



# PANOQUELL<sup>®</sup>-CA1 (fuzapladib sodium for injection)

## Safety Data Sheet

### SECTION 1: Identification

#### 1.1. Identification

Product name : PANOQUELL<sup>®</sup>-CA1  
(fuzapladib sodium for injection)

#### 1.2. Recommended use and restrictions on use

Use of the substance/mixture : PANOQUELL<sup>®</sup>-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.

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### 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 | : <b>IF DRY</b> – Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal.<br><b>IF WET</b> - soak up and place in labeled containers for disposal.<br>Always wash area with large amounts of water and prevent run off into drains. |

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### 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)                                 |

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|                      |  |
|----------------------|--|
| 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<br>pH: Not applicable   |
| Serious eye damage/irritation     | : Not classified<br>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                                  |

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### 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.