WHO International Standard
2nd International Standard for Anti-Hepatitis A, Immunoglobulin, Human
NIBSC code: 97/646
Instructions for use
(Version 4.0, Dated 26/04/2013)

1. INTENDED USE
The Second International Standard for Anti Hepatitis A, immunoglobulin, human, was established in 1998 by the Expert Committee for Biological Standardisation and will serve as a biological reference preparation for antibodies to hepatitis A virus. This material was calibrated against the First International Standard for Anti-Hepatitis A Virus (Ferguson et al., 2001).

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
This material has an assigned unitage of 49 International Units per ampoule i.e 98 International Units per ml when reconstituted as directed below in 0.5ml distilled water.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains a freeze-dried residue comprising, under an atmosphere of nitrogen:
1ml 8% human intramuscular immunoglobulin containing antibodies to hepatitis A virus.

5. STORAGE
Unopened ampoules should be stored at -20°C or below.

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. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

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 using 0.5ml distilled water. Following addition of the distilled water, the ampoules should be left at ambient temperature for approximately 30 minutes or until dissolved and then mixed thoroughly, avoiding the generation of excessive foam. Ensure that the entire freeze dried residue is dissolved in this solution. This will result in a solution of 98IU/ml.

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

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 and Chemical properties</th>
<th>Corrosive: No</th>
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<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Other (specify): Contains material of human origin</td>
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</tbody>
</table>

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

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<tr>
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<tbody>
<tr>
<td><strong>Inhalation:</strong> Seek medical advice</td>
</tr>
<tr>
<td><strong>Ingestion:</strong> Seek medical advice</td>
</tr>
<tr>
<td><strong>Contact with eyes:</strong> Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td><strong>Contact with skin:</strong> 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
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: 1.0g

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_biolrefstandardsrev2004.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.