MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metacam® (meloxicam) 1.5 mg/mL Oral Suspension for Dogs
Product No. : Not applicable
GHS Product Identifier: Not applicable

Synonyms: Meloxicam
Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Oxicam class of non-steroidal anti-inflammatory drugs (NSAID).

Manufacturer:
Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Hwy
St. Joseph, MO 64506-2002

Intended Use: For the control of pain and inflammation associated with osteoarthritis in dogs.

Emergency Telephone*:*
Transportation Emergency: (800) 424-9300

Medical Emergency (24HR): (866) 638-2226

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid (viscous suspension) 1.5 mg/mL
Color: Yellowish
Odor: Honey-like

WARNING!
For oral use only in dogs only.
Not for human use.
Contact with liquid may cause eye and skin irritation.

Precautionary Statements:
Wear protective gloves and eye/face protection.

Accidental human ingestion can cause serious reactions or anaphylactic reaction and systemic effects.
Keep only in original container.
Store at 15°- 30° C (59-86° F).
Fire-fighting: Use carbon dioxide, dry chemicals, water spray, foam or material appropriate for the surrounding fire.
Avoid contact with eyes, skin and clothing.
Wash thoroughly with soap and water after handling.
Spills: Cover with absorbent or contain. Collect and dispose.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If swallowed, seek medical advice immediately and show this container or label.
This material and its container must be disposed of in a safe way.
Keep out of reach of children.
Keep away from food, drink, and animal feedstuffs.

Acute effect: The most common reactions are anorexia, nausea and diarrhea.

When administering any NSAID, appropriate lab testing to establish hematological and serum biochemical baseline data is recommended prior to use. All dogs should undergo a thorough history and physical examination before administering Meloxicam. Owners should be advised to observe their dog for signs of potential drug toxicity.

Precautions/Contraindications: Do not use in cats. Dogs with known hypersensitivity to Meloxicam and other NSAIDs should not receive Metacam® 1.5 mg/mL Oral Suspension. Use of additional NSAIDs is contraindicated. Do not give if the dog is taking aspirin. Dogs should be evaluated for pre-existing conditions and currently prescribed medications prior to treatment with Metacam®. Anesthetic drugs may affect renal perfusion; approach concomitant use of anesthetics and NSAIDs cautiously. The use of parenteral fluids during surgery is recommended. Concurrent use with another NSAID, corticosteroid, or nephrotoxic medication should be avoided or monitored closely or corticosteroid should be avoided.

The safe use of Metacam® in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Safety has not been established for IM (intramuscular) injection. Use a syringe of appropriate size to ensure precise dosing.
Use with caution in dogs that are dehydrated, concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. Anesthetic drugs may affect renal perfusion; approach concommitment use of anesthetics and NSAIDs cautiously.
NSAIDs may inhibit the prostaglandin effects that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with an underlying or pre-existing disease that has not been previously diagnosed.
Concomitant use of Metacam® with other with other anti-inflammatory drugs, such as corticosteroids, should be avoided or closely monitored. The use of concomitantly protein-bound drugs with Metacam® 1.5mg/mL Oral Suspension has not been studied dogs. Protein-bound drugs, such as cardiac, anticonvulsant and behavioral medications have not been studied. The

influence of the concomitant drugs may inhibit the metabolism of the Metacam® 1.5 mg/mL Oral Suspension. Drug compatibility should be monitored in patients requiring adjunctive therapy.

To Prevent Accidental Overdosing in Small Dogs under 10 pounds (4.5 kg): Administer drops on food only, never directly in mouth. Dosing is based on weight of dog.

Overdosage: Gastrointestinal, renal and hepatic toxicity may occur. Diarrhea and fecal occult blood have been reported.

ADVERSE REACTIONS TO PRODUCT: Anaphylactoid reactions may occur. Cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, kidney and liver side effects. If side effects occur, pet owners should contact their veterinarian. Sensitivity to drug-associated adverse events varies with the individual patient. The common side effects reported in field studies were vomiting and soft stool/diarrhea. These are usually mild but may be serious. If side effects occur, pet owners should halt therapy and contact their veterinarian. Renal failure has been reported as an outcome of repeated oral dosing of cats.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. Causes eye irritation. Exposure may cause eye tearing, redness, and discomfort.

Skin Contact: Not expected to be a hazard to the skin with prescribed use. Causes skin irritation. Exposure may cause redness, itching and inflammation.

Ingestion: Not expected to be an ingestion hazard with prescribed use. Ingestion may cause vomiting, nausea or other systemic effects.

Injection: Not applicable

Chronic Health Effects: Possible hypersensitization (development of abnormal sensitivity).

Target Organ(s): Gastrointestinal tract, kidneys, liver

OSHA Regulatory Status: Nonhazardous, exempt

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	EC No.	CAS- No.	Concentration	Classification	Notes
Meloxicam	----	71125-38-7	1.5 mg/mL	----	----

The full texts for all R-Phrases are displayed in Section 16.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Injection: Not applicable.

Note to Physician: For oral use in dogs only. Not for human use.
Antidote: Epinephrine is indicated for anaphylactoid reactions.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemicals, water spray, foam or material appropriate for the surrounding fire.

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, nitrogen oxide

Flammability Class: 0

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear appropriate personal protective equipment. See Section 8.

Spill Cleanup Methods: Small liquid spill: Use an absorbent to soak up the product and place into container for later disposal. For large liquid spill: Absorb or cover with dry earth, sand or other material and transfer to containers.

Environmental Precautions: Flush spill area with water spray. Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

Fire and Explosion Protection: Not flammable

Storage: Keep only in the original container. Store at 15°- 30° C (59-86° F). Keep out of reach of children. Keep away from food, drink, and animal feedstuffs.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

For Exposures:

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Meloxicam	BIEL*	TWA	150 µg/m^3	--
Meloxicam	BIEL*	STEL (15 minutes)	600 µg/m^3	--
Meloxicam	BIEL*	STEL (1 hour)	300 µg/m^3	--

*BIEL is the BI (Boehringer Ingelheim) Exposure Control Level. Where lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

Engineering Controls: Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Respiratory Protection: Not generally required when handling vials or containers. 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures*:* Eye bath, washing facilities, shower

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Yellowish
Odor: Honey-like
Odor Threshold: No data available
Physical State: Liquid (viscous suspension) 1.5 mg/mL
pH: 3.5-4.5 (acidic)
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: > 93.3°C (> 200°F)
Flammability Limit – Upper (%): Not applicable
Flammability Limit – Lower (%): Not applicable
Evaporation rate: No data available
Vapor Pressure: No data available
Vapor Density (Air=1): No data available
Specific Gravity: 1.56 (water = 1)
Solubility: Insoluble
Partition Coefficient (n-Octanol/water): No data available
Autoignition Temperature: No data available
Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: Strong oxidizing agents

Hazardous Decomposition Products: None known

Possibility of Hazardous Reactions: Hazardous polymerization will not occur**.**

11 TOXICOLOGICAL INFORMATION

Specified Substances

Acute Toxicity

Chemical Name	Test Results
2H-1,2-Benzothiazine-3-carboxamide, 4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-1,1-dioxide	Oral LD_{50} (rat): 84 mg/kg Oral LD_{50} (mouse): 470 mg/kg Oral LD_{50} (rabbit): 320 mg/kg

Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetance) were the most common adverse reactions associated with the administration of meloxicam.

Six Week Study

In a six week target animal safety study, meloxicam was administered orally at 1,3, and 5X the recommended dose with no significant clinical adverse reactions. Animals in all dose groups (control 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clotting time, or buccal mucosal bleeding times.

Six Month Study

In a six month target animal safety study, meloxicam was administered orally at 1, 3 and 5X the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1,3, and 5X) the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1,3, and 5X) the recommended dose exhibited some gastrointestinal distress (diarrhea and vomiting). Treatment related changes seen in hematology and chemistry included decreased red blood cell counts in seven of 24 dogs (four 3X and three 5X dogs), decreased hematocrit in 18 of 25 dogs (including three control dogs), dose-related neutrophilia in one 1X, two 3X and three 5X dogs, evidence of regenerative anemia in two 3X and one 5X dog. Also noted were increased BUN in two 5X dogs and decreased albumin in one 5X dog.

12 ECOLOGICAL INFORMATION

Ecotoxicity: No data available
Persistence and degradability: No data available
Mobility in soil: No data available
Other adverse effects: No data available

Germany WGK: Meloxicam (:2H-1,2-benzothiazine-3-carboxamide, 4-hydroxy-2-methyl-n-(5-methyl-2-thiazolyl)-,1,1-dioxide: ID No: 7588; Class: 2: water-endangering

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

RCRA Information: Not applicable

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR: Not regulated

RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.
WHMIS Classification: Noncontrolled, exempt

Inventory Status
This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.
This material is **not** listed on the DSL Inventory.

Canada CEPA Schedule 1 - None

US Regulations
CERCLA Hazardous Substance List (40 CFR 302.4): None

SARA Title III
Section 302Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): None

FEDERAL LAW restricts this drug to use by or on the order of a licensed veterinarian.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): None
California Hazardous Substance List: None
Massachusetts Right-To-Know List: None
Minnesota Hazardous Substances List: None
New Jersey Right-To-Know List: None
Pennsylvania Right-To-Know List: None
Rhode Island Right-To-Know List: None

European Regulations
Austria MAK List (Annex I): None

Denmark (Annex 3.6, April 2005): None
Germany (Dangerous Substances Ordinance 2004, Annex III): None
Norway (List of Dangerous Substance): None
Sweden (Sensitizers- Annex 3): None
Switzerland (Toxins List 1): None

16 OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	2	0	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	2	0	0	N/A

*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Xi- Irritation
R36- Irritating to eyes.
R38-Irritating to skin.
S25- Avoid contact with eyes.
S26-In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S7- Keep container closed.
S24 - Avoid contact with skin.
S37 – Wear suitable gloves.

ABBREVIATIONS:
BIEL - Boehringer Ingelheim Exposure Control Level.
BIV - Boehringer Ingelheim Vetmedica, Inc.
AIHA- American Industrial Hygiene Association
N/A - Not applicable.
N/E - Not established.

References:

1. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database
2. Metacam® Product Information, Package Insert, Boehringer Ingelheim Vetmedica, Inc.
3. RTECS
4. Food & Drug Administration. www.fda.gov
5. Food & Drug Administration, NADA 141-219
6. GHS Manual

Revised: Sections 2,8,12,15
Supercedes: 2/15/07
Prepared by: Boehringer Ingelheim Vetmedica, Inc.
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