

SAFETY DATA SHEETS

This SDS packet was issued with item:

078932958

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

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SAFETY DATA SHEET

1. Identification

Product identifier	Credelio Tablets
Other means of identification	
Item Code	CA5452, CA5458, CA5456, CA5454, CA5451
Synonyms	CREDELIO 900 mg CHEWABLE TABLETS FOR DOGS * CREDELIO 450 mg CHEWABLE TABLETS FOR DOGS * CREDELIO 225 mg CHEWABLE TABLETS FOR DOGS * CREDELIO 112.5 mg CHEWABLE TABLETS FOR DOGS * CREDELIO 56.25 mg CHEWABLE TABLETS FOR DOGS * A-20224 A * A-20225 A * A-20226 A * A-20227 A * A-20228 A * Lotilaner tablets * AHC 2224920 tablets * IOB920 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	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
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	%
Lotilaner	IsOxazoline Benzamide derivative 3-Methly-5-[(S)-5-(3,4,5-trichlorophenyl)-5-trifluoromethyl-4,5-dihydro-isoxazol-3-yl]-thiophene-2-carboxylic acid [(2,2,2-trifluoroethylcarbamoyl)-methyl]-amide IOB 920 AHC 2224920 (IOB920) Polymorph G - Isoxazoline AHC 2224920	1369852-71-0	35

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 None known.

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 (CO2).

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.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away.

Methods and materials for containment and cleaning up Prevent entry into waterways, sewer, basements or confined areas. 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 Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container.

8. Exposure controls/personal protection

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

Exposure guidelines Novartis Internal Exposure Limit (NPIEL): 100 ug/m3 8 hour TWA (Lotilaner)

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	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	Solid.
Form	Tablet.
Color	Not available.
Odor	Not available.
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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Peroxides. Phenols.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Credelio Tablets		
Acute		
Dermal		
LD	Rat	> 2000 mg/kg
Oral		
LD	Rat	> 2000 mg/kg

Skin corrosion/irritation Rabbit: No irritation.
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Mild eye irritation.
Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer. (Lotilaner)
Based on available data, the classification criteria are not met.

Skin sensitization Mouse Local Lymph Node Assay (LLNA): Negative
Based on available data, the classification criteria are not met.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Negative (Lotilaner)
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 No significant adverse effects reported. (Lotilaner)
Based on available data, the classification criteria are not met.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure No significant target organ toxicity reported. (Lotilaner)
Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Lotilaner (CAS 1369852-71-0)		
Other	EC50	Pseudokirchnerella subcapitata
		> 10.7 mg/l, 72 hours (OECD Test Guideline 201)
	NOEC	Pseudokirchnerella subcapitata
		0.053 mg/l, 72 hours (OECD Test Guideline 202)
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna)
		0.805 mg/l, 48 hours (OECD Test Guideline 202)

Components		Species	Test Results
	NOEC	Water flea (Daphnia magna)	0.22 mg/l, 48 hours (OECD Test Guideline 202)
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	0.451 mg/l, 96 hours (OECD Test Guideline 203)
	NOEC	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	0.31 mg/l, 96 hours (OECD Test Guideline 202)
Persistence and degradability	No data is available on the degradability of this product.		
Bioaccumulative potential			
Mobility in soil	No data available.		
Other adverse effects	Not available.		

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations.

14. Transport information

General information Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

DOT

Not regulated as dangerous goods.

IATA

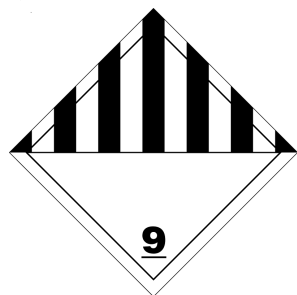
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Lotilaner)
Transport hazard class(es)
 Class 9
 Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Not available.
Other information
 Passenger and cargo aircraft Allowed with restrictions.
 Cargo aircraft only Allowed with restrictions.

IMDG

UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Lotilaner)
Transport hazard class(es)
 Class 9
 Subsidiary risk -
Packing group III
Environmental hazards
 Marine pollutant Yes
EmS F-A, S-F
Special precautions for user Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

IATA; IMDG





15. Regulatory information

US federal regulations

This product is not known to be 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 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 03-02-2017

Revision date 03-26-2019

Version # 05

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:

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