



**Non WHO Reference Material  
Aspergillus Fumigatus Extract  
NIBSC code: 78/575  
Instructions for use  
(Version 6.0, Dated 24/07/2013)**

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

#### 1. INTENDED USE

This is comprised of a batch of ampoules coded 78/575. Each ampoule contains the residue after freeze drying of approximately 0.6ml of an extract of *Aspergillus fumigatus* Extract.

#### 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 unitage has been assigned to this material.

#### 4. CONTENTS

Country of origin of biological material: United Kingdom.

The reagent consists of a freeze dried extract prepared from 2.4 litres of<sup>1</sup>. *Aspergillus fumigatus* extract. The extract was made from a 14 day culture of *Aspergillus fumigatus* strain I355, containing very few spores, using a culture medium as described in the double dialysis technique of<sup>2</sup>. Edwards<sup>(3)</sup>. The culture filtrate was concentrated by air dialysis and dialysed against running water and the mycelium was disrupted in a Hughes press by aqueous extraction and the products mixed.

At NIBSC the extract was distributed in 0.6ml volumes at room<sup>3</sup>. temperature into approximately 4000 ampoules, coded 78/575. The mean weight of liquid contents of 68 checkweight ampoules taken at intervals<sup>4</sup>. during the fill was 0.6043gm +/- 0.71%. The contents of the ampoules were then freeze dried and secondarily desiccated under the conditions normally used for international biological standards<sup>(4)</sup>. The mean dry weight was 2.42mg (n=6) and moisture content was 0.63% (n=3).

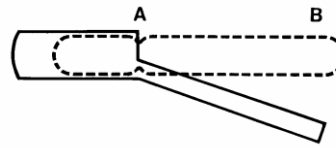
#### 5. STORAGE

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

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

#### 7. USE OF MATERIAL

**No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution**

The total contents of the ampoule should be reconstituted with 0.6ml distilled water and dissolved gently by swirling to avoid froth. The reconstituted reagent should be used as soon as possible after reconstitution.

The reagent has been studied and found to have activity in RAST inhibition, and CIE and to give characteristic profiles in HPLC and isoelectric focusing<sup>(1,2)</sup>

#### 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.

Accelerated degradation studies have shown freeze dried allergen extracts stored in unopened ampoules at -20°C to be extremely stable over a number of years. .

#### 9. REFERENCES

Brighton, W.D, Topping, M.D., Seagrott, V. report of a collaborative trial of 9 extracts of *Aspergillus fumigatus*. NIBSC unpublished report (1977).

Ford, A. Characterisation of Moulds in Purificacion y Estandarizacion de Alergenos. Editors: J.A. Ojeda Casas, M. Martin Esteban, C. Pascual Marcos. Dpto. De Alergia de Abello, S.A. Madrid, 1982. pp 43-53.

Edwards, J.H. The double dialysis method of producing farmer's lung antigens. J. Lab. Clin. Med. **79**: 683-688 (1972)

Campbell, P.J., International Biological Standards and Reference Preparations. II. Procedures used for the production of biological standards and reference preparations. J. Biol. Stand. **2**: 259-267 (1974).

#### 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: Freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of biological origin
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> 0.01g
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable.
<b>Attached:</b> No