Medicines & Healthcare products Regulatory Agency



WHO International Standard Opacity 5IRP NIBSC code: 76/522 Instructions for use (Version 7.0, Dated 25/03/2024)

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1. INTENDED USE

The 5th IRP of Opacity is a plastic rod for visual estimations of the opacity of bacterial suspensions.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

Not human or bovine source material

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

10 International Units of opacity

The results of the international collaborative study showed that the opacity of the rod was approximately 10 per cent more than the Third International Opacity Reference Preparation. In terms of this reference preparation therefore, each rod and any suspension of bacteria matching it has approximately 11.0 International Units of Opacity. However, at a meeting of the Expert Committee on Biological Standardization held in Geneva in December the opacity of the rod was defined as 10 International Units. The replacement preparation was determined as sufficiently similar to the original not to require recalibration by collaborative study.

4. CONTENTS

Country of origin of biological material: United Kingdom. The plastic rod is contained in a Pyrex test tube and is supplied with two further identical empty test tubes having internal diameters similar to that of the tube containing the rod.

5. STORAGE

Storage conditions do not affect the stability of the material.

6. DIRECTIONS FOR OPENING

Other - describe below...

7. USE OF MATERIAL

The ways in which the rod may be used and its calibration in terms of the Third International Opacity Reference Preparation have been described in a report of an international collaborative study (Perkins et al 1973).

It is intended for comparisons of opacity made only by eye and attempts to use the rod in a densitometer or nephelometer are likely to provide anomalous readings

8. STABILITY

Reference materials are held at NIBSC within assured, temperaturecontrolled storage facilities. Reference Materials should be stored on receipt as indicated on the label. They remain valid with the assigned potency and status until withdrawn or amended.

Users who have any data supporting any change in the characteristics of this material are encouraged to contact NIBSC.

9. REFERENCES

Perkins F.T., Sheffield F.W., Outschoorn A..S., and Hemsley D.A. (1973) An International collaborative study on the measurement of the opacity of bacterial suspensions. Journal of Biological Standardization, 1, 1-10

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 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:		Corrosive:	No	
Solid plastic rod in test tube				
Stable:	Yes	Oxidising:	No	
Hygroscopic:	No	Irritant:	No	
Flammable:	No	Handling:See	e caution, Section 2	
Other (specify):	No special precautions			

Toxicological properties

Effects of inhalation:	N/A
Effects of indestion	N/A
Encolo of mgeation.	I W/FX
Effects of skip	NI/A
Effects of skin	N/A
absorption:	
aboolption	

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Suggested First Aid			
Inhalation:	N/A		
Ingestion:	Seek medical advice		
Contact with	N/A		
eyes:			
Contact with skin:	N/A		
Action on Spillage and Method of Disposal			

Broken glass from the test tube should be disposed of in the appropriate glass 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 freezedrying.

Net weight: 100 g.

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_Int er_biolefstandardsrev2004.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.

