**WHO Reference Reagent**

The 1st International Reference Preparation for Anti-
Staphylococcal P-V Leucocidin Serum, Equine
NIBSC code: SPLS

**Instructions for use**

(Version 4.0, Dated 14/10/2010)

1. **INTENDED USE**
   This material is the freeze dried residue of a horse antiserum to
   Staphylococcus aureus P-V Leucocidin. This material has been prepared
   and characterised by The National Institute for Medical Research,
   London, England. This material is intended for use in the calibration of
   the contents of ‘effective constituent’ in national or working standard
   preparations and for the expression of these contents in the respective
   International Units.

2. **CAUTION**
   This preparation is not for administration to humans or animals in
   the human food chain

   The material is not of human or bovine origin. As with all materials of
   biological origin, this preparation should be regarded as potentially
   hazardous to health. It should be used and discarded according to
   your own laboratory’s safety procedures. Such safety procedures
   should include the wearing of protective gloves and avoiding the
   generation of aerosols. Care should be exercised in opening
   ampoules or vials, to avoid cuts.

3. **UNITAGE**
   Each ampoule contains 150 units of antibody to F toxin and 150 units of
   antibody to S toxin.

4. **CONTENTS**
   Country of origin of biological material: United Kingdom.
   Each ampoule contains the freeze-dried residue of 1 ml of horse serum
   diluted with an equal volume of distilled water. Each ampoule contains
   150 units of antibody to F toxin and 150 units of antibody to S toxin.

5. **STORAGE**
   For long-term storage, this material should be stored at -20°C.
   Please note: because of the inherent stability of lyophilized
   material, NIBSC may ship these materials at ambient temperature.

6. **DIRECTIONS FOR OPENING**
   Tap the ampoule gently to collect the material at the bottom (labelled)
   end. Ensure ampoule is scored all round at the narrow part of the
   neck, with a diamond or tungsten carbide tipped glass knife file or
   other suitable implement before attempting to open. Place the
   ampoule in the ampoule opener, positioning the score at position ‘A’;
   shown in the diagram below. Surround the ampoule with cloth or
   layers of tissue paper. Grip the ampoule and holder in the hand and
   squeeze at point ‘B’. The ampoule will snap open. Take care to avoid
   cuts and projectile glass fragments that enter eyes. Take care that no
   material is lost from the ampoule and that no glass falls into the
   ampoule.

   ![Side view of ampoule opening device containing an ampoule positioned ready to open. ‘A’ is the score mark and ‘B’ the point of applied pressure. Care should be taken on opening to prevent the contents escaping.](image)

7. **USE OF MATERIAL**
   No attempt should be made to weigh out any portion of the freeze-dried
   material prior to reconstitution
   The entire contents of each ampoule should be completely dissolved in an
   accurately measured amount of solvent (distilled water, saline or buffer) and
   the solution kept cool (e.g. 4°C) prior to use. It is recommended that the
   solution is used immediately or aliquots should be stored at -20°C. The
   ampoules contain no bacteriostat and the preparations should not be
   assumed to be sterile.

8. **STABILITY**
   Reference materials are held at NIBSC within assured, temperature-
   controlled storage facilities. Reference Materials should be stored on
   receipt as indicated on the label.

   NIBSC follows the policy of WHO with respect to its reference materials.

9. **REFERENCES**

10. **ACKNOWLEDGEMENTS**
    WHO

11. **FURTHER INFORMATION**
    Further information can be obtained as follows;
    This material: enquiries@nibsc.org
    WHO Biological Standards:
    http://www.who.int/biologicals/en/
    JCITM Higher order reference materials:
    http://www.bipm.org/en/committees/jc/jcitm/
    Derivation of International Units:
    http://www.nibsc.org/standardisation/international_standards.aspx
    Ordering standards from NIBSC:
    http://www.nibsc.org/products/ordering.aspx
    NIBSC Terms & Conditions:
    http://www.nibsc.org/terms_and_conditions.aspx

12. **CUSTOMER FEEDBACK**
    Customers are encouraged to provide feedback on the suitability or use
    of the material provided or other aspects of our service. Please send any
    comments to enquiries@nibsc.org

13. **CITATION**
    In all publications, including data sheets, in which this material is
    referenced, it is important that the preparation’s title, its status, the NIBSC
    code number, and the name and address of NIBSC are cited and cited
    correctly.

14. **MATERIAL SAFETY SHEET**
    Classification in accordance with Directive 2000/54/EC, Regulation (EC)
    No 1272/2008: Not applicable or not classified

<table>
<thead>
<tr>
<th>physical and Chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No Irritant: No</td>
</tr>
<tr>
<td>Flammable: No Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): contains horse serum</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>
Suggested First Aid

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation:</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Ingestion:</td>
<td>Seek medical advice</td>
</tr>
<tr>
<td>Contact with eyes:</td>
<td>Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td>Contact with skin:</td>
<td>Wash thoroughly with water.</td>
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</tbody>
</table>

Action on Spillage and Method of Disposal

Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

15. LIABILITY AND LOSS
In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC’s Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) (“Conditions”) apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient’s attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*: United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.</td>
</tr>
<tr>
<td>Net weight: approximately 53.5 mg</td>
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<tr>
<td>Toxicity Statement: Toxicity not assessed</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable.</td>
</tr>
<tr>
<td>Attached: No</td>
</tr>
</tbody>
</table>

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use.

The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.