



**WHO International Standard
Dog (*Canis familiaris*) Hair/Dander Extract
NIBSC code: 84/685
Instructions for use
(Version 5.0, Dated 24/07/2013)**

1. INTENDED USE

The first International Standard for Dog (*Canis familiaris*) extract consists of ampoules coded 84/685, containing freeze-dried aliquots of an extract of dog dander. This preparation was established as the 1st International Standard for Dog (*Canis familiaris*) Hair/Dander extract by the Expert Committee on Biological Standardization of the World Health Organization in 1986 and a potency of 100,000 International Units has been assigned to each ampoule.

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

A potency of 100,000 International Units has been assigned to each ampoule

4. CONTENTS

Country of origin of biological material: United Kingdom.

Biological Activity.

The 1st International Standard was assessed together with 3 other freeze-dried preparations of dog hair/dander extract in an international collaborative study involving 15 laboratories in 9 countries⁽¹⁾. Examination of the activity of these preparations was by RAST inhibition, quantitative in immunoelectrophoresis (CIE/CRIE and rockets), isoelectric focusing, quantitative skin testing, histamine release and other methods. The proposed standard was found to have biological activity and to be suitable for use as a standard. The following antigens were identified: Dog Ag 3, 13 (now designated as Can f I⁽²⁾) and dog serum albumin. Each ampoule was assigned 100,000 International Units of potency. Subsequent studies have shown that 1000 IU correspond to approximately 1 µg of Can f I⁽³⁾.

Bulk Material

The first International Standard for Dog (*Canis familiaris*) Hair/Dander Extract consists of a freeze-dried extract prepared from an equal mixture by weight of dander from Alsatian and Poodle breeds. The extract was made at 1% wt/vol in 0.125M ammonium bicarbonate buffer at +4°C, clarified and ultra-filtered in a hollow-fibre filter with a cut-off of 2,000 daltons. The extract was freeze-dried after processing.

Distribution into ampoules

In 1984 the bulk freeze-dried material was reconstituted with sterile distilled water to give a protein concentration of 0.6mg.ml⁻¹, the pH was adjusted to between 7 and 8, sterile filtered and distributed at room temperature into 4,000 ampoules, coded 84/685. The mean weight of liquid content of 65 checkweight ampoules taken at intervals during the fill was 1.00405gm ± 0.15%. The contents of the ampoules were then freeze-dried under the conditions normally used for international biological standards⁽⁴⁾. The mean dry weight was 2.36mg (n=6) and the moisture content was 0.21% (n=3).

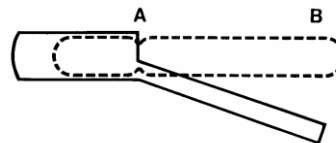
5. STORAGE

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 0.5ml of distilled water and dissolved by gently swirling to avoid froth. The reconstituted reagent should be used as soon as possible after reconstitution

8. STABILITY

Accelerated degradation studies have shown that the 1st International Standard is very stable in unopened ampoules stored at -20°C. The predicted loss of activity is <0.1% of the original potency per year when stored at that temperature.

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

1. Larsen, IN., Ford, A., Gjesing, B., Levy, D., Petrunov, B., Silvestri, L. & Lowenstein, H. The Collaborative Study of the International Standard of Dog (*Canis domesticus*) Hair/Dander Extract. *J. Allergy Clin. Immunol.* 82:318-330 (1988).
2. Schou, C, Svendsen, UG, & Lowenstein, H. Purification and characterization of the major dog allergen *Can f I*. *Clin. Exp. Allergy* 21:321-328 (1991).
3. Schou, C, Hansen, G.N., Lintner, T & Lowenstein, H. Assay for the major dog allergen, *Can f I* : Investigation of house dust samples and commercial dog extracts. *J. Allergy Clin. Immunol.* 88:847-853 (1991).
4. Campbell, PJ International Biological Standards and Reference Preparations. H. Procedures used for the production of biological standards and reference preparations. *J. Biol. Stand.* 2:259-267 (1974).

10. ACKNOWLEDGEMENTS

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Columbus, Ohio, USA; Allergy Laboratories, Oklahoma City, Okla., USA, ALK Laboratories, Copenhagen, Denmark; Antigen Laboratories, Liberty, Mo., USA, Beecham, Betchworth, Surrey, UK; Berkeley Biologicals, Berkeley, CaR, USA; Center Laboratories, Port Washington, N.Y., USA; Diephuis Pharmacia, Groningen, The Netherlands; Greer Laboratories; Lenoir, N.C., USA, HAL Allergen Laboratories, Haarlem, The Netherlands; Hollister-Stier, Spokane, Wash., USA, Laboratories Hamon, Montreal, Canada; Lofarma, Milano, Italy; Meridian Bio-Medical, Denver, Colo., USA, NYCO, Oslo, Norway; Omega Laboratories, Montreal, Canada; Pharmacia, Uppsala, Sweden and Stallergenes Laboratories, Pads, France

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

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):	<i>Contains material of biological origin</i>
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 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
* 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: 0.01g
Toxicity Statement: Non-toxic
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.