WHO International Standard
1st International Standard for Sabin monovalent Polio vaccine
  type 3
NIBSC code: 16/202
Instructions for use
(Version 3.0, Dated 11/09/2018)

1. INTENDED USE
This International Standard is the primary biological standard for the
potency assay (TCID50) for live attenuated Type 3 Polio vaccines.

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
Type 3 Sabin monovalent Polio vaccine : 6.66 log10 TCID50/ml

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each vial contains 0.5ml of liquid containing
Sabin Poliovirus type 3
2% bovine albumin
Minimal essential medium

5. STORAGE
Unopened vial should be stored at -20°C or colder. Repeat freeze
thawing should be avoided.

6. DIRECTIONS FOR OPENING
Vials have a screw cap; an internal stopper may also be present. The
cap should be removed by turning anti-clockwise. Care should be
taken to prevent loss of the contents. Please note: If a stopper is
present on removal of the cap, the stopper should remain in the vial or
be removed with the cap.
The vial contains a V insert in which the material is contained. Please
take care when opening and mixing the contents.

7. USE OF MATERIAL
The material is supplied in its final form and must not be further diluted
other than for the assay procedure.

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.

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

9. REFERENCES
Collaborative Study Report WHO/BS/2017.2313

10. ACKNOWLEDGEMENTS
The Collaborative study participants

11. FURTHER INFORMATION
Further information can be obtained as follows:
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
Derivation of International Units:
http://www.bipm.org/en/committees/jc/jctlm/
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
referred to, 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>Pink liquid</td>
</tr>
<tr>
<td>Stable: Yes</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
</tr>
<tr>
<td>Flammable: No</td>
</tr>
<tr>
<td>Other (specify): Does not contain material of human origin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
</tr>
<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Suggested First Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation: Seek medical advice</td>
</tr>
<tr>
<td>Ingestion: Seek medical advice</td>
</tr>
<tr>
<td>Contact with eyes: Wash with copious amounts of water. Seek medical advice</td>
</tr>
<tr>
<td>Contact with skin: Wash thoroughly with water.</td>
</tr>
</tbody>
</table>

Action on Spillage and Method of Disposal
Spillage of ampoule contents should be taken up with absorbent material wetc 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
16. INFORMATION FOR CUSTOMS USE ONLY

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>* 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.</td>
<td></td>
</tr>
<tr>
<td>Net weight:</td>
<td>0.5g</td>
</tr>
<tr>
<td>Toxicity Statement:</td>
<td>Non-toxic</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable.</td>
<td>Attached: No</td>
</tr>
</tbody>
</table>

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_biological_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.