

SAFETY DATA SHEET



Section 1 - Identification

Product identifier	Mavacoxib Tablets
Other means of identification	
Synonyms	TROCOXIL
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary product used as non-steroidal, anti-inflammatory drug (nsaid)
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	productsupport.au@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

Section 2 - Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Specific target organ toxicity, repeated exposure	Category 2
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

Label elements, including precautionary statements

Hazard symbol(s)



Health
hazard

Exclamation
mark

Signal word	Warning
Hazard statement(s)	May cause damage to organs through prolonged or repeated exposure. (Gastro-intestinal tract. Kidneys.) Harmful to aquatic life with long lasting effects.
Precautionary statement(s)	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray. Avoid release to the environment.
Response	Get medical advice/attention if you feel unwell.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental information	None.
Other hazards which do not result in classification	None known.

Section 3 - Composition and information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Sugar	57-50-1	< 60
Microcrystalline cellulose	9004-34-6	< 30
Mavacoxib	170569-88-7	5
Magnesium Stearate	557-04-0	1 - < 3
Sodium lauryl sulfate	151-21-3	1 - < 3

Composition comments Other components below reportable levels

Section 4 - First aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical advice/attention if you feel unwell. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
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.

Personal protection for first-aid responders Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. 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.

Symptoms caused by exposure Prolonged exposure may cause chronic 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, gastrointestinal system and kidney effects, diarrhea and vomiting.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

Section 5 - Firefighting measures

Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Hazchem code	None.
General fire hazards	No unusual fire or explosion hazards noted.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
Extinguishing media	
Suitable extinguishing media	Water fog. Alcohol resistant foam. Powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

Section 6 - Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
For emergency responders	Keep unnecessary personnel away. Avoid dust formation. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Clean surface thoroughly to remove residual contamination.

Small Spills: 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.

Section 7 - Handling and storage**Precautions for safe handling**

Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse. Observe good industrial hygiene practices. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Conditions for safe storage, including any incompatibilities

Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

Section 8 - Exposure controls and personal protection**Control parameters**

Follow standard monitoring procedures.

Occupational exposure limits**Zoetis**

Components	Type	Value
Mavacoxib (CAS 170569-88-7)	TWA	0.001 mg/m ³
Sodium lauryl sulfate (CAS 151-21-3)	TWA	0.3 mg/m ³

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inhalable dust.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	Inhalable fibers.
Sugar (CAS 57-50-1)	TWA	10 mg/m ³	Inhalable dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Magnesium Stearate (CAS 557-04-0)	TWA	3 mg/m ³	Respirable fraction.
		10 mg/m ³	Inhalable fraction.
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m ³	
Sugar (CAS 57-50-1)	TWA	10 mg/m ³	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	20 mg/m ³	Inhalable dust.
		4 mg/m ³	Respirable dust.
		10 mg/m ³	Inhalable dust.
Sugar (CAS 57-50-1)	STEL	20 mg/m ³	
	TWA	10 mg/m ³	

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	4 mg/m ³	Inhalable dust.
Sugar (CAS 57-50-1)	TWA	4 mg/m ³	Inhalable dust.

Biological limit values

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

Appropriate 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 aerosols.
Individual protection measures, for example personal protective equipment (PPE)	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
Thermal hazards	Not applicable.
Hygiene measures	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.

Section 9 - Physical and chemical properties

Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	311 °F (155 °C) estimated
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other physical and chemical parameters	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.
Appearance	Tablet
Physical state	Solid.
Form	Solid.
Color	Brown.

Section 10 - Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.

Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

Section 11 - Toxicological information

Information on possible routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.	
Skin contact	No adverse effects due to skin contact are expected.	
Sodium lauryl sulfate		Species: Rabbit Severity: Mild Moderate
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Mavacoxib		Species: Rabbit Severity: Slight
Eye contact	Direct contact with eyes may cause temporary irritation.	
Mavacoxib		Species: Rabbit Severity: Minimal
Sodium lauryl sulfate		Species: Rabbit Severity: Moderate
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Ingestion	Expected to be a low ingestion hazard.	
Symptoms related to exposure	Prolonged exposure may cause chronic 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, Gastrointestinal and kidney effects, diarrhea and vomiting.	
Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.	
Components	Species	Test Results
Magnesium Stearate (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	1092
Mavacoxib (CAS 170569-88-7)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD	Rat	500 mg/kg (Minimum Lethal Dose)
Chronic		
Oral		
NOAEL	Dog	20 mg/kg, 6 months (No effects at maximum dose, 20 mg/kg/day for 28 days)
Subacute		
Oral		
LOAEL	Rat	5 mg/kg/day, 1 months (Gastrointestinal system, Kidney)
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Oral LD50 Sodium lauryl sulfate (CAS 151-21-3)	Rat	> 5000 mg/kg
Acute Oral LD50 Sugar (CAS 57-50-1)	Rat	1288 mg/kg
Acute Oral LD50	Mouse	14000 mg/kg
	Rat	29700 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met. Prolonged skin contact may cause temporary irritation.	
Corrosivity Mavacoxib		Result: Irritant Species: Rabbit Severity: Slight
Serious eye damage/irritation	Based on available data, the classification criteria are not met. Direct contact with eyes may cause temporary irritation.	
Eye Contact Mavacoxib		Species: Rabbit Severity: Minimal
Sodium lauryl sulfate		Species: Rabbit Severity: Moderate
Microcrystalline cellulose		Species: Rabbit Severity: Non-irritating
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Skin sensitization Mavacoxib		Species: Guinea Pig Severity: Negative
Sodium lauryl sulfate		Species: Guinea Pig Severity: Negative
Mavacoxib		Species: Mouse Severity: Negative
Sodium lauryl sulfate		Species: Mouse Severity: Negative
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity Mavacoxib		Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Sodium lauryl sulfate		Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
Mavacoxib		In Vitro Chromosome Aberration Result: Negative Species: Human Lymphocytes

Mutagenicity Mavacoxib		In Vivo Micronucleus Result: Negative Species: Rat	
Carcinogenicity	Due to partial or complete lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.		
ACGIH Carcinogens			
Magnesium Stearate (CAS 557-04-0)		A4 Not classifiable as a human carcinogen.	
Sugar (CAS 57-50-1)		A4 Not classifiable as a human carcinogen.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.		
Specific target organ toxicity - single exposure	Not classified.		
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure. (Gastrointestinal tract. Kidneys.)		
Aspiration hazard	Not an aspiration hazard.		
Chronic effects	May cause damage to organs through prolonged or repeated exposure.		
Other information	Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.		
Section 12 - Ecological information			
Ecotoxicity	Avoid release to the environment. Harmful to aquatic life with long lasting effects.		
Components	Species	Test Results	
Mavacoxib (CAS 170569-88-7)	EbC50	Skeletonema costatum (Marine Diatom)	3.9 mg/L, 96 Hours
	EC50	Activated sludge	> 100 mg/L, 3 Hours
	LC50	Scophthalmus maximus (Turbot)	> 3.2 mg/L, 96 Hours
		Tisbe battagliai (Marine Copepod)	4 mg/L, 48 Hours
Sodium lauryl sulfate (CAS 151-21-3)			
Aquatic			
Fish	LC50	Oncorhynchus mykiss (Rainbow Trout)	3.6 mg/L, 96 Hours
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia obtusa)	9.2 - 10.4 mg/l, 48 hours
Fish	LC50	Carp (Cyprinus carpio)	1.31 mg/l, 96 hours
Persistence and degradability	No data available for this product.		
Bioaccumulative potential	No data available.		
Mobility in soil	No data available for this product.		
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.		
Section 13 - Disposal considerations			
Disposal methods	Avoid release to the environment. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.		
Residual waste	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.		
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.		
Section 14 - Transport information			
ADG			
Not regulated as dangerous goods.			

RID

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

Section 15 - Regulatory information**Safety, health and environmental regulations**

National regulations This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals.

Poison Schedule (Product): Schedule 4

APVMA No: 64466	TROCOXIL 6MG CHEWABLE TABLETS FOR DOGS
APVMA No: 64465	TROCOXIL 20MG CHEWABLE TABLETS FOR DOGS
APVMA No: 64464	TROCOXIL 30MG CHEWABLE TABLETS FOR DOGS
APVMA No: 64463	TROCOXIL 75MG CHEWABLE TABLETS FOR DOGS
APVMA No: 64462	TROCOXIL 95MG CHEWABLE TABLETS FOR DOGS

Australia Medicines & Poisons Appendix E

Sodium lauryl sulfate (CAS 151-21-3)

Australia Medicines & Poisons Schedule 4

Mavacoxib (CAS 170569-88-7)

High Volume Industrial Chemicals (HVIC)

Not listed.

Importation of Ozone Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10, as amended)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Microcrystalline cellulose (CAS 9004-34-6)	2000 TONNES/YR Threshold Category: 2B
	400 TONNES/YR Threshold Category: 2A
Sugar (CAS 57-50-1)	2000 TONNES/YR Threshold Category: 2B
	400 TONNES/YR Threshold Category: 2A

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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).

Section 16 - Any other relevant information

Issue date	13 February 2014
Revision date	23 February 2023
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals.
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.