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.

For details of this International Standard, please refer to the enclosed package insert from the Statens Serum Institut.

The preparation is labelled ‘Rabies immunoglobulin’. 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 preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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 30 International Units of rabies antibody

4. CONTENTS
Country of origin of biological material: USA, Austria and Germany.
This material contains the freeze dried residue of human immunoglobulin containing antibodies to rabies virus. This consists of approximately 50mg protein, 23mg amino acetic acid and 2.8mg sodium chloride. The plasma from which it was produced originated in the USA, Austria and Germany.

5. STORAGE
Ampoules should be stored at -20°C on receipt. Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING
DIN ampoules have an ‘easy-open’ coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar. Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

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

Ampoules should be reconstituted in 1ml dH2O. This material can be used in RFFIT or mouse neutralisation tests.

8. STABILITY
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities and they 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. They remain valid with the assigned potency and status until withdrawn or amended.

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

9. REFERENCES


10. ACKNOWLEDGEMENTS
Not applicable.

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/jc/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 appearance</th>
<th>Freeze-dried powder</th>
<th>Corrosive</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable</td>
<td>Yes</td>
<td>Oxidising</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic</td>
<td>No</td>
<td>Irritant</td>
<td>No</td>
</tr>
</tbody>
</table>

National Institute for Biological Standards and Control
Potters Bar, Herfordshire, EN6 3QG. T: +44 (0)1707 641000. nibsc.org
WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory

WHO International Standard
The 2nd International Standard for ANTI-RABIES IMMUNOGLOBULIN, HUMAN
NIBSC code: RAI
Instructions for use
(Version 6.0, Dated 15/09/2016)
Flammable: No
Handling: See caution, Section 2
Other (specify): Contains material of human origin

Toxicological properties

Effects of inhalation: Not established, avoid inhalation
Effects of ingestion: Not established, avoid ingestion
Effects of skin absorption: Not established, avoid contact with skin

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*: Denmark
* 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: 1g
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_biologicalstandardsrev2004.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.
1. GENERAL INTRODUCTION

International biological standards and international biological reference reagents provide a means of producing uniformity throughout the world in the designation of the potency of preparations used in the prophylaxis, therapy, or diagnosis of disease. Where the country cannot be represented by a specific quantity of "effective constituent", the standard can be utilized to establish the total quantity of the effective constituent. The standard can also be utilized to obtain the "effective constituent" in the assessment of new preparations or in the evaluation of existing ones. The standard is available in quantities of 100 international units of active principle.

2. USE OF THE STANDARD

The standard preparation contains the International Unit (IU) of active principle. It is used in the determination of the potency of the biological preparations. It is also used in the evaluation of the biological standards and reference materials for the production of biologicals. The standard preparation is stored in a refrigerator at 2-8°C.

3. METHOD OF PREPARATION

The standard preparation is made by the lyophilization of the International Standard of Active Principle. The lyophilization process involves the removal of water and the preservation of the active principle in a dry form.

4. REFERENCES

2. Biologicals, in press