

SAFETY DATA SHEETS

This SDS packet was issued with item:

078770306

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 078770272 078770280 078770298 078770314



SAFETY DATA SHEET

1. Identification

Product identifier	Deramaxx®
Other means of identification	
Item Code	CA4980, CA4985, CA4990, CA4995
Synonyms	Deramaxx 12 mg Tablets * Deramaxx 25 mg Tablets * Deramaxx 75 mg Tablets * Deramaxx 100 mg Tablets
Recommended use	Veterinary Pharmaceutical
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	Category 2
	Specific target organ toxicity, repeated exposure	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning
Hazard statement	
H361	Suspected of damaging the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
Precautionary statement	
Prevention	
P201	Obtain special instructions before use.
P260	Do not breathe dust.
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 related 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	%
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

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	Do not rub eyes. 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. Prolonged exposure may cause chronic effects.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	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

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Not available.
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	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.
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. 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. 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. 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 until all safety precautions have been read and understood. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Exposure guidelines	Novartis Internal Exposure Limit (NPIEL): 0.8 mg/m ³ 8 hour TWA (Deracoxib)
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	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	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.
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	Solid.
Form	Tablet.
Color	Not available.
Odor	Slight Beef.
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)	Insoluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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 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)		
Acute		
Oral		
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

Issue date	05-27-2015
Revision date	02-05-2019
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 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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