



**WHO International Standard**  
**1st WHO International Standard for Meningococcal Serogroup C polysaccharide**  
**NIBSC code: 08/214**  
**Instructions for use**  
**(Version 5.0, Dated 05/03/2021)**

### 1. INTENDED USE

The freeze-dried preparation of *Neisseria meningitidis* serogroup C capsular polysaccharide (MenC), provided by GlaxoSmithKline Biologicals (Rixensart, Belgium) was prepared in ampoules (2008) at the Centre for Biological Reference Materials (CBRM, NIBSC) and coded 08/214. A collaborative study was carried out on this material by 12 laboratories in 2011 to determine the MenC content in SI units based on the Resorcinol assay, and to evaluate its suitability for use as a standard for quantification of MenC in final fills and bulks of MenC vaccines (including Resorcinol, DMAB and HPAEC-PAD assays). The content of the ampoule was determined using sialic acid standards in the Resorcinol assay. The material is suitable for use in the quantification of MenC content by other assays, although users should verify its suitability and determine the uncertainty of measurement in their specific assay. NIBSC, Potters Bar, UK is the custodian and distributor of this material.

### 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

The 1st WHO International Standard for Meningococcal Serogroup C Polysaccharide, 08/214, has a content of  $1.192 \pm 0.192$  mg MenC PS/ampoule, as determined by the Resorcinol assay. The residue weight of the MenC PS = 351.67g/mol (95% O-acetylated)  
Conversion factor of MenC to sialic acid or NANA:  
 $1.137\text{g MenC} = 1\text{g sialic acid or NANA (with 95\% O-acetylation)}$   
 $(351.67 \text{ (MenC residue weight)} / 309.27 \text{ (Free NANA weight)})$

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
Each ampoule contains the freeze-dried powder of 1 ml of MenC PS in 0.56 mg/ml NaCl. Each ampoule contains 1.5 mg of dry material as estimated by weighing after freeze drying, with a moisture content of approximately 1.87%.

### 5. STORAGE

Ampoules should be stored at or below  $-20^{\circ}\text{C}$ .  
**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 manufacturer's 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

Re-suspend the contents of the ampoule in 1ml of distilled water. To ensure complete solubilisation of the material allow to dissolve for at least 2 hours at room temperature or 12 hours at  $4^{\circ}\text{C}$  prior to use. The reconstituted material should be aliquoted and frozen at or below  $-20^{\circ}\text{C}$ . The standard can be used directly as a reference in the physico-chemical assays or for calibrating of secondary standards.

This MenC standard is 95% O-acetylated, and is appropriate for the measurement of the MenC content of material that has a similar O-acetylation level. If the standard is to be used for measuring the MenC content of a non-O-acetylated sample, or one with lower % O-acetylation, a correction will have to be used, following the calculation of the formula weight as listed in Annex 2 of the ECBS report. For a sample with 70% O-acetylation, for example, which has a residue weight of 341.17, the MenC content measured with the IS will need to be corrected by multiplying the measured ug MenC PS/ml content measured by 0.97 ( $341.17 / 351.67$ ). For a non-O-acetylated MenC PS, the measured ug MenC PS/ml content will need to be multiplied by 0.89 ( $311.77/351.67$ ).

### 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.

The freeze-dried standard has been shown to be stable for 10 years at  $-20^{\circ}\text{C}$ .

Reconstituted standard can be kept at 1 mg/ml for 6 months at  $-20^{\circ}\text{C}$ . Accelerated degradation studies revealed the freeze dried standard to be stable up to one year at  $37^{\circ}\text{C}$ .

### 9. REFERENCES

Caroline Vipond, Barbara Mulloy, Peter Rigsby, Barbara Bolgiano and the MenC IS Working Group. Evaluation of a candidate International Standard for Meningococcal Serogroup C polysaccharide. WHO/BS/2011.2169

Vipond C, Mulloy B, Rigsby P, et al. Evaluation of a candidate International Standard for Meningococcal Group C polysaccharide. *Biologicals* 2012;40:353-63.

### 10. ACKNOWLEDGEMENTS

The MenC IS working group for full details see report WHO/BS/2011.2169

### 11. FURTHER INFORMATION

Further information can be obtained as follows;  
This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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 white powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): No special handling precautions	
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](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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 5g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> 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\\_efstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biol_efstandardsrev2004.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.