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Safety of toys —

Part 12: Microbiological safety

Sécurité des jouets —

Partie 12: Sécurité microbiologique

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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 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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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 ≥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.

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 testing 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 their technique. It is necessary to take special precautions, not only for reasons of hygiene but also to ensure good reproducibility of the results.

Colony counts shall be performed in accordance with ISO 11930.

Powders intended to be mixed with water shall be tested after mixing; testing shall take into account the effects of mixing variation of ± 10 % of water volume.

Annex A provides information regarding good manufacturing practice for process water.

5 Risk assessment

5.1 General

Prior to conducting microbiological testing, products shall be evaluated to determine if they are susceptible to microbial growth. Pay particular attention to repeat-use products that are susceptible to contamination by foreseeable use (e.g. finger paints, soft dough).

5.2 Evaluation

Evaluate the products as follows:

The formulations of products in the scope of this document shall first be evaluated for their potential for microbiological degradation using the methods outlined in ISO 29621. In general, products with a low likelihood of supporting microbial growth are anhydrous or have some other characteristic which serves to inhibit microbial growth. These products include but are not limited to the following:

— products with a water activity below 0,5; water activity to be determined in accordance with ISO 18787;

— siloxane and siloxane-derivative-based products with low water content;

— wax- and oil-based products, such as;

  — lip balms;

  — pomades;

  — ointments;

— powders (anhydrous or nearly so and non-hygroscopic);

— products with an alcohol content ≥ 200 ml/l volume fraction;

— products with a pH < 3 or > 10.

NOTE An alternative method is provided in Reference [12] as an option.

Aqueous liquids, such as fibre-bound inks in pens and some pastes in tubes, are unlikely to be contaminated during foreseeable use and do not require microbial testing.

5.3 Exception for testing

Products determined not susceptible after evaluation are considered to conform with this document.

6 Microbiological cleanliness of toy materials

All toy materials within the scope of this document which have been determined to present a risk shall be microbiologically clean. Toy materials shall conform with all of the following conditions when they are opened for the first time from their packages in order to be considered acceptable from the standpoint of microbiological cleanliness.

a) Limits for total aerobic mesophilic count (TAMC) and total yeast and mould count (TYMC) as follows (assessed separately):

   — infant products: 100 CFU/ml or 100 CFU/g maximum;

   — face paints for use by a child or on a doll: 100 CFU/ml or 100 CFU/g maximum;

   — materials specifically intended to be used in or around the eye area or mucous membrane, for example lipstick or eye shadow: 100 CFU/ml or 100 CFU/g maximum;

   — all other products: 1 000 CFU/ml or 1 000 CFU/g maximum.

b) Bile-tolerant gram-negative bacteria:

   — all products: 100 CFU/ml or 100 CFU/g maximum.

c) Absence (<1 CFU/g) of the following organisms:

   — *Pseudomonas aeruginosa*;

   — *Escherichia coli*;

   — *Staphylococcus aureus*;

   — *Salmonella spp.*;

   — *Candida albicans*.

The test unit (e.g. volume, mass, item) is as defined in the respective test method(s). See also Clause 8.

Due to variation introduced during multiple dilutions, up to 0,3 order of magnitude ($\log_{10}$) greater than the above limits can be considered compliant (i.e. a result of up to 200 CFU/ml can be considered to meet a limit of 100 CFU/ml and a result of up to 2 000 CFU/ml can be considered to meet a limit of 1 000 CFU/ml if multiple dilutions are required during testing).

7 Microbiological challenge (preservation effectiveness)

All aqueous toy materials shall be adequately protected against microbial insult. Toy materials in the scope of this document shall be challenged as follows:

— 1 % volume fraction inoculum with between 1×10^5 and 1×10^6 CFU/ml.

— Minimum organism suite: *Staphylococcus aureus*, ATCC 6538; *Escherichia coli*, ATCC 8739; *Pseudomonas aeruginosa*, ATCC 9027; *Candida albicans*, ATCC 10231; and *Aspergillus brasiliensis*, ATCC 16404 (no micellium present). Other organisms of interest are optional and equivalent strains are acceptable.

— Minimum sampling intervals: 7 days, 14 days and 28 days after inoculation.

— Minimum material sample size: 10 g.

NOTE Earlier and/or more frequent intervals are optional.