**WHO International Standard**

**Follicle Stimulating Hormone, (FSH, Urofollitropin), Urinary, Human For Bioassay**

**NIBSC code: 92/512**

**Instructions for use**

(Version 3.0, Dated 22/01/2008)

**1. INTENDED USE**

This consists of a batch of ampoules (coded 92/512) containing highly purified human urinary follicle stimulating hormone obtained from menopausal urine. It was established as the First International Standard for Follicle Stimulating Hormone, Urinary, Human for bioassay by the Expert Committee on Biological Standardization of the World Health Organisation at its forty sixth meeting in 1995 (1). It is intended for use in calibration of preparations of urinary FSH by bioassay.

**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 preparation has been assigned a unitage of 121 International Units per ampoule.

**4. CONTENTS**

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue, after freeze drying, of 1ml of a solution which contained:

- FSH approximately 10 μg
- Human plasma albumin 2mg
- Mannitol 10mg
- Sodium chloride 15.4mM

**5. STORAGE**

Unopened 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**

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**

For practical purposes each ampoule contains the same amount of the same materials. Dissolve all the contents in a known amount of buffer solution. No attempt should be made to weigh portions of the freeze dried powder.

The material has not been sterilised and contains no bacteriostat.

**8. STABILITY**

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.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. For information specific to a particular biological standard, contact standards@nibsc.ac.uk.

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

NIBSC follows the policy of WHO with respect to its reference materials. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

**9. REFERENCES**


**10. 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
11. 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

12. 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.

13. 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>
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<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
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<tr>
<td>Hygroscopic: Yes</td>
<td>Irritant: No</td>
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<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Contains material of human origin. Can react with oxidising materials. Avoid contact with acids and alkalis.</td>
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<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
<td></td>
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<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
<td></td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Suggested First Aid</th>
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<tbody>
<tr>
<td>Inhalation: Seek medical advice</td>
<td></td>
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<tr>
<td>Ingestion: Seek medical advice</td>
<td></td>
</tr>
<tr>
<td>Contact with eyes: Wash with copious amounts of water. Seek medical advice</td>
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<tr>
<td>Contact with skin: Wash thoroughly with water.</td>
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<tr>
<th>Action on Spillage and Method of Disposal</th>
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<tr>
<td>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.</td>
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<tr>
<td>Absorbent materials used to treat spillage should be treated as biological waste.</td>
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</tbody>
</table>

15. 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: 13mg
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_efstandardsrev2004.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.