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Safety of toys —

Part 12:
Microbiological Safety

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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 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 the document.

Safety of Toys — Part 12: Microbiological Safety

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 products that are or contain materials which are aqueous in nature, supplied as or with a toy or 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. Powders and similar substances intended to be mixed with water by the child are also in scope for microbiological cleanliness and are to be tested before and after mixing; such items are in scope for microbiological challenge only if they are intended for repeated use and will be stored between play sessions (manufacturers should consider the potential effect of variations in mixing proportions). 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 standard are inappropriate to apply to products that are consumer complaint returns, as there is no way to establish what conditions the toys may have been subject to before being returned. Toys in which the aqueous materials are contained so that there is no accessibility either before or after use-and-abuse testing are exempt from these requirements.

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

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 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 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*

EC-type approval protocol No. 2 Microbiological safety of toys containing aqueous media REV 4

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 (USP), 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 (USP), Volume 35 (or most current), Chapter 1231 Water for Pharmaceutical Purposes

United States Pharmacopeia (USP) Volume 35 (or most current), Method 51 Antimicrobial Effectiveness Testing

3 Terms and definitions

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

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 https://www.electropedia.org/

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

Note 1 to entry: Water activity (denoted Aw) 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: Water activity is to be determined in accordance with ISO 18787

3.2
heterotrophic plate count
HPC
method that measures colony formation on culture media of heterotrophic bacteria under aerobic conditions

Note 1 to entry: Heterotrophic microorganisms require carbon (other than carbon dioxide) as an energy source (in contrast to autotrophic microorganisms, which can convert sunlight and CO_2 into complex organic molecules).

3.3
infant product
product marketed for children 36 months of age or younger

3.4
total aerobic mesophilic count
TAMC
measure of colony formation on culture media of aerobic organisms

3.5
total aerobic yeast count
TAYC
method that measures colony formation on culture media of yeasts and moulds 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 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 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 are to be performed in accordance with ISO 11930.

5 Microbiological cleanliness

5.1 General

All aqueous toy materials shall be microbiologically clean.

5.2 Aqueous toy materials

Aqueous toy materials shall be considered acceptable from the standpoint of microbiological cleanliness if they comply with all the following conditions, when they are opened for the first time from their package:

— Limits for heterotrophic plate count or total aerobic mesophilic count and total aerobic yeast count as follows (TAMC and TAYC assessed separately):

  — infant products 100 cfu/ml or per gm maximum;

  — face paints for use by a child or on a doll: 100 cfu/ml or per gm maximum;

  — materials specifically intended to be used in or around the eye area, or mucous membrane, e.g., lipstick, eye shadow: 100 cfu/ml or per gm maximum;

- all other products: 1 000 cfu/ml or per gm maximum.

- Absence of the following organisms by test:
  - *Pseudomonas aeruginosa*
  - *Escherichia coli and other bile-tolerant gram-negative bacteria*
  - *Coagulase-positive 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 0.2 order of magnitude greater than the above limits may be considered acceptable (i.e., a result of up to 200 cfu/ml may be considered to meet a limit of 100 cfu/ml, and a result of up to 2 000 cfu/ml may be considered to meet a limit of 1 000 cfu/ml if multiple dilutions are required during testing).

6 Risk assessment

6.1 General

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

6.2 Evaluation

Evaluate the products as follows:

The formulations of products subject to this document shall first be evaluated for their potential for microbiological degradation using the methods outlined in the "Microbiological Risk Factor Assessment of Atypical Cosmetic Products" within the CTFA Microbiology Guidelines, or those in ISO 29621. In general, products with a low likelihood of supporting microbial growth are anhydrous or have a water activity below 0,5 or have some other characteristic which serves to inhibit microbial growth. These characteristics include but are not limited to the following:

- Wax-based products;
- Siloxane and siloxane derivative-based products;
- Lip balms;
- Pomades;
- Ointments;
- Powders (anhydrous or nearly so, and non-hygroscopic; powders intended to be mixed with water are to be tested after mixing);
- Products with an alcohol content equal to or greater than 20 % (vol /vol), and
- Products with a pH of less than 3 or greater than 10.