



MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metacam® (meloxicam) 5 mg/mL Solution for Injection-

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

Emergency Telephone:

Transportation Emergency: (800) 424-9300

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

Intended Use: Cats: For the control of postoperative pain and inflammation associated with orthopedic surgery, ovario-hysterectomy, and castration when administered prior to surgery. Dogs: For the control of pain and inflammation associated with osteoarthritis.

Non-emergency Telephone: (800) 821-7467

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Aqueous liquid 5 mg/mL; 10 mL vial

Color: Clear yellow

Odor: Like ethanol



WARNING!

Flammable liquid and vapor.

Cats – Subcutaneous injection only.

**Dogs – Intravenous or subcutaneous injection only.
Not for human use.**

Precautionary Statements:

Keep away from ignition sources such as heat/sparks/open flames-No smoking.

Wear protective gloves and eye/face protection.

Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.

Keep only in original container.

Store at a controlled room temperature, 20°- 25° C (68°-77° F).

Fire-fighting: Use carbon dioxide, dry chemicals, water spray or foam.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Spills: Cover with nonflammable 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.

Cats:

Acute effect: Control and relief of postoperative pain and inflammation.

Potential side effects: The majority of cats will not experience side effects from Meloxicam. Inflammation, hemorrhage, myofiber atrophy, panniculitis, fibrin deposition and fibroblast proliferation at the injection site may occur in cats.

Lethargy, vomiting, inappetance and transient pain immediately after injection have occurred.

Used for the control of postoperative pain and inflammation associated with orthopedic surgery, ovario-hysterectomy and castration when administered prior to surgery.

Safe use of Metacam® 5 mg/ml Solution for Injection in cats younger than 4 months of age, cats used for breeding or in pregnant or lactating queens has not been evaluated. Meloxicam is not recommended for use in cats with bleeding disorders, as safety has not been established. Safety has not been established for use in cats with bleeding disorders, as safety has not been established. Safety has not been established for intravenous (IV) or intramuscular (IM) use in cats. When administering Metacam® 5 mg/ml Solution for Injection, use a syringe of appropriate size to ensure precise dosing.

As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, kidney and liver side effects. Pets 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 parental fluids during surgery is recommended. Concurrent use of nephrotoxic medications should be carefully approached. Concurrent or follow-up use with an NSAID (including meloxicam) or

corticosteroid should be avoided. If side effects should occur, pet owners should contact their veterinarian.

Warning: Do not administer a second dose of Meloxicam. Do not follow Meloxicam dose with any other NSAID. Metacam® is for subcutaneous injection use in cats. DO NOT USE IV in cats.

When administering any NSAID, appropriate lab testing to establish hematological and serum biochemical baseline data is recommended prior to use in cats. All cats should undergo a thorough history and physical examination before administering Meloxicam. Owners should be advised to observe their cat for signs of potential drug toxicity. Pets should be evaluated for pre-existing conditions and currently prescribed medications prior to treatment with Metacam®.

Overdosage: Gastrointestinal, renal and hepatic toxicity may occur. Diarrhea and fecal occult blood have been reported. Repeated use in cats has been associated with acute renal failure and death.

DOGS:

Acute effect: Control of pain and inflammation associated with osteoarthritis in dogs. Metacam® is for subcutaneous and intravenous injection use in dogs. Dogs with known hypersensitivity to Meloxicam and other NSAIDs should not receive Metacam® 5 mg/mL Solution for Injection.

Meloxicam is not recommended for use in dogs with bleeding disorders.

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 concomitant 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.

The use of concomitantly protein-bound drugs with Metacam® 5 mg/mL Solution for Injection has not been studied in 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® 5 mg/mL Solution for Injection. Drug compatibility should be monitored in patients requiring adjunctive therapy. The effect of cyclo-oxygenase inhibition and the potential for thromboembolic occurrence or hypercoagulable state has not been studied.

Safe use 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 administration.

As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, kidney, or liver side effects. The most 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. Pets should be evaluated for pre-existing conditions and currently prescribed medications prior to treatment with Metacam®.

When administering any NSAID, appropriate lab testing to establish hematological and serum biochemical baseline data is recommended prior to use in dogs. 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. Pets should be evaluated for pre-existing conditions and currently prescribed medications prior to treatment with

Metacam®, then monitored regularly while on therapy. Concurrent use with another NSAID, corticosteroid, or nephrotoxic medication should be avoided or monitored closely.

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.

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. Exposure to liquid in eye may cause eye irritation.

Skin Contact: Not expected to be a hazard to the skin with prescribed use. Exposure to liquid to skin may cause transient irritation.

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

Injection: Swelling at injection site may occur.

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

Target Organ(s): Skin, muscles, 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 | 5 mg/mL | ---- | ---- |
| Ethanol | 2005786 | 64-17-5 | 15 % | R11, S(2), 7, 16 | ---- |

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: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

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: In case of accidental injection, wash the site thoroughly. Contact a physician immediately.

Note to Physician: For animal injection 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 or foam.

Unsuitable Extinguishing Media: Water Jet. USE WATER WITH CAUTION. Material will float and may ignite on the surface of the water. Use water spray to keep fire-exposed containers cool. Water may be ineffective in fighting the fire.

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

Unusual Fire & Explosion Hazards: Vapors may cause a flash fire or ignite explosively. Vapors may travel considerable distance to a source of ignition and flash back. Prevent build-up of vapors to explosive concentrations.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide

Flammability Class: IC

6 ACCIDENTAL RELEASE MEASURES

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

Spill Cleanup Methods: Small liquid spill: Eliminate all ignition sources. Use water to disperse vapors and dilute spill to a nonflammable mixture. Use a non-combustible material like vermiculite, earth or sand 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 non-combustible material and transfer to containers.

Environmental Precautions: Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7 HANDLING AND STORAGE

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

Fire and Explosion Protection: Keep away from heat, sparks and flame. Keep from contact with oxidizing materials. Comply with all national, state and local codes pertaining to the storage, handling, dispensing and disposal of flammable liquids.

Storage: Keep only in the original container. Store at a controlled room temperature, 20°- 25° C (68°-77° F). Do not refrigerate. Avoid freezing. 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 | -- |
| Ethanol | ACGIH | TWA | 1000 ppm | Irritation |
| Ethyl alcohol | NIOSH | IDLH | 3300 ppm | -- |
| Ethyl alcohol | OSHA | TWA | 1000 ppm | -- |
| Ethyl alcohol | Cal OSHA | TWA | 1000 ppm | -- |
| Ethanol (ethyl alcohol) | Alberta | TWA | 1000 ppm | Irritation |
| Ethanol | British Columbia | TWA | 1000 ppm | -- |
| Ethanol | Ontario | TWAEV | 1000 ppm | -- |
| Ethyl alcohol | Quebec | TWA | 1000 ppm | -- |
| Alcohol etílico (etanol) | Mexico | TWA | 1000 ppm | -- |
| Ethanol | Austria | TWA | 1000 ppm | -- |
| Ethanol | Austria | Ceiling | 2000 ppm | -- |
| Alcool éthylique | Belgium | TWA | 1000 ppm | -- |
| Ethanol | Denmark | TWA | 1000 ppm | The MAL-factor is: 7 m ³ air/10g substance |
| Etanoli | Finland | TWA | 1000 ppm | -- |
| Etanoli | Finland | 15-minute limit | 1300 ppm | -- |
| Alcool éthylique | France | TWA | 1000 ppm | Indicative OEL |
| Ethanol | Germany | Limit Value | 500 ppm | Short term exposure classification |

| | | | | category: II |
|-----------------------------|--------------------------|---------------------------|------------------------|-------------------------|
| Ethanol | Greece | TWA | 1000 ppm | -- |
| Ethanol | Iceland | TWA | 1000 ppm | -- |
| Ethanol | Ireland | OEL | 1000 ppm | -- |
| Etanolo | Italy | TWA | 1000 ppm | -- |
| Ethanol | Netherlands | MAC TWA | 1000 ppm | -- |
| Etanol | Norway | Threshold Limit Value | 1000 ppm | -- |
| Etanol (Alcool Etílico) | Portugal | 8-hr Exposure Limit | 1000 ppm | -- |
| Alcohol Etílico | Spain | VLA-ED | 1000 ppm | -- |
| Etanol | Sweden | NGV | 500 ppm | -- |
| Etanol | Sweden | KTV | 1000 ppm | -- |
| Ethanol | Switzerland | TWA | 500 ppm | -- |
| Ethanol | Switzerland | STEL | 1000 ppm | -- |
| Ethanol | United Kingdom | TWA | 1000 ppm | -- |
| Ethanol | Bulgaria | OEL | 1000 ppm | -- |
| Ethanol | Croatia | 8hr Concentration | 1000 ppm | -- |
| Ethanol | Czech Republic | TWA | 1000 ppm | -- |
| Ethanol | Estonia | TWA | 500 ppm | -- |
| Ethanol | Estonia | STEL | 1000 ppm | -- |
| Ethanol | Hungary | TWA | 1900 mg/m ³ | -- |
| Ethanol | Latvia | TWA | 1000 mg/m ³ | -- |
| Ethanol | Lithuania | TWA | 500 ppm | -- |
| Ethanol | Lithuania | STEL | 1000 ppm | -- |
| Etanol (alcohol etylowy) | Poland | TWA (NDS) | 1900 mg/m ³ | -- |
| Alcool etilic | Romania | TWA | 1900 mg/m ³ | -- |
| Alcool etilic | Romania | STEL | 1900 mg/m ³ | -- |
| Ethanol | Russian Federation | TWA (MAC) | 1000 mg/m ³ | MAC applies to vapor |
| Ethanol | Russian Federation | Ceiling Limit (MAC) | 2000 mg/m ³ | MAC applies to vapor |
| Etilalkohol | Serbia and Montenegro | MAC | 1900 mg/m ³ | -- |
| Etylalkohol | Slovakia | TWA (NPHV) | 500 ppm | -- |
| Etilalkohol | Slovenia | TWA | 1900 mg/m ³ | -- |
| Ethyl Alcohol | Australia | TWA | 1000 ppm | -- |
| Ethyl Alcohol | Hong Kong | TWA | 1000 ppm | -- |

| | | | | |
|------------------------------|-------------|----------|------------------------|------------|
| Ethyl Alcohol | India | TWA | 1000 ppm | -- |
| Ethanol | Indonesia | TWA | 1000 ppm | -- |
| Ethanol | Korea | TWA | 1000 ppm | -- |
| Ethanol | Malaysia | TWA | 1000 ppm | -- |
| Ethanol | New Zealand | TWA | 1000 ppm | -- |
| Ethyl Alcohol | Philippines | TWA | 1000 ppm | -- |
| Ethanol | Thailand | TWA | 1000 ppm | -- |
| Ethanol | Vietnam | TWA | 1000 mg/m ³ | -- |
| Ethyl Alcohol | Singapore | TWA | 1000 ppm | -- |
| Ethyl Alcohol | Taiwan | TWA | 1000 ppm | -- |
| Alcohol Etilico | Mexico | TWA | 1000 ppm | -- |
| Ethanol | Argentina | TWA(CMP) | 1000 ppm | -- |
| Alcohol Etilico | Brazil | TWA | 780 ppm | -- |
| Alcohol Etilico | Chile | TWA | 800 ppm | -- |
| Ethanol | Columbia | TWA | 1000 ppm | Irritation |
| Alcohol Etilico | Peru | TWA | 1000 ppm | -- |
| Alcohol Etilico, ver Ethanol | Venezuela | TWA(CAP) | 1000 ppm | -- |

*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: Clear yellow

Odor: Like ethanol

Odor Threshold: No data available

Physical State: Aqueous liquid 5mg/mL vial

pH: 8.0 – 8.9

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: 36.6°C (98°F)

Flammability Limit – Upper (%): No data available

Flammability Limit – Lower (%): No data available

Evaporation rate: No data available

Vapor Pressure: No data available

Vapor Density (Air=1): No data available

Specific Gravity: 1.56

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: Heat; ignition sources

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- | Oral LD ₅₀ (rat): 84 mg/kg |

| | |
|--------------------------------------|---|
| N-(5-methyl-2-thiazolyl)-1,1-dioxide | Oral LD ₅₀ (mouse): 470 mg/kg Oral LD ₅₀ (rabbit): 320 mg/kg |
|--------------------------------------|---|

Cats

A field study involving 138 cats was conducted. Of the 72 cats receiving Metacam® 5 mg/mL Solution for Injection, six cats (8.3%) experienced post-treatment elevated serum blood urea nitrogen (BUN) levels. The pre-treatment values were in the normal range. Of the 66 cats in the butorphanol treatment group, no cats experienced post-treatment elevated serum blood urea nitrogen levels. Nine cats (12.5%) receiving Metacam® 5 mg/mL Solution for Injection, had post-treatment anemia. Pre-treatment, these cats all had hematocrit and hemoglobin values in the normal range. Four cats (6.1%) in the butorphanol treatment group had post-treatment anemia. All but one cat, who had a mild anemia pre-treatment (hematocrit =21% and hemoglobin =7.0 g/dL) had normal pretreatment values. Twenty-four hours after the injection with Metacam® 5 mg/mL Solution for Injection, one cat experienced pain upon palpation of the injection site.

3 Day Target Animal Safety Study - Dogs

In a three day safety study, Metacam 5 mg/mL Solution for Injection was administered intravenously to Beagle dogs at 1,3, and 5 times the recommended dose (0.2, 0.6 and 1.0 mg/kg) for three consecutive days. Vomiting occurred in 1 of 6 dogs in the 5X group. Fecal occult blood was detected in 3 of 6 dogs in the 5X group. No clinically significant hematologic changes were seen, but serum chemistry changes were observed. Serum alkaline phosphatase (ALP) was significantly increased in one 1X dog and two of the 5X dogs. One dog in the 5X group had a steadily increasing GGT over 4 days, although the values remained within the reference range. Decreases in total protein and albumin occurred in 2 of 6 dogs in the 3X group and 3 of 6 dogs in the 5X group. Increases in blood urea nitrogen (BUN) occurred in 3 of 6 dogs in the 1X group and 2 of 6 dogs in the 5X group. Increased urine protein occurred in 2 dogs in the 5X group. Increased urine protein excretion was noted in 2 of 6 dogs in the control group, 2 of 6 dogs in the 1X group, 2 of 6 dogs in the 3X group, and 5 of 6 dogs in the 5X group. Two dogs in the 5X group developed acute renal failure by Day 4. Bicarbonate levels were at or above normal levels in 1 of the 3X dogs and 2 of the 5X dogs.

Effect on Buccal Mucosal Bleeding Time (BMBT)-Dogs

Metacam 5 mg/mL Solution for Injection (0.2mg/kg) and placebo (0.4 mL/kg) were administered as single intravenous injections to 8 female and 16 male Beagle dogs. There was no statistically significant difference (p>0.05) in the average BMBT between the two groups.

Listed Carcinogens

| Chemical Name | IARC | NTP | OSHA | ACGIH |
|--|--------------------------|------------------|------|-------|
| Alcoholic beverages (alcohol) | 1- Carcinogenic to human | -- | -- | -- |
| Alcoholic beverage consumption (alcohol) | -- | Known carcinogen | -- | -- |

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; Glycine: ID: 6704; Class 1: slightly water-endangering; Sodium Chloride (Natriumchlorid): ID: 270; Class 1: slightly water-endangering; Ethanol: ID No. 96; Class 1: slightly 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: ORM-D

TDG:

UN: 1170

Proper Shipping Name: Consumer Commodity; Limited Quantity

Packing Group: III

ADR:

UN: 1170

Proper Shipping Name: Ethanol Solution

Packing Group: III

Hazard ID No.: 33

RID:

UN: 1170

Proper Shipping Name: Ethanol Solution

Packing Group: III

Hazard ID No.: 30

IATA:

Class: 9, ID 8000

Special Provision: A112

IMDG:

UN: 1170

Proper Shipping Name: Dangerous goods in limited quantities of Class 3

Packing Group: III

| | |
|-----------|-------------------------------|
| 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 302 Extremely 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):

WARNING: This product contains a chemical known to the state of California to cause cancer and birth defects or other reproductive harm.

California Prop 65 chemicals: Alcoholic beverages, when associated with alcohol abuse

California Hazardous Substance List: Ethyl alcohol

Massachusetts Right-To-Know List: Ethanol

Minnesota Hazardous Substances List: Ethyl alcohol

New Jersey Right-To-Know List: Ethanol

Pennsylvania Right-To-Know List: Ethanol

Rhode Island Right-To-Know List: Ethanol

European Regulations

Austria MAK List (Annex I): Ethylalkohol, S. ethanol

Denmark (Annex 3.6, April 2005): None

Germany (Dangerous Substances Ordinance 2004, Annex III): None

Norway (List of Dangerous Substance): Etanol

Sweden (Sensitizers- Annex 3): None

Switzerland (Toxins List 1): Aethanol G-1158

| | |
|-----------|--------------------------|
| 16 | OTHER INFORMATION |
|-----------|--------------------------|

Hazard Ratings

| | Health Hazard | Fire Hazard | Reactivity Hazard |
|-------------|----------------------|--------------------|--------------------------|
| HMIS | 1* | 3 | 0 |

| | Health Hazard | Fire Hazard | Reactivity Hazard | Special Hazard |
|-------------|----------------------|--------------------|--------------------------|-----------------------|
| NFPA | 1 | 3 | 0 | N/A |

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

R11 – Highly flammable
R43 - May cause sensitization by skin contact.
S7- Keep container closed
S16 – Keep away from sources of ignition – No smoking.
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

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 6/22/07

Supercedes: 02/15/07

Revision: Updated Section 2

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