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Child care articles — General safety —

Part 3: Chemical hazards

Articles de puériculture — Sécurité générale —

Partie 3: Dangers chimiques

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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 310, *Child care articles*.

A list of all parts in the ISO 24929 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.

Child care articles — General safety —

Part 3: Chemical hazards

1 Scope

This document establishes principles for the classification of child care articles based on chemical hazards, behavioural habits, physiological characteristics, exposure routes and chemical risk assessment methods related to classification. It specifies general and fundamental chemical requirements applicable to all child care articles. It also describes the relationship between this document and specific product standards.

NOTE 1 Chemical hazards that are unique to specific product categories of child care articles are addressed in corresponding product standards.

NOTE 2 There are many child care articles, and many materials and chemical substances are used. This document cannot cover all child care articles and all chemical hazardous substances, which is why this document also gives principles for dealing with unknown products and chemical substances.

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 8124-3, *Safety of toys — Part 3: Migration of certain elements*

ISO 8124-6, *Safety of toys — Part 6: Certain phthalate esters*

ISO 12460-1, *Wood-based panels — Determination of formaldehyde release — Part 1: Formaldehyde emission by the 1-cubic-metre chamber method*

ISO 14184-1, *Textiles — Determination of formaldehyde — Part 1: Free and hydrolysed formaldehyde (water extraction method)*

ISO 14362-1, *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres*

ISO 14362-3, *Textiles — Methods for determination of certain aromatic amines derived from azo colorants — Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene*

ISO 17226-1, *Leather — Chemical determination of formaldehyde content — Part 1: Method using high-performance liquid chromatography*

ISO 17234-1, *Leather — Chemical tests for the determination of certain azo colourants in dyed leathers — Part 1: Determination of certain aromatic amines derived from azo colourants*

ISO 17234-2, *Leather — Chemical tests for the determination of certain azo colorants in dyed leathers — Part 2: Determination of 4-aminoazobenzene*

AfPS-GS-2019-01-PAK, *Product Safety Commission (AfPS) — GS Specification — Testing and assessment of Polycyclic Aromatic Hydrocarbons (PAHs) in the awarding of GS Marks*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 Terms related to product classification on chemical hazards

3.1.1
child care article
article which is designed or obviously intended to facilitate seating, bathing, changing, feeding, mouthing, sleeping, transportation, activity and protection for young children

3.1.1.1
bathroom supplies
products intended for children to use in toilets, bathrooms, etc., for washing, defecating, bathing, changing diapers, etc.

EXAMPLE Infant bathers, bath tubs, changing units (for domestic use), bath seats, reducers.

3.1.1.2
early education product
product designed to assist children with developing balance, standing and walking independently

EXAMPLE Baby walking frames.

3.1.1.3
protective equipment
product that is installed on another product to prevent the other product from causing injury to children (e.g. pinch, bruise) and product that limits the range of activities of children

EXAMPLE Small protective devices, playpens, safety barriers.

3.1.1.4
feeding utensil
product used to assist children in eating and drinking

EXAMPLE Spoon, fork, plate, bowl, food feeder, drinking cup, feeding bottle, training cup and straw.

3.1.1.5
soother
product used to meet children's non-nutritive sucking needs

3.1.1.6
sleeping product
product that has a surface for a child to lie on and that is designed or marketed for a child to sleep on or to soothe or settle a child

EXAMPLE Bassinets, carry cots, bedside sleepers, footmuff, bed nests, sleep bags, cot bumpers, bed guards, infant inclined sleep products.

3.1.1.7
transportation product
product intended to hold and transport a child, where the movement of the product can be powered by the child or others

EXAMPLE Prams, tricycles with a pushchair function, baby walking frames, child seats for cycles, hip carriers, framed baby carriers.

3.2 Terms related to chemical safety risk

3.2.1
chemical hazard
inherent property of a chemical substance that can cause adverse effects when the human body is exposed to it

3.2.2
concentration
amount of a material or agent dissolved or contained in unit quantity in a given medium or system

3.2.3
plasticized material
substance with plasticity that is processed by adding plasticizers

Note 1 to entry: Common plasticized materials include plastics (e.g. polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, polyurethanes), rubber, coating, paints, decals (see C.2.2).

Note 2 to entry: Polymer plasticizers, most commonly phthalate esters, give the material improved flexibility and durability.

3.2.4
risk
probability of adverse health effects occurring in the human body under specified circumstances due to exposure to an agent

3.2.5
toxicity
inherent property of an agent to cause an adverse biological effect

3.3 Terms related to exposure

3.3.1
accessible
<part or component> contactable by any portion forward of the collar of the accessibility probe

Note 1 to entry: The accessibility probe is described in ISO 8124-1:2022, 5.7.

[SOURCE: ISO 8124-1:2022, 3.1]

3.3.2
daily exposure time
total daily contact time of a chemical substance with children under a certain exposure route

Note 1 to entry: It can be calculated by statistically calculating the single exposure time and daily exposure times.

3.3.3
dermal exposure
exposure (3.3.4) related to contact with the child's skin

Note 1 to entry: Some chemical substances can remain on children's skin and then penetrate children's bodies.

3.3.4
exposure
contact between chemicals and children for a specified duration

3.3.5
exposure route
manner in which a chemical enters the child's body after *exposure* (3.3.4)

Note 1 to entry: For example, through the mouth or by inhalation or skin contact.

3.3.6
inhalation exposure
exposure (3.3.4) related to inhalation into a child's body through breathing

3.3.7
oral exposure
exposure (3.3.4) related to the ingestion of chemicals into a child's body through oral contact

Note 1 to entry: Child care articles come into contact with children's mouths through sucking, chewing, licking, etc. and some chemical substances can enter children's bodies through saliva.

Note 2 to entry: Child care articles or parts thereof can contain chemical substances, which after being swallowed, can enter children's bodies through gastric juice digestion.

4 Principles for establishing chemical safety requirements

4.1 Principles

4.1.1 General

In order to determine the general chemical safety technical requirements in child care articles, the principles in this document are based on an assessment of the exposure risk of chemical substances that potentially exist in child care articles, which screened out high-risk chemical substances and set corresponding limit requirements based on product characteristics, as well as a comprehensive consideration of the toxicological properties of chemical substances, children's development level and behaviour, and possible exposure routes.

4.1.2 Classification of child care articles based on chemical hazards

There are many types of child care articles. Based on the accessibility, function, handling, material, volume or mass of the product, reasonable exposure due to sucking, licking, swallowing, inhalation or prolonged contact with the skin, and children's behavioural characteristics, child care articles can be divided into several categories, such as bathroom supplies, early education products and protective equipment, feeding products utensils and soother, sleeping products, transportation products and seats, etc. Details related to child care article classification are included in Annex A.

4.1.3 Toxicological properties of chemical substances

Toxicological data are the basis for establishing chemical safety indicators. The establishment of chemical safety requirements requires the knowledge of potential exposure risks of the chemical substances and the necessity of including these chemical substances in the regulated chemical list of child care articles. In order to obtain said knowledge, the toxicological properties and release characteristics of the chemical substances should be fully investigated.

4.1.4 Physiological development level and behaviours of children

In the process of establishing chemical safety requirements, full consideration should be given to the physiological development level of children at different ages, as well as children's normal and foreseeable use of child care articles. These behaviours include touching, mouthing, breathing and dermal contact behaviours. Annex B provides reference data on children's physiological development levels and behaviours.

4.1.5 Exposure routes

Based on the characteristics of the product and the behavioural characteristics of the child, the route of exposure to chemicals in different child care articles can be different. Possible exposure routes of chemical substances in children's products include ingestion, inhalation and dermal contact, etc. Annex B gives the possible exposure routes and related exposure parameters of chemical substances in child care articles.

4.2 Assessment of chemical safety of child care articles

Based on the principles given in 4.1, this document evaluates the chemicals in products. Generally, hazardous chemicals that are commonly found in various child care articles, have already been restricted in other products, and pose exposure risks to children during use are classified as Level 1. Potential hazardous chemicals found only in specific products are classified as Level 2. The evaluation process for generic and specific chemical safety requirements of products is shown in Annex C. The general chemical safety requirements specified in this document establish fundamental technical criteria. Chemical safety provisions stipulated in corresponding product standards are technical specifications developed on the basis of the general chemical safety requirements, adapted to the characteristics of specific products, and may refine the general requirements as appropriate. All child care articles shall conform to both the general chemical safety requirements and the specific product safety requirements. In case of any conflict between them, the specific product safety requirements shall prevail.

5 General and basic requirements and recommendations

5.1 General

Materials such as plastics, rubber, coatings, textiles and leather are commonly used in child care articles. The potential high-risk chemicals in these materials can have adverse effects on children during use. Based on the principles outlined in 4.1, this document evaluates the product characteristics of child care articles, toxicological properties of potential chemical substances, child development levels and behaviours, and exposure routes. Ultimately, migratable elements, phthalates, azo colorants, formaldehyde and polycyclic-aromatic hydrocarbons (PAHs) should be controlled for child care articles. The relevant information on each chemical can be found in Annex C.

5.2 Requirements

5.2.1 General

See Table 1 for common materials and hazardous substances in child care articles. See 5.2.3 to 5.2.7 for the restriction requirements of hazardous chemical substances.

Table 1 — Chemicals by material

Materials	Migration of certain elements (see 5.2.3)	Phthalates (see 5.2.4)	Azo colorants (see 5.2.5)	PAHs (see 5.2.6)	Formaldehyde (see 5.2.7)
Plastics	X	X			
Coating	X	X			
Rubber	X	X		X (exclude silicon rubber)	
Fabric	X		X		X
Leather	X		X		X
Resin-bonded wood	X				X
Other materials	X				
NOTE Other materials (e.g. paper and paperboard, wood, bamboo) are included, but metal, glass and ceramic are excluded.					

5.2.2 Sampling

The sample for testing shall be representative of the material used in mass production. Identical materials may be combined and treated as a single test portion. Test portions may be composed of more than one material or colour only if physical separation, such as dot printing, patterned textiles or mass limitation reasons, precludes the formation of discrete specimens.

The above sample requirement does not preclude the testing of materials before they are used to manufacture (raw materials from the manufacturing process).

The manufacturing process should ensure that no additional prohibited risks are added to the materials.

Where a surface is coated with a multi-layer of paint or similar coating, the test sample shall not include any of the base material. Paint and other similar surface-coating material means a fluid, semi-fluid or other material, with or without a suspension of finely divided colouring matter, which changes to a solid film when a thin layer is applied to a metal, wood, leather, cloth, plastic or another surface.

NOTE If the composite materials (e.g. coated fabric) can be mechanically separated, the coating and fabric are tested separately.

For migration of certain elements and phthalates tests, a test portion of less than 10 mg from a single laboratory sample shall not be tested.

If the mass of the test portion from a single sample is greater than 10 mg but less than the normal mass for testing, the test materials should be supplemented as follows:

a) supplement the identical material from other locations of the same sample;

b) sampling from raw materials: if raw materials are used instead of finished product, this should be noted in the test report.

5.2.3 Migration of certain elements

All accessible materials within the accessible area (see Table 1) shall not exceed the maximum acceptable element migration in Table 2, considering the correction factor.

The test procedure given in ISO 8124-3 shall be used.

Table 2 — Maximum acceptable element migration from child care article materials

Element	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
Limit (mg/kg)	60	25	1 000	75	60	90	60	500

5.2.4 Phthalates

All accessible plasticized materials within the protected volume (see Table 1) shall not contain phthalates exceeding the limits in Table 3.

The test procedure given in ISO 8124-6 shall be used.

Table 3 — Maximum acceptable phthalates in child care articles

Substance	CAS Registry Number®[1)]	Limit
Bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	Sum of the four substances less than 0,1 % by mass
Dibutyl phthalate (DBP)	84-74-2	
Benzyl butyl phthalate (BBP)	85-68-7	
Diisobutyl phthalate (DIBP)	84-69-5	
Di-n-octyl phthalate (DNOP)	117-84-0	Sum of the three substances less than 0,1 % by mass
Di-isononyl phthalate (DINP)	28553-12-0	
	68515-48-0	
Di-isodecyl phthalate (DIDP)	26761-40-0	
	68515-49-1	

5.2.5 Azo colorants

Coloured fabrics, leather within the protected volume that can come into direct and prolonged contact with the human skin or oral cavity shall not contain aromatic amines as given in Table 4.

Table 4 — Limits of aromatic amines in child care articles

Substance	CAS Registry Number®	Limit (mg/kg)
4-aminobiphenyl	92-67-1	30
benzidine	92-87-5	30
4-chloro-o-toluidine	95-69-2	30
2-naphthylamine	91-59-8	30
o-aminoazotoluene	97-56-3	30
5-nitro-o-toluidine	99-55-8	30
4-chloroaniline	106-47-8	30
4-methoxy-m-phenylenediamine	615-05-4	30
4,4’-diaminodiphenylmethane	101-77-9	30
3,3’-dichlorobenzidine	91-94-1	30
3,3’-dimethoxybenzidine	119-90-4	30
3,3’-dimethoxybenzidine	119-93-7	30
4,4’-methylenedi-o-toluidine	838-88-0	30
P-cresidine	120-71-8	30
4,4’-methylene-bis-(2-chloro-aniline)	101-14-4	30
4,4’-oxydianiline	101-80-4	30
4,4’-thiodianiline	139-65-1	30
o-toluidine	93-53-4	30
4-methyl-m-phenylenediamine	95-80-7	30
2,4,5-trimethylaniline	137-17-7	30
2-methoxyaniline	90-04-0	30
4-aminoazobenzene	60-09-03	30
2,4-xylidine	95-68-1	30
2,6-xylidine	87-62-7	30

1) CAS Registry Number® is a trademark of the American Chemical Society (ACS). This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

The test procedure given in ISO 14362-1 and ISO 14362-3 for fabric, and ISO 17234-1 and ISO 17234-2 for leather, shall be used.

A test portion below 0,2 g in a single laboratory sample shall be exempted from the test. All colours shall be tested. Up to three colours may be combined as one specimen.

Azo colorants that can form 4-aminoazobenzene generate amines aniline (CAS Registry Number® 62-53-3) and 1,4-phenylenediamine (CAS Registry Number® 106-50-3) under the conditions of ISO 14362-1 and ISO 17234-1. Due to detection limits, it can occur that only aniline is detected. If aniline of above 5 mg/kg is detected, then the presence of these colorants shall be tested as per ISO 14362-3 for fabric or ISO 17234-2 for leather, which can release 4-aminoazobenzene.

"White" and uncoloured fibres, threads or fabrics are not considered to contain azo colorants and, therefore, these parts should not be tested. However, attention should be paid to "pale printed" materials as they can contain azo colorants.

5.2.6 Polycyclic-aromatic hydrocarbons (PAHs)

All accessible natural and synthetic rubber (exclude silicon rubber) components within the protected volume that come into direct as well as prolonged or short-term repetitive contact shall not contain more than 0,5 mg/kg of any of the listed PAHs in Table 5.

The test procedure given in AfPS-GS-2019-01-PAK shall be used.

Table 5 — Limits of PAHs in child care articles

Substance	CAS Registry Number®	Limit
Benzo[a]pyrene (BaP)	50-32-8	0,5 mg/kg
Benzo[e]pyrene (BeP)	192-97-2	0,5 mg/kg
Benzo[a]anthracene (BaA)	56-55-3	0,5 mg/kg
Chrysen (CHR)	218-01-9	0,5 mg/kg
Benzo[b]fluoranthene (BbFA)	205-99-2	0,5 mg/kg
Benzo[j]fluoranthene (BjFA)	205-82-3	0,5 mg/kg
Benzo[k]fluoranthene (BkFA)	207-08-9	0,5 mg/kg
Dibenzo[a,h]anthracene (DBAhA)	53-70-3	0,5 mg/kg

5.2.7 Formaldehyde

All accessible fabric and leather materials within the protected volume shall not release formaldehyde in excess of 20 mg/kg (see Table 6).

All resin-bonded wood shall not release formaldehyde in excess of 0,124 mg/m^3 (see Table 6).

Table 6 — Maximum acceptable formaldehyde in child care articles

Material	Substance	CAS Registry Number®	Limit
Fabric and leather	Formaldehyde	50-00-0	20 mg/kg
Resin-bonded wood			0,124 mg/m^3

For formaldehyde released from fabric and leather, the test procedure given in ISO 14184-1 for fabric and ISO 17226-1 for leather shall be used.

Different types of fabrics shall be tested separately but the colour difference can be ignored. A test portion below 1,0 g in a single laboratory sample shall be exempted from the test.

For formaldehyde released from fibreboard, the test procedure given in ISO 12460-1 shall be used.