SLOVENSKI STANDARD
SIST EN 12885:1999

01-december-1999

Biotehnologija - Merila za delovanje celiļ nih razbijalcev

Biotechnology - Performance criteria for cell disrupters

Biotechnik - Leistungskriterien für Zellaufschlußgeräte

Biotechnologie - Criteres de performance pour les broyeurs de cellules

Ta slovenski standard je istoveten z: **EN 12885:1999**

ICS:

07.080	Biologija. Botanika. Zoologija	Biology. Botany. Zoology
07.100.01	Mikrobiologija na splošno	Microbiology in general

SIST EN 12885:1999 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12885

February 1999

ICS 07.080; 07.100.01

Descriptors: biotechnology, material, cells (biology), safety, hazards, environmental protection, accident prevention, contamination, micro-organisms, definitions, classifications, characteristics, leaktightness, cleaning, sterilization, verification, tests, marking, packing

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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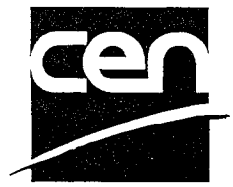

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Foreword

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of an identical text or by endorsement, at the latest by August 1999, and conflicting national standards shall be withdrawn at the latest by August 1999.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)

EN ISO 4288 Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and Procedures for the assessment of surface texture (ISO 4288:1996)

3 Definitions

For the purposes of this standard, the following definitions apply :

3.1 cell disrupter

Equipment used in breakage and/or reduction of size of viable and non-viable microorganisms.

3.2 clean

Condition of (a) product, surface, device, gases and/or liquids with residual soil below a defined threshold value.

3.3 cleanability

Ability to be made clean.

3.4 hazard

Intrinsic property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN1620].

NOTE : Harm is an injury or damage to health of people and/or to the environment.

3.5 leakage

Egress from equipment.

3.6 leaktightness

Ability of component of equipment or unit of equipment to limit egress.

3.7 microorganism

Any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic material [EN1619].

NOTE : For the purposes of this standard, the term microorganism covers the term of biological agent, according to the Directive 90/679/EEC : microorganisms, including those which have been genetically modified, cell cultures and human endoparasites which may be able to provoke any infection, allergy or toxicity .

3.8 process microorganism

Microorganism used for production purposes in a biotechnological process or constituting (part of) the product itself.

3.9 risk

Combination of the probability and the degree of the possible injury or damage to health in a hazardous situation [EN 1070].

3.10 soil

Any unwanted matter (including product residues, microorganisms, dust and debris) [ISO/CD 14159].

3.11 sterile

State of being free from viable microorganisms.

NOTE 1 : In practice no such absolute statement regarding the absence of viable microorganisms can be proven. However, sterile conditions can be regarded as established by using an accepted or recognized method of sterilization.

NOTE 2 : The process of inactivation of viable microorganisms during a sterilization procedure is usually described by an empirical mathematical function, commonly an exponential function. By their mathematical nature, such functions can be reduced to very low numbers, but not to zero. However, these empirical functions can be applied to control or assess the process parameters of a sterilization procedure to realize a desired degree of inactivation of viable microorganisms.

3.12 sterilizability

Ability of components of equipment, units of equipment or process plants to be made sterile.

3.13 sterilization

Process used to reach a sterile state .

3.14 target microorganism

Process microorganism and/or other microorganisms relevant for a specific process.

NOTE : For safety testing procedures, non-pathogenic microorganisms should be used where possible.

4 Hazards

The following hazards shall be taken into account :

- release of microorganisms by leakage during operation ;

- release of microorganisms after operation due to insufficient inactivation and/or removal of microorganisms when the cell disrupter is opened or dismantled ;

- release of microorganisms due to partial or complete seal breakage due to inappropriate operation of the cell disrupter, e.g. dry operation of high-pressure-homogenizers ;

- release of microorganisms due to pressure build-up by clogging, overloading or inappropriate opening of the cell disrupter.

NOTE : Leakage occurs as liquid, slurry or aerosol. Given the nature of the function of cell disrupters, it is likely that any leakage will contain both viable microorganisms and non-viable microorganisms.

5 Performance classes

5.1 General

The cell disrupter shall be classified for the following performance criteria with regard to the contained use of microorganisms :

- leaktightness ;

- cleanability ;

- sterilizability.

The performance of the cell disrupter shall be determined separately for each of these criteria in accordance with tables 1, 2 and 3.

NOTE : A cell disrupter can for example be in class SI-A for sterilizability, but in class LI-C for leaktightness.

5.2 Leaktightness

The performance classes for leaktightness of the cell disrupter are given in table 1.