WHO International Standard
2nd International Reference Reagent 1994 Poliomyelitis Vaccine
(Inactivated)
NIBSC code: 91/574
Instructions for use
(Version 3.01, Dated 11/03/2008)

1. INTENDED USE
Preparation 91/574 was established by the WHO Expert Committee on Biological Standardisation in 1994 as the 2nd International Reference Reagent for poliomyelitis vaccine (inactivated) (WHO, 1995). It was shown to be suitable for determination of antigenic content and immunogenicity of inactivated poliovirus vaccines by in vitro and in vivo assays respectively (Wood et al, 1995; Wood and Heath, 1995).

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

The material is of bovine origin. The material is certified to be obtained from animals taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE & which has not been fed rations containing ruminant derived protein during that period. 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
430 D antigen units per ml for type 1 antigen
95 D Antigen units per ml for type 2 antigen
285 D antigen units per ml for type 3 antigen

4. CONTENTS
Country of origin of biological material: The Netherlands.
The preparation is a trivalent blend of formaldehyde-inactivated monovalent pools of poliovirus type 1 (Mahoney), poliovirus type 2 (MEF-1) and poliovirus type 3 (Saukett). A nominal volume of ~0.8 ml 91/574 is filled in each ampoule. To remove the reagent from the ampoule it is necessary to use some form of transfer pipette rather than a volumetric pipette. The contents of the ampoules should not be assumed to be sterile. A portion of the same trivalent blend was also donated by the manufacturer to the European Pharmacopoeia Commission. This was separately filled and evaluated for use in in vitro assays in a separate collaborative study. The European Pharmacopoeia Commission established this material as the "Inactivated poliovaccine type 1-2-3, European Pharmacopoeia Biological Reference Preparation Batch No. 1". The potency assigned to the WHO and EPC reference materials is identical.

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
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 manufacturers instructions provided with the ampoule breaker.

7. USE OF MATERIAL
The 2nd International Reference Reagent should be used to calibrate laboratory reference reagents. This material is supplied for use in its final form and must not be further diluted other than as required for individual assay procedures. Each ampoule/vial is intended to be used only once. The vial should be opened as directed in section 6.

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

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

10. ACKNOWLEDGEMENTS

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

<table>
<thead>
<tr>
<th>Physical and Chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance:</td>
</tr>
<tr>
<td>Liquid</td>
</tr>
<tr>
<td>Stable</td>
</tr>
<tr>
<td>Hygroscopic</td>
</tr>
<tr>
<td>Flammable</td>
</tr>
<tr>
<td>Handling/See caution</td>
</tr>
</tbody>
</table>

Flammable: No
Irritating: No
Sensitising: No
Toxic: No
Explosive: No
Explosive at high pressures: No
Corrosive: No
Point of ignition: Not applicable
Flash point: Not applicable
Explosion limits: Not applicable
Reactivity: Not applicable
Other (specify):

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 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*: The Netherlands
* 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: 0.510 g

Toxicity Statement: Toxicity not assessed

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_InternationalBloodStandardsrsv2004.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.