WHO International Standard
INTERFERON ALPHA 1 (D), (Human rDNA-derived)
NIBSC code: 83/514
Instructions for use
(Version 6.0, Dated 12/04/2013)

1. INTENDED USE
This material is the 1st WHO International Standard for IFN Alpha 1 (D)
It is for use as the primary biological reference standard for IFN Alpha 1 (D)

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
8000 International Units (IU) per ampoule.

4. CONTENTS
Country of origin of biological material: United Kingdom.
Each ampoule contains a freeze-dried residue comprising, under an
atmosphere of nitrogen:
IFN alpha 1 (D) approximately 1.12 micrograms
2mg human serum albumin
6-salt phosphate buffered saline

The IFN alpha 1 (D) protein was expressed in E. coli.

5. STORAGE
For economy of use, it is recommended that the final solution or dilutions
thereof be sub-divided into several small aliquots and stored at -20ºC 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
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.

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 0.5ml of sterile distilled water
and transfer to a sterile container. Rinse the ampoule with 0.4ml of sterile
distilled water and add to the first solution. Make up the total volume to 1.0ml
with sterile distilled water. The final solution will contain IFN alpha 1 (D) at a
concentration of 8000 International Units per ml. Use carrier protein where
dilution is required. It is recommended that initial dilutions, i.e. 1:10; 1:100,
are either made in cell culture medium containing - 5% v/v –10% v/v calf
serum or in phosphate-buffered saline, pH 7.0 – 7.4, containing 0.3% v/v
bovine casein to prevent adsorption of IFN to container surfaces.

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
1. Interferon standards: a memorandum (report to the World Health
Organisation on a workshop on interferon standards, September 1978).
Handbook of Experimental Pharmacology, vol 71. Berlin, Springer-Velag,
of a WHO Scientific Group).
5. Grossberg, S.E & Galasso, G.J Problems in standardisation: an
interferon standards committee report. In: DeMaeyer, E. et al. ed. The
biology of the interferon system. Amsterdam, Elsevier/North Holland
Biomedical Press, 1981, pp19-22
Establishment of new and replacement World Health Organisation
International Biological Standards for human interferon alpha and omega,
Journal of Immunological Methods, 257, 17-33.
7. This standard was produced under WHO guidelines cited in the WHO

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG, T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

Page 1 of 2
10. ACKNOWLEDGEMENTS
N/A

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/jcglm/
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: White Powder</td>
<td>Corrosive: No</td>
</tr>
<tr>
<td>Stable: Yes</td>
<td>Oxidising: No</td>
</tr>
<tr>
<td>Hygroscopic: Yes</td>
<td>Irritant: No</td>
</tr>
<tr>
<td>Flammable: No</td>
<td>Handling: See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify): Contains material of human origin</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicological properties</th>
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<tbody>
<tr>
<td>Effects of inhalation: Not established, avoid inhalation</td>
<td></td>
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<tr>
<td>Effects of ingestion: Not established, avoid ingestion</td>
<td></td>
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<tr>
<td>Effects of skin absorption: Not established, avoid contact with skin</td>
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<table>
<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>
<td></td>
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<tr>
<td>Contact with eyes: Wash with copious amounts of water. Seek medical advice</td>
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<tr>
<td>Contact with skin: Wash thoroughly with water.</td>
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<thead>
<tr>
<th>Action on Spillage and Method of Disposal</th>
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<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>
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</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

<table>
<thead>
<tr>
<th>Country of origin for customs purposes*: United Kingdom</th>
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<tbody>
<tr>
<td>Net weight: 1g</td>
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<tr>
<td>Toxicity Statement: Toxicity not assessed</td>
</tr>
<tr>
<td>Veterinary certificate or other statement if applicable. 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_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.