SAFETY DATA SHEETS

This SDS packet was issued with item:

078456986

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078361619 078361627 078885069

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

021281644 021281645



MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metacam® (meloxicam) 2 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:

1

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 2 mg/mL; 10 mL vial and 50 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, inappeteance 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® 2 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® 2 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® 2 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 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.

The use of concomitantly protein-bound drugs with Metacam® 2 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® 2 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. Cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal, kidney and liver side effects. If side effects occur, pet owners should contact their veterinarian. Sensitivity to drugassociated 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	2 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.

EXPOSURE CONTROLS / PERSONAL PROTECTION

For Exposures:

8

Exposure Limits:

Chemical Name	Source	Туре	Exposure Limits	Notes
Meloxicam	BIEL*	TWA	$150 \mu\mathrm{g/m}^3$	
Meloxicam	BIEL*	STEL	$600 \mu \text{g/m}^3$	
25.1	D. T. T. T.	(15 minutes)	200 / 3	
Meloxicam	BIEL*	STEL	$300 \mu\mathrm{g/m}^3$	
Total 1	A GGTT	(1 hour)	1000	*
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	TWA	1000 ppm	
	Columbia			
Ethanol	Ontario	TWAEV	1000 ppm	
Ethyl alcohol	Quebec	TWA	1000 ppm	
Alcohol etilico (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 m3 air/10g
				substance
Etanoli	Finland	TWA	1000 ppm	
Etanoli	Finland	15-minute	1300 ppm	
		limit		
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	1000 ppm	
		Concentration	• •	
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	
Linyi Meonoi	India	1 777	1000 ppin	
Etanol	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	
Etanol	Argentina	TWA(CMP)	1000 ppm	
Alcool 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 Etanol	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

PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear yellow **Odor:** Like ethanol

Odor Threshold: No data available

Physical State: Aqueous liquid 2 mg/mL vial

pH: 8.0 - 8.9

Melting Point: No data available Freezing Point: No data available Boiling Point: No data available Flash Point: 35.6° C (96.0 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: 1.0 **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 – Meloxicam drug substance	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

Consult the MSDS for Metacam 5 mg/mL Solution for Injection produced by BIVI, 2621 North Belt Highway, St. Joseph, MO.

Listed Carcinogens

Chemical Name	IARC	NTP	OSHA	ACGIH
Alcoholic beverages (alcohol)	1- Carcinogenic to human	1	1	
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; 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

<u>TDG</u>: UN: 1170

Proper Shipping Name: Consumer Commodity; Limited Quantity

Packing Group: III

<u>ADR:</u> UN: 1170

Proper Shipping Name: Ethanol Solution

Packing Group: III

Hazard ID No.: 33

<u>RID</u>: UN: 1170

Proper Shipping Name: Ethanol Solution

Packing Group: III Hazard ID No.: 30

<u>IATA</u>:

Class: 9, ID 8000

Special Provision: A112

<u>IMDG</u>: UN: 1170

15

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

Packing Group: III

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):

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): None

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

New MSDS

Prepared by: Boehringer Ingelheim Vetmedica, Inc.

Issue Date: 06/05/07

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MATERIAL SAFETY DATA SHEET

PRODUCT AND COMPANY IDENTIFICATION

Product Name: Metacam® (meloxicam) 2 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: Emergency Telephone:

Boehringer Ingelheim Vetmedica, Inc. <u>Transportation Emergency:</u> (800) 424-9300

2621 North Belt Hwy
St. Joseph, MO 64506-2002 Medical Emergency (24HR): (866)638-2226

Intended Use: Non-emergency Telephone: (800) 821-7467

For the control of pain and inflammation

associated with osteoarthritis.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Aqueous liquid 2 mg/mL; 10 mL vial and 50 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.

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	2 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.

EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

8

Chemical Name	Source	Type	Exposure	Notes
			Limits	
Meloxicam	BIEL*	TWA	$150 \mu g/m^3$	
Meloxicam	BIEL*	STEL	$600 \mu \text{g/m}^3$	
		(15 minutes)		
Meloxicam	BIEL*	STEL	$300 \mu g/m^3$	
		(1 hour)		
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	

^{*}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: **Eve 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

PHYSICAL AND CHEMICAL PROPERTIES

Color: Clear yellow Odor: Like ethanol

Odor Threshold: No data available

Physical State: Aqueous liquid 2 mg/mL vial

pH: 8.0 - 8.9

Melting Point: No data available Freezing Point: No data available Boiling Point: No data available Flash Point: 35.6° C (96.0 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: 1.0 **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 – Meloxicam drug substance	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

Consult the MSDS for Metacam 5 mg/mL Solution for Injection produced by BIVI, 2621 North Belt Highway, St. Joseph, MO.

Listed Carcinogens

Chemical Name	IARC	NTP	OSHA	ACGIH
Alcoholic beverages (alcohol)	1- Carcinogenic to human	1		
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; 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:

Proper Shipping Name: UN1170, Ethanol Solution, 3, III

TDG:

Proper Shipping Name: UN1170, Ethanol Solution, 3, III

ADR:

Proper Shipping Name: UN1170, Ethanol Solution, 3, III

Hazard ID No.: 33

RID:

Proper Shipping Name: UN1170, Ethanol Solution, 3, III

Hazard ID No.: 30

IATA:

Proper Shipping Name: UN1170, Ethanol Solution, 3, III

IMDG:

Proper Shipping Name: UN1170, Ethanol Solution, 3, 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 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):

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): None

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: 06/05/07 **Revision Date:** 2/4/2013

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SAFETY DATA SHEET

1. Identification

Product identifier Metacam® (Meloxicam) 5 mg/mL Solution for Injection

Other means of identification

Synonyms Meloxicam

Recommended useCats: 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.

Recommended restrictions Not for use in humans.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer Boehringer Ingelheim Vetmedica, Inc.

Address 2621 North Belt Hwy

St. Joseph, MO 64506-2002

Transportation emergency For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call

CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300

Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency

(24HR):

(866)638-2226

Non-Emergency calls: (800) 821-7467

2. Hazard(s) identification

Physical hazardsFlammable liquidsCategory 3Health hazardsSerious eye damage/eye irritationCategory 2A

OSHA defined hazards Not classified.

Label elements

Version #: 01



Signal word Warning

Revision date: -

Hazard statement Flammable liquid and vapor. Causes serious eye irritation.

Precautionary statement

Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly

closed. Ground/bond container and receiving equipment. Use explosion-proof

electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash thoroughly after handling. Do not eat, drink or smoke

when using this product. Wear protective gloves/eye protection/face protection.

Response If swallowed: Immediately call a poison center/doctor. If on skin (or hair): Take off immediately all

contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse mouth. If eye irritation persists: Get medical advice/attention. In case of fire: Use appropriate

media to extinguish.

Issue date: 29-May-2015

Storage Store locked up. Keep from freezing. Store at a controlled room temperature, 20°- 25° C (68°-77°

F.)

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Metacam® (Meloxicam) 5 mg/mL Solution for Injection

None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Ethanol	64-17-5	15%
Meloxicam	71125-38-7	5 mg/mL

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Wash off with soap and water. Get medical attention if irritation develops and persists. Skin contact

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

systemic effects.

Most important symptoms/effects, acute and

delayed

Indication of immediate medical attention and special treatment needed

Side effects are usually mild, but serious side effects can occur. Anaphylactoid reactions may occur.

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

General information Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. If anaphylactoid reactions occur,

epinephrine may be used as an antidote.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Specific hazards arising from

the chemical

Special protective equipment

and precautions for firefighters Fire fighting

equipment/instructions

Specific methods

General fire hazards

Water spray. Carbon dioxide (CO2). Dry chemical powder. Foam.

Do not use water jet as an extinguisher, as this will spread the fire.

Vapors may form explosive mixtures with air. Vapors may travel considerable distance to a source

of ignition and flash back. During fire, gases hazardous to health may be formed.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Use standard firefighting procedures and consider the hazards of other involved materials.

Flammable liquid and vapor.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Keep combustibles (wood, paper, oil, etc.) away from spilled material. The product is immiscible with water and will spread on the water surface. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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7. Handling and storage

Precautions for safe handling Do not hand

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Explosion-proof general and local exhaust ventilation. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Avoid contact with eyes. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store at controlled room temperature at 20–25 °C (68-77°F). Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Туре	Value	
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3	
		1000 ppm	
US. ACGIH Threshold Limit Valu	es		
Components	Туре	Value	
Ethanol (CAS 64-17-5)	STEL	1000 ppm	
US. NIOSH: Pocket Guide to Che	emical Hazards		
Components	Туре	Value	
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3	

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general 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. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Provide eyewash station.

1000 ppm

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing.

limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. In the United States of America, if respirators are used, a program should be instituted to assure compliance

with OSHA 29 CFR 1910.134.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using do not smoke. Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance Clear yellow liquid.

Physical state
Form
Liquid.
Color
Clear yellow.
Odor
Ethanol odor.
Odor threshold
Not available.

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SDS US

8 - 9.7 pН

Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

96.0 °F (35.6 °C) Flash point **Evaporation rate** Not available. Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Flammability limit - upper

(%)

Not available.

Not available.

(%)

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available. Vapor pressure Not available. Vapor density Not available. Not available. Relative density

Solubility(ies)

Insoluble Solubility (water) Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperature Not available. Not available. **Decomposition temperature** Not available. **Viscosity**

10. Stability and reactivity

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

stability Possibility of Material is stable under normal conditions.

hazardous No dangerous reaction known under conditions of normal use.

reactions

Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the

flash point. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

Conditions to avoid

products

None known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Prolonged inhalation may be harmful.

Prolonged skin contact may cause temporary irritation. Skin contact

Eye contact Causes serious eye irritation.

Ingestion No harmful effects expected in amounts likely to be ingested by accident.

Symptoms related to the physical, chemical and toxicological characteristics Accidental human injection can cause serious local reactions or anaphylactic reaction and

systemic effects.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye

irritation

Causes serious eye irritation.

Respiratory or skin sensitization

Not a respiratory sensitizer. Respiratory sensitization

Skin sensitization This product is not expected to cause skin sensitization.

Metacam® (Meloxicam) 5 mg/mL Solution for Injection

Version #: 01 Revision date: -Issue date: 29-May-2015 **Germ cell mutagenicity**No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicityThis product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity -

single exposure

Not classified.

Specific target organ toxicity -

repeated exposure

Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Possible hypersensitization (development of abnormal sensitivity).

12. Ecological information

Ecotoxicity

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.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Ethanol (CAS 64-17-5) -0.31

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Incinerate the material under controlled conditions in an approved incinerator. Do not discharge

into drains or water courses. Dispose of in accordance with all applicable regulations. Do not contaminate water, food, or feed by disposal. If discarded, this product is considered a RCRA

ignitable waste, D001.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code D001: Waste Flammable material with a flash point <140 F

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

UN number UN1170

UN proper shipping name Ethanol solutions

Transport hazard class(es)

Class 3
Subsidiary risk Label(s) 3
Packing group III

Special precautions for user Not available.

Special provisions 24, B1, IB3, T2, TP1

Packaging exceptions 4b, 150
Packaging non bulk 203
Packaging bulk 242

IATA

UN number UN1170

UN proper shipping name Ethanol S

Transport hazard class(es)

Ethanol Solution

Class 3 Subsidiary risk -

Metacam® (Meloxicam) 5 mg/mL Solution for Injection Version #: 01 Revision date: - Issue date: 29-May-2015 SDS US

Packing group III Environmental hazards No. ERG Code 3L

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN1170 UN proper shipping name Ethanol Solution

Transport hazard class(es)

Class 3

Subsidiary risk
Packing group III

Environmental hazards

Marine pollutant No. S F-E, S-D

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

One or more components are not listed on TSCA.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not applicable.

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Ethanol (CAS 64-17-5) LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act Not regulated.

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Ethanol (CAS 64-17-5)

US. New Jersey Worker and Community Right-to-Know Act

Ethanol (CAS 64-17-5)

US. Pennsylvania Worker and Community Right-to-Know Law

Ethanol (CAS 64-17-5)

Metacam® (Meloxicam) 5 mg/mL Solution for Injection Version #: 01 Revision date: - Issue date: 29-May-2015

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Ethanol (CAS 64-17-5)

International Inventories

Inventory name	On inventory (yes/no)*
Australian Inventory of Chemical Substances (AICS)	No
Domestic Substances List (DSL)	No
Non-Domestic Substances List (NDSL)	No
Inventory of Existing Chemical Substances in China (IECSC)	No
European Inventory of Existing Commercial Chemical Substances (EINECS)	No
European List of Notified Chemical Substances (ELINCS)	No
Inventory of Existing and New Chemical Substances (ENCS)	No
Existing Chemicals List (ECL)	No
New Zealand Inventory	Yes
Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
	Australian Inventory of Chemical Substances (AICS) Domestic Substances List (DSL) Non-Domestic Substances List (NDSL) Inventory of Existing Chemical Substances in China (IECSC) European Inventory of Existing Commercial Chemical Substances (EINECS) European List of Notified Chemical Substances (ELINCS) Inventory of Existing and New Chemical Substances (ENCS) Existing Chemicals List (ECL) New Zealand Inventory Philippine Inventory of Chemicals and Chemical Substances

^{*}A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

Issue date 29-May-2015

Revision date - 01

United States & Puerto Rico

HMIS® ratings Health: 1

Flammability: 3 Physical hazard: 0

NFPA ratings



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Metacam® (Meloxicam) 5 mg/mL Solution for Injection Version #: 01 Revision date: - Issue date: 29-May-2015 No

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).