
Safety of toys —
Part 12:
Microbiological safety

Sécurité des jouets —
Partie 12: Sécurité microbologique



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Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General	2
5 Risk assessment	3
5.1 General.....	3
5.2 Evaluation.....	3
5.3 Exception for testing.....	3
6 Microbiological cleanliness of toy materials	4
7 Microbiological challenge (preservation effectiveness)	4
8 Test procedures	5
8.1 General requirements.....	5
8.2 Microbiological cleanliness.....	5
8.3 Preservation effectiveness.....	5
Annex A (informative) Process water — Manufacturing aqueous toy materials	6
Bibliography	7

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 document 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).

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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*.

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 ASTM F963, with some modifications to narrow the scope and facilitate use of the document in multiple jurisdictions.

However, it should not be construed that a toy manufactured in conformity 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.

Conformity with the requirements of this document will minimize potential hazards associated with toys due to lack of microbiological cleanliness or inadequate preservation, either of which can result in illness or injury resulting from use of the toy in its 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. Nor will this document eliminate the need for parental supervision in situations where children of various ages have access to the same toy(s).

Safety of toys —

Part 12: Microbiological safety

1 Scope

This document specifies acceptable criteria for microbiological cleanliness and adequacy of preservation of the specified toy materials. The requirements in this document apply to all toys that are, contain or are supplied with aqueous materials (e.g. paste, putty, liquid or gel). In addition, this document applies to toys that are or include a cosmetic (including those intended for use on a toy as well as on the child). Powders and similar substances intended to be mixed with water are also within the scope of this document.

The cleanliness and preservation effectiveness requirements are applicable to a toy as it is initially received by the consumer in an unopened and undamaged container and do not apply after a toy is subjected to reasonably foreseeable conditions of normal use and abuse, unless specifically noted otherwise. The microbial limits and test methods contained in this document are inappropriate to apply to products that are consumer complaint returns, as there is no way to establish what conditions the toys have been subject to before being returned.

The following are excluded from the scope of this document:

- materials that are inaccessible during normal use or reasonably foreseeable abuse;
- powder or powder-like materials intended to show biological phenomena, e.g. shrimp eggs, seeds, soil;
- food.

2 Normative references

The following documents are referred to in the text in such a way that some or all of 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 6222, *Water quality — Enumeration of culturable micro-organisms — Colony count by inoculation in a nutrient agar culture medium*

ISO 7899 (all parts), *Water quality — Detection and enumeration of intestinal enterococci*

ISO 9308 (all parts), *Water quality — Enumeration of Escherichia coli and coliform bacteria*

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

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

ISO 17516, *Cosmetics — Microbiology — Microbiological limits*

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

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

ISO 18787, *Foodstuffs — Determination of water activity*

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

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

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

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

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

ISO 29621, *Cosmetics — Microbiology — Guidelines for the risk assessment and identification of microbiologically low-risk products*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21148 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

aqueous toy material

toy material with a water activity of $\geq 0,5$

Note 1 to entry: Water activity (denoted A_w) is the partial vapour pressure of water in the toy material divided by the vapour 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.

3.2

aerobic mesophilic microorganisms

aerobic bacteria, yeast and mould with optimal growth at temperatures between 25 °C and 40 °C

3.3

infant product

product marketed for children under 36 months

3.4

total aerobic mesophilic count

TAMC

measure of *aerobic mesophilic microorganism* (3.2) formation on culture media

3.5

total yeast and mould count

TYMC

measure of yeast and mould colony formation on culture media under aerobic conditions

4 General

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 sanitation and hygiene and to use aseptic techniques which ensure, as far as possible, exclusion of extraneous contamination.