

SAFETY DATA SHEETS

This SDS packet was issued with item:

078948591

N/A



PANOQUELL[®]-CA1 (fuzapladib sodium for injection)

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : PANOQUELL[®]-CA1
(fuzapladib sodium for injection)

1.2. Recommended use and restrictions on use

Use of the substance/mixture : PANOQUELL[®]-CA1 is a prescription drug used for the management of clinical signs associated with acute onset of pancreatitis in dogs.

1.3. Details of the supplier of the safety data sheet

Ceva Animal Health, LLC
8735 Rosehill Road, Suite 300
Lenexa, KS 66245

1.4. Emergency telephone number

Emergency Number : Chemtrec 1-800-424-9300

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements

GHS US labeling

No labeling applicable

2.3. Other hazards

Not applicable

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Each of the components are nonhazardous or less than the 1% concentration cut off limits.

PANOQUELL®-CA1 (fuzapladib sodium for injection)

Safety Data Sheet

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash the exposed skin with water for at least 15 minutes. If redness and swelling occur, seek medical advice immediately and show the package insert or label to the physician.
First-aid measures after eye contact	: Wash the eyes with water for at least 15 minutes. If wearing contact lenses, rinse the eyes first, then remove contacts and continue to rinse with water.
First-aid measures after ingestion	: Rinse mouth out with water. Do not induce vomiting unless directed to do so by medical personnel. Seek medical advice immediately and show the package insert or label to the physician.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation	: No specific effects and/or symptoms are known.
Symptoms/effects after skin contact	: No specific effects and/or symptoms are known.
Symptoms/effects after eye contact	: May cause slight irritation.
Symptoms/effects after ingestion	: No specific effects and/or symptoms are known.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known
Explosion hazard	: None known

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
--------------------------------	--

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Avoid contact with skin and eyes.
----------------------	-------------------------------------

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
----------------------	---

6.2. Environmental precautions

Do not discharge into sewer or waterways.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material if this is without risk.
Methods for cleaning up	: IF DRY – Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET - soak up and place in labeled containers for disposal. Always wash area with large amounts of water and prevent run off into drains.

PANOQUELL[®]-CA1 (fuzapladib sodium for injection)

Safety Data Sheet

6.4. Reference to other sections

No additional information available.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes, skin, and clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store unopened vials at room temperature, 59°-77°F (15°-25°C). Store the reconstituted product at refrigerated conditions, 36°-46°F (2°-8°C). Use within first 28 days of first puncture.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Fuzapladib sodium

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: None required under normal product handling conditions.
Hand protection	: None required under normal product handling conditions.
Eye protection	: None required under normal product handling conditions.
Skin and body protection	: None required under normal product handling conditions.
Respiratory protection	: None required under normal product handling conditions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Powder
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: Not applicable
pH solution	: Not applicable
Melting point	: 265°C (Active ingredient – fuzapladib sodium)
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: 8 minutes (Burning Rate Test – active ingredient only)
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: Insoluble – 0.01 g/mL active ingredient only
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: 439°C (ASTM type ignition point test – active ingredient only)
Decomposition temperature	: 265°C (active ingredient only)

PANOQUELL®-CA1 (fuzapladib sodium for injection)

Safety Data Sheet

Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosion limits	: No data available
Explosive properties	: Not explosive.
Oxidizing properties	: Non oxidizing material according to EC criteria.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

Stable under normal handling and storage conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Oral Toxicity LD50 = 522 mg/kg (rat) active ingredient, fuzapladib sodium only
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: Not applicable
Serious eye damage/irritation	: Not classified pH: Not applicable
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: Not applicable
Symptoms/effects	: No specific effects and/or symptoms are known

PANOQUELL[®]-CA1 (fuzapladib sodium for injection)

Safety Data Sheet

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Product/Packaging disposal recommendations : Dispose of contents/containers in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

United States Environmental Protection Agency's Toxic Substances Control Act (TSCA): Exempt

15.2. US State regulations

PANOQUELL[®]-CA1

U.S. - California - Proposition 65 - Other information	California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm
--	---

SECTION 16: Other information

Date of Preparation : 03/02/2023
Other Information : This document has been prepared in accordance with the SDS requirements of the OSH Hazard Communication Standard 29 CFR 1910.1200.

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety, and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.