

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Metacam 20 mg/mL Solution for Injection
Product code:	A007982
Recommended use:	Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby inserting anti-inflammatory, anti-endotoxic, anti-exudative, analgesic and antipyretic properties. For use in cattle, sheep, pigs and horses.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 980 1600 Fax: +64 9 980 1601
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	27 June 2018

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Liquid	
Product components:		
Name	CAS	Proportion
Ethanol	64-17-5	10-30%
Meloxicam (4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide)	71125-38-7	2%
Ingredients determined not to be hazardous, including water.	N/A	Balance

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	3.1C, 6.1E, 6.4A, 6.8B, 6.9B, 9.1D
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	3.1C Flammable liquids: medium hazard 6.1E (Oral) - Substance that is acutely toxic 6.4A Substance that is irritating to the eyes 6.8B Substance that is suspected to be a human reproductive or developmental toxicant 6.9B (Single exposure) - Substance that is harmful to human target organs or systems 6.9B (Repeated exposure) - Substance that is harmful to human target organs or systems 9.1D Substance that is slightly harmful to the aquatic environment or is otherwise designed for biocidal action
	Hazard Statements H226 Flammable liquid and vapour. H303 May be harmful if swallowed. H319 Causes serious eye irritation. H361 Suspected of damaging fertility or the unborn child. H371 May cause damage to organs by oral. H373 May cause damage to organs through prolonged or repeated

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exposure by oral.
H401 Toxic to aquatic life.

Precautionary statement – Prevention

P102 Keep out of reach of children.
P103 Read label before use.
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash contaminated skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement – Response

P101 If medical advice is needed, have product container or label at hand.
P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P309+P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
P312 Call a POISON CENTER or doctor/physician if you feel unwell.
P314 Get medical advice/attention if you feel unwell.
P337+P313 If eye irritation persists: Get medical advice/attention.
P370+P378 In case of fire: Use carbon dioxide, dry chemical, foam, water fog or water mist.

Precautionary statement – Storage

P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Precautionary statement – Disposal

P501 In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:

For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.
Ingestion: If swallowed, seek immediate medical attention. Do NOT induce vomiting. Wash out mouth thoroughly with water.
Eyes: If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. Seek medical attention.
Skin: Wash affected area thoroughly with soap and water. If

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Workplace facilities:	symptoms develop, seek medical attention.
Required instructions:	In case of accidental injection, wash the site thoroughly. Contact a physician immediately and show the packet insert or label to the physician. <u>Inhalation:</u> If inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms develop and/or persist, seek medical attention.
Notes for medical personnel:	No special facilities required. Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse. Treat symptomatically. Note to Physician: For animal injection only. Not for human use. Antidote: Epinephrine is indicated for anaphylactoid reactions

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Flammable liquid and vapour.
Fire hazard properties:	Vapour/air mixtures may ignite explosively. Flashback along the vapour trail may occur. Runoff to sewer may create fire or explosion hazard. Under fire conditions this product may emit toxic and/or irritating fumes including carbon monoxide and carbon dioxide.
Extinguishing media and methods:	Use carbon dioxide, dry chemical, foam, water fog or water mist.
Hazchem code:	N/A
Recommended protective clothing:	Fire fighters should wear Self-Contained Breathing Apparatus and full protective clothing to prevent exposure to vapours, fumes or products of combustion. Water spray may be used to cool down heat-exposed material.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	For minor spills: refer to product label for specific instructions. Avoid inhalation of fumes, and skin or eye contact. Absorb with an inert material and place in an appropriate waste disposal container. In the event of a major spill: Wear appropriate personal protective equipment and clothing to prevent exposure. Extinguish or remove all sources of ignition and stop leak if safe to do so. Increase ventilation. Evacuate all unprotected personnel. If possible, contain the spill. Place inert absorbent, non-combustible material onto spillage. Use clean non-sparking tools to collect the material and place into suitable labelled containers for subsequent recycling or disposal. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs, inform the local water and waste management authorities in accordance with local regulations.
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Avoid contact with skin and eyes. Wear overalls, impervious gloves and safety glasses. Use in designated areas with local exhaust ventilation, away from sparks, flames and other ignition sources. Use approved flammable liquid storage containers in the work area. Prevent release of vapours and mists into workplace air. Keep containers tightly closed. Take precautionary measures against static discharges. Do not empty into drains. Ensure a high level of personal hygiene is maintained when using this product, that is, always wash hands before eating, drinking, smoking or using the toilet facilities. Use as directed on label or package insert. Avoid exposure. Do not handle until all safety precautions have been read and understood. It is recommended that pregnant or
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Approved handlers:	breastfeeding women should not handle this product unless adequate exposure protection can be assured at all times. Female personnel planning pregnancy should be made aware of the potential risks.
Conditions for safe storage:	Not required
Store site requirements:	Store in a cool, dry, well-ventilated area away from sources of ignition, oxidising agents, strong acids, foodstuffs, and clothing. Keep containers closed when not in use, securely sealed and protected against physical damage. Inspect regularly for deficiencies such as damage or leaks. Have appropriate fire extinguishers available in and near the storage area. Take precautions against static electricity discharges. Use proper grounding procedures. Protect from freezing. Ensure that storage conditions comply with applicable local and national regulations. For information on the design of the storeroom, reference should be made to Australian Standard AS1940 - The storage and handling of flammable and combustible liquids. Not to be used after 28 days of opening.
Store site requirements:	Store below 25 °C.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	No exposure standards have been established for this material. However, the available exposure limits for ingredients are listed below: Ethanol: TWA: 1000 ppm, 1880 mg/m ³ TWA (Time Weighted Average): The average airborne concentration of a particular substance when calculated over a normal eight- hour working day, for a five-day week.
Application in the workplace:	Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.
Engineering controls:	Industrial application: This substance is hazardous and should be used with a local exhaust ventilation system, drawing vapours away from workers' breathing zone. A flame-proof exhaust ventilation system is required. If the engineering controls are not sufficient to maintain concentrations of vapours/mists below the exposure standards, suitable respiratory protection must be worn. Refer to relevant regulations for further information concerning ventilation requirements.
Personal protection:	Respiratory Protection Industrial application: If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable vapour/mist filter should be used. ¹ Eye Protection Industrial application: glasses with side shields, full face shield or chemical goggles should be worn. Final choice of appropriate eye/ face protection will vary according to individual circumstances. ² Hand Protection Wear impervious chemical resistant gloves such as butyl rubber or nitrile rubber. Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. ³ Body Protection Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist. When large quantities are handled the use of plastic aprons and rubber boots is recommended.
References:	1. Reference should be made to Australian/New Zealand Standards AS/NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any

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necessary changes for individual circumstances.

2. Eye protection devices should conform with Australian/ New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:

Formulation type: Liquid
Appearance: Colourless glass injection vials of 20 mL, 50 mL, 100 mL and 250 mL
Specific gravity: Not available
Boiling Point: 78 °C (approximate) (related to solvents)
Vapour Pressure: Not available
Solubility in Water: Soluble (20 °C)
Odour: Alcohol-like
Flash Point: 36.6 °C (literature)
Auto-ignition Temperature: 425 °C (related to solvents)
Flammability: Flammable
Explosion properties: Not explosive

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:

Stable under normal conditions of use and storage.

Conditions to avoid:

Heat, open flames and other sources of ignition.

Material to avoid:

Strong oxidizing agents.

Hazardous decomposition products:

Under fire conditions this product may emit toxic and/or irritating fumes including carbon monoxide and carbon dioxide

Hazardous polymerization:

Will not occur.

Specific data:

N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data:

Acute Toxicity - Oral

Meloxicam

LD50 (rat): 83.5 mg/kg Ethanol

LD50 (rat): 6200 mg/kg

Acute Toxicity - Inhalation

Ethanol

LC50 (rat): 95.6 mg/l/4h

Acute Toxicity - Dermal

Ethanol

LD50 (rat): >2000 mg/kg

Ingestion

May be harmful if swallowed. Ingestion of this product may cause irritation to the mouth, throat, oesophagus and stomach with symptoms of nausea, abdominal discomfort, vomiting and diarrhoea.

Inhalation

Inhalation of product vapours may cause irritation of the nose, throat and respiratory system.

Skin

May be irritating to skin. The symptoms may include redness, itching and swelling. Meloxicam:

Species: Rabbit Exposure time: 4 h

Method: OECD Test Guideline 404 Result: No skin irritation

Ethanol:

Species: Rabbit

Method: OECD Test Guideline 404 Result: No skin irritation

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Eye

Causes serious eye irritation. On eye contact this product will cause tearing, stinging, blurred vision, and redness. Serious eye damage/eye irritation

Meloxicam:

Species: Rabbit

Result: No eye irritation Ethanol:

Species: Rabbit Result: Eye irritation

Method: OECD Test Guideline 405

Respiratory sensitisation

Not expected to be a respiratory sensitiser.

Skin Sensitisation

Not expected to be a skin sensitiser.

Germ cell mutagenicity

Not considered to be a mutagenic hazard. Meloxicam:

Genotoxicity in vitro:

Test Type: Ames-test, Species: Salmonella typhimurium, Result: negative

Test Type: HGPRT assay, Species: V79 cells (Chinese hamster), Result: negative

Test Type: Chromosomal aberration test, Species: Human lymphocytes, Result: negative Genotoxicity in vivo :

Test Type: Micronucleus test, Species: Mouse (oral), Dose: 300 mg/kg Remarks: In vivo tests did not show any chromosomal changes.

Ethanol:

Genotoxicity in vitro: Test Type: Ames-test, Species: Salmonella typhimurium, Result: negative

Carcinogenicity

Not considered to be a carcinogenic hazard. Meloxicam

Species: Mouse, Application Route: Oral, Exposure time: 48 month(s), Dose: 8 mg/kg Remarks: Did not show carcinogenic effects in animal experiments.

Species: Rat, Application Route: Oral, Exposure time: 48 month(s), Dose: 0,8 mg/kg Remarks: Did not show carcinogenic effects in animal experiments

Reproductive Toxicity

Suspected of damaging fertility or the unborn child. Classified as a suspected human reproductive or developmental toxicant.

Meloxicam:

Effects on fertility:

Test Type: Study of Fertility and Early Embryonic Development, Species: Rat, Dose: 4 mg/kg, Application Route: Oral Remarks: Did not show teratogenic effects in animal experiments

Test Type: Study for Effects on Embryo-Fetal Development, Species: Rabbit, Dose: 80 mg/kg, Application Route: Oral Remarks: Did not show teratogenic effects in animal experiments

Test Type: Pre- and Postnatal development study, Species: Rat, NOAEL: < 0.125 mg/kg, F1: < 0.125 mg/kg

STOT-single exposure

May cause damage to organs by oral.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure by oral. Meloxicam:

Species: Rat

NOAEL: = 0.4 mg/kg, Application Route: Oral, Exposure time: 52 weeks Species: Rat

NOAEL: < 1 mg/kg, Application Route: Oral, Exposure time: 18 months Species: guinea pig

NOAEL: = 1 mg/kg, Application Route: Oral, Exposure time: 52 weeks

Aspiration Hazard

Not expected to be an aspiration hazard.

Other Information

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Meloxicam:
Test Type: Maximisation Test Species: Guinea pig
Result: Did not cause sensitisation on laboratory animals. Ethanol:
Species: Guinea pig
Method: OECD Test Guideline 406
Result: Did not cause sensitisation on laboratory animals.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

Toxic to aquatic life.

Data organisation :

Persistence and degradability

Meloxicam:

Biodegradability : Result: Not rapidly biodegradable

Biodegradation: 31.3%, Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Ethanol:

Biodegradability : Result: Readily biodegradable

Biodegradation: 94%

Biochemical Oxygen Demand (5d) : 930 - 1,670 mg/g

Chemical Oxygen Demand (COD): 1.99 mg/g

ThOD : 2,100 mg/g

Mobility

Not available

Bioaccumulative Potential

Meloxicam:

Bioaccumulation : Remarks: No appreciable bioaccumulation potential is to be expected (log Pow) 1-3).

Partition coefficient: n-octanol/water: log Pow: = 1.7

Method: OECD Test Guideline 107 log Pow: = 0.2

Method: OECD Test Guideline 107 log Pow: = -0.3

Method: OECD Test Guideline 107

Ethanol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow)<1).

Partition coefficient: n-octanol/water: log Pow: -0.32

Other Adverse Effects

Not available

Environmental Protection

Prevent this material entering waterways, drains and sewers.

Acute Toxicity - Fish

Meloxicam:

LC50 (*Brachydanio rerio* (zebrafish)): = 50 mg/l/96h

Test Type: static test, Method: OECD Test Guideline 203

Ethanol:

LC50 (golden orfe): = 8,140 mg/l/48h

Acute Toxicity - Daphnia

Meloxicam

EC50 (*Daphnia magna* (Water flea)): > 13 mg/l/48h

Test Type: static test, Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

Ethanol:

EC50 (*Daphnia magna* (Water flea)): = 9,268 - 14,221 mg/l/48h

Acute Toxicity - Algae

Meloxicam

EC50 (*Desmodesmus subspicatus*): > 100.1 mg/l/72h

Method: OECD Test Guideline 201

NOEC (*Desmodesmus subspicatus*): = 100.1 mg/l/72h

Method: OECD Test Guideline 201

Ethanol:

Lowest Observed Effect Concentration (*Scenedesmus quadricauda*)

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Environmental risk and safety phrases:

(Green algae): = 5,000 mg/l/7d

Acute Toxicity - Bacteria

Meloxicam

NOEC (activated sludge, industrial): > 1,000 mg/l Method: OECD 209

Ethanol:

EC5 (Pseudomonas putida): = 6,500 mg/l/16h

Prevent this material entering waterways, drains and sewers.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :

Dispose of waste according to applicable local and national regulations. Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes including emptied containers are controlled wastes and should be disposed of in accordance with all applicable local and national regulations.

Product Disposal:

Product wastes are controlled wastes and should be disposed of in accordance with all applicable local and national regulations. This product can be disposed through a licensed commercial waste collection service. In this specific case the product is a flammable substance and therefore can be sent to an approved high temperature incineration plant for disposal.

Personal protective clothing and equipment as specified in Section 8 of this SDS must be worn during handling and disposal of this product. The ventilation requirements as specified in the same section must also be followed, and the precautions given in Section 7 of this SDS regarding handling must also be followed.

Do not dispose into the sewerage system. Do not discharge into drains or watercourses or dispose where ground or surface waters may be affected.

In New Zealand, the disposal agency or contractor must comply with the New Zealand Hazardous Substances (Disposal) Regulations 2001. Further details regarding disposal can be obtained on the EPA New Zealand website under specific group standards.

Container Disposal:

The container or packaging must be cleaned and rendered incapable of holding any substance. It can then be disposed of in a manner consistent with that of the substance it contained. In this instance the packaging can be disposed through a commercial waste collection service.

Alternatively, the container or packaging can be recycled if the hazardous residues have been thoroughly cleaned or rendered non-hazardous.

In New Zealand, the packaging (that may or may not hold any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with regulations.

SECTION 14: TRANSPORT INFORMATION

Relevant information:

Not classified as dangerous for rail, road, air or sea transport.

Note: This product is exempted from being classified as Dangerous Goods Class 3, UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), packing group III, since the Special Provision (SP) 'An

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Other requirements:	aqueous solution containing not more than 24% alcohol by volume is not subject to the provisions of this Standard (SP 144 in NZS 5433:2012 and IMDG and SP A58 in IATA) is applicable to this product. N/A
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SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A007982 See www.foodsafety.govt.nz for registration conditions Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian. Approved pursuant to the HSNO Act, Approval Code HSR002068 See www.epa.govt.nz for approval conditions Classified as Hazardous according to the New Zealand Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. HSNO name: Flammable liquid containing 16 - 30 g/litre meloxicam
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.
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