

SAFETY DATA SHEETS

This SDS packet was issued with item:

078906566

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078897290

Version: 1
Date issued December 2010

ONSIOR[®] 6 mg Tablets for Cats

Section 1. IDENTIFICATION OF CHEMICAL PRODUCT AND COMPANY

Product information

Substance No. : 000070002436
 NAH Substance Code : A-20059 B
 Product name : ONSIOR 6 mg Tablets for Cats
 Product use : For the control of acute pain and inflammation associated with musculoskeletal disorders or soft tissue surgery in cats.

Company : Novartis Animal Health Australasia Pty Ltd
 ACN 076 745 198
 54 Waterloo Road
 North Ryde NSW 2113

Telephone : (02) 9805 3555

Fax : (02) 9888 8387

MSDS creation date : December 2010

MSDS revision date : December 2015

Section 2. HAZARDS IDENTIFICATION

Risk advice to man and the environment

Health hazards : No hazards to be specially mentioned.

Environmental hazard in case of accident (Spillage/Leakage) : No hazards to be specially mentioned.

SUSDP classification : S4

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature

Use : Veterinary medicinal product / Anti-inflammatory
 Type of preparation : Tablet vet. use

Hazardous components

Denomination	CAS-No.	Symbol(s)	R-phrases(s) For the full text of the R-phrases mentioned in this Section, see Section 16.	Concentration (% w/w)
Robenacoxib	220991-32-2	Xn, N	R63, R51/53	6.25

Section 4. FIRST AID MEASURES

Label regulated first aid statement : If poisoning occurs contact a doctor or Poisons Information Centre (Phone 13 1126).

General advice : If you feel unwell, seek medical advice (show the label where possible).

Skin contact : Wash off with soap and water.

Eye contact : Rinse eyes with clean water for several minutes .

Ingestion : Drink water as a precaution.

Notes to physician

Poisoning Symptoms : No information available.

Antidote : No specific antidote is known! Apply symptomatic therapy.

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Section 5. FIRE-FIGHTING MEASURES

- Combustibility : yes
- Suitable extinguishing media : Dry powder, foam, carbon dioxide (CO₂) or water spray (do not use water jet).
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Combustion products are toxic and/or irritant. Measures have to be taken to prevent the contaminated extinguishing agent from seeping into the ground or from spreading uncontrollably.

Section 6. ACCIDENTAL RELEASE MEASURES

- Methods for cleaning up : Refer to protective measures listed in sections 7 and 8.
Collect material in specially marked, tightly closing containers.
Spilled product cannot be used further and must be disposed of.
If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
- Additional advice : No hazards to be specially mentioned.

Section 7. HANDLING AND STORAGE

Handling

- Safe handling advice : No special handling advice required.
Handle in accordance with good industrial hygiene and safety practice.

Storage

- Advice on common storage : Store separately from feed, food and stimulants.
- Novartis storage class : 20.2
- Max. Storage temperature: : 25 °C
- Min. Storage temperature: : -10 °C
- Other data : Store the product in closed original containers.
Protect from light and humidity.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Open handling

- Respiratory protection : No personal respiratory protective equipment normally required.
- Hand protection : No special protective equipment required.
- Eye protection : No special protective equipment required.
- Skin and body protection : No special protective equipment required.
- Hygiene measures : General industrial hygiene practice.
Wash hands before breaks and at the end of workday.

Version: 1
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ONSIOR® 6 mg Tablets for Cats

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Form	: solid, round, biconvex, tablet
Colour	: beige - brown
Odour	: like meat (artificial flavour)
Tablet/Capsule properties	Tablet/capsule weight: 96 mg Diameter: 6 mm Thickness: 3.3 mm Tablet imprints: "NA", "AK"

Section 10. STABILITY AND REACTIVITY

Chemical Stability	: Stable under normal conditions.
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Section 11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	: LD50 > 2,000 mg/kg Species: rat Remarks: Derived from the active ingredient(s)
Skin irritation	: non irritant Species: rabbit Remarks: Derived from the active ingredient(s)
Sensitisation	: Did not cause skin sensitization. Species: guinea pig Remarks: Derived from the active ingredient(s)
Mutagenicity (in vitro)	: negative Ames test salmon. typhimurium Remarks: Derived from the active ingredient(s)
	: negative Chromosome aberrations test in human lymphocytes Remarks: Derived from the active ingredient(s)
	: negative Gene mutation test lymphoma cells Remarks: Derived from the active ingredient(s)
Mutagenicity (in vivo)	: negative Species: rat Micronucleus test Remarks: Derived from the active ingredient(s)

Section 12. ECOLOGICAL INFORMATION

Ecotoxicity effects

Toxicity to fish	: LD50 Remarks: no data available
Toxicity to daphnia	: EC50 > 100 mg/l Species: Daphnia Exposure time: 48 h Remarks: Derived from the active ingredient(s)
Toxicity to algae	: EBC50 > 100 mg/l Species: Selenastrum capricornutum (green algae) Exposure time: 72 h Remarks: Derived from the active ingredient(s)

Version: 1
Date issued December 2010

ONSIOR® 6 mg Tablets for Cats

Toxicity to microorganisms : EC50 > 100 mg/l
Species: act.sewage sludge
Exposure time: 3 h
Remarks: Derived from the active ingredient(s)

Behaviour in environmental compartments
Elimination information (persistence and degradability)

Biodegradability : not readily biodegradable
Remarks: Derived from the active ingredient(s)

Section 13. DISPOSAL CONSIDERATIONS

Product : Dispose of empty used containers by wrapping in paper and putting in garbage. Refer to protective measures listed in sections 7 and 8. Collect material in specially marked, tightly closing containers. Dispose of in an incinerator approved for chemicals. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.

Contaminated packaging : Dispose of empty containers in an incinerator approved for chemicals. Damaged Containers: Place original containers in specially marked larger ones. Check possibilities of recycling large empty containers, drums and barrels.

Section 14. TRANSPORT INFORMATION
ADR/RID

UN-Number : FREE
Class : Not classified as dangerous good

IMDG

UN-Number : FREE
Class : Not classified as dangerous good

ICAO/IATA

UN-Number : FREE
Class : Not classified as dangerous good

Section 15. REGULATORY INFORMATION

Australia : Product first registered in Australia on 29/9/10 by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Section 16. OTHER INFORMATION
R-phrases(s) (Text of R-phrases mentioned in Section 3)

R63 : Possible risk of harm to the unborn child.
R51/53 : Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

This product is a registered veterinary chemical and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredient of this product has been submitted to the Federal health and environmental authorities and has been evaluated by expert toxicologists and environmental scientists.

This Material Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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SAFETY DATA SHEET

1. Identification

Product identifier	Onsior 6 mg tablets
Other means of identification	
Item Code	CA4875
Synonyms	A-20059 B
Recommended use	Veterinary Product
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Company Name	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
Phone:	1-877-Elanco1 (1-877-352-6261)
Emergency Telephone:	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Email:	elanco_sds@elanco.com
Transportation Emergency Telephone:	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity (the unborn child)	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	
H361	Suspected of damaging the unborn child.
Precautionary statement	
Prevention	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P281	Use personal protective equipment as required.
Response	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
Storage	Not available.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Robenacoxib	[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	220991-32-2	6.25

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

4. 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.
Most important symptoms/effects, acute and delayed	May cause reproductive effects.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	If you feel unwell, seek medical advice (show the label where possible). 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.

5. Fire-fighting measures

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 firefighters	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.
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	Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Following product recovery, flush area with water.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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. 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/personal protection

Occupational exposure limits	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Novartis Internal Exposure Limit (NPIEL): 8 hour TWA 0.7 mg/m ³ (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, such as personal protective equipment

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.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards Not available.

General hygiene considerations 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.

Color Beige to Brown.

Odor Meaty.

Odor 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.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Explosive properties Not explosive.

Oxidizing properties Not oxidizing.

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.
Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

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

Skin corrosion/irritation (active ingredient) Rabbit: No skin irritation.
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Slightly irritating to the eyes of rabbits. (active ingredient)
Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

Skin sensitization (active ingredient) Guinea pig: Not a skin sensitizer.
Based on available data, the classification criteria are not met.

Germ cell mutagenicity (active ingredient) In vitro and in vivo tests did not show mutagenic effects.
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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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)

Specific target organ toxicity - single exposure No significant target organ toxicity reported. (active ingredient)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure No significant target organ toxicity reported. (active ingredient)
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

Components		Species	Test Results
	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 Kow)

Robenacoxib 1.42 pH= 9

Mobility in soil No data available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations.

14. Transport information

DOT

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

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	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, including date of preparation or last revision

Issue date 12-15-2015

Revision date 03-24-2019

Version # 05

List of abbreviations EC50: Effective Concentration 50%.
LD50: Lethal Dose 50%.
NOEC: No observed effect concentration.
TWA: Time Weighted Average Value.

Disclaimer 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 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.

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