1. INTENDED USE
This material has been prepared and characterised by the Statens Serum Institut (SSI), Copenhagen, Denmark. With effect from 1st July 1997, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK is the custodian and distributor of this material. The package insert from SSI is attached.

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 1100 International Units of Gas-Gangrene Antitoxin (Clostridium Novyi).

4. CONTENTS
Country of origin of biological material: United Kingdom.
This preparation contains the freeze-dried residue of 1.0 ml horse serum.

5. STORAGE
Uncapped ampoules 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.

7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.
See attached SSI product insert.

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.

It is the policy of WHO not to assign an expiry date to their International Reference Materials.

Units assigned to this material were valid at the time of calibration and there is no data available on long term stability. However, freeze-dried serum standards are expected to undergo negligible loss of activity during long term storage at the indicated storage temperature [1].

9. REFERENCES
5. WHO/BS/803.

10. ACKNOWLEDGEMENTS
N/A

11. FURTHER INFORMATION
Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jctlm/
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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td></td>
</tr>
<tr>
<td>Corrosive: No</td>
<td></td>
</tr>
<tr>
<td>Stable: Yes</td>
<td></td>
</tr>
<tr>
<td>Oxidising: No</td>
<td></td>
</tr>
<tr>
<td>Hygroscopic: Yes</td>
<td></td>
</tr>
<tr>
<td>Irritant: No</td>
<td></td>
</tr>
<tr>
<td>Flammable: No</td>
<td></td>
</tr>
<tr>
<td>Handling: See caution, Section 2</td>
<td></td>
</tr>
<tr>
<td>Other (specify): Contains equine serum</td>
<td></td>
</tr>
</tbody>
</table>

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

**Suggested First Aid**

- **Inhalation:** Seek medical advice
- **Ingestion:** Seek medical advice
- **Contact with eyes:** Wash with copious amounts of water. Seek medical advice
- **Contact with skin:** Wash thoroughly with water.

**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**

- **Country of origin for customs purposes*: United Kingdom**
  - 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.
- **Net weight:** Approx 100mg
- **Toxicity Statement:** Non-toxic
- **Veterinary certificate or other statement if applicable.**
- **Attached:** No

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_biol_efsstandardsrev2004.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.
THE INTERNATIONAL STANDARD
for
GAS-GANGRENE ANTITOXIN (Cl. novyi), EQUINE
(3rd international standard preparation)

1. THE STANDARD PREPARATION
The standard preparation was established in 1966. It is prepared from batch of
horse serum obtained from the Wellcome Research Laboratories, U.K. The
"antitoxin was raised against filtrates of Cl. novyi (oedematia) type B
strain 725CN isolated from a sheep from Australia and obtained from dr.
Henderson of the Lister Institute" (information from dr. I. Batty, Wellcome
Research Laboratories). Originally the standard preparation was named Gas-
Gangrene Antitoxin (Oedematia) but was later renamed

2. AMPUL CONTENTS
The serum was distributed into ampoules (1 ml/ampoule) and freeze-dried. By
definition the total contents of each ampoule contains 1100 International
Units (IU) of Gas-Gangrene Antitoxin (Cl. Novyi).

3. USE OF THE STANDARD
The standard preparation was examined in a small international collaborative
study in four laboratories in four countries. All four laboratories used
neutralization tests in mice.

4. GENERAL REMARKS ABOUT INTERNATIONAL REFERENCE MATERIALS
International biological standards and international biological reference
reagents provide a means of ensuring uniformity throughout the world in the
designation of the potency or activity of preparations used in the prophylaxis,
therapy, or diagnosis of disease, where this cannot be expressed in terms of
physical or chemical quantities. The International Units are units of quantities of "effective constituent".

The standard is the material as it exists in the ampoules; the "material" thus
includes the effective constituents together with all the other constituents
that may be present (moisture, carrier, buffer, salt etc., according to the
form in which the standard is available).

International biological reference materials are intended for use in the
standardization of the contents of "effective constituent" in national or working
standard preparations and for the expression of these contents in the
respective International Units. For the routine use in the laboratory the
national or working standards should be used in order to save as much as
possible the international reference materials. These are only sent to
individual laboratories in very limited amounts. International Reference
Materials are distributed free of charge to National Control Laboratories of
Member States of the World Health Organization. Other laboratories are due to
pay a handling charge.

February 1996

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5. REFERENCES

