

1. Identification

Product identifier	Onsior 20 mg tablets
Other means of identification	
Item Code	CA4885
Synonyms	CGS 34975 20 MG TAB * A-20023 D
Recommended use	Veterinary Product
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name	Novartis Animal Health
Address	
3200 Northline Avenue, Suite 300 Greensboro, NC 27408	
Telephone	1-336-387-1000
SDS E-mail	lilly_msds@lilly.com
SDS telephone	1-877-Elanco1 (1-877-352-6261)
Emergency Telephone Numbers	Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973 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	ROBENACOXIB UNGROUND COX975 UNGROUND	220991-32-2	6.25
Other components below reportable levels			93.75

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	Not available.
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	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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. For waste disposal, see section 13 of the SDS.
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. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
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)		
Acute		
Oral		
LD50	Rat	500 - 2000 mg/kg OECD Test Guideline 423

Skin corrosion/irritation No skin irritation.

Corrosivity

Robenacoxib

OECD Test Guideline 404
Result: No skin irritation.
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization

Not a respiratory sensitizer.

Skin sensitization

Not a skin sensitizer.

Skin sensitization

Robenacoxib

OECD Test Guideline 406
Result: Not sensitizing.
Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Robenacoxib

OECD Test Guideline 471- Ames Test
Result: Negative.
Species: Salmonella Typhimurium
OECD Test Guideline 473- Chromosome aberrations test
Human Lymphocytes
Result: Negative.
OECD Test Guideline 474- Micronucleus test
Result: Negative.
Species: Rat
OECD Test Guideline 476- Gene mutation test lymphoma cells
Result: Negative.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

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. (Robenacoxib)

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

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 Kow)

Robenacoxib 1.42 pH= 9

Mobility in soil No data available.

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.

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Disposal methods

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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.

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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

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.

Safe Drinking Water Act (SDWA)	Not regulated.
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US state regulations**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. 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
Version #	01
Lilly Lab Code	Health: 1 Fire: 0 Reactivity: 0 Special 1: R

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 MATERIAL 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:

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