

Section 1 - Identification of the Material and Supplier

Australia Pty Ltd

ABN 94 156 476 425
Level 6, 5 Rider Blvd
Rhodes NSW 2138 AUSTRALIA
Tel: 1800 814 883
Fax: (02) 8876 0444
Email: productsupport.au@zoetis.com



Chemical nature: Mavacoxib is a non-steroidal anti-inflammatory drug:-
4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide.

Trade Name: **Trocoxil**

Product Use: Veterinary product used as non-steroidal, anti-inflammatory drug (NSAID)

Creation Date: **June 2011**

This version issued: **22 September 2021** and is valid for 5 years from this date

Section 2 - Hazards Identification

Appearance: Brown tablets

Classification of the Substance or Mixture

GHS - Classification

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 3

Chronic aquatic toxicity: Category 3

Label Elements

Signal Word:

Warning

Hazard Statements:

H373 - May cause damage to organs through prolonged or repeated exposure (gastrointestinal system, kidneys)

H412 - Harmful to aquatic life with long lasting effects

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P273 - Avoid release to the environment

P314 - Get medical attention/advice if you feel unwell

P501 - Dispose of contents/container in accordance with all local and national regulations

Precautionary Statements:



Other Hazards

Short Term:

May cause irritation if tablets are crushed or broken. May produce slight eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain. May cause slight skin irritation. Signs and symptoms might include skin rash, itching, redness or swelling.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, kidneys. May have long-term toxic effects on the aquatic environment.

MATERIAL SAFETY DATA SHEET

Known Clinical Effects:

Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation. Ingestion of this material may cause effects similar to those seen in clinical use including changes in blood chemistry, kidney effects, effects on gastrointestinal system, diarrhea and vomiting.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 - Composition/Information on Ingredients

Hazardous Ingredients	CAS No	Conc %	GHS Classification
Sugar	57-50-1	<60	Not Listed
Microcrystalline cellulose	9004-34-6	<30	Not Listed
Mavacoxib	170569-88-7	5	Acute Tox. 4 (H302) STOT RE 2 (H373) Aq. Acute 2 (H401) Aq. Chronic 2 (H411)
Sodium lauryl sulfate	151-21-3	2	Not Listed
Magnesium Stearate	557-04-0	1	Not Listed
Ingredients	CAS No	Conc %	GHS Classification
Artificial powdered beef flavor	Not Assigned	*	Not Listed
Croscarmellose sodium	74811-65-7	*	Not Listed

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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

Section 4 - First Aid Measures

Description of First Aid Measures**Eye Contact:**

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

MATERIAL SAFETY DATA SHEET

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Section 5 - Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen sulfur and products of fluorine

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions. Dust can form an explosive mixture in air.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water used to fight fire.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid dust formation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / by a Collecting: Contain the source of spill if it is safe to do so. Collect spilled material method that controls dust generation. A damp cloth or a filtered vacuum

Should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Avoid generating airborne dust. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

MATERIAL SAFETY DATA SHEET

Section 7 - Handling and Storage

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Keep away from heat, sparks, flame and all other sources of ignition. Ground and bond all bulk transfer equipment. Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Wash thoroughly after handling. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Keep container tightly closed when not in use. Keep in a cool, well-ventilated place.

Specific end use(s):

No data available

Section 8 - Exposure Controls and Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sugar

ACGIH Threshold Limit Value (TWA) **10 mg/m³**

Australia TWA **10 mg/m³**

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) **10 mg/m³**

Australia TWA **10 mg/m³**

Mavacoxib

Zoetis OEL TWA 8-hr **0.001mg/m³**

Sodium lauryl sulfate

Zoetis OEL TWA 8-hr **0.3 mg/m³**

Magnesium Stearate

ACGIH Threshold Limit Value (TWA) **10 mg/m³**

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

MATERIAL SAFETY DATA SHEET

Section 9 - Physical and Chemical Properties:

Physical State:	Tablet	Color:	Brown
Odor:	No data available	Odor Threshold:	No data available
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available		
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available		
Mavacoxib Log P	2.09, 3.67 (ionic, neutral forms)		
Decomposition Temperature (°C):	No data available		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):	No data available		
Flammability (Solids):	No data available		
Flash Point (Liquid) (°C):	No data available		
Upper Explosive Limits (Liquid) (% by Vol.):	No data available		
Lower Explosive Limits (Liquid) (% by Vol.):	No data available		

Section 10 - Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Keep away from heat and other sources of ignition, including electrostatic discharge. Avoid dispersion as a dust cloud. Dust may form explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors. Hazardous combustion products may include oxides of carbon, nitrogen, sulfur and products of fluorine.

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information:	Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.
-----------------------------	--

MATERIAL SAFETY DATA SHEET

Routes of exposure: skin contact

Acute Toxicity: (Species, Route, End Point, Dose)**Mavacoxib**

Rat Oral Minimum Lethal Dose 500 mg/kg
 Rat Dermal LD50 > 2000mg/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Sugar

Rat Oral LD50 29700 mg/kg
 Mouse Oral LD50 14000mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
 Rabbit Dermal LD50 > 2000 mg/kg

Magnesium Stearate

Rat Oral LD 50 1092 gm/kg/13 weeks

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)**Mavacoxib**

Eye Irritation	Rabbit	Minimal	
Skin Irritation	Rabbit	Slight	
Skin Sensitization - LLNA	Mouse		Negative
Skin Sensitization - Beuhler	Guinea Pig		Negative

Sodium lauryl sulfate

Eye Irritation	Rabbit	Moderate	
Skin Irritation	Rabbit	Mild Moderate	
Skin Sensitization - GPMT	Guinea Pig		Negative
Skin Sensitization - LLNA	Mouse		Negative

Microcrystalline cellulose

Skin Irritation	Rabbit	Non-irritating	
Eye Irritation	Rabbit	Non-irritating	

Irritation / Sensitization Comments: May cause eye irritation.

Skin Irritation / Sensitization May cause skin irritation.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**Mavacoxib**

6 Month(s)	Dog	Oral	20 mg/kg/28 days	NOAEL	No effects at maximum dose
1 Month(s)	Rat	Oral	5 mg/kg/day	LOAEL	Gastrointestinal system, Kidney

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Mavacoxib**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

MATERIAL SAFETY DATA SHEET

Issued by: Zoetis Australia Pty Ltd

Phone: 1800 814 883

Poisons Information Centre: 13 11 26 from anywhere in Australia, (0800 764 766 in New Zealand)

In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Rat Negative

Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), oral >5000 mg/kg

Section 12 - Ecological Information

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. Releases to the environment should be avoided.

Toxicity:**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Mavacoxib**

Skeletonema costatum (Marine Diatom) OPPTS EbC50 96 Hours 3.9 mg/L

Tisbe battagliai (Marine Copepod) ISO LC50 48 Hours 4.0 mg/L

Scophthalmus maximus (Turbot) OPPTS LC50 96 Hours > 3.2 mg/L

Activated sludge OECD EC50 3 Hours > 100 mg/L

Sodium lauryl sulfate

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 3.6 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mavacoxib Log P 2.09, 3.67 (ionic, neutral forms)

Mobility in Soil: No data available

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities use a commercial waste disposal service.

Section 14 - Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under IATA, ADG or IMDG regulations.

MATERIAL SAFETY DATA SHEET

Section 15 - Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poison Schedule Schedule 4

Sugar

CERCLA/SARA 313 Emission reporting Not Listed
Australia (AICS): Present

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting Not Listed
Australia (AICS): Present

Mavacoxib

CERCLA/SARA 313 Emission reporting Not Listed

Sodium lauryl sulfate

CERCLA/SARA 313 Emission reporting Not Listed
Australia (AICS): Present

Magnesium Stearate

CERCLA/SARA 313 Emission reporting Not Listed
Australia (AICS): Present

Artificial powdered beef flavor

CERCLA/SARA 313 Emission reporting Not Listed

Croscarmellose sodium

CERCLA/SARA 313 Emission reporting Not Listed
Australia (AICS): Present

Section 16 - Other Information

This version issued: 22 September 2021 and is valid for 5 years from this date

Supersedes: Revision issued 1 Oct 2016

Revision History:

Date of Revision	Reason
17 Nov 2014	Update to GHS
01 Jul 2016	Revision for consistency with Zoetis organisation
01 Oct 2016	Minor corrections and updates. Addition of ingredients to Section 3
22 Sep 2021	Periodical revision

Contact Points:

MATERIAL SAFETY DATA SHEET

Zoetis
Police and Fire Brigade:

1800 814 883
Dial 000

If ineffective:

**Dial Poisons Information
Centre (13 11 26 from anywhere in
Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read 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" (December 2011)

© 2021 Zoetis Inc, All rights reserved.

End of Safety Data Sheet

MATERIAL SAFETY DATA SHEET