



SAFETY DATA SHEET
(REACH regulation no. 1907/2006 and 453/2010)

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

1.1 Product Identifier

Product name: Meloxoral 1.5 mg/ml oral suspension

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

Use: Non-Steroidal Anti-Inflammatory Drug (NSAID)

1.3 Details of the supplier of the safety data sheet

Registered company name: Le Vet B.V.

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Telephone: +31-(0)348-565858.

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1.4 Emergency telephone number:**+31-(0)6-10203326**

SECTION 2: HAZARDS IDENTIFICATION

Appearance:**Classification of the Substance or Mixture****GHS – Classification**

Reproductive Toxicity: Category 1

EU Classification:

EU Indication of danger: Not classified

Label Elements**Signal Word:** Harmful**Hazard Statements:** H301 – Toxic if swallowed
H360 – May damage fertility or the unborn child**Precautionary Statements:** P201 – Obtain special instructions before use
P202 – Do not handle until all safety precautions have been read and understood
P280 – Wear protective gloves/protective clothing/eye protection/face protection
P264 – Wash hands thoroughly after handling
P270 – Do not eat, drink or smoke when using this product
P263 – Avoid contact during pregnancy/while nursing
P308 + P313 – IF exposed or concerned: Get medical attention/advice
P501 – Dispose of contents/container in accordance with all local and national regulations

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

No substances fulfill the criteria set forth in annex II section A of the REACH regulation (EC) no. 1907/2006

3.2 Mixtures

Composition:

Ingredient	CAS-no.	Quantity
Meloxicam	71125-38-7	1.5 mg/ml
Sodium benzoate	532-32-1	1.75 mg/ml
Sorbitol	50-70-4	Classified
Glycerol	56-81-5	Classified
Polysorbate 80	9005-65-6	Classified
Disodium phosphate 12 H ₂ O	10039-32-4	Classified
Silica, colloidal anhydrous	7631-86-9	Classified
Hydroxyethylcellulose	9004-62-0	Classified
Citric acid monohydrate	5949-29-1	Classified
Sodium cyclamate	139-05-9	Classified
Sucralose	56038-13-2	Classified
Anise aroma	n.a.	Classified
Water, purified	7789-20-0	Ad 1.0 ml

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures

Eye 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.
Skin Contact:	Remove and wash contaminated clothing immediately. Wash affected area thoroughly with soap and water. If the patient feels unwell seek medical advice.
Ingestion:	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Inhalation:	Remove patient to fresh air, keep warm and at rest. If any signs or symptoms occur or persist seek medical advice.

Most important Symptoms and Effects, Both Acute and Delayed**Symptoms and Effects**

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

Medical Conditions

Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

SECTION 5: FIREFIGHTING 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.

Special hazards arising from the substance or mixture**Hazardous Combustion**

Products: No data available.

Fire/Explosion Hazards: No data available.

Advice for firefighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning up**Measures for Cleaning /**

Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration

for Large Spills: Clean up operations should only be undertaken by trained personnel.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, including any Incompatibilities

Storage Conditions: Store as directed by product packaging

Specific end use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters**Occupational****Exposure Limits:** Contains no substances with occupational exposure limit values.**Exposure controls****Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate, unless the process generates dust, mist or fumes.**Personal Protective****Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.**Eyes:** Wear safety glasses or goggles if eye contact is possible.**Skin:** Impervious, disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Suspension
Odor: Smells like anise
Colour: Yellow/green
Molecular formula: Mixture
Molecular weight: Mixture**Solvent Solubility:** Not applicable
Water Solubility: Not applicable
pH: Not applicable
Melting/Freezing Point: No data available
Boiling Point (°C): No data available
Partition Coefficient: No data available
Evaporation Rate: No data available
Vapor Pressure: No data available
Vapor Density: No data available
Viscosity: No data available**Flammability:****Autoignition Temperature (Solid):** No data available
Flammability (Solids): No data available
Flash Point (Liquid): No data available
Upper Explosive Limits (Liquid): No data available
Lower Explosive Limits (Liquid): No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity

No data available

Chemical stability

Stable under normal conditions of use.

Possibility of hazardous reactions

No data available

Conditions to avoid

No data available

Incompatible materials

No data available.

Hazardous decomposition products

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

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects**Acute Toxicity: (Species, Route, End Point, Dose)****Meloxicam**

Rat	Oral	LD ₅₀	83.5 mg/kg
Mouse	Oral	LD ₅₀	470 mg/kg
Rabbit	Oral	LD ₅₀	320 mg/kg

Irritation/sensitization: (Study type, Species, Severity)**Meloxicam**

Skin Sensitization - M & K Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Meloxicam**

52 Week(s)	Rat	Oral	0.2 mg/kg b.w.	NOEL	Kidney, Gastrointestinal System
4 Week(s)	Dog	Oral	0.4 mg/kg b.w.	NOEL	Gastrointestinal system, Kidney

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**Meloxicam**

Embryo / Fetal Development	Rat	Oral	1 mg/kg/day	NOAEL	Not teratogenic, Embryotoxicity, Maternotoxic
Reproductive & Fertility	Rat	Oral	0.125 mg/kg/day	LOAEL	Neonatal mortality, Neonatal toxicity
Embryo / Fetal Development	Rabbit	Oral	1 mg/kg/day	NOAEL	Not teratogenic, Embryotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Meloxicam**

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Meloxicam

104 Week(s)	Rat	Oral	0.8 mg/kg/day	NOEL	Not carcinogenic
2 Year(s)	Mouse	Oral	8 mg/kg/day	NOAEL	Not carcinogenic

SECTION 12: ECOLOGICAL INFORMATION

Environmental Overview: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity: No data available.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation, unless specified below.

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

SECTION 15: REGULATORY INFORMATION

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

Particular provisions: Veterinary medicinal product, under the scope of 2001/82/EC as amended

Chemical safety assessment: No data available

SECTION 16: OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Toxic to Reproduction: Category 1

H301 – Toxic if swallowed

H360 – May damage fertility or the unborn child

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Name: MELOXORAL 1.5 MG/ML ORAL SUSPENSION