



SAFETY DATA SHEET

1. Identification

Product identifier **Onsior 10 mg tablets**

Other means of identification

Item Code CA4880

Synonyms A-20010 E * CGS 34975 10MG TAB

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.

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

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	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

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

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.
Partition coefficient (n-octanol/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)		
<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/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 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. (Active ingredient(s))
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(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

Components		Species	Test Results
Aquatic			
<i>Acute</i>			
Algae	EbC50	Green algae (<i>Selenastrum capricornutum</i>)	29 mg/l, 72 hours , OECD Test Guideline 201
	ErC50	Green algae (<i>Selenastrum capricornutum</i>)	51 mg/l, 72 hours , OECD Test Guideline 201
	NOEC	Green algae (<i>Selenastrum capricornutum</i>)	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)

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 02-10-2019

Version # 03

List of abbreviations TWA: Time Weighted Average

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 MERCHANT ABILITY 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.

For additional information contact:

Elanco Animal Health

0011+1-877-352-6261

0011+1-800-428-4441