

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078770272

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

078770264 078770280 078770298 078770306 078770314



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Deramaxx®</b>
<b>Other means of identification</b>	
<b>Item Code</b>	CA4980, CA4985, CA4990, CA4995
<b>Synonyms</b>	Deramaxx 12 mg Tablets * Deramaxx 25 mg Tablets * Deramaxx 75 mg Tablets * Deramaxx 100 mg Tablets
<b>Recommended use</b>	Veterinary Pharmaceutical
<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	Category 2
	Specific target organ toxicity, repeated exposure	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.
H373	May cause damage to organs through prolonged or repeated exposure.
<b>Precautionary statement</b>	
<b>Prevention</b>	
P201	Obtain special instructions before use.
P260	Do not breathe dust.
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 related 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	%
Deracoxib	Deracoxib Unground NOA 448123A NOA 448123 B Deracoxib Mikro 4-(3-(difluoromethyl)-5-(3-fluoro-4-methoxyphenyl)-1H-pyrazol-1-yl)benzenesulfonamide	169590-41-4	5

**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>	Do not rub eyes. 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. Prolonged exposure may cause chronic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	NOT FOR HUMAN USE! 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

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Not available.
<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>	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. 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>	Keep unnecessary personnel away. 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. Sweep up or vacuum up spillage and collect in suitable container for disposal. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Following product recovery, flush area with water.
<b>Environmental precautions</b>	Never return spills to original containers for re-use. Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

<b>Precautions for safe handling</b>	Do not handle until all safety precautions have been read and understood. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

### 8. Exposure controls/personal protection

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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<b>Exposure guidelines</b>	Novartis Internal Exposure Limit (NPIEL): 0.8 mg/m <sup>3</sup> 8 hour TWA (Deracoxib)
<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>	Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
<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.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Slight Beef.
<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>	Insoluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 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>	Avoid high humidity conditions. 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
Deracoxib (CAS 169590-41-4)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	> 600 mg/kg

**Skin corrosion/irritation** No skin irritation. (similar substance)  
Due to partial or complete lack of data the classification is not possible.

**Serious eye damage/eye irritation** Due to lack of data the classification is not possible.

#### Respiratory or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Not a skin sensitizer. (similar substance)  
Due to partial or complete lack of data the classification is not possible.

**Germ cell mutagenicity** Result in genetic toxicity assays (in vitro and in vivo): Negative (Deracoxib)  
Based on available data, the classification criteria are not met.

**Carcinogenicity** Not listed by IARC, NTP, ACGIH or OSHA.  
Due to 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. Deracoxib, 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.

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

**Specific target organ toxicity - repeated exposure** Kidney effects. Gastrointestinal effects. (Deracoxib)

**Aspiration hazard** Not an aspiration hazard.

## 12. Ecological information

**Ecotoxicity** This material has not been tested for environmental effects. Based on structurally similar compounds, deracoxib may be toxic to aquatic organisms.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** Not available.

## 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.

## 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.  
One or more components are not listed on TSCA.

**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**

<b>Issue date</b>	05-27-2015
<b>Revision date</b>	02-05-2019
<b>Version #</b>	03
<b>List of abbreviations</b>	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 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.

For additional information contact:

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