Non WHO Reference Material
Soluble Tumour Necrosis Factor Receptor Type I
NIBSC code: 96/528
Instructions for use
(Version 6.0, Dated 30/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

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
The exact amount of soluble TNF receptor required to neutralise TNF will be dependent on the TNF concentration used in the assay method employed. Bioassay calibration using an appropriate TNF ligand with a suitable dilution of the sTNF RI should be determined for individual methods. The following information is provided as a guide, based on bioassays performed at NIBSC.

After reconstitution, a 1:5000 dilution of the ampoule contents neutralised the cytotoxic activity of 20 U/ml of the International standard for TNF alpha using KD4-clone 21 cells (1, 2).

4. CONTENTS
Country of origin of biological material: United Kingdom. Each ampoule contains the residue after freeze-drying of 1.0ml of a solution containing:

- Soluble TNF RI, approximately 10 micrograms
- Potassium phosphate buffer
- 1.0mg Trehalose
- 2.0mg Human serum albumin

The sTNF RI protein was expressed in E. coli.

5. STORAGE
For economy of use, it is recommended that the solution be sub-divided into several small aliquots and stored at –40°C or below. Avoid repeated thawing/freezing. 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
No attempt should be made to weigh out any portion of the freeze dried material. Dissolve the total contents of the ampoule in 0.5 ml of sterile distilled water. Rinse the ampoule with about 0.4 ml of sterile distilled water and make the total volume up to 1.0ml with sterile distilled water. The solution will contain soluble TNF RI at a concentration of 10 micrograms/ml. Use carrier protein where extensive dilution is required.

8. STABILITY
This preparation has not been assessed for long term stability, but evidence from similar materials prepared by an equivalent process indicates that long term stability is likely to be maintained and the material is suitably stable for shipment at ambient temperature. 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. REFERENCE

10. ACKNOWLEDGEMENTS
N/A

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/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

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Potters Bar, Hertfordshire, EN6 3QX. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards, UK Official Medicines Control Laboratory

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Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

### Physical and Chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance</td>
<td>Lyophilised powder</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>No</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 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.

### 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.

### 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**: 4.6g
- **Toxicity Statement**: Toxicity not assessed
- **Veterinary certificate or other statement if applicable**: Attached: No