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Safety of Toys — Part 12: Microbiological Safety

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Contents

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 181, Safety of Toys.

This is the first edition of this document.

A list of all parts in the ISO 8124 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is largely based upon existing requirements in the United States of America toy safety standard, ASTM F963, with some modifications to narrow the scope and facilitate use of the standard in multiple jurisdictions.

However, it should not be construed that a toy manufactured in compliance with this document. will be in full compliance with relevant national toy safety requirements in the market where the product is intended to be distributed. The user of this document is therefore advised to be aware of relevant national requirements.

Compliance with the requirements of this document will minimize potential hazards associated with toys resulting from their use in their intended play modes (normal use) as well as unintended play modes (reasonably foreseeable abuse).

This document will not, nor is it intended to, eliminate parental responsibility in the appropriate selection of toys. In addition, this document will not eliminate the need for parental supervision in situations where children of various ages may have access to the same toy(s).

Safety of Toys — Part 12: Microbiological Safety

1 Scope

The requirements in this document apply to all toys (i.e. any product designed or clearly intended for use in play by children under 14 years of age) that are or include a cosmetic (including those intended for use on a toy as well as on the child), paste, putty, powder, liquid, or gel that is aqueous in nature. They are applicable to a toy as it is initially received by the consumer and, in addition, they apply after a toy is subjected to reasonably foreseeable conditions of normal use and abuse unless specifically noted otherwise.

The requirements of this document specify acceptable criteria for microbiological cleanliness and adequacy of preservation of toy materials within the scope of the standard.

This document does not purport to cover or include every conceivable potential microbiological hazard of a particular toy or toy category.

When conducting microbiological examinations for any product, it is especially important that:

— only those microorganisms which are present in the samples be isolated or enumerated,
— the microorganisms do not contaminate the environment.

In order to achieve this, it is necessary to pay attention to personal hygiene and to use working techniques which ensure, as far as possible, exclusion of extraneous contamination.

Since, in this document, it is possible to give only a few examples of the precautions to be taken during microbiological examinations, a thorough knowledge of the microbiological techniques and of the microorganisms involved is essential. It is important that the analyses be conducted as accurately as possible, including calculation of the number of microorganisms.

A large number of manipulations can, for example, unintentionally lead to cross-contamination and the analyst should always verify the accuracy of the results given by his/her technique. It is necessary to take special precautions, not only for reasons of hygiene, but also to ensure good reproducibility of the results.

2 Normative references

The following documents are referred to in the text in such a way that some or allof their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11930, *Cosmetics – Microbiology – Evaluation of the antimicrobial protection of a cosmetic product*

ISO 16212, *Cosmetics – Microbiology – Enumeration of yeast and mould*

ISO 18415:2007, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*

ISO 18416:2007, *Cosmetics — Microbiology — Detection of Candida albicans*

ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 21150:2006, *Cosmetics — Microbiology — Detection of Escherichia coli*

ISO 22716, Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing *Practices*

ISO 22717:2007, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

ISO 22718:2006, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

European Union: The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation 8th revision, 2012-12-11, § 4.4.
ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

Cosmetic, Toiletry and Fragrance Association (CTFA) Microbiological Guidelines, Methods M-1 Determination of the Microbial Content of Personal Care Products

Cosmetic, Toiletry and Fragrance Association (CTFA) Microbiological Guidelines, Methods M-2 Examination for and Identification of Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Candida albicans

Cosmetic, Toiletry and Fragrance Association (CTFA) Microbiological Guidelines, Methods M-3 A Method for Preservation Testing of Water Miscible Personal Care Products

Cosmetic, Toiletry and Fragrance Association (CTFA) Microbiological Guidelines, Methods M-6 A Method for Preservation Testing of Atypical Personal Care Products

United States Food and Drug Administration Bacteriological Analytical Manual

United States Pharmacopeia, Volume 35 (or most current), Method 61 Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests

United States Pharmacopeia USP), Volume 35 (or most current), Method 62 Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms

United States Pharmacopeia, Volume 35 (or most current), Chapter 1231 Water for Pharmaceutical Purposes

United States Pharmacopeia (USP), Volume 35 (or most current), Method 61 Antimicrobial Effectiveness Testing

European Pharmacopoeia, ("microbiological examination of non-sterile products") Chapter 2.6.12

European Pharmacopeia, ("microbiological examination of non-sterile products") Chapter 2.6.13

European Pharmacopeia, ("efficacy of antimicrobial preservation") Chapter 5.1.3

EC-type approval protocol No. 2 Microbiological safety of toys containing aqueous media REV 3

3 Terms and definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

—ISO Online browsing platform: available at https://www.iso.org/obp

—IEC Electropedia: available at http://www.electropedia.org/

For the purposes of this document, the following terms and definitions apply.

3.1
aqueous toy material
a toy material with a water activity of 0,5 or greater

Note 1 to entry: Water activity (denoted A_w) is the partial vapor pressure of water in the toy material divided by the vapor pressure of pure water at the same temperature. It is a measure of unbound water in the material and is not necessarily the equivalent of moisture content.

Note 2 to entry: powdered material intended to be mixed with water or other aqueous liquid is within scope.

3.2
total aerobic microbial count
Total aerobic microbial count (TAMC) is a method that measures colony formation on culture media of aerobic bacteria

Note 1 to entry: Heterotrophic microorganisms require carbon (other than carbon dioxide) as an energy source (contrast with autotrophic microorganisms, which can convert sunlight and CO2 into complex organic molecules in vivo).

Note 2 to entry: Total aerobic microbial count is alternatively referred to as Total aerobic plate count or Heterotrophic plate count.

4 Microbiological Cleanliness

All aqueous toy materials shall be microbiologically clean.

Aqueous toy materials shall be considered acceptable from the standpoint of microbiological cleanliness if they comply with all the following conditions:

1. Total aerobic microbial count as follows:
   1.1. Infant products: 500 cfu/ml or per gm maximum
   1.2. Face paints for use by a child or on a doll: 500 cfu/ml or per gm maximum
   1.3. Materials intended or likely to be used in the eye area: 500 cfu/ml or per gm maximum
   1.4. All other products: 5 000 cfu/ml or per gm maximum

2. Absence of the following organisms by test:
   2.1. *Pseudomonas* sp.
   2.2. Escherichia coli
   2.3. Coagulase-positive *Staphylococcus aureus*
   2.4. *Salmonella* sp.

5 Microbiological Challenge (Preservation Effectiveness)

All aqueous toy materials must be adequately protected against microbial insult or shelf-life degradation.

Aqueous toy materials shall be challenged as follows:

1. Day zero microbial inoculation as follows:
   1.1. Minimum inoculum 500 000 – 1 000 000 cfu/ml

1.2. Minimum organism suite: *Staphylococcus aureus*, ATCC 6538; *Escherichia coli*, ATCC 8739; *Pseudomonas aeruginosa*, ATCC 9027; *Candida albicans*, ATCC 10231; and *Aspergillus brasiliensis*, ATCC 16404
1.3. Minimum sampling intervals: 14 and 28 days after inoculation

NOTE More frequent internals are optional.

2. Evaluation criteria:
2.1. Bacteria: > log 2 reduction (i.e., population <1% of initial inoculum at 14 days; no increase between 14 and 28 days.
2.2. Moulds, fungi and yeasts: no increase from initial inoculum at either 14- or 28-days post inoculation.

6 Test Procedures

1. Microbiological Cleanliness of process water shall be evaluated in accordance with the following:
1.1. United States Pharmacopeia, Volume 35 (or most current), Chapter 1231 Water for Pharmaceutical Purposes

2. Microbiological Cleanliness of products may be determined in accordance with any appropriate combination of the following:
2.1. United States Pharmacopeia, Volume 35 (or most current), Method 61 Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
2.2. United States Pharmacopeia, Volume 35 (or most current), Method 62 Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms
2.3. CTFA Microbiological Guidelines, Methods M-1 Determination of the Microbial Content of Personal Care Products
2.4. CTFA Microbiological Guidelines, Methods M-2 Examination for and Identification of Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Candida albicans
2.5. U.S. Food and Drug Administration Bacteriological Analytical Manual
2.6. ISO 16212, *Cosmetics — Microbiology — Enumeration of yeast and mould*
2.7. ISO 18415:2007, *Cosmetics — Microbiology — Detection of specified and non-specified microorganisms*
2.8. ISO 18416:2007, *Cosmetics — Microbiology — Detection of Candida albicans*
2.9. ISO 21148, *Cosmetics — Microbiology — General instructions for microbiological examination*
2.10. ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*
2.11. ISO 21150:2006, *Cosmetics — Microbiology — Detection of Escherichia coli*
2.12. ISO 22717:2007, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*
2.13. ISO 22718:2006, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*
2.14. European Pharmacopoeia, Chapter 2.6.12 ("microbiological examination of non-sterile products")
2.15. European Pharmacopeia, Chapter 2.6.13 ("microbiological examination of non-sterile products")
2.16. EC-type approval protocol No. 2 Microbiological safety of toys containing aqueous media REV 3

3. Preservation effectiveness of products may be determined by any of the following:
3.1. ISO 11930, *Cosmetics — Microbiology — Evaluation of the antimicrobial protection of a cosmetic product*
3.2. United States Pharmacopeia (USP) <51> Antimicrobial Effectiveness Testing
3.3. CTFA Microbiological Guidelines, Methods M-3 A Method for Preservation Testing of Water Miscible Personal Care Products

3.4. CTFA Microbiological Guidelines, Methods M-6 A Method for Preservation Testing of Atypical Personal Care Products
3.5. European Pharmacopeia, ("efficacy of antimicrobial preservation") Chapter 5.1.3
3.6. United States Pharmacopeia (USP), Volume 35 (or most current), Method 61 Antimicrobial Effectiveness Testing
3.7. EC-type approval protocol No. 2 Microbiological safety of toys containing aqueous media REV 3

Annex A
(informative)

Process Water

A.1 Good manufacturing practice for water

Good manufacturing practice for water used in manufacturing aqueous toy materials is for the water to meet the following requirements:

1. Total aerobic microbial count of < 10 cfu/ml
2. Absence of coliform bacteria by test

NOTE: The various methods for producing acceptable water each present different potential for contaminating the final product. Purified water produced by distillation is sterile, provided that the production equipment is suitable and sterile. On the other hand, ion-exchange columns, microfiltration units, and reverse osmosis units require special attention in that they afford sites for microorganisms to foul the system and contaminate the effluent. Frequent monitoring may thus be called for, particularly with the use of these units following periods of shutdown of more than a few hours.