



**WHO International Standard
Streptokinase -3rd International Standard 2001
NIBSC code: 00/464
Instructions for use
(Version 4.0, Dated 26/03/2008)**

1. INTENDED USE

Streptokinase is a plasminogen activator derived from *Streptococcus haemolyticus*. Streptokinase possesses no proteolytic or esterolytic activity itself and must form a 1:1 complex with plasminogen resulting in a plasminogen activator complex able to generate plasmin from free plasminogen. The plasmin generated in this way is able to digest fibrin and hence dissolve blood clots.

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

Bulk Streptokinase was dissolved in 4.5 L of 10 mM Hepes buffer, pH 7.4, containing 0.15 M NaCl and 5 mg/ml Human Albumin. The final concentration of Streptokinase was approximately 10 micrograms/ml. This solution was dispensed in 1 ml aliquots into ampoules before freeze drying and secondary desiccation. The mean weight of solution dispensed into ampoules before drying was 1.006g (% cv = 0.06). The mean residual moisture remaining after secondary desiccation was 0.15 %. The contents of the ampoules should be reconstituted in 1 ml of distilled water. The activity of the solution thus formed was determined in an International Collaborative Study involving 16 laboratories from 12 countries and was found to be 1030 International Units (IU) per ampoule. The Standard was established by the Expert Committee on Biological Standardisation of the World Health Organisation (WHO) in November 2001 and designated the 3rd International Standard for Streptokinase code 00/464.

4. CONTENTS

Country of origin of biological material: United Kingdom.

5. STORAGE

Unopened ampoules should be stored in the dark at or below -20°C.
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. 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

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

Ampoules are shipped at ambient temperatures and should be stored unopened in the dark at -20 °C upon arrival. To reconstitute, allow the

ampoule to warm to room temperature and ensure that the lyophilised material is all in the base of the ampoule before carefully snapping off the top of the ampoule. The contents should be reconstituted using 1 ml of distilled water and mixed gently to produce a clear, colourless solution. This solution should be stored on ice and used as soon as possible by dilution into appropriate assay buffer under conditions defined for your assay. Following reconstitution, the activity is stable for several hours when the solution is maintained on ice. However, the potency is not guaranteed after further freezing and thawing of the reconstituted solution.

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.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

10. ACKNOWLEDGEMENTS

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: Yes	Irritant:	No
Flammable: No	Handling:	See caution, Section 2
Other (specify):	Contains material of human 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 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: 10mg
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_biologicalstandardsrev2004.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.