



**Working Standard  
Diphtheria toxin liquid  
NIBSC code: 12/282  
Instructions for use  
(Version 3.0, Dated 28/11/2013)**

**This material is not for in vitro diagnostic use.**

**1. INTENDED USE**

This working standard is intended for use in assays (in vitro and in vivo) to measure the potency of diphtheria antitoxin. It can also be used as a positive control in toxicity assays.

**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**

No units are formally assigned to this standard. It has a nominal labelled Lf content of 1 Lf/ml.

Based on results obtained from in-house testing at NIBSC, the minimum cytotoxic dose in Vero cells is approximately 4 µLf/ml and the minimum reactive dose in guinea pigs (by intradermal challenge) is approximately 12.5 µLf/dose (0.2 ml dose). Therefore the in vivo specific toxicity is approximately 80,000 Lr/Lf.

**4. CONTENTS**

Country of origin of biological material: Japan.  
Each ampoule contains 1 ml of diphtheria toxin in 0.75% peptone buffer.

**5. STORAGE**

Unopened ampoules should be stored at +4°C. Do not freeze.

**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**

The dose of toxin to be used should be determined in each individual laboratory according to the specific intended use.

**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.

Results from accelerated degradation studies (using the Vero cell assay) suggest that this material will undergo negligible loss of

biological activity (approximately 1% per year) when stored at the recommended storage temperature of +4°C.

Once opened, it is recommended that the toxin should be used on the day of opening and not stored for future use unless supported by appropriate stability data.

**9. REFERENCES**

N/A

**10. ACKNOWLEDGEMENTS**

N/A

**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:<br>Clear yellowish liquid | Corrosive: No                    |
| Stable: Yes                                    | Oxidising: No                    |
| Hygroscopic: No                                | Irritant: Unknown                |
| Flammable: No                                  | Handling: See caution, Section 2 |



|  |  |
|--|--|
| Other (specify):   | May be fatal if toxin enters bloodstream (LD50 estimated at 0.1 µg/Kg).                          |
|  | Material should be shipped as Packing Group III (UN3172).  |
| <b>Toxicological properties</b>  |  |
| Effects of inhalation:   | Not known  |
| Effects of ingestion:  | Not known  |
| Effects of skin absorption:  | Not known  |
| <b>Suggested First Aid</b>   |  |
| Inhalation:  | Remove to fresh air and seek medical advice if unwell or breathing becomes difficult             |
| Ingestion:   | Wash out mouth with water and administer fresh water if person is conscious; seek medical advice |
| Contact with eyes:   | Flush with copious amounts of water for at least 15 min. Seek medical advice                     |
| Contact with skin:   | Remove contaminated clothing and shoes; wash thoroughly with soap and water.                     |
| <b>Action on Spillage and Method of Disposal</b>   |  |
| Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant (such as 10% chlorox). Rinse area with an appropriate disinfectant followed by water.<br>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

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| <b>Country of origin for customs purposes*:</b> Japan<br>* 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> 1 g   |
| <b>Toxicity Statement:</b> Toxic   |
| <b>Veterinary certificate or other statement</b> if applicable.<br><b>Attached:</b> No   |