>50</sub> >2000 mg/kg (rat, oral)
<b>Skin irritation/sensitization:</b>	Non irritant (rabbit)
<b>Reproductive toxicity:</b>	No data available
<b>Carcinogenicity:</b>	No data available
<b>Mutagenicity:</b>	Negative at Ames, Mouse micronucleus and Human lymphocytes 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

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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