



SAFETY DATA SHEET

1. Identification

Product identifier	ONSIOR 5MG TABLETS FOR DOGS	
Other means of identification		
Synonyms	A-20022 D * CGS 34975 5MG TAB	
Item Code	CA4870	
Recommended use of the chemical and restrictions on use		
Recommended use	Veterinary Product	
Restrictions on use	Not available.	
Details of manufacturer or importer		
Company name	Elanco Australasia Pty Ltd. ACN: 076 745 198	
Address	112 Wharf Road West Ryde, NSW 2114 Australia	
Telephone	1800 995 709 (toll free)	
E-mail	lilly_msds@lilly.com	
Emergency phone number	Elanco Australasia 1800 995 709 (toll free)	
24 hr emergency contact number	CHEMWATCH 1800 039 008 (spills and accidents)	
24 hr emergency contact number (Local)	CHEMWATCH +61 2 9186 1132 (spills and accidents)	

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	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

Signal word

Warning

Hazard statement(s)

Suspected of damaging the unborn child. Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Response

IF exposed or concerned: Get medical advice/attention.

Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards which do not result in classification	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
Robenacoxib	220991-32-2	6.25
[5-Ethyl-2-(2,3,5,6-tetrafluoro-phenylamino)-phenyl]-acetic acid		
COX 975 MIKRO		
ROBENACOXIB MICRO.		
COX975 UNGROUND		
NOA 455365 A		
NOA 455365 B		
COX975 UNGROUND		
ROBENACOXIB		
ROBENACOXIB UNGROUND		

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

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 attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Personal protection for first-aid responders	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
Symptoms caused by exposure	May cause reproductive effects.
Medical attention and special treatment	Treat symptomatically.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
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.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away.

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. Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

7. Handling and storage

Precautions for safe handling Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store locked up. Storage temperature: between 2 °C and 25 °C.
Store in original tightly closed container. Protect from humidity. Protect from light.

8. Exposure controls and personal protection

Control parameters Novartis Internal Exposure Limit (NPIEL): 8 hour TWA 0,7 mg/m3 (Robenacoxib)

Occupational exposure limits No exposure limits noted for ingredient(s).

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

Exposure guidelines No exposure standards allocated. Novartis Internal Exposure Limit (NPIEL): 8 hour TWA 0,7 mg/m3 (Robenacoxib)

Appropriate engineering controls 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.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection If contact is likely, safety glasses with side shields are recommended. (AS/NZS 1337)

Skin protection

Hand protection Wear appropriate chemical resistant gloves. (AS 2161)

Other Wear suitable protective clothing.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment. (AS/NZS 1715)

Thermal hazards Not available.

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. Observe any medical surveillance requirements.

9. Physical and chemical properties

Appearance Tablet.
Physical state Solid.
Form Tablet.
Colour Beige to Brown.

Odour Meaty.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

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

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit – upper (%) Not available.

Vapour pressure	Not available.
Vapour 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.
Oxidising properties	Not oxidising.

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 oxidising agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Acute toxicity

Components	Species	Test results
Robenacoxib (CAS 220991-32-2)		
<u>Acute</u>		
Oral		
LD50	Rat	500 - 2000 mg/kg OECD Test Guideline 423

Skin corrosion/irritation	Rabbit: No skin irritation. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Slightly irritating to the eyes of rabbits. (Active ingredient) Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation	
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.
Skin sensitisation	Guinea pig: Not a skin sensitiser. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Due to partial or complete lack of data the classification is not possible. (Active ingredient(s))
Reproductive toxicity	Suspected of damaging the unborn child. Like other inhibitors of cyclooxygenase (COX) activity, may produce adverse effects on the fetus or neonate when administered during the last trimester of gestation. This substance may have unwanted effects on the reproductive system of both sexes and on pregnancy and/or unborn/offspring. (Active ingredient(s))
Specific target organ toxicity - single exposure	No significant target organ toxicity reported. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (Active ingredient(s)) Based on available data, the classification criteria are not met.
Aspiration hazard	Not applicable.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Components		Species	Test results
Robenacoxib (CAS 220991-32-2)			
<i>Acute</i>			
	EC10	Activated sludge	21 mg/l, 3 hours , OECD Test Guideline 209
	EC50	Activated sludge	126 mg/l, 3 hours , OECD Test Guideline 209
Aquatic			
<i>Acute</i>			
Algae	EbC50	Green algae (Selenastrum capricornutum)	29 mg/l, 72 hours , OECD Test Guideline 201
	ErC50	Green algae (Selenastrum capricornutum)	51 mg/l, 72 hours , OECD Test Guideline 201
	NOEC	Green algae (Selenastrum capricornutum)	18 mg/l, 72 hours , OECD Test Guideline 201
Crustacea	EC50	Daphnia	7.2 mg/l, 48 hours , OECD Test Guideline 202
	NOEC	Daphnia	5.6 mg/l, 48 hours , OECD Test Guideline 202

Persistence and degradability The product is not readily biodegradable.

Bioaccumulative potential

Partition coefficient n-octanol / water (log K_{ow})

Robenacoxib 1.42 pH= 9

Mobility in soil No data available for this product.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods 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 (see: Disposal instructions).

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.

15. Regulatory information

Safety, health and environmental regulations

National regulations Poison Schedule: 4
APVMA approval number: 63104

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Robenacoxib (CAS 220991-32-2)

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

Not listed.

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

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

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

Not listed.

Restricted Carcinogenic Substances

Not regulated.

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 Chemical Substances (AICS)	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 Toxic Chemical Substances (TCS)	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).

16. Other information

Issue date	22-November-2016
Revision date	18-October-2017
Disclaimer	<p>As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.</p> <p>For additional information contact: Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441</p>
Revision information	<p>Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties</p>