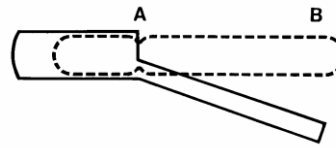




**WHO International Standard
Inhibin A, Human, Recombinant
NIBSC code: 91/624
Instructions for use
(Version 3.0, Dated 25/01/2008)**



1. INTENDED USE

This consists of a batch of ampoules coded 91/624 containing recombinant DNA-derived human inhibin A. It is intended for use as a research standard for bioassay and immunoassay.

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

150000 International Units of rDNA-derived human inhibin A per ampoule.

Uncertainty: the International Unit of 91/624 is assigned without uncertainty. Where required, the uncertainty of the ampoule content of 91/624 may be considered to be the co-efficient of variation of the fill volume, which was determined to be 0.2%.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue, after freeze-drying, of a solution which contained.

Recombinant human inhibin	approx	5µg
Trehalose	"	2mg
Human plasma albumin	"	5mg
TRIS buffer	"	6.06mg
Sodium chloride	"	8.77mg

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

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.

For economy of use the solution can be kept for several months if the solution is subdivided into several small containers, which are frozen rapidly below -70°C and then stored below -30°C in the dark; repeated freezing and thawing should be avoided. If extensive dilutions are prepared, a carrier protein (0.1% w/v) should be added, which is free of peptidase.

The material has not been sterilized and contains no bacteriostat.

8. COLLABORATIVE STUDY AND ASSIGNMENT OF UNITAGE

The preparation of recombinant DNA-derived 32 kDa human inhibin A in ampoules 91/624 was evaluated by 15 laboratories in nine countries for its suitability to serve as an International Standard for human inhibin. On the basis of the results of this Study the preparation in ampoules coded 91/624 was established by the Expert Committee on Biological Standardization of the World Health Organization at its meeting in October 1994 as the International Standard for Inhibin, Recombinant Human with an assigned unitage of 150000 International Units per ampoule (1). Further details can be found in Rose & Gaines Das (2). In any publication arising from use of this material, please ensure that you quote this publication

9. 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.

10. REFERENCES

1. WHO Tech Rep Ser No 626, 1995
2. Rose MP & Gaines Das RE (1996). *Biologicals* 24, 1-18.

11. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to: CBRM for ampouling; participants in the collaborative study and Dr. Rose E. Gaines-Das, Biostatistics, NIBSC, for analysing the data.

12. 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

13. 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

14. 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.

15. MATERIAL SAFETY SHEET

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

Physical and Chemical properties	
Physical appearance: Freeze dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains material of human origin. Can react with oxidising materials. Avoid contact with acids and alkalis	
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.	

16. 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.

17. 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: 22mg
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_standardsrev2004.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.