NIBSC Confidence in Biological Medicines

Non WHO Reference Material Long-Acting Thyroid Stimulator (LATS) NIBSC code: 65/122 Instructions for use (Version 4.0, Dated 28/03/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The MRC Research Standard B for Long-acting Thyroid Stimulator (LATS-B) is a serum sample from a single patient exhibiting LATS activity. The preparation replaced the earlier MRC LATS-A standard, and provided approximate continuity of unitage. Each ampoule of MRC Research Standard B contains 30-40% of the activity present in one ampoule of MRC Research Standard A (described by Dorrington and Munro, 1964). The suggested dosage of Research Standard B (which may need to be adjusted to suit the sensitivity of individual mouse strains) is one, one half and one quarter of an ampoule per mouse, injected intravenously in 0.5 ml; i.e. 0.015, 0.0075 and 0.00375 units per mouse.

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.

The preparation contains human serum and human serum albumin. The serum donor was subsequently tested and found to be free of either HIV antibodies or HepBSAg. The preparation has been tested and found negative for HBsAg, Anti-HIV, Anti-HCV and HCV RNA by PCR. 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 is defined to contain 0.015 units of LATS activity.

4. CONTENTS

Country of origin of biological material: United Kingdom. Each ampoule contains the freeze-dried residue of approximately 10 mg of human serum albumin and 0.0385 mls of LATS-active human serum.

5. STORAGE

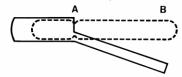
Unopened ampoules should be stored at -20°C

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 quantity of long-acting thyroid stimulator. The entire content of each ampoule should be completely dissolved in an accurately measured amount of diluent. No attempt should be made to weigh out portions of the freeze dried powder. Suitable diluents are PBS, saline and most assay buffers. If the contents are to be diluted extensively, the addition of 0.05-0.1% protein (HSA or BSA) is recommended to minimise adsorption. The use of water to reconstitute ampoule contents is not recommended. The material has not been sterilized and the ampoules contain no bacteriostat.

8. STABILITY

NIBSC follows the policy of WHO with respect to its reference materials. 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. 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. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Dorrington and Munro (1964). J. Endocrinol., 31, 21.

10. ACKNOWLEDGEMENTS

Grateful acknowledgements are due to Professor D.S Munro for kindly arranging donation of the serum.

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

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



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

(LC) NO 1272/2008. Not applicable of flot classified			
Physical and Chemical properties			
Physical	Corrosive:	No	
appearance: Freeze			
dried powder			
Stable:	Oxidising:	No	
Yes			
Hygroscopic:	Irritant:	No	
Yes			
Flammable:	Handling:	See caution, Section 2	
No			
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			
	ash with copious ar	mounts of water. Seek	
medical advice			
Contact with skin: W	ash thoroughly with	water.	
Action on Spillage and Method of Disposal			
Spillage of ampoule contents should be taken up with absorbent			
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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

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: 10mg

Toxicity Statement: Non-toxic

Veterinary certificate or other statement if applicable.

Attached: No

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