Medicines & Healthcare products Regulatory Agency



Non WHO Reference Material Neisseria meningitidis serogroup C polysaccharide NIBSC code 07/318 NIBSC code: 07/318

Instructions for use (Version 3.0, Dated 30/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This material is intended as a coating antigen used in standardised ELISA to detect anti-meningococcal serogroup C antibody levels in human serum.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is not of human or bovine origin. 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

When reconstituted in 1ml of water vial contents are approximately 1mg/ml meningococcal serogroup C polysaccharide.

4. CONTENTS

Country of origin of biological material: United Kingdom.

The contents of the ampoule should be rehydrated with sterile water to yield a stock solution of 1.0mg/ml. Assigned content of vial valid at time of manufacture – no information on long term stability.

5. STORAGE

The contents of the ampoule should be rehydrated with sterile water to yield a stock solution of 1.0 mg/ml. Store in aliquots at -20° C and avoid excessive freeze-thawing.

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

The preparation can be used for coating ELISA plates together with methylated human serum albumin (NIBSC reagent code 12/176).

8. STABILITY

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

No information is available on long term stability of the material. Stability of the reconstituted material should be determined by the user. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

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9. REFERENCES

Gheesling et al 1994 J. Clin. Microbiol. 32, 1475-1482

10. ACKNOWLEDGEMENTS

This serogroup C meningococcal polysaccharide was kindly provided to NIBSC by GlaxoSmithKline for distribution as a standard reagent.

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

Physical and Chemical properties		
Physical appearance: Freeze dried powder	Corrosive:	No
Stable: Yes	Oxidising:	No
Hygroscopic: No	Irritant:	No
Flammable: No	Handling:	See caution, Section 2
Other (specify): No special precautions		
Toxicological properties		
Effects of inhalation: Not established, avoid inhalation		ablished, avoid inhalation
Effects of ingestion: Not established		
Effects of skin absorption: Not established, avoid contact with skin		
Suggested First Aid		
Inhalation:	eek medical advice	
Ingestion: S	eek medical advice	
Contact with eyes: Wash with copious amounts of water. Seek medical advice		
Contact with skin: \	ash 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

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: 4.5g. Toxicity Statement: Toxicity not assessed Veterinary certificate or other statement if applicable. Attached: No

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