

Metacam 20 mg/mL Solution for Injection

Version 1

Issue Date: 25 June 2021

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Section 1 - Identification of the Material and Supplier

Product name: Metacam 20 mg/mL Solution for Injection

APVMA Code: 54061

Recommended Use: Animal injection for use as described on the product label.

Supplier name: Boehringer Ingelheim Animal Health Australia Pty Ltd

Address: Level 1, 78 Waterloo Road

North Ryde NSW 2113 AUSTRALIA

Telephone number (toll-free): 1800 808 691

All hours emergency phone number - Poisons Information Centre 131126 anywhere in Australia

Chemical nature: Injection containing meloxicam for use in various livestock species.

This version issued: June, 2021 and is valid for 5 years from this date. Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature

This product is classified as: Hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria. Ethanol solutions containing 24% ethanol or less are exempt from being treated as flammable.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG)

Code, IATA or IMDG/IMSBC criteria. **UN Number:** None allocated







GHS Signal word: DANGER

Flammable liquids Category 3

Serious eye damage/eye irritation Category 2/2A

Specific Target Organ toxicity - repeated exposure Category 1

HAZARD STATEMENT:

H226: Flammable liquid and vapour.

H319: Causes serious eye irritation.

H372: Causes damage to organs through prolonged or repeated exposure.

PREVENTION

P102: Keep out of reach of children.

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 and hot surfaces. - No smoking.

P233: Keep container tightly closed.

P260: Do not breathe fumes, mists, vapours or spray.

P262: Do not get in eyes, on skin, or on clothing.

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.
P272: Contaminated work clothing should not be allowed out of the workplace.

P280: Wear protective gloves, protective clothing and eye or face protection.

RESPONSE

P314: Get medical advice or attention if you feel unwell.

SAFETY DATA SHEET

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P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water.

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.

P337+P313: If eye irritation persists: Get medical advice.

P381: Eliminate all ignition sources if safe to do so.

P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

STORAGE

P405: Store locked up.

P410: Protect from sunlight.

P411+P235: Store at temperatures not exceeding 25°C. Keep cool.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview

Physical Description & Colour: Colourless liquid.

Odour: Alcohol odour.

Major Health Hazards: may cause serious damage to health by prolonged exposure, may cause serious irritation to eyes. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc, %	TWA (mg/m³)	STEL (mg/m³)
Ethanol	64-17-5	15	1880	not set
Meloxicam	71125-38-7	2	not set	not set
Other non hazardous ingredients including water	secret	to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed liquid. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15 minutes or until the product is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately. Take special care if exposed person is wearing contact lenses.

Ingestion: If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

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Section 5 - Fire Fighting Measures

Fire and Explosion Hazards: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: In case of fire, use carbon dioxide, dry chemical, foam or water fog.

Fire Fighting: When fighting fires involving significant quantities of this product, no special equipment is believed to be necessary.

Flash point: Approx 37°C
Upper Flammability Limit: No data.
Lower Flammability Limit: No data.
Autoignition temperature: No data.

Flammability Class: Flammable Category 3 (GHS); exempt from DG status.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

Section 8 - Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits TWA (mg/m³) STEL (mg/m³)
Ethanol 1880 some not set

The ADI for Meloxicam is set at 0.0001mg/kg/day. The corresponding NOEL is set at 0.125 [LOEL]mg/kg/day. ADI means Acceptable Daily Intake; NOEL means No-observable-effect-level. Data from Australian ADI List, March 2017.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems. **Ventilation:** This product should only be used where there is ventilation that is adequate to keep exposure below the TWA levels. If necessary, use a fan.

Eye Protection: Protective glasses or goggles must be worn when this product is being used. Failure to protect your eyes may lead to severe harm to them or to general health. Emergency eye wash facilities must also be available in an area close to where this product is being used.



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Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when lengthy skin contact is likely.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber, PVC, nitrile.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

Eyebaths or eyewash stations and safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

Section 9 - Physical and Chemical Properties:

Physical Description & colour: Colourless liquid.
Odour: Alcohol odour.
Boiling Point: Not available.

Freezing/Melting Point: No specific data. Liquid at normal temperatures.

Volatiles: No data. **Vapour Pressure:** No data. **Vapour Density:** No data. Specific Gravity: No data. Water Solubility: Soluble. pH: No data. Volatility: No data. **Odour Threshold:** No data. **Evaporation Rate:** No data. Coeff Oil/water Distribution: No data **Autoignition temp:** No data.

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: strong oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

Local Effects:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient Risk Phrases

Ethanol No risk phrases at concentrations found in this product

Flammable liquid – category 2

Eye irritation – category 2A

Meloxicam >=1%Conc<10%: Xn; R48/22

Specific target organ toxicity (repeated exposure) – category 1

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Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in

normal use. In addition product is unlikely to cause any discomfort in normal use.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product is a severe eye irritant. Symptoms may include stinging and reddening of eyes and watering which may become copious. Other symptoms such as swelling of eyelids and blurred vision may also become evident. If exposure is brief, symptoms should disappear once exposure has ceased. However, lengthy exposure or delayed treatment is likely to cause permanent damage.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: Significant oral exposure is considered to be unlikely. Available data shows that this product is not harmful. This product is unlikely to cause any irritation problems in the short or long term.

Long Term Exposure: Believed to be cumulative by ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA. **NTP:** No significant ingredient is classified as carcinogenic by NTP.

IARC: Ethanol is classed 1 by IARC - carcinogenic to humans.

See the IARC website for further details. A web address has not been provided as addresses frequently change.

Section 12 - Ecological Information

Insufficient data to be sure of status.

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Meloxicam, is mentioned in the SUSMP.

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail (7th edition)

AICS
Australian Inventory of Chemical Substances
SWA
Safe Work Australia, formerly ASCC and NOHSC
CAS number
Chemical Abstracts Service Registry Number

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Hazchem Code Emergency action code of numbers and letters that provide information to emergency

services especially firefighters

IARC International Agency for Research on Cancer

International Air Transport Association the trade association for the world's airlines.

IMSBC Formerly IMDG, the code for carriage of Dangerous Goods by sea freight.

NOS Not otherwise specified

NTP National Toxicology Program (USA)

SUSMP Standard for the Uniform Scheduling of Medicines & Poisons

UN Number United Nations Number

SUPPLIER STATEMENT: The product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information in this SDS is based on the level of knowledge at the time of preparation and relates to the product in the state in which it is supplied. The information describes the product from the safety point of view and is not intended to guarantee any particular properties and shall not establish a legally valid contractual relationship

Please read SDS and all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (Feb 2016)

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