



**Non WHO Reference Material  
IFU for NIBSC8  
NIBSC code: IPSC/001 & IPSC/002  
Instructions for use  
(Version 6.0, Dated 18/08/2021)**

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

**1. INTENDED USE**

Research only.

**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**

1x10E6 cells/vial.

**4. CONTENTS**

Country of origin of biological material: United Kingdom.  
Human pluripotent stem cell line provided as cryopreserved cultures in 2ml or 5ml plastic cryovials. Each vial contains human pluripotent stem cells cryopreserved in media containing bovine serum or a serum replacement and cryoprotectant (DMSO and/or ethylene glycol).

**5. STORAGE**

Storage in the vapour phase of liquid nitrogen – vials shipped on dry ice at -79°C or in liquid nitrogen Dry Shippers below -150°C

**6. DIRECTIONS FOR OPENING**

Care should be taken to prevent loss of the contents. Cryovials have a screw cap. The cap should be removed by turning anti-clockwise. Care should be taken on removal of cap to prevent the contents escaping

**7. USE OF MATERIAL**

This material is supplied in its final format and should not be further diluted other than as required for the potency assay.

**8. STABILITY**

Cryopreserved cells are held within assured, temperature-controlled storage facilities in the vapour phase of liquid nitrogen. It is therefore, the policy of UKSCB not to assign an expiry date to their human pluripotent stem cell lines.  
Storage on receipt should be as indicated on the label

Users who have data supporting any deterioration in the characteristics of any cell line are encouraged to contact NIBSC.

**9. REFERENCES**

In any circumstance where the recipient publishes a reference to NIBSC materials, it is important that the title of the preparation and any NIBSC/UKSCB code number, and the name and address of NIBSC/UKSCB are cited correctly.

**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/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

**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: Frozen Liquid (Colourless or yellow)	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): N/A	
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
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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.
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#### 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> N/A
<b>Toxicity Statement:</b> Toxic
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> 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](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.