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BIOTECHNOLOGY - PERFORMANCE

CRITERIA FOR VESSELS -

PART 5: KILL TANKS

National Standards Authority of Ireland Dublin 9 Ireland

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

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Biotechnologie - Critères de performance des récipients -Partie 5: Cuves de décontamination Biotechnik - Leistungskriterien für Behälter - Teil 5[.] Abtötungsbehälter

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

Management Centre: 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of an identical text or by endorsement, at the latest by September 2001, and conflicting national standards shall be withdrawn at the latest by September 2001.

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

This standard is one of a series of European Standards concerned with performance criteria for vessels. These standards are:

EN 13311-1, Biotechnology - Performance criteria for vessels - Part 1: General performance criteria.

EN 13311-2, Biotechnology - Performance criteria for vessels - Part 2: Pressure protection devices.

EN 13311-3, Biotechnology - Performance criteria for vessels - Part 3: Glass pressure vessels.

EN 13311-4, Biotechnology - Performance criteria for vessels - Part 4: Bioreactors.

EN 13311-5, Biotechnology - Performance criteria for vessels - Part 5: Kill tanks.

EN 13311-6, Biotechnology - Performance criteria for vessels - Part 6: Chromatography columns.

Annexes A, B and C are informative.

This standard includes a bibliography.

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.

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Introduction

Kill tanks are used to inactivate microorganisms in liquids or slurries by subjecting them to steam, heat, chemicals or radiation. Kill tanks are part of the closed system but can be used as well for treatment of waste water from for example sewers and showers. Kill tanks can be continuous or batch operated systems. Examples of kill tank systems are given in annex B.

Kill tanks are used to inactivate process microorganisms prior to release from the closed system or to further downstream processing in uncontained conditions.

Use of this European Standard will aid the equipment manufacturer in the classification of kill tanks with regard to safe performance 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 kill tanks used in biotechnological processes with respect to the potential hazards to the worker and the environment from microorganisms in use.

This European Standard applies where the intended use of kill tanks includes hazardous or potentially hazardous microorganisms used in biotechnological processes 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 revisions 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 (including amendments).

EN 13311-1:2001 Biotechnology - Performance criteria for vessels - Part 1 : General performance criteria

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in EN 13311-1:2001 apply.

4 Hazards

The following hazards shall be taken into account.

- a) Release of microorganisms by leakage before or during operation.
- b) Release of microorganisms by exhaust gases.

c) Release of microorganisms caused by insufficient inactivation when the load of the kill tank is discharged or further processed or when the kill tank is opened or dismantled.



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