WHO International Standard
INTERLEUKIN-6 (IL-6, Human rDNA derived)
1st International Standard
NIBSC code: 89/548
Instructions for use
(Version 4.0, Dated 19/06/2014)

1. INTENDED USE
Calibrant for IL-6 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. 1.0 µg IL-6. The assigned potency is
100,000 international units (IU) per ampoule.

4. CONTENTS
Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze-drying of 1.0 ml of a
solution that contained:

1.0 µg IL-6 protein produced in CHO cells
3.0 mg trehalose
1.0 mg human serum albumin
0.05 mol/l sodium acetate buffer

The material has not been sterilised and contains no bacteriostat.

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
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.

Side view of ampoule opening device containing an ampoule positioned
ready to open. 'A' is the score mark and 'B' the point of applied pressure.

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 a 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 sub-divided into
several small containers, which are frozen rapidly to below –40°C 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. It is the policy of WHO not to assign an expiry date
to their international reference materials. Accelerated degradation studies
have indicated that this material is suitably stable, when stored at -20°C or
below, for the assigned values to remain valid until the material is
withdrawn or replaced. These studies have also shown that the material
is suitably stable for shipment at ambient temperature without any effect
on the assigned values. Once reconstituted, diluted or aliquoted, 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 WHO International Collaborative Study of IL-6 is cited in the following
paper:
Gaines Das, R.E & Poole, S. (1993). The international standard for

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/jc4tcm/
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
referred to, 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:</td>
<td></td>
</tr>
<tr>
<td>Freeze-dried powder</td>
<td></td>
</tr>
<tr>
<td>Corrosive:</td>
<td>No</td>
</tr>
<tr>
<td>Stable:</td>
<td>Yes</td>
</tr>
<tr>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>Yes</td>
</tr>
<tr>
<td>Irritant:</td>
<td>No</td>
</tr>
<tr>
<td>Flammable:</td>
<td>No</td>
</tr>
<tr>
<td>Handling:</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*: United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
</tr>
<tr>
<td>Net weight: 5mg</td>
</tr>
<tr>
<td>Toxicity Statement: Toxicity not assessed</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable, Attached: No</td>
</tr>
</tbody>
</table>

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_bioolefstandardsrev2004.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.