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

1.1 Product identification

Product Name: Methadyne 10 mg/ml solution for injection for dogs and cats
Product code: 519315

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

Relevant identified uses: Veterinary medicine. Solution for Injection used as analgesia, premedication for general anaesthesia or neuroleptanalgesia in dogs and cats in combination with a neuroleptic drug.

Uses advised against: For Animal use only – Not for use in humans.

Reason why uses advised against: Methadone can cause respiratory depression following spillage onto the skin or accidental self-injection.

1.3 Details of the Supplier of the Safety Data Sheet

Supplier: JUROX (UK) Private Limited Company
Street/P.O. Box: Second Floor, Richmond House, 105 High Street,
Postcode / City: Crawley, West Sussex RH10 1DD,
Country: UK
Telephone: +44 1293 510 681
E-mail (competent person): info@jurox.co.uk
National contact: richard.beckwith@jurox.co.uk

1.4 Emergency telephone number

Please contact: 01293 510681
Opening hours: 24 hours a day, 365 days a year
Other comments: Language(s) of the phone service: English

Section 2: HAZARDS IDENTIFICATION

2.1 Classification according to regulation (EC) No 1272/2008 [CLP]

H373 - Specific target organ toxicity - repeated exposure Category 2;
H412 - Chronic Aquatic Hazard Category 3.

2.2 Label elements: Labelling according to Regulation (EC) No 1272/2008 [CLP]:

Hazard pictograms:

Health hazard

Signal Word: WARNING

Hazard statements

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
</tr>
</tbody>
</table>

Supplementary statements: Not applicable.
Precautionary statements – Prevention:
P260 Do not breathe vapours.
P273 Avoid release to the environment.

Precautionary statements – Response:
P314 Get medical advice/attention if you feel unwell.

Precautionary statements – Storage: Not applicable.

Precautionary statements – Disposal:
P501 Dispose of contents / container in accordance with local regulations.

2.3 Other hazards

Methadone can cause respiratory depression following spillage onto the skin or accidental self-injection. Methadone is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. People with known hypersensitivity to methadone should avoid contact with the veterinary medicinal product. Methadone has the potential to cause stillbirths. Pregnant women are advised not to handle the product.

Section 3: COMPOSITION / INFORMATION ON ACTIVE INGREDIENTS

3.1 Substances: This product is a mixture. Health hazard information is based on its components.

3.2 Mixtures

<table>
<thead>
<tr>
<th>1. CAS No.</th>
<th>2. EC No.</th>
<th>3. Index No.</th>
<th>4. REACH No.</th>
<th>% w/w</th>
<th>NAME</th>
<th>HAZARD (according to regulation (EC) No 1272/2008 [CLP])</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>&gt;90</td>
<td>Other nonhazardous ingredients</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

**General Information:** Respiratory depression, systemic hypotension, respiratory arrest, shock, cardiac arrest and death may occur. Consult the National Poisons Information Service (dial 111) or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

**Following 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.

**Following skin contact:** If skin contact occurs: Immediately remove all contaminated clothing, including footwear and 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.

**Following ingestion:** If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Contact a doctor or the National Poisons Information Service (dial 111) immediately.

**Following injection:** Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical
Following inhalation:
If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Self-protection of the first aider:
Protective glasses or goggles are recommended when handling bulk quantities of this product. When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

4.2 Most important symptoms and effects, both acute and delayed
Symptoms and Effects of Exposure:
Methadone side effects generally encompass a broad range of symptoms that may commonly include constipation, drowsiness, dry mouth, euphoria, light headedness, slowed breathing, and weakness. Additional side effects of methadone that are not as common often include palpitations, hives, impaired concentration, nausea, skin rash, sweating, vomiting, muscle twitching, and disorientation.

4.3 Indication of any immediate medical attention and special treatment needed
Recommended First Aid Facilities:
Ready access to running water and soap is required. Accessible eyewash is required.
Advice to Doctor:
Treat symptomatically for a narcotic analgesic.

Section 5: FIRE-FIGHTING MEASURES (BULK PRODUCT)

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

5.2 Special hazards arising from the substance or mixture
Hazardous combustion products: If involved in a fire, may emit noxious or irritating fumes.

5.3 Advice for firefighters
Flammability: Not combustible. Not considered to be a significant fire risk, however containers may burn.
Protective equipment: Wear breathing apparatus plus protective gloves in the event of a fire.

Section 6: ACCIDENTAL RELEASE MEASURES (Large spills)

6.1 Personal precautions, protective equipment and emergency procedures
6.1.1 For non-emergency personnel
Protective equipment: See Section 8.
Personal precautions: For large spills: Ventilate area. Clear area of excess personnel.
Emergency procedure:
For small spills: Wash area well with excess water.
For large spills: Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Wash spill site after pick-up complete. Dispose of waste safely according to local regulations as well as the Misuse of Drugs Regulations (2001).
For individual vials: Dispose of any unused veterinary medicinal product or empty containers in accordance with label directions and the Misuse of Drugs Regulations (2001).

6.1.2 For emergency responders
Protective equipment: See Section 8.
Personal precautions: For large spills: Ventilate area. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves.
Emergency procedure:
For small spills: Wash area well with excess water.
For large spills: Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Wash spill site after pick-up complete. Dispose of waste safely according to local regulations as well as the Misuse of Drugs Regulations (2001).
For individual vials: Dispose of any unused veterinary medicinal product or empty containers in accordance with label directions and the Misuse of Drugs Regulations (2001).
6.2 Environmental precautions

**Spillage:** Prevent spillage from entering drains or waterways.

6.3 Methods and material for containment and cleaning up

6.3.1 Containment techniques: See Section 6.1.

6.3.2 Clean-up procedures

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

6.4 Reference to other sections: See Section 8 for Personal protection and Section 13 for Disposal considerations.

**Section 7: HANDLING AND STORAGE**

7.1 Precautions for safe handling

**Protective measures:** Use individual vials according to label directions. Handle bulk product in a well-ventilated area. The product must be handled in accordance with the Misuse of Drugs Regulations (2001). Avoid contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required.

**Measures to prevent fire:** Keep the product away from combustibles.

**Measures to prevent aerosol and dust generation:** Not applicable.

**Measures to protect the environment:** Prevent spillage from entering drains or waterways.

**Advice on general occupational hygiene:** Do not eat, drink or smoke when handling this product.

7.2 Conditions for safe storage, including any incompatibilities

**Technical measures and storage conditions:** Methadone is a Schedule 2 Controlled drug, therefore the product must be stored in accordance with the Misuse of Drugs Regulations (2001). Store below 30°C. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. Keep out of reach of children.

**Packaging materials:** Store product in original packaging.

**Requirements for storage rooms and vessels:** Keep storage area free from debris, wastes and combustibles.

7.3 Specific end use(s): See section 1.2. Use individual vials according to label directions. Always read the label before use. See label for further information on handling and storage.

**Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION**

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

8.1 Control parameters

**Derived No Effect Level (DNEL):** Not available.

**Predicted No Effect Level (PNEC):** Not available.

**Occupational Exposure Limits (OEL):** Not available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

**Engineering Controls:** Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

8.2.2 Individual protection measures, such as personal protective equipment:

**Protective Equipment:**

- **Eye Protection:** Protective glasses or goggles are recommended when handling bulk quantities of this product.
- **Skin Protection:** When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.
- **Respiratory Protection:** Not required for the normal use of this product.
- **Other:** For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

**Thermal Hazards:** Not available.

8.2.3 Environmental exposure controls: See Section 12.
SAFETY DATA SHEET
METHADYNE 10 mg/mL

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

| (a) APPEARANCE:  | (h) EVAPORATION RATE: | (o) PARTITION CO-EFFICIENT |
| Clear, colourless solution | Not available | (n-octanol / water): Not available |
| (b) ODOUR: | (i) FLAMMABILITY: | (p) AUTO-IGNITION TEMPERATURE |
| Not available | Not flammable | (°C): Not applicable |
| (c) ODOUR THRESHOLD: | (j) UPPER / LOWER EXPLOSIVE LIMITS (%): | (q) DECOMPOSITION TEMPERATURE: |
| Not available | Not available | Not available |
| (d) pH: | (k) VAPOUR PRESSURE (kPa): | € VISCOSITY (cSt): |
| 4.5 – 6.5 | Not available | Not applicable |
| € MELTING POINT / FREEZING POINT (°C): | (l) VAPOUR DENSITY (Air = 1): | (s) EXPLOSIVE PROPERTIES: |
| Not applicable. | Not available | Not available |
| (f) INITIAL BOILING POINT AND BOILING RANGE (°C): | (m) RELATIVE DENSITY |
| Not available | (Water = 1): 1.0068 | |
| (g) FLASH POINT (°C): | (n) SOLUBILITY IN WATER (g/L): | |
| Not combustible | Miscible |

Section 10: STABILITY AND REACTIVITY

10.1 Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

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

10.3 Possibility of hazardous reactions: Unlikely under normal storage conditions.

10.4 Conditions to avoid: Protect this product from light.

10.5 Incompatible materials: Oxidising agents.

10.6 Hazardous decomposition products: No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. Adverse effects may occur following ingestion of methadone. May result in rapid shallow breathing, temporary paralysis or weakness of muscles, reduced urine output, drowsiness, nausea, vomiting, flushed face, irregular heartbeat, constipation, loss of appetite, general feeling of discomfort, false sense of well-being, dry mouth, stomach cramps, confusion, headache, visual disturbances and symptoms of shock (cold clammy skin, rapid weak pulse, dizziness, weakness and fainting). Doses of 50 mg or less have been known to be lethal to nontolerant adults. The fatal dose in children is 10-20 mg.

Methadone hydrochloride: Oral LD50: 95mg/kg (rat).
Methadone: Oral LD50: 70mg/kg (mouse).

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route. Adverse effects may occur following skin absorption (see ingestion).

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.
**Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be respiratory or skin sensitiser. However, contact dermatitis has been reported with morphine and other narcotic analgesics.

**Germ Cell Mutagenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

**Carcinogenicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

**Reproductive Toxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. However, there is some evidence that methadone readily crosses the placental barrier and may cause respiratory depression in neonates and withdrawal syndrome in neonates. Cases of intra-uterine death have been reported during methadone usage in the late mid-trimester or last trimester of pregnancy. Methadone is secreted in breast milk in concentration approaching plasma levels.

**Specific Target Organ Toxicity (STOT): Single exposure:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure. As with other potent opioids, clinically significant respiratory depression may occur after single exposure.

**Specific Target Organ Toxicity (STOT): Repeated exposure:** Based on available data for the ingredients, the mixture is classified as **Specific target organ toxicity – repeated exposure Category 2.** Repeated exposure to opioid analgesics may result in physical dependence. Prolonged exposure to methadone can cause cardiac abnormalities (Q-T interval prolongation) in some patients.

**Aspiration Hazard:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

### Section 12: ECOLOGICAL INFORMATION

**12.1 Toxicity**
Based on available data for the ingredients, the mixture is classified as **Chronic Aquatic Hazard Category 3.**
Methadone hydrochloride is harmful in the aquatic environment.
Methadone hydrochloride: Algae EC₅₀ (96 h) 1.358 mg/L;
Fish EC₅₀ (96 h) 3.482 mg/L.

**12.2 Persistence and degradability**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone hydrochloride</td>
<td>HIGH</td>
<td>HIGH</td>
</tr>
</tbody>
</table>

**12.3 Bioaccumulative potential**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Bioaccumulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone hydrochloride</td>
<td>MED (log KOW = 4.1665)</td>
</tr>
</tbody>
</table>

**12.4 Mobility in soil**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone hydrochloride</td>
<td>LOW (KOC = 72790)</td>
</tr>
</tbody>
</table>

**12.5 Results of PBT and vPvB assessment:** No data is available on the product.

**12.6 Other adverse effects:** No data is available on the product.
13.1 Waste treatment methods

13.1.1 Product / Packaging disposal: Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the label instructions as well as local regulations and the Misuse of Drugs Regulations (2001).

13.1.2 Waste treatment options: Not relevant as any unused product must be disposed of in accordance with the Misuse of Drugs Regulations (2001).

13.1.3 Sewage disposal options: Not Available.

14.1 UN number: Not applicable.

14.2 UN proper shipping name: Not applicable.

14.3 Transport hazard class (es): Class: Not applicable; Subrisk: Not applicable.

14.4 Packing Group: Not applicable.

14.5 Environmental hazards: Not applicable. The product is not a marine pollutant.

14.6 Special precautions for user: The product must be transported in accordance with the Misuse of Drugs Regulations (2001) and local and international controlled drug legislation.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture

Methadone Hydrochloride(125-56-4) is found on the following regulatory lists:
- European Customs Inventory of Chemical Substances ECICS (English).
- European Union – European Inventory of Existing Commercial Chemical Substances (EINECS) (English).

15.2 Chemical safety assessment
No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCF</td>
<td>BioConcentration Factor.</td>
</tr>
<tr>
<td>CLP</td>
<td>The CLP Regulation (for “Classification, Labelling and Packaging”) is a European Union regulation from 2008 which aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS).</td>
</tr>
<tr>
<td>DNEL</td>
<td>Derived No-Effect Level.</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission.</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification and Labelling of Chemicals.</td>
</tr>
<tr>
<td>HAZCHEM Code</td>
<td>Emergency action code of numbers and letters that provide information to emergency services especially firefighters.</td>
</tr>
<tr>
<td>IBC Code</td>
<td>International Bulk Chemical Code.</td>
</tr>
</tbody>
</table>
KOC  Soil/water partition coefficient.
LD\textsubscript{50}  The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50\% of animals.
Log-KOW  The logarithm of the KOW (Octanol Water Partition Coefficient). The KOW is the ratio of a compound’s concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
MARPOL  Stands for marine pollution, is the International Convention for the Prevention of Pollution from Ships.
OEL  Occupational Exposure Limits.
PBT  Persistent, Bioaccumulative and Toxic substance.
PNEC  Predicted No Effect Concentration.
POM-V  Prescription Only Medicine – Veterinarian (UK).
Ph  Partial pressure of Hydrogen.
PVC  Polyvinyl chloride.
REACH  Registration, Evaluation, Authorisation and Restriction of Chemicals. This is the key chemical control regulation in the European Union.
SDS  Safety Data Sheet.
STOT  Specific Target Organ Toxicity.
UN  United Nations.
UN Number  Number identifying a hazardous substance, assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods.
VPvB  Very Persistent, Very Bioaccumulative.
VPO  Veterinary Practitioner Only.
UK  United Kingdom.

**Full text of Hazard Statements referred to under section 3**

- **H301**  Toxic if swallowed.
- **H373**  May cause damage to organs through prolonged or repeated exposure.
- **H400**  Very toxic to aquatic life.
- **H410**  Very toxic to aquatic life with long lasting effects.
- **H412**  Harmful to aquatic life with long-lasting effects

**References**

2. EPA New Zealand Chemical Classification and Information Database (CCID) [http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx](http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx)

**This Version Issued:**  18 September 2018

**Supersedes:** This is the first SDS for the product.

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**Disclaimer**

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