

Section 1. Identification

Product identifier : Credelio Tablets

Product code : Not available.

Other means of identification : CA5452; CA5458; CA5456; CA5454; CA5451; CREDELIO 112.5 mg CHEWABLE TABLETS FOR DOGS; CREDELIO 225 mg CHEWABLE TABLETS FOR DOGS; CREDELIO 450 mg CHEWABLE TABLETS FOR DOGS; CREDELIO 56.25 mg CHEWABLE TABLETS FOR DOGS; CREDELIO 900 mg CHEWABLE TABLETS FOR DOGS; Credelio Tab 112.5MG; Credelio Tab 225MG; Credelio Tab 450MG; Credelio Tab 56.25MG; Credelio Tab 900MG; IOB920 tablets; Lotilaner tablets; AHC 2224920 tablets; A-20228 A; A-20227 A; A-20226 A; A-20225 A; A-20224 A; ; Credelio; Credelio Tablets; CREDELIO TAB 56.25MG X60BLCD CA (yellow); CREDELIO TAB 112.5MG X60BLCD CA (magenta); CREDELIO TAB 225MG X60BLCD CA (orange); CREDELIO TAB 450MG X60BLCD CA (green); CREDELIO TAB 900MG X60BLCD (blue)

Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Veterinary pharmaceutical.

Uses advised against : None known.

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Section 2. Hazard(s) identification

Classification of the substance or mixture : SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1

Percentage of the mixture consisting of ingredient(s) of unknown acute oral toxicity: 8%

Percentage of the mixture consisting of ingredient(s) of unknown acute dermal toxicity: 48%

Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 85%

Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment: 9%

GHS label elements

Hazard pictograms :



Signal word : **WARNING**

Hazard statements : **H410 - Very toxic to aquatic life with long lasting effects.**

Section 2. Hazard(s) identification

Precautionary statements

- Prevention** : P273 - Avoid release to the environment.
Response : P391 - Collect spillage.
Storage : Not applicable.
Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements : Not applicable.

Other hazards which do not result in classification : None known.

Section 3. Composition and ingredient information

Substance/mixture : Mixture

Ingredient name	% (w/w)	CAS number
lotilaner	≥30 - ≤60	1369852-71-0
Cellulose	≥30 - ≤60	9004-34-6
Sodium lauryl sulphate	≤3	151-21-3
Silica, amorphous, fumed, cryst.-free	≤3	112945-52-5
magnesium distearate	≤3	557-04-0

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Section 4. First aid measures

- Eye contact** : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Specific treatments : No specific treatment.
Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : This material is very toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Hazchem code : 2Z

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Section 6. Accidental release measures

Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

Methods and material for containment and cleaning up

- Small spill** : Move containers from spill area. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Cellulose	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours. Form: fibres
Silica, amorphous, fumed, cryst.-free	EH40/2005 WELs (United Kingdom (UK), 8/2018). TWA: 6 mg/m ³ 8 hours. Form: inhalable dust TWA: 2.4 mg/m ³ 8 hours. Form: respirable dust
magnesium distearate	Safe Work Australia (Australia, 4/2018). TWA: 10 mg/m ³ 8 hours.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Section 8. Exposure controls and personal protection

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Solid. [tablets]
- Colour** : Not available.
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : Not available.
- Solubility** : Not available.
- Solubility in water** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.

Section 9. Physical and chemical properties

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Iotilaner	LD50 Dermal	Rat	>2000 mg/kg	-
	LD50 Oral	Rat	>2000 mg/kg	-
Cellulose	LD50 Oral	Rat	>5 g/kg	-
Sodium lauryl sulphate	LD50 Oral	Rat	1288 mg/kg	-
Silica, amorphous, fumed, cryst.-free	LD50 Oral	Rat	3160 mg/kg	-
magnesium distearate	LD50 Oral	Rat	>10000 mg/kg	-
Credelio Tablets	LD50 Dermal	Rat	>2000 mg/kg	-
	LD50 Oral	Rat	>2000 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Sodium lauryl sulphate	Eyes - Mild irritant	Rabbit	-	250 ug	-
	Eyes - Moderate irritant	Rabbit	-	24 hours 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	10 mg	-
	Skin - Mild irritant	Dog	-	24 hours 25 mg	-
	Skin - Mild irritant	Guinea pig	-	24 hours 25 mg	-
	Skin - Mild irritant	Human	-	2 hours 2 %	-
	Skin - Mild irritant	Human	-	504 hours 0.3 %	-
	Skin - Mild irritant	Human	-	24 hours 0.06 %	-
	Skin - Mild irritant	Human	-	22 hours 10 %	-
	Skin - Mild irritant	Human	-	47 hours 0.5 %	-
	Skin - Mild irritant	Human	-	18 hours 2 %	-
	Skin - Moderate irritant	Human	-	48 hours 3 %	-
	Skin - Moderate irritant	Human	-	24 hours 0.1 %	-
Skin - Moderate irritant	Mouse	-	24 hours 25 mg	-	

Section 11. Toxicological information

	Skin - Mild irritant	Pig	-	24 hours 25 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 50 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 25 mg	-

Sensitisation

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Sodium lauryl sulphate	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.

Section 11. Toxicological information

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
Sodium lauryl sulphate	1288	300	N/A	N/A	N/A
Silica, amorphous, fumed, cryst.-free	3160	N/A	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
lotilaner	Acute EC50 >10.7 mg/l	Algae	72 hours
	Acute NOEC 0.053 mg/l	Algae	72 hours
Sodium lauryl sulphate	Acute EC50 1200 µg/l Marine water	Algae - Skeletonema costatum	96 hours
	Acute LC50 900 µg/l Marine water	Crustaceans - Artemia salina - Adult	48 hours
	Acute LC50 1400 µg/l Fresh water	Daphnia - Daphnia pulex - Neonate	48 hours
	Acute LC50 590 µg/l Fresh water	Fish - Cirrhinus mrigala - Larvae	96 hours
	Chronic NOEC 1.25 mg/l Marine water	Algae - Ulva fasciata - Zoea	96 hours
	Chronic NOEC 1 mg/l Fresh water	Crustaceans - Pseudosida ramosa - Neonate	21 days
	Chronic NOEC 3.2 mg/l Fresh water	Daphnia - Daphnia magna - Neonate	21 days
	Chronic NOEC >1357 µg/l Fresh water	Fish - Pimephales promelas	42 days

Persistence and degradability

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Sodium lauryl sulphate	-2.03	-	low

Mobility in soil

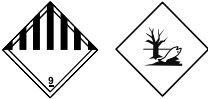
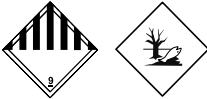
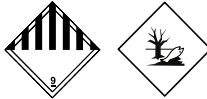

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spill material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	ADG	ADR/RID	IMDG	IATA
UN number	UN3077	UN3077	UN3077	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (lotilaner)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (lotilaner)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (lotilaner)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (lotilaner)
Transport hazard class(es)	9 	9 	9 	9 
Packing group	III	III	III	III
Environmental hazards	Yes.	Yes.	Yes.	Yes.

Additional information

- ADG** : The product is not regulated as a dangerous good when transported by road or rail in either an IBC, or in other container types if ≤ 500 kg. This product is not regulated as a dangerous good when transported in sizes of ≤ 5 L or ≤ 5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
Hazchem code 2Z
- ADR/RID** : This product is not regulated as a dangerous good when transported in sizes of ≤ 5 L or ≤ 5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
- IMDG** : This product is not regulated as a dangerous good when transported in sizes of ≤ 5 L or ≤ 5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
- IATA** : This product is not regulated as a dangerous good when transported in sizes of ≤ 5 L or ≤ 5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of Marpol and the IBC Code : Not available.

Section 15. Regulatory information

[Standard Uniform Schedule of Medicine and Poisons](#)

5

[Model Work Health and Safety Regulations - Scheduled Substances](#)

No listed substance

[Inventory list](#)

Australia : Not determined.

Section 16. Any other relevant information

[History](#)

Date of issue/Date of revision : 10/20/2020

Date of previous issue : No previous validation

Version : 0.01

Key to abbreviations : ADG = Australian Dangerous Goods
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
SUSMP = Standard Uniform Schedule of Medicine and Poisons
UN = United Nations

[Procedure used to derive the classification](#)

Classification	Justification
SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1	Calculation method
LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1	Calculation method

References : Not available.

Indicates information that has changed from previously issued version.

[Notice to reader](#)

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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