HEALTH AND SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY

JUROX (UK) LIMITED
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PRODUCT NAME: ALFAXAN 10 MG / ML SOLUTION FOR INJECTION FOR DOGS, CATS AND PET RABBITS

LEGAL CATEGORY: POM-V(UK)

LICENCE NUMBER: UK: Vm 25296/4003

LICENCE ISSUE DATE: 25/07/2017 (UK)

PHYSICAL FORM: Clear, colourless aqueous

PRODUCT TYPE: General anaesthetic

CONTAINER: 10 mL glass vial

2. COMPOSITION / INFORMATION ON ACTIVE INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>% w/w</th>
<th>HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfaxalone</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Hydroxypropyl-beta-cyclodextrin</td>
<td>&lt; 10%</td>
<td></td>
</tr>
<tr>
<td>Other non-hazardous ingredients</td>
<td>&lt; 1%</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>To 100%</td>
<td></td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Not hazardous (by GHS criteria)

4. FIRST AID MEASURES

Eye contact: If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.

Dermal contact: If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

Ingestion: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical assistance immediately.

Injected: In case of accidental self-injection, seek medical attention and show the product literature to the doctor.

Inhalation: Not applicable

Notes to physician: Alfaxalone is a steroid anaesthetic. Treat symptomatically. There is no specific antidote.

5. FIRE-FIGHTING MEASURES (BULK PRODUCT)

Flammability: Not flammable

Extinguishing media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective equipment: Wear fire-fighting protective equipment and full face-piece self-contained breathing apparatus.

Explosive hazards: None known

Hazardous combustion products: If involved in a fire, may emit noxious fumes. Non-combustible. Not considered to be a significant fire risk.

6. ACCIDENTAL RELEASE MEASURES (Large spills)

Spillage: Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up/absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.

Decontamination procedure: Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this substance.

7. HANDLING AND STORAGE

Handling: This product is only available to a veterinarian. Avoid accidental injection, and contact with skin and eyes.

Storage: Keep out of reach and sight of children. Store below 30°C, under secure conditions appropriate to local requirements for this class of veterinary medicine.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits: Due to the small volumes involved, and the methods of administration, exposure under normal conditions of use would likely be limited to splashing on to skin or in to eyes, or accidental self-injection.

Protective Equipment: As for good veterinary practice.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>APPEARANCE:</th>
<th>SPECIFIC GRAVITY:</th>
<th>pH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear colourless solution</td>
<td>1.02 – 1.03</td>
<td>6.5 – 7.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOLUBILITY IN WATER:</th>
<th>FLASH POINT:</th>
<th>ODOUR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqueous solution</td>
<td>Not flammable</td>
<td>Odourless</td>
</tr>
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</table>

10. STABILITY AND REACTIVITY

Stability: When stored appropriately this product should show no significant degradation before the date of expiry on the container.

11. TOXICOLOGICAL INFORMATION

Eye contact: Not classified as an eye irritant, but may cause transient discomfort and redness following eye contact.

Dermal contact: Not a skin irritant. Not a skin sensitiser.

Ingestion: Unlikely to present a hazard, due to the low oral bioavailability of alfaxalone.

Alfaxalone: Oral LD50; > 300 mg/kg (rat)
Hydroxypropyl-beta-cyclodextrin: Oral LD50; >5,000 mg/kg (rat)

Injection: Significant CNS effects are expected only from the intravenous route, and this is unlikely from accidental self-injection.

Alfaxalone: Intravenous LD50; 19 mg/kg (rat)

Inhalation: Unlikely to present an inhalation hazard under normal conditions of use, due to the non-volatile nature of the product.

Chronic effects: No adverse effects were reported from intraperitoneal administration to rats of up to 50 mg/kg/day for one month, or up to 20 mg/kg/day for 3 months.

Other: Not known to be a reproductive toxicant, mutagen or carcinogen.

12. ECOLOGICAL INFORMATION

No environmental effects are anticipated.

13. DISPOSAL CONSIDERATIONS

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the label instructions and local regulations and procedures.

14. TRANSPORT INFORMATION

Transportation and shipping of the material is not restricted. It has no known significant hazards requiring special packaging or labelling.

15. REGULATORY INFORMATION


16. OTHER INFORMATION

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