Non WHO Reference Material
INTERLEUKIN-1 BETA (IL-1B, Human, rDNA derived)
NIBSC code: 86/552
Instructions for use
(Version 5.0, Dated 19/06/2014)

This material is not for in vitro diagnostic use.

1. INTENDED USE
Calibrant for IL-1B assays

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 approx. 0.75 µg IL-1B. The assigned potency is 82,000 international units per ampoule.

4. CONTENTS
Country of origin of biological material: IL-15: USA/SA, HSA:UK.

Each ampoule contains the residue after freeze-drying of 0.5 ml of a solution that contained:

- 0.75 µg IL-1B
- 3.0 mg trehalose
- 1.0 mg human serum albumin
- 0.05 mol/l sodium phosphate buffer
- Dry nitrogen at slightly less than atmospheric pressure.

The material has not been sterilized and contains no bacteriostat.

5. STORAGE
Store at –20°C or below in the dark

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.

For all practical purposes each ampoule contains the same amount of the same materials. Dissolve the total contents in a known amount of suitable buffer solution with carrier protein (free of peptidase), where extensive dilution is required, to minimise loss by surface adsorption.

For economy of use it is recommended that the solution be subdivided into several small containers, which are frozen rapidly to below –40°C and then stored below –40°C in the dark. Repeated freezing and thawing should be avoided.

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. An arbitrary unitage was assigned to this preparation at the time of production without confirmation of long term stability. Evidence from similar materials prepared by an equivalent process indicates that long term stability is likely to be maintained and the material is suitable for shipment at ambient temperature without any effect on the assigned values. Once reconstituted, diluted or aliquotted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES
The evaluation of this reference preparation is described in:

10. ACKNOWLEDGEMENTS
The IL-1B contained in this ampoule was selected from three preparations generously contributed to WHO by the Immunex Corporation, Cistron Biotechno and Biogen SA.

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

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 contents should be taken up with absorbent material wetted with an appropriate virucidal agent. Rinse area with an appropriate virucidal agent 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: 4mg
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. Attached: No