Box Jellyfish Antivenom

SAFETY DATA SHEET

Page 1 of 5 - Date of Issue: 19 September 2013

IMPORTANT NOTICE This Safety Data Sheet (SDS) is prepared by bioCSL Pty. Ltd. in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (December 2011). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

   Product Name  Box Jellyfish Antivenom
   Other Names   Chironex fleckeri antivenom
   Manufacturer’s Product Code  05565401
   Use           For the treatment of patients who, following a box jellyfish sting, exhibit manifestations of systemic envenoming or who have extensive local involvement causing extreme pain which does not respond to routine analgesic therapy.

   Adrenaline should always be readily available whenever the injection is given.

   Supplier Name   bioCSL Pty. Ltd. (ABN 26 160 735 035)
   Address        63 Poplar Road, Parkville, Victoria 3052, Australia
   Telephone      +61 03 9389 2000
   Emergency Telephone 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

   Not classified as hazardous according to the criteria of SWA
   Not classified as a dangerous good by the criteria of the ADG Code

3. COMPOSITION/INFORMATION ON INGREDIENTS

   Name:                      CAS number:     Proportion:
   Box Jellyfish Antivenom    -             20000 Units
   Phenol                     108-95-2       0.22% w/v
   Sodium Chloride            7647-14-5     0.8% w/v
   Ovine plasma protein       -             <10% w/v
   Water for Injections       -             up to 100%

4. FIRST AID MEASURES

   Accidental Injection     If allergic reaction occurs seek immediate medical attention.

   Eye                      Separate eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.
Swallowed
DO NOT induce vomiting. If exposed subject is fully conscious, wash out mouth with water and give plenty of water to drink. If hypersensitivity occurs, seek immediate medical attention.

Skin
Remove contaminated clothing. Flush area with copious amounts of water.

First Aid Facilities
Adrenaline should always be readily available whenever the injection is given.

Aggravated Medical Conditions
In individuals hypersensitive to sheep plasma protein, may precipitate an acute allergic reaction.

Symptoms and signs of anaphylaxis include pallor, rapid heart rate, shortness of breath, skin rash, hives, coughing, bronchospasm or loss of consciousness.

See product information leaflet for information regarding pre-existing conditions.

Advice To Doctor
Treat symptomatically. Cases of anaphylaxis may require treatment with adrenaline, oxygen, intravenous steroids and airway management including intubation.

The sooner the onset of an allergic reaction, the more severe the reaction.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard
Non-combustible. Not considered a significant fire risk.

Fire Extinguishing Media
No restrictions.

Hazchem Code
None allocated.

6. ACCIDENTAL RELEASE MEASURES

Minor Spills
– Wear protective gloves and safety glasses.
– Remove broken glass.
– Clean up spill immediately using absorbent paper towels.
– Place spilled material in clean, dry, sealed container for disposal.
– Decontaminate area with 1% sodium hypochlorite in water.

Major Spills
– Wear protective gloves and safety glasses.
– Contain and absorb spills using earth, sand or inert absorbent.
– Remove broken glass.
– Collect residues and seal in labelled drums for disposal.
– Decontaminate area with 1% sodium hypochlorite in water.

7. HANDLING AND STORAGE

– Transport and store at 2 to 8 degrees C (do not freeze).
– Protect from light.
– Store as per Schedule 4 pharmaceutical.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards
No exposure limits set by SWA or ACGIH

Engineering Controls
None under normal operating conditions.
Personal Protection  For good infection control, gloves should be worn when administering an injection.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear to slightly opalescent, colourless to light straw coloured solution in a glass vial.</td>
</tr>
<tr>
<td>Odour</td>
<td>Slight odour</td>
</tr>
<tr>
<td>pH</td>
<td>6.2-7</td>
</tr>
<tr>
<td>Boiling Point/Melting Point</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>Not determined</td>
</tr>
<tr>
<td>Vapour Density</td>
<td>Not determined</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.033</td>
</tr>
<tr>
<td>Flashpoint</td>
<td>Not flammable</td>
</tr>
<tr>
<td>Flammability Limits</td>
<td>Not flammable</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Miscible</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not known to be incompatible with other materials.</td>
</tr>
<tr>
<td>Stability</td>
<td>Stable under anticipated storage and handling conditions (refer section 7).</td>
</tr>
<tr>
<td>Decomposition Products</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

**Special Warning:** When medicinal products prepared from animal plasma are administered, infectious diseases due to the transmission of infective agents cannot be totally excluded. This applies to pathogens of hitherto unknown origin. This possibility must always be considered and should be conveyed, whenever possible, to patients who may receive the product. Historically there have been no known recorded cases of transmission of viruses by this product.

**Accidental Injection** May cause redness at injection site. In individuals hypersensitive to sheep plasma protein, may precipitate an acute allergic reaction.

  Symptoms and signs of anaphylaxis include pallor, rapid heart rate, shortness of breath, skin rash, hives, coughing, bronchospasm or loss of consciousness.

**Eye** May cause irritation.

**Swallowed** May cause irritation of the gastro-intestinal tract. In hypersensitive individuals, may precipitate an acute allergic reaction (anaphylaxis). Severe allergic reactions will usually occur within the first few hours of ingestion, see Acute Health Effects: Accidental Injection.
12. ECOLOGICAL INFORMATION

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.
- Use an on site licensed incinerator, if permitted by licence. Alternatively, dispose via a licensed commercial incinerator.

14. TRANSPORT INFORMATION

- **UN Number**: None allocated
- **DG Class**: None allocated
- **Subsidiary Risk**: None allocated
- **Packing Group**: None allocated
- **Hazchem Code**: None allocated

15. REGULATORY INFORMATION

- **Poisons Schedule Number**: Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

- **Last Revised**: 19 September 2013
- **Reason for Revision**: SDS update

**Abbreviations**

- SWA – Safe Work Australia
- ACGIH – American Conference of Governmental Industrial Hygienists
- ADG Code – Australian Dangerous Goods Code
- UN Number – United Nations Number
- DG Class – Dangerous Goods Class
- CAS Number – Chemical Abstract Service Number
Contact Point
Company Contact: +61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service: 13 11 26
Australian Police, Fire Brigade or Ambulance: 000
New Zealand Poisons Information Centre, 24 hour service: (03) 4747 000
New Zealand Police, Fire Brigade or Ambulance: 111

Whilst the information contained in this document is based on data which, to the best of our knowledge, was accurate and reliable at the time of preparation, no responsibility can be accepted by us for errors and omissions. Users are advised to make their own determination as to the suitability of this information in relation to their particular purposes and specific circumstances. Since the information contained in this document may be applied under conditions beyond our control, we can accept no responsibility for any loss or damage by any person acting or refraining from action as a result of this information.