



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Onsior 40 mg tablets</b>
<b>Other means of identification</b>	
<b>Item Code</b>	CA4890
<b>Synonyms</b>	CGS 34975 40 MG TAB * A-20011 E
<b>Recommended use</b>	Veterinary Product
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name</b>	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 US
<b>Phone:</b>	1-877-Elanco1 (1-877-352-6261)
<b>Emergency Telephone:</b>	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
<b>Email:</b>	elanco_sds@elanco.com
<b>Transportation Emergency Telephone:</b>	CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

## 2. Hazard(s) identification

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



<b>Signal word</b>	Warning
<b>Hazard statement</b>	
H361	Suspected of damaging the unborn child.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	
P308 + P313	IF exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Not available.
<b>Disposal</b>	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	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

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	May cause reproductive effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

#### 6. Accidental release measures

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

#### 7. Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	Novartis Internal Exposure Limit (NPIEL): 8 hour TWA 0.7 mg/m <sup>3</sup> (Robenacoxib)

<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Beige to Brown.
<b>Odor</b>	Meaty.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
Robenacoxib (CAS 220991-32-2)		
<b>Acute</b>		
<b>Oral</b>		
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/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** Guinea pig: Not a skin sensitizer. (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 ingredients)  
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))

#### 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(s))

**Specific target organ toxicity - single exposure** No significant target organ toxicity reported. (active ingredients)  
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

Components	Species	Test Results
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EbC50	Green algae ( <i>Selenastrum capricornutum</i> )
	ErC50	Green algae ( <i>Selenastrum capricornutum</i> )
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )
Crustacea	EC50	Daphnia
	NOEC	Daphnia
		29 mg/l, 72 hours , OECD Test Guideline 201
		51 mg/l, 72 hours , OECD Test Guideline 201
		18 mg/l, 72 hours , OECD Test Guideline 201
		7.2 mg/l, 48 hours , OECD Test Guideline 202
		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)**

**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** 12-16-2015

**Revision date** 03-26-2019

**Version #** 03

**List of abbreviations** TWA: Time Weighted Average

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