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Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel. (01) 807 3838

**BIOTECHNOLOGY – PERFORMANCE
CRITERIA FOR CELL DISRUPTERS**

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English version

Biotechnology - Performance criteria for cell disrupters

Biotechnologie - Critères de performance pour les broyeurs
de cellules

Biotechnik - Leistungskriterien für Zellaufschlußgeräte

This European Standard was approved by CEN on 28 January 1999.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPAISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.

This draft European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Cell disrupters are used to break or reduce the size of viable or non-viable microorganisms. The term homogenizers may be used in dealing with specific types of cell disrupters (e.g. high pressure homogenizers) which are also used in specific applications such as in dairy industry.

The general safety of cell disrupters used in biotechnological processes is covered by EN 292-1, EN 292-2 (see annex B [6], [7]) and EN 1672-2.

Use of this European Standard will aid the equipment manufacturer in the classification with regard to biosafety performance of cell disrupters in biotechnological processes. The classification is easily understandable and readily utilizable for the user and the regulatory authorities.

1 Scope

This European Standard specifies performance criteria for cell disrupters used in biotechnological processes with respect to the potential risks of microorganisms in use for the worker or the environment.

This European Standard applies where the intended use of the cell disrupter includes hazardous or potentially hazardous microorganisms used in biotechnological processes and/or where exposure of the worker or the environment to such microorganisms is restricted for reasons of safety.

2 Normative references

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1672-2	Food processing machinery - Basic concepts - Part 2 : Hygiene requirements
EN 12296	Biotechnology - Equipment - Guidance on testing procedures for cleanability
EN 12297	Biotechnology - Equipment - Guidance on testing procedures for sterilizability
EN 12298	Biotechnology - Equipment - Guidance on testing procedures for leaktightness
EN 12460	Biotechnology - Large-scale process and production - Guidance on equipment selection and installation in accordance with the biological risk
EN ISO 4287	Geometrical Product Specifications (GPS) - Surface texture: Profile method - Terms, definitions and surface texture parameters (ISO 4287:1997)

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