Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

**Non WHO Reference Material**
**Interleukin-2 (Human, rDNA derived)**
**NIBSC code: 86/564**
**Instructions for use**
**(Version 1.0, Dated 29/08/2024)**

This material is not for in vitro diagnostic use

## 1. INTENDED USE

This is a secondary standard for Interleukin-2, calibrated against the 2nd WHO International Standard for IL-2 (86/500). The standard is intended to be used as a secondary standard to calibrate working standards and as a working standard for Interleukin-2.

## 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 assigned potency is 247 International Units per ampoule. Calibrated against the 2nd WHO International Standard for human IL-2 (86/500).

## 4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 0.5 ml of Phosphate Buffered Saline containing:

IL-2, approximately 15.3 ng
2.5 mg trehalose
5.0 mg human serum albumin

The IL-2 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. 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. 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

Dissolve the total contents of the ampoule with 0.5ml of sterile distilled water. Rinse the ampoule with about 0.4ml of sterile phosphate buffered saline (PBS) and make up the total volume to 1.0ml with PBS. This solution will contain IL-2 at a concentration of 247 International Units/ml. Use carrier protein where extensive dilution is required.

## 8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. 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

Gearing, A.J.H and Thorpe, R. (1988) The international standard for human interleukin-2. Calibration by international collaborative study. Journal of Immunological Methods, 114, 3-9.
WHO Collaborative study report for 2nd https://iris.who.int/bitstream/handle/10665/96604/WHO_BS_2012.2194_eng.pdf?sequence=1&isAllowed=y

## 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/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

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

| Physical and Chemical properties | |
|---|---|
| Physical appearance: Freeze-dried powder | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: Yes |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): Contains material of human origin. | |

| 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. |

## 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

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|---|
| **Country of origin for customs purposes*:** United Kingdom<br>* 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:** 0.5042 g |
| **Toxicity Statement:** Non-toxic |
| **Veterinary certificate or other statement** if applicable.<br>**Attached:** No |