WHO International Standard
Transforming Growth Factor - Beta 3 (Human rDNA derived).
NIBSC code: 09/234
Instructions for use
(Version 3.0, Dated 23/04/2013)

1. INTENDED USE
This preparation coded 09/234 is the primary biological standard for
Transforming Growth Factor - Beta 3 (TGF-β3).

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. 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 assigned potency agreed on the basis of an International
Collaborative Study is 19,000 International Units of biological activity per
ampoule.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1.0 ml of 0.1%
acetic acid that contained:

TGF-β3, approximately 1.0 microgram
10mg human serum albumin

The TGF-β3 protein was expressed in E.coli.

5. STORAGE
For economy of use, it is recommended that the solution be sub divided
into several small aliquots and stored at -40ºC or below. Avoid repeated
thawing/freezing. Unopened ampoules should be stored at -20ºC.
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.

Tap the ampoule gently to collect the material at the bottom (labelled)
end. Ensure that the disposable ampoule safety breaker provided is
pushed down on the stem of the ampoule and against the shoulder of
the ampoule body. Hold the body of the ampoule in one hand and the
disposable ampoule breaker covering the ampoule stem between the
thumb and first finger of the other hand. Apply a bending force to open
the ampoule at the coloured stress point, primarily using the hand
holding the plastic collar.

Care should be taken to avoid cuts and projectile glass fragments that
might enter the eyes, for example, by the use of suitable gloves and an
eye shield. Take care that no material is lost from the ampoule and no
glass falls into the ampoule. Within the ampoule is dry nitrogen gas at
slightly less than atmospheric pressure. A new disposable ampoule
breaker is provided with each DIN ampoule.

7. USE OF MATERIAL
No attempt should be made to weigh out any portion of the freeze-dried
material prior to reconstitution. Dissolve the total contents of the ampoule
in 1.0ml of 0.1% acetic acid. The solution will contain TGF-β3 at a
concentration of 19,000 IU/ml . Use carrier protein where extensive dilution is
required.

8. STABILITY
Reference materials are held at NIBSC within assured, temperature-
controlled storage facilities and they should be stored on receipt as
indicated on the label. It is the policy of WHO not to assign an expiry date
to their international reference materials. Accelerated degradation studies
have indicated that this material is suitably stable, when stored at -20ºC
or below, for the assigned values to remain valid until the material is
withdrawn or replaced. These studies have also shown that the material
is suitably stable for shipment at ambient temperature without any effect
on the assigned values. 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
This standard was produced under WHO guidelines cited in the WHO

Report of a Collaborative study for Proposed 1st International
Standard for Transforming Growth Factor-β3 (TGF-β3).
WHO/BS/2011.2163
http://www.who.int/biologicals/expert_committee/BS2011.2163TGF_beta
3.pdf

The 1st International standard for transforming growth factor-β3 (TGF-β3)
Journal of Immunological Methods 380 (2012) 1–9

10. ACKNOWLEDGEMENTS
We are thankful to the manufacturers for their generous donations of TGF-
β3 preparations used in the collaborative study, and to the study participants
for their contributions in evaluating the preparations.

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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Freeze dried powder</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: No</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
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<tr>
<td>Other (specify): Contains material of human origin</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
</tr>
<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
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<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
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</tbody>
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<thead>
<tr>
<th>Suggested First Aid</th>
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<tbody>
<tr>
<td>Inhalation: Seek medical advice</td>
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<tr>
<td>Ingestion: Seek medical advice</td>
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<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>
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</table>

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<tr>
<th>Action on Spillage and Method of Disposal</th>
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<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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 |
| 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_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.