

SAFETY DATA SHEETS

This SDS packet was issued with item:

078923330

N/A



SAFETY DATA SHEET

1. Identification

Product identifier **Onsior 20 mg/ml Injection**

Other means of identification

Item Code CA4886

Synonyms A-20053 B * ROBENACOXIB LIVI 400MG/20ML * ONSIOR 20 MG/ML INJ * ROBENACOXIB 2.0 % IJL * CGS 34975 2.0 % IJL

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 Flammable liquids Category 3

Health hazards Reproductive toxicity Category 2

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement

H226 Flammable liquid and vapor.
H361 Suspected of damaging fertility or the unborn child.

Precautionary statement

Prevention

P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
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

P303 + P361 +
P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P370 + P378 In case of fire: Use appropriate media for extinction.
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage

P405 Store locked up.
P403 + P235 Store in a well-ventilated place. Keep cool.

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	2
Ethanol		64-17-5	12

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

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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 exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance.

5. Fire-fighting measures**Suitable extinguishing media**

Alcohol resistant foam. Water fog. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

General fire hazards

Flammable liquid and vapor.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapor. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Keep combustibles (wood, paper, oil, etc.) away from spilled material.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight.

Conditions for safe storage, including any incompatibilities

Store in a cool, dry place with adequate ventilation. Keep away from incompatible materials, open flames, and high temperatures.

8. Exposure controls/personal protection**Occupational exposure limits****US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3 1000 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3 1000 ppm

Biological limit values

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

Exposure guidelines

Novartis Internal Exposure Limit (NPIEL): 0.7 mg/m3 8 hour TWA (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. Provide eyewash station.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Wear safety glasses with side shields (or goggles).

Skin protection**Hand protection**

Wear protective 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.

9. Physical and chemical properties**Appearance****Physical state**

Liquid.

Form

Liquid.

Color

Colorless to slightly colored.

Odor

Not available.

Odor threshold	Not available.
pH	7.4 - 8.4
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	101.7 °F (38.7 °C) Closed Cup
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)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Density	1.06 g/ml
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	Avoid temperatures exceeding the flash point. 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
Ethanol (CAS 64-17-5)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Inhalation		
LC50	Rat	124.7 mg/l, 4 h
Oral		
LD50	Rat	7060 mg/kg

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	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Eye		
Onsior 20 mg/ml Injection		Result: No eye irritation Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Carcinogenicity	The ethanol carcinogenicity information reported below only applies when it is consumed in alcoholic beverages.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Ethanol (CAS 64-17-5)	1 Carcinogenic to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Ethanol (CAS 64-17-5)	Known To Be Human Carcinogen	
Reproductive toxicity	Suspected of damaging fertility or the unborn child. Like other inhibitors of cyclooxygenase (COX) activity, the substance 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	Due to lack of data the classification is not possible.	
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.	
Aspiration hazard	Not an aspiration hazard.	

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.		
Components		Species	Test Results
Ethanol (CAS 64-17-5)			
Aquatic			
Fish	LC50	Rainbow Trout	13 g/l, 96 hr
<i>Acute</i>			
Algae	EC50	Algae	1450 mg/l, 8 d
Crustacea	LC50	Daphnia	9.3 g/l, 48 hr
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

Components		Species	Test Results
	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. (Active ingredient)

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Ethanol	-0.31
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

General information Product is an aqueous solution containing <24% ethanol and the following special provisions/exceptions/exemptions may be applied: Special Provision A58 (ICAO/IATA), Special Provision 144 (IMDG, ADR, UN Orange Book), US 49 CFR 173.150(e)(1), and Canada TDG 1.36(b).

DOT

UN number	UN1170
UN proper shipping name	ETHANOL SOLUTION
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Label(s)	3
Packing group	III
Special precautions for user	Not available.
Special provisions	24, B1, IB3, T2, TP1
Packaging exceptions	4b, 150
Packaging non bulk	203
Packaging bulk	242

IATA

UN number	UN1170
UN proper shipping name	ETHANOL SOLUTION
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	III
Environmental hazards	No.
ERG Code	3L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

IMDG

UN number	UN1170
UN proper shipping name	ETHANOL SOLUTION
Transport hazard class(es)	
Class	3
Subsidiary risk	-
Packing group	III

Environmental hazards**Marine pollutant**

No.

EmS

F-E, S-D

Special precautions for user

Not available.

**Transport in bulk according to
Annex II of MARPOL 73/78 and
the IBC Code**

Not established.

DOT**IATA; IMDG****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)

Ethanol (CAS 64-17-5)

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**Flammable (gases, aerosols, liquids, or solids)
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**

WARNING: 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.
WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

Ethanol (CAS 64-17-5)

Listed: April 29, 2011

Listed: July 1, 1988

California Proposition 65 - CRT: Listed date/Developmental toxin

Ethanol (CAS 64-17-5)

Listed: October 1, 1987

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 #** 05**List of abbreviations** STEL: Short Term Exposure Limit.
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:

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