Safety Data Sheet

Canalevia™-CA1

(crofelemer delayed-release tablets)

File No.: SDS-008
Effective Date: Nov 05, 2021
Supersedes: N/A

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY UNDERTAKING

1.1 Product Identifier

Product name:	Canalevia-CA1 (crofelemer delayed-release tablets)
Chemical name:	Crofelemer; proanthocyanidin polymer; made up of (+)-catechin, (-)-epicatechin, (+)-gallocatechin and (-)-epigallocatechin monomer units
Synonyms:	Mytesi; crofelemer

1.2 Recommended use and restrictions on use:

Recommended use:	For oral use in dogs
Restriction on use:	Veterinary pharmaceutical agent
Uses advised against:	Not for human use

1.3 Manufacturer:

Jaguar Animal Health
200 Pine Street, Suite 600
San Francisco, CA 94104

1.4 Emergency Telephone Number:

EMERGENCY PHONE	877-787-3001
FAX	415-371-8311

SECTION 2: HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

GHS-US classification: Acute Tox 4 (Oral), H302

2.2 Label elements

GHS-US labeling:

2.3 Other hazards:

No additional information available.

The complete toxicology of this product has not been fully evaluated. Until the potential health hazards associated with exposure to the substance are characterized, it is recommended that users handle the material in a conservative fashion, minimizing all routes of entry.

In an acute study in rats, orally administered crofelemer in solution failed to produce any signs of toxicity at a dose of 300 mg/kg.

Acute intravenous toxicity studies indicate that the LD_{50} of the drug is greater than 50 mg/kg in both rats and mice.

It is recommended that you use a NIOSH/MSHA-approved respirator equipped with HEPA filters whenever working with the powder under circumstances where there is opportunity for the powder to become airborne.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Crofelemer	148465-45-6	Not Listed	Not Listed	Acute Tox 4 (Oral), H302	25.0
Microcrystalline cellulose PH-102 SCG	9004-34-6-B	232-674-9	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Colloidal Silicon Dioxide	7631-86-9	231-545-4 EEC No. 418-260-2	Not Listed	Not Hazardous	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	Skin irritation, H315 Serious eye irritation, H319, Respiratory irritation, H335	*
Eudragit L 30 D-55	25212-88-8	Not Listed	Not Listed	Acute Tox 4 (Inhalation), H332	*
Triethyl citrate	77-93-0	201-070-7	Not Listed	Not Hazardous	*
Purified water	7732-18-5	231-791-2	Not Listed	Not Hazardous	*
Titanium Dioxide CI 77891	13463-67-7	236-675-5	Not Listed	Not Listed	*
Potassium Hydroxide	1310-58-3	Not Listed	Not Listed	Not Listed	*
Xanthan Gum	11138-66-2	Not Listed	Not Listed	Not Listed	*
Methyl Paraben	99-76-3	Not Listed	Not Listed	Not Listed	*
Propyl Paraben	94-13-3	Not Listed	Not Listed	Not Listed	*
Talc	14807-96-6	238-877-9	Not Listed	Not Listed	*
Chlorite-group minerals	1318-59-8	Not Listed	Not Listed	Not Listed	*
Silica, Crystalline, Quartz	14808-60-7	Not Listed	Not Listed	Not Listed	*

*** = proprietary**

SECTION 4: FIRST AID MEASURES

4.1: Description of First aid measures

Eyes: Immediately rinse with plenty of water and continue for at least 15 minutes. Seek medical attention.
Skin: Wash the affected areas with soap and water. Remove contaminated clothing and shoes. Seek medical attention, if needed.
Inhalation: Move to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention.
Ingestion: Seek medical attention for an overdose. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

4.2: Most important symptoms and effects, both acute and delayed

Symptoms/injuries after eye contact:	May cause irritation.
Symptoms/injuries after skin contact:	None under normal use.
Symptoms/injuries after inhalation:	May cause respiratory irritation.
Symptoms after ingestion:	None under normal use. The most common adverse events (>3%) occurring in clinical trial patients at the therapeutic dose were upper respiratory infection, bronchitis, cough, flatulence, and increased serum bilirubin.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: Water, Carbon Dioxide or chemical extinguishers may be used.

Unsuitable extinguishing media: None

5.2 Special hazards arising from the substance/mixture

Fire Hazard:	None known
Explosion hazard:	None known
Hazardous decomposition products:	None known

5 .3 Advice for Firefighters

Protective equipment and Precaution for firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH approved, and full protective turnout gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Canalevia-CA1 tablets are safe and non-hazardous. Recover the product by vacuuming, sweeping, or shoveling. The product can be disposed of as non-hazardous waste.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Wash thoroughly after handling. Canalevia-CA1 is safe and non-hazardous and can be handled safely without the use of personal protective equipment.

7.2 Precautions for safe storage

Store in a dry, away from sunlight, controlled room temperature at 20ºC to 25ºC (68ºF to 77ºF). Excursions permitted between 15ºC and 35ºC (59ºF to 86ºF).

7.3 Specific end use(s)

Veterinary pharmaceutical agent for use in dogs only

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

No additional information is available

8.2 Exposure controls:

Appropriate engineering controls:	Provide adequate general and local ventilation
Hand protection:	None required under normal product handling conditions
Eye protection:	None required under normal product handling conditions
Skin and body protection:	Wear suitable protective clothing
Respiratory protection:	In case of inadequate ventilation, wear respiratory protection.
Other:	Wash hands, face, and other potentially exposed areas after handling the product (particularly before eating, drinking, or smoking). Clean protective equipment thoroughly after each use

Canalevia-CA1 is safe and non-hazardous and poses no threat to plants, wildlife, or humans.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Capsule-shaped tablet
Color:	White
Physical state:	Solid
Odor:	Odorless
Odor threshold:	No data available
pH:	No data available
Relative evaporation rate (butylacetate = 1):	No data available
Melting point:	No data available
Freezing point:	No data available
Boiling point:	No data available
Flash point:	No data available
Self-ignition temperature:	No data available
Decomposition temperature:	No data available
Flammability (solid, gas):	No data available
Lower explosive limit:	No data available
Upper explosive limit:	No data available
Vapor pressure:	No data available
Log Pow (partition coefficient):	No data available
Log Kow:	No data available
Relative vapor density at 20° C:	No data available
Relative density:	No data available
Density:	No data available
Solubility:	No data available

SECTION 10: STABILITY AND REACTIVITY

10.1: Reactivity
No additional information available.
10.2: Chemical stability
The product is stable at normal handling and storage conditions.
10.3: Possibility of hazardous reactions
No additional information available.
10.4: Conditions to avoid
High temperature.
10.5: Incompatible materials
Strong bases. Strong oxidizing agents.
10.6: Hazardous decomposition products
No additional information available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity (Canalevia-CA1):	Not classified
Oral toxicity (Canalevia-CA1):	Not classified
Crofelemer (148465-45-6):	LD_{50}, oral, rat: >600 mg/kg; LD_{50}, oral, dog: >1200 mg/kg
Microcrystalline cellulose (9004-34-6-B):	LD_{50}, oral, rat: >5000 mg/kg; LD_{50}, dermal, rabbit: >2000 mg/kg
Croscarmellose sodium (74811-65-7):	LD_{50}, oral, rat: >5050 mg/kg; LD_{50}, dermal, rabbit: >2000 mg/kg
Colloidal Silicon Dioxide (7631-86-9):	LD_{50}, oral, rat: >5050 mg/kg; LD_{50}, dermal, rabbit: >2000 mg/kg
Magnesium Stearate (557-04-0):	No data available
Repeat dose toxicity (Canalevia-CA1):	Not classified
Crofelemer (148465-45-6):	Mouse: In females, the NOAEL for 13 weeks of dosing was 40 mg/kg/day. In males, no NOAEL was established (<40 mg/kg/day). Rat: No NOAEL (<60 mg/kg/day) for 26 weeks of dosing was established in either females or males due to lack of

	a dose response pattern. Dog: The NOAEL for 9 months of dosing was 50 mg/kg/day.
Skin corrosion/irritation (Canalevia-CA1):	Not classified
Serious eye damage/irritation (Canalevia-CA1):	Not classified
Respiratory or skin sensitization (Canalevia-CA1):	Not classified
Germ cell mutagenicity (Canalevia-CA1):	Not classified.
Crofelemer (148465-45-6):	AMES test shows that crofelemer is not mutagenic.
Carcinogenicity (Canalevia-CA1):	Not classified
Reproductive toxicity (Canalevia-CA1):	Not classified
Crofelemer (148465-45-6):	At oral doses up to 738 mg/kg/day (177 times the recommended human dose of 4.2 mg/kg), had no effects on fertility or reproductive performance in male and female rats.
STOT: single exposure (Canalevia-CA1):	Not classified
STOT: repeated exp (Canalevia-CA1):	Not classified
Aspiration hazard (Canalevia-CA1):	Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity
Crofelemer is extracted from naturally-occurring plant latex. No other information available
12.2 Persistence and degradability
No other information available
12.3 Bio accumulative potential
No other information available
12.4 Mobility in soil
No other information available
12.5 Other adverse effects
No other information available

SECTION 13: ECOLOGICAL INFORMATION

13.1 Waste treatment methods
Waste disposal method: Dispose of as non-hazardous material

SECTION 14: TRANSPORT INFORMATION

In accordance with DOT / IATA / ICAO / IMO - this product is not regulated

14.1 UN Number
Not applicable
14.2 UN proper shipping name
Hazard class: Non-hazardous

SECTION 15: REGULATORY INFORMATION

TSCA status:	Not determined
CERCLA status:	Not determined
SARA status:	Not determined
RCRA status:	Non-hazardous
PROP. *65* (CA) status:	Not determined

SECTION 16: OTHER INFORMATION

OTHER INFORMATION
LEGEND:

NA = Not Applicable
ND = Not Determined
NOAEL = No Observed Adverse Event Level
STOT = Specific Target Organ Toxicity
CA1 = Conditionally approved by the FDA/CVM

USER'S RESPONSIBILITY:

THIS BULLETIN CANNOT COVER ALL POSSIBLE SITUATIONS THAT THE USER MAY EXPERIENCE DURING PROCESSING. EACH ASPECT OF YOUR OPERATION SHOULD BE EXAMINED TO DETERMINE IF, OR WHERE, ADDITIONAL PRECAUTIONS MAY BE NECESSARY. ALL HEALTH AND SAFETY INFORMATION CONTAINED IN THIS BULLETIN SHOULD BE PROVIDED TO YOUR EMPLOYEES OR CUSTOMERS. IT IS YOUR RESPONSIBILITY TO USE THIS INFORMATION TO DEVELOP APPROPRIATE WORK PRACTICE GUIDELINES AND EMPLOYEE INSTRUCTIONAL PROGRAMS FOR YOUR OPERATION.

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