

Child use and care articles — Safety guidelines

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National foreword

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Child use and care articles - Safety guidelines

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Artikel für Säuglinge und Kleinkinder - Sicherheitsleitfaden

This Technical Report was approved by CEN on 23 March 2004. It has been drawn up by the Technical Committee CEN/TC 252.

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Foreword

This document (CEN/TR 13387:2004) has been prepared by Technical Committee CEN/TC 252 “Child use and care articles”, the secretariat of which is held by AFNOR.

This document supersedes CR 13387 :1999

This is a revision of CR 13387 first published in 1999. It is a non-normative CEN publication which provides guidance information on common hazards that should be taken into consideration when developing safety standards for child use and care articles.

These guidelines deal with hazards that are common to child use and care articles. They have been drawn-up by a working group of experts set up by CEN Technical Committee, TC 252 Child use and care articles, with the prime objective of harmonizing the approach to hazard and risk assessment and prevention. The guidelines give recommendations on preventive safety measures to avoid injuries that could be caused by child use and care articles.

The standards being drafted by CEN/TC 252 are for child use and care articles intended for children from birth to 48 months of age who form a very vulnerable group in society. Up to 18 months of age the development of knowledge takes place through the combined use of sensory and motor skills, i.e. children learn to see, hear, taste, smell and feel. Their movements are aimed at achieving familiarity with their environment. As children become older they achieve increased muscular control and balance. Even up to 48 months of age children are unpredictable in their behaviour. Special consideration has to be given to the fact that these children cannot understand how to avoid risks and thus are involuntarily exposed to them.

Child use and care articles constitute a group with large variations between the different products. However many safety hazards associated with this diverse group of products are very similar. These guidelines identify many of these safety hazards and give details that enable similar safety principles to be applied to the drafting of standards across the group of products.

The described measures are based upon safety requirements in existing standards and in standards under development for different groups of articles within the scope of CEN/TC 252.

Where similar safety issues have been applied in standards that have either been developed or are under development by CEN/TC 52 (safety of toys), CEN/TC 136 (safety of playground equipment) and CEN/TC 207 (safety of children’s nursery furniture), these have also been taken into consideration when drafting this document.

The information given in these guidelines reflects the current state of the art. Standards and regulations will continuously be developed. Other sources may also provide useful information for the reader. Some of the test methods offered have yet to be fully validated.

Introduction

These guidelines present safety specifications and test methodology relating to hazards that are common to child use and care articles. A common approach to product information is also considered.

The general safety philosophy given in section 1 is based on the premise that child use and care articles should be designed to be safe.

Detailed safety information is given in the following sections:

- chemical hazards (section 2);
- mechanical hazards (section 3);
- thermal hazards (section 4);
- product information (section 5).

These guidelines contain two annexes and a bibliography:

- Annex A contains anthropometric data and details of the abilities of children from birth to 48 months of age;
- Annex B describes a risk assessment procedure;
- bibliography of reference literature.

How to use these guidelines

The safety specifications and test methods given are intended to give guidance and to lead to consistency when writing safety standards for child use and care articles. In addition, these guidelines can assist those with a general professional interest in child safety.

The safety specifications detailed do not constitute an exhaustive set of specifications that can be directly applied to all child use and care articles. As subsequent sections explain, their applicability to particular products should be decided by experts. When analysing the hazards and risks associated with child use and care articles, the need to balance the reduction of hazards and risk with the capability for manufacture and use of the product should be considered.

There may also be alternative means of achieving similar levels of safety that are not envisaged in these guidelines.

In these guidelines a rationale is given for a particular hazard explaining the potential hazard to the child. Wherever possible, requirements, test equipment and test methods are given which can be used when drafting standards. It should be noted that the terminology in these guidelines is not that required for standards, and that the word *shall* has to be used in standards, not *should* as given in these guidelines.

A general safety philosophy is given in section 1 of these guidelines.

Chemical hazards are addressed in section 2. The chemical properties associated with the use of, and availability to, materials for the construction, coating and/or packaging of child use and care articles that may damage a child's health are considered.

Mechanical hazards are addressed in section 3. “Mechanical hazard” is a general designation for physical factors which may give rise to injury due to the mechanical properties of products or parts of products.

Thermal hazards are addressed in section 4. “Thermal hazard” is a general designation for the combustible properties of materials and/or their ability to conduct high and low temperatures which may give rise to injuries from burns and scalds.

Product information is addressed in section 5.

Annex A provides tables of anthropometric data and abilities of children from birth to 48 months of age. It presents a compilation of data in current literature. Only sources that explain the method by which the measurements were taken, and of which the sample size was large enough to give reliable results, have been selected.

Annex B describes an outline risk assessment procedure.

The Bibliography contains a list of reference literature and lists the standards that have been considered when drafting these guidelines.

These guidelines do not cover hazards related to acoustics. The sensitivity of children to loud noise is basically unknown. There are scientists who hold the opinion that, since the auditory canal in children is smaller than in adults, there is a difference in amplification which makes children more sensitive to high frequency sounds. Impulse sounds are especially hazardous since permanent damage to hearing may occur after only one exposure to high peak sound levels.

The products on the current work programme of CEN/TC 252 emit little or no noise. However, in the event of a product emitting a potentially hazardous level of noise, requirements to reduce the risk of damage to hearing due to high continuous and/or impulse noise levels given in EN 71-1 may be used. Child use and care articles that are manifestly designed to emit noise should not be capable of harming a child's hearing. The related restrictions according to the EU-legislation for occupational noise should not be exceeded.

The diagram in Figure 1 may be used as a structure for the understanding and use of these guidelines. The suggested sequence is:

- a) Consider the safety philosophy:
 - read and understand the general safety philosophy given in section 1.
- b) Undertake a risk analysis:
 - conduct a risk analysis following the procedure outlined in Annex B;
 - for additional guidance refer to ISO/IEC Guide 50;
 - identify the potential for injury associated with the product e.g. injury statistics and surveillance systems, research studies, recalls, complaint data etc.
- c) Establish the ability/age range of the child using the product:
 - establish an ability/age range for the child who uses the product;
 - consult the anthropometric data in Annex A;
 - for additional information consult other sources of data e.g. CHILDATA.

- d) Consult the hazard categories in sections 2 to 4:
 - consider the chemical hazards identified in section 2 and select any relevant requirements and test methodologies;
 - consider the mechanical hazards identified in section 3 and select any relevant requirements and test methodologies;
 - consider the thermal hazards identified in section 4 and select any relevant requirements and test methodologies.
- e) Consult the product information in section 5:
 - determine the wordings for markings, purchase information and instructions for use.

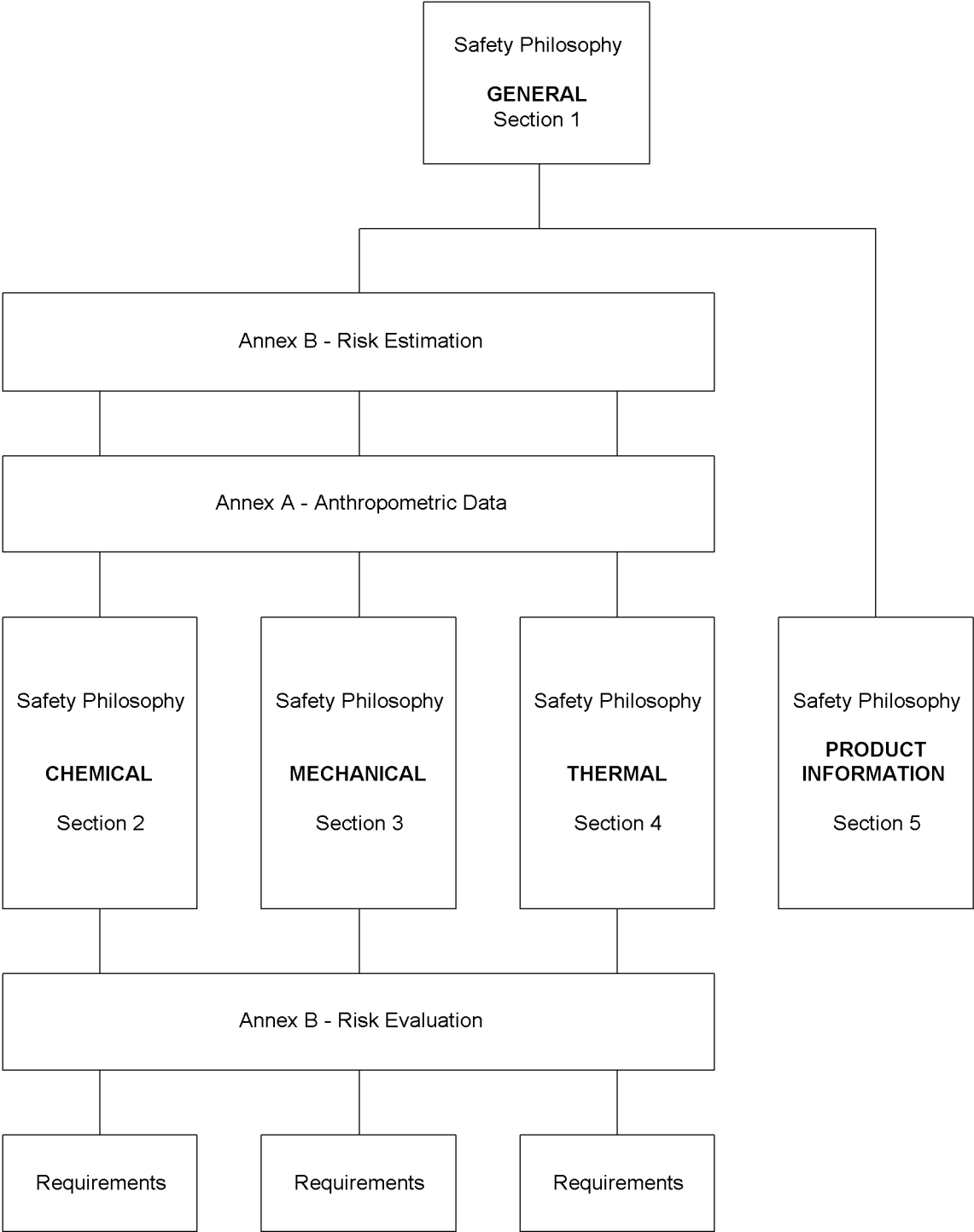


Figure 1 — Structure for the use of this report

General safety - Contents list

- 1.1 Terms/definitions used in the report
- 1.2 Built-in safety
- 1.3 Accident data

1 General safety

Safety is often a balance between being safe from injury and the other demands of a child use and care article, for example, ensuring that the item is fit for purpose as well as meeting consumers' needs and expectations.

Attention should be paid to:

- the child's stage of development (ability, weight, age, etc.);
- the intended or foreseeable use of the product, bearing in mind a child's unpredictable behaviour. This unpredictable behaviour exposes children to injury in ways that differ from those of adults, making children a particularly vulnerable group in society;
- the hazard presented by the product in the environmental circumstances under which the product and the child come into contact with each other.

Where the function of a product or part of a product changes by virtue of its use and is beyond the scope of child use and care articles, appropriate requirements should be applied. For example, toys attached to child use and care articles shall comply with appropriate toy safety requirements.

These recommendations are not exclusive and attention is drawn to the importance of ensuring that all potential hazards relevant to the product are fully addressed e.g. hygiene, the effects of electrical power etc., where other safety standards may apply.

1.1 Terms/definitions used in the report

Terms and definitions specifically related to chemical, mechanical and thermal hazards and also for product information are given in the relevant clauses.

1.1.1 Terms identical to those given in the definitions in CEN/CENELEC Memorandum no 9.

Harm: physical injury and/or damage to health or property.

Hazard: a potential source of harm or a product characteristic which could lead to injury.

Intended use: the use of a product, process or service under conditions or for purposes in accordance with specifications and instructions provided by the supplier (including information for publicity purposes).

Risk: the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.

Safety: freedom from unacceptable risk of harm. (It should be understood that young children cannot be expected to appreciate risk adequately. Risks generally considered by society as acceptable have to be taken into account when referring to the safety of children).

1.1.2 Common terms/definitions

Hazard characterisation: the quantitative evaluation of the nature of the adverse health effects following exposure to a risk source(s).

Hazard identification: the identification of a risk source(s) capable of causing adverse effect(s).

Risk analysis: the investigation of available information to identify hazards and to estimate risks.

Risk assessment: the evaluation, including the identification of the related uncertainties, of the likelihood and severity of an adverse effect(s) following exposure under defined means to a risk source(s).

Reasonably: should, where appropriate, take account of the foreseeable use and unpredictable behaviour of children.

1.2 Built-in safety

Standards related to child use and care articles should always be formulated with children and their safety in mind and there is no doubt about their importance in reducing children's injuries.

Child use and care articles should be designed with the intention of making them safe. Hazards should be eliminated wherever possible. For cases where a hazard cannot be eliminated or sufficiently minimized – by design or safeguards – product related information should be given. However product related information should not be used as an alternative to safe design. "Built-in" safety, which does not require any further human action, is the most effective means of preventing accidents and injuries associated with products. This is best built-in at the design and manufacturing stages of product development so that no safety device or action is needed when the product is used.

If a safety device is needed, it should wherever possible, be one which works automatically without human intervention. Next in order of effectiveness is a safety device which requires a single action. Least effective is when safety has to be considered in relation to the product each time it is used.

1.3 Accident data

A basis for risk assessment is given in Annex B.

Accident and injury data such as EHLASS "European Home and Leisure Accident Surveillance System" and/or other equivalent information sources should be consulted.

The absence of an accident history cannot be a good reason for an automatic presumption of a low level of risk. Other factors should be taken into account, particularly when the possible severity of injury is high.

Appropriate data may not be available for many reasons, including the absence or ineffectiveness of a data collection system, the time delay in collating and presenting statistics, changes in product design and use conditions etc. For example, historical information related to a product or material used in a hot climate may not apply to its use in colder countries or vice versa.

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2 Chemical hazards and risk

2.1 General

The inherent early vulnerability of young children combined with their different stages of development and learning, exposes them to potential chemical risk from the constantly changing range and variety of child use and care articles to which they have access, either intended or not. This is of considerable importance as chemical hazards and risk represents a more 'unseen', usually long-term, danger than mechanical or thermal hazards.

The chemical properties of materials used to manufacture and package child use and care articles, as well as the substances and preparations used in treating and coating these materials, may generate different hazards - hazards resulting from the ingestion, skin contact and inhalation of materials that may have a harmful acute or chronic toxic, carcinogenic or mutagenic and/or allergic and/or corrosive or irritant effect. However, it is important to remember that hazard is only part of the equation and assessment of risk requires the combination of hazard and exposure.

This clause generally only addresses hazard due to the general lack of exposure data available. This remains a critical research need and will form the basis of subsequent revision of these guidelines as relevant data becomes more available.

It is intended that this clause be used in the manner indicated in the safety philosophy (2.3). In this way the nature of the hazard and the risk is identified; the methods indicated in 2.5 to 2.17 may be used to assist derivation of the risk by providing levels of content or migration for specific chemicals. Where risk is considered to exist, an appropriate risk management strategy should be considered. When risk has been eliminated or reduced to the lowest practicable level, the methods indicated in 2.5 to 2.17 may then be considered to ensure acceptable levels are not exceeded. Where a method provided is not considered applicable, or not available at present, a suitable alternative may be considered.

2.2 Terms related to chemical hazards and risk

A number of different definitions may be found for the following terms, e.g. in ISO/IEC Guide 50 or CEN/CENELEC Memorandum 9, but those used here represent the European Commission's (EC) independent expert Scientific Committee of Toxicity, Ecotoxicity and the Environment (CSTEE) more detailed guidance on 'standardising' current variability in (chemical) risk assessment procedures (http://europa.eu.int/comm/food/fs/sc/ssc/out83_en.pdf).

Risk assessment: the evaluation, including the identification of the related uncertainties, of the likelihood and severity of an adverse effect(s) occurring to people following exposure under defined means to a risk source(s).

Hazard identification: either - the identification of a risk source(s) capable of causing adverse effect(s) to people, together with a qualitative description of the nature of these effect(s):

- or - the determination of particular hazards people may be exposed to, including related toxicity data;
- or - the determination of substances of concern and the adverse effects they may inherently have on people under certain conditions of exposure, taking into account toxicity data.

Hazard characterisation: either - the quantitative or semi-quantitative evaluation of the nature of the adverse health effects to people following exposure to a risk source(s):

- or - the qualitative and, whenever possible, quantitative description of the nature of the hazard (or possible adverse effect[s]) associated with a biological, chemical or physical agent, based on one or more elements, such as mechanisms of action involved, biological extrapolations, dose-response and dose-effect relationships, and their respective related uncertainties.

Exposure assessment: either - the quantitative or semi-quantitative evaluation of the likely exposure of people to a risk source(s) from one or more media:

- or - the quantitative and qualitative analysis of the presence of a chemical (including its derivative) which may be present in a given environment and the influence of the possible consequences it may have for a given population of particular concern.

Risk characterisation: either - the quantitative or semi-quantitative estimate, including related uncertainties, of the probability of occurrence and severity of adverse health effect(s) in a given population under defined exposure conditions, based on hazard identification, hazard characterisation and exposure assessment:

- or - the integration of evidence, reasoning and conclusions collected in hazard identification, dose-response assessment and exposure assessment and the estimation of the probability, including related uncertainties, of occurrence of an adverse effect if a chemical is administered, taken or absorbed by a particular organism or population;
- or - the qualitative and/or quantitative estimation, including related uncertainties, of the severity and probability of occurrence of known and potential adverse effects of a chemical in a given population.

No observable adverse effect level (NOAEL): The highest dose that does not give a biological end-point effect(s).

Tolerable daily intake (TDI)/Acceptable level (in mg/kg of body weight, BW): The maximum permissible amount of a chemical which may find its way into the body, by all routes, and from all sources in the course of an average day during a person's lifetime.

Lowest observable (adverse) effect level (LO(A)EL): The lowest observed dose shown to give a biological end-point effect(s).

2.3 Safety philosophy

2.3.1 General

A new chemicals legislation strategy for registration, evaluation and authorisation of chemicals (REACH) is currently under discussion within Europe. This system will authorise chemical substances of high concern. Such substances will not be permitted for use except for authorised purposes. Whether or how this REACH system will apply to substances and articles is still under debate at the time of publication. It is advised that up-to-date information be sought on REACH as it becomes known.

Existing general European legislation covers both health and environmental effects from chemicals for professional and consumer use, but for the reduction of risks of high concern due to the use of chemicals in certain types of products, the new approach products directives are relevant for ensuring safety. These directives protect people from acute risks from chemicals in products, but the long-term or chronic effects from chemicals are not their main focus. However, child use and care articles do not currently have such a directive.

The Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (currently under revision) covers all packaging placed on the European market and all packaging waste, whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used.

The assessment of health risk from exposure to chemicals is of paramount importance to ensuring children's safety. When drafting safety standards for child use and care articles it is necessary to consider the possibility of chemical hazards arising from ingestion, skin contact and inhalation of materials used in the construction, coating and/or packaging of these articles. Ingestion is of particular importance as young children frequently mouth anything within reach.

The degree of risk depends on the hazard of the particular chemical constituent, its concentration in the child use and care article, and the extent of exposure (contact with and transfer from the article) to the child. To carry out an assessment of the risk from a toxic substance potentially present in some part of a child use and care article, all the necessary relevant experts should be consulted, for example chemists, toxicologists and socio-economists.

However, risk assessment is intended to be of practical use, and yet there is wide variability in the quality and quantity of data on different risk sources. Until now though, there have been few attempts to systematically co-ordinate such assessments. The International Programme on Chemical Safety (IPCS) has an active programme on harmonisation of approaches to the assessment of health risks. It should help ensure openness, transparency and consistency in the process of hazard identification and evaluation of chemicals, prioritisation of those chemicals, and subsequent adoption of commonly acceptable exposure scenarios and characterisation of the degree of risk. Appropriate risk management strategies should then be considered. The following strategy is based on this recommended approach.

2.3.2 General strategy

Specification of the problem in an unambiguous and transparent form is essential for an effective risk assessment process. The scientific information necessary for this relates to the:

- nature of the hazard (what, why, how, unexpected, scale);
- possible adverse effects to health (severity, speed, frequency of effect);
- relevant sources of exposure;
- age range and development of the child; and
- route and nature of exposure.

How these questions are addressed provides the basis of the approach for the risk assessment. Four main stages are generally accepted to be relevant to any assessment:

- hazard identification;
- hazard characterisation (and prioritisation of chemicals);
- exposure assessment; and
- risk characterisation.

It is important that there is transparency and consistency in, and therefore between, risk assessment processes. Any assessment should lead to a value judgement being able to be made on the results.

2.3.3 Potential hazards of chemical constituents

It is first necessary to consider what hazardous chemicals might be present in the child use and care article as particular materials give rise to specific hazards.

Table 2.3A illustrates many of the materials that may be used and the main hazardous substances potentially present in each case. It should not be taken as an exhaustive 'list' of materials nor of the possible chemical hazards. Readers are also directed to the Ospar list of chemicals for priority action (http://www.ospar.org/documents/02-03/OSPAR03/SR-E/ANNEX12_List%20of%20chemicals%20for%20priority%20action.doc). The possible hazards may be even wider than those indicated in the table, although the chemical risk may not necessarily be significant.

Table 2.3A — Materials likely to be used and their associated hazards

A=Migration of certain elements. **B**= Dyestuffs/pigments, **C**=Flame retardants, **D**=Plasticisers, **E**=Formaldehyde, **F**=Preservatives, **G**=Allergies, **H**=Other toxic substances.

Type of Material	Type of Hazard							
	A	B	C	D	E	F	G	H
Constructional								
Bamboo	X	X	X					
Basketwork	X	X	X					
Chipboard/plywood	X	X	X		X			X(j,y)
Metals/alloys	X						X(Ni)	
Plastics	X	X	X	X		X		X(n,w,y)
Rubber	X	X	X			X	X	X(h,s,t)
Wood	X	X	X					X(j,y)
Sheet								
Fur	X	X	X		X	X	X(m)	
Leather	X	X				X	X(Cr)	X(j,y)
Paper/board	X	X	X			X		X(d,j,y)
Plastics	X	X	X	X		X		X(n,w,y)
Rubber	X	X	X			X	X	X(h,s,t)
Textiles	X	X	X	X	X	X		X(j,n,p,y)
Coatings								
Enamel	X							
Metal plating	X						X(Ni)	
Paint/varnish	X	X	X		X			
Plastics	X	X	X	X		X		
Rubber	X	X	X			X	X	X(h,s)
Fillings/Paddings								
Feathers	X	X	X			X	X(m)	
Foamed plastics	X	X	X	X		X		
Hair	X	X	X					
Straw	X		X				X	
Wadding (natural)	X	X	X		X		X	X(p)
Wadding (man-made)	X	X	X	X		X		
Other								
Bristles	X	X						
Cord/string/rope	X	X	X	X	X	X		
Cork	X	X	X					

where

Cr- chromium, d- dioxins, h- N-Nitrosamines and N-Nitrosatable substances, j- polychlorophenol, m- fine particles, n- vinyl chloride monomer, Ni- nickel, p- pesticides, s- accelerants/vulcanisation agents, t- volatile compounds, w- bisphenol A, and y- organometallics.

All such hazards have to be assessed individually to discover the extent of the risk. For each identified chemical, consideration should first be given to relevant toxicological evaluation(s) based on:

- information available for supply from related stakeholders (e.g. industry);
- literature searching strategy (e.g. published scientific literature in standard toxicological and related texts);
- evaluations undertaken for the use of a particular chemical in other consumer product areas (e.g. food contact materials, organic chemical release from toys and cosmetics); and
- known accident data, although the absence of accident data does not necessarily indicate the presumption of a low level of risk.

The typical toxicological information to be gathered for a meaningful assessment requires identification of the most significant end-point(s) from the following range of tests:

- acute toxicity;
- skin and eye irritation;
- skin sensitisation;
- sub-chronic toxicity;
- carcinogenicity;
- mutagenicity; and
- reproductive toxicity.

For a few chemicals, more detailed examination of aspects of neurotoxicity, immunotoxicity, endocrine toxicity or other special studies may be required. In some cases, knowledge of the mechanism by which the observed toxicity is induced may be required to assess whether the mechanism of action is relevant to people.

The toxicological data should be used to derive a numerical score of toxicological priority as the means of identifying priority chemicals for further assessment. The modified IPS (Informal working group on Priority Setting) ranking scheme, should form the basis of this prioritisation step. It enables combination of toxicological hazard assessment and exposure estimation to determine a human health priority score.

Chemicals should be ranked for mutagenicity, carcinogenicity, reproductive toxicity, skin sensitisation and severe target organ toxicity by the above hazard-ranking procedure. Scores for mutagenicity and reproduction, in particular, may be modified in light of toxicological interpretation of the data.

'High ranking' chemicals (based on evidence of effects in animals that may be relevant to humans, or evidence to suggest/clear effects in humans) are already likely to have been prohibited for use in consumer products. It should be noted that chemicals already classified as Category 1 or 2 for carcinogenicity, mutagenicity or toxicity for reproduction under Directive 67/548/EEC are restricted for consumer use. In some cases it is probable that the levels of such chemicals in the products should be kept as low as is practically possible; standards and methods should then be developed at the limit of detection. Where there is insufficient data to evaluate at least the mutagenicity, reproductive toxicity and skin sensitisation end-points, a 'ranking' suggesting generation of additional relevant toxicological information should be used. Where there is either no evidence of, or only limited data on, toxic effects in animals or humans and where such data exists, it is either clearly irrelevant or unlikely to occur in humans, a more subjective assessment is required. Consideration should then be made of available usage information, potential exposure routes and amount of migratable chemicals (*second tier assessment*, see 2.3.5).

2.3.4 Potential characteristics of use

The qualitative characteristics of the use of the child use and care article should then be identified. Factors that should be considered include the:

- intended and foreseen age range and ability of the child;
- conditions under which the article is to be used (taking into account the normal behaviour of children, the degree of supervision, the simultaneous use of the article by more than one child and all phases of the life cycle of the article);
- environment in which the article is to be used, e.g. indoors taking into account factors such as ventilation;
- length of time of exposure to the article; and
- likely route(s) of exposure to the article, e.g. ingestion, skin contact or inhalation.

2.3.5 Potential routes of chemical exposure

2.3.5.1 General

There are three major routes by which chemicals can enter the body; ingestion, skin contact and inhalation. Where exposure through more than one route is likely, an additive approach may be used. When data is unavailable for one route of exposure, extrapolation from another route may be possible, although there are inherent uncertainties in such cases.

In addition, there may also be the potential risk of an allergic reaction to natural materials, e.g. fur, feathers, rubber and leather, by children who are particularly disposed to allergies. Furthermore, the presence of mould, if prone to development, may also give rise to allergic reaction.

2.3.5.2 Ingestion

The possible risk of a child ingesting a hazardous substance as a result of mouthing (licking or sucking) an article is the most important of the potential chemical hazards. Ingestion includes both extraction by saliva and the act of swallowing, e.g. paint removed by teeth or extractable chemical constituent from a material, such as plasticiser from polyvinylchloride (PVC).

General guidance in determining daily intake from observed release levels is as follows:

The analytical result obtained for the mass of analyte extracted C (mg) first needs to be converted into a release rate C_1 , the mass extracted per cm^2 of sample per hour of extraction.

$$C_1 = \frac{C}{S \times T} \left(\text{mg/cm}^2/\text{h} \right)$$

where

S is the surface area of the sample in cm^2 ; and

T is the extraction time in hours.

This is then converted into a daily intake, I .

$$I = C_1 \times A \times M \text{ (mg/day)}$$

where

A is the area of item mouthed by a child in cm²; and

M is the maximum mouthing period in hours/day.

2.3.5.3 Skin contact

A further possible route of exposure is from contact between the child use and care article and a child's skin. This is usually only a consideration when a child repeatedly touches (part of) an article in use. For example, transfer of a water-soluble chemical, e.g. a dye from a textile such as a bed-sheet. There may be a risk of allergic reaction from skin contact with certain chemical constituents within child use and care articles, e.g. nickel and formaldehyde, although usually direct and prolonged contact is required before the body becomes sensitised.

There may also be the potential transfer, by fingers, of a chemical from a child use and care article to the mouth. However, such problems are usually considered under ingestion where the risk is greater.

General guidance in determining daily intake from observed release levels is as follows:

The analytical result obtained for the mass of chemical extracted C (mg) first needs to be converted into a release rate C_1 , the mass extracted per cm² of sample per hour of extraction.

$$C_1 = \frac{C}{S \times T} \text{ (mg/cm}^2\text{/h)}$$

where

S is the surface area of the sample in cm²; and

T is the extraction time in hours.

This is then converted into a daily intake, I .

$$I = C_1 \times A \times M \times F \text{ (mg/day)}$$

where

A is the area of skin of the child in cm² in contact with the material of the child use and care article;

M is the duration in hours/day of skin contact with the material of the child use and care article; and

F is the fraction of chemical absorbed through the skin, e.g. 1 (assumes 100 % absorption) if no data to indicate otherwise.

NOTE it is important that for dermal exposure, these parameters are considered on a case-by-case basis for specific child use and care articles.

2.3.5.4 Inhalation

There is also the potential risk from inhalation of released volatile compounds from child use and care article, e.g. siloxanes from silicone soothers or feeding bottle teats, or formaldehyde from plywood or chipboard. These restrictions should still apply even if the dimensions of the part might mean that the amount of volatile compounds released by the article is minimal.

General guidance in determining daily intake from observed release levels is as follows:

The analytical result obtained for the mass of chemical extracted C (mg) first needs to be converted into a release rate C_1 , the mass extracted per m^3 of air per hour of extraction.

$$C_1 = \frac{C}{V \times T} \quad (\text{mg}/\text{m}^3/\text{h})$$

where

V is the volume of air in m^3 ; and

T is the extraction time in hours used in the experiment in hours.

This is then converted into a daily intake, I .

$$I = C_1 \times VR \times M \quad (\text{mg}/\text{day})$$

where

M is the maximum exposure period in hours/day; and

VR is the ventilation rate of the child in m^3/h .

The following shows accepted ventilation rates used by the US Environment Protection Agency (EPA) in a lead absorption model:

Age (years)	Ventilation rate (m^3/day)	Ventilation rate (m^3/h)
0-1	2.0	0.080
1-2	3.0	0.125
2-5	5.0	0.208
5-7	7.0	0.292

NOTE it is suggested that exposure limits should be based on World Health Organisation (WHO) air quality guidelines for those chemicals that have such limits. For others, occupational exposure limits may be available (assume 8 h exposure/day), where an additional safety factor of 10 can be used to reflect the fact that children may be more sensitive than working adults. For some chemicals, TDIs derived from oral exposure may be available. Here assumptions would have to be made as to the extent of absorption from the lungs into the systemic circulation and what proportion of the TDI is to be allocated to child use and care articles. If appropriate data is not available, 100 % absorption should be assumed.

2.3.5.5 Exposure modelling

Lack of good exposure data is frequently a problem. Where such data is unavailable, 'best' or 'worst case' exposure estimates may need to be generated; the emphasis is usually on the latter in the first instance with subsequent refinement in the event of any identified concern. Default assumptions should be made about the human body where required. The UK Department of Trade and Industry (DTI) publishes 'Childdata', which is a useful source of collated information for physical measurements of children. However, there is currently little other validated data available to assist with exposure assessments. Compilation of such data, where it exists, will be included in subsequent revision of this document. In the meantime, common exposure model scenarios and their validation are required to replace the current estimated or measured exposure-related data. Laboratory-based studies may also be used to overcome difficulties associated with the absence of exposure-related data. Literature and information review may be used to establish appropriate exposure parameters and scenarios and to derive relevant criteria for exposure assessment. Existing candidate laboratory studies can then be reviewed or new studies derived and the limit values produced can be used as part of any risk assessment. However, these laboratory-based studies may produce, or be refined to produce, limit values in line with toxicologically acceptable measured or estimated exposure limit values obtained from other sources on a known product. Through validation by collaborative trial, the values obtained from these laboratory-based studies can then be considered against limit values. The CONSUMER EXPOSURE models application (CONSEXPO 3.0), a computer software modelling tool based on mathematical contact, exposure and uptake models, may be useful in the assessment of human exposure to chemicals from consumer products. It contains the algorithms which are contained in the 1996 EU Technical Guidance Documents in support of the Commission Directive 93/67/EEC - Risk Assessment for new Notified Substances, Commission Regulation 1488/94 - Risk Assessment for Existing Substances and the 1996 EU System for the Evaluation of Substances (EUSES) (EUR 17308 EN).

2.3.5.6 Exposure release levels

The proposed approach of second tier assessment using measured, estimated or predicted intake or exposure has been adapted from the EC Scientific Committee for Food (SCF) strategy based on three exposure classes:

— **Low level release, corresponding to an intake of $<1\mu\text{g/kg}$ bodyweight (BW)/day:**

in such cases, only in vitro mutagenicity data (as the generally accepted critical adverse effect indicator of carcinogenicity) are required. The three accepted tests are the bacterial test for gene mutation, test for clastogenicity and for aneugenicity, and mammalian cell mutation assay (mouse lymphoma assay preferred);

— **Medium level release, corresponding to an intake of $1\text{--}100\mu\text{g/kgBW/day}$; and**

in such cases, bio-accumulation data (octanol/water partition coefficient), the above three in vitro mutagenicity studies, a 90-day oral study and sensitisation data are required.

— **High level release, corresponding to an intake of $100\text{--}1000\mu\text{g/kgBW/day}$:**

in such cases, a full data package including absorption, distribution, metabolism and elimination (ADME), reproductive and development studies is required. The need for carcinogenicity data should be considered on a case-by-case basis in light of the results of the mutagenicity studies (genotoxic or non-genotoxic) and the fact that exposure to chemicals in child use and care articles does not constitute life-time exposure.

2.3.6 Risk characterisation

Risk characterisation presents the comparison of levels of concern with exposure levels.

For risks from most chemicals, a uni-dimensional approach is usually used, based on the assumption that for all effects (other than cancer) there is a threshold level of exposure below which no (observable) adverse effects occur (NOAEL). Data are usually derived by extrapolating from high-dose animal studies to low-dose human exposure, and from small animal groups to the larger diverse human population.

Whilst likely for an individual, biological variability in response to identical exposures within a population makes things more difficult; hence the introduction of uncertainty/safety factors to provide acceptable limits. The tolerable daily intake (TDI) of a chemical is derived by dividing the NOAEL by an appropriate uncertainty factor (usually 100) which represents inter-species and inter-individual differences. Where a NOAEL is unavailable, a lowest observable [adverse] effect level (LO[A]EL) may be used; in such cases a further uncertainty factor (usually 5) may be introduced.

The daily intake is then compared to the TDI for the chemical. The level of chemical released from one particular child use and care article should not exceed some fraction of this TDI. However, child use and care articles are not usually the only possible source of exposure to the chemical. A 10 % contribution to the total fraction from child use and care articles seems reasonable, although there may be justification for a higher value in certain situations.

$$I \text{ (mg/day)} < 10 \% \text{ TDI (mg/kgBW)} \times W$$

where

W is the weight of the child in kg.

Quantitative risk assessment by low-dose extrapolation is generally used for non-threshold (e.g. genotoxic) substances, such as *N*-Nitrosamines, giving an estimate of risk for a particular level of exposure or an estimate of exposure for a pre-defined level of risk. It is necessary to reduce the levels of these chemicals to as low as is reasonably practical.

2.3.7 Risk management

Risk management then weighs the policy alternatives in light of this result and, if required, as a means for selecting and implementing appropriate risk reduction/control options.

The identification of any risks requires safety measures, either to remove the risk completely or, at least, to reduce it to as low a level as is reasonably practical. This may be by limiting access to the chemical hazard(s) by material selection or design, or by limiting or preventing access to the hazard(s) by 'coating'. This may include, if appropriate, application of the Precautionary Principle. Consensus on this point is usually determined by the state-of-the-art.

However risk assessment results do not account for how individuals and societies value certain adverse consequences, i.e. the public perception of risk. No transparent framework yet exists for allowing risks and benefits to be compared.

Any residual risk that cannot be removed by the above safety measures should be communicated to the user/carer.

Any outcome may need to be amended as new information becomes available or new perceptions developed.

This strategy may give rise to requirements and accompanying test methods, the requirements allowing assessment whether the acceptable level of risk has been reached, rather than prescribing a specific solution.

2.4 Chemical hazard-reducing specifications

There are available chemicals for which total content or migration limits may be required because of health (toxicological) concerns following identification of toxicological hazard or exposure to low levels of the substances.

The following sub-clauses (2.5 to 2.17) provide general guidance for helping set appropriate limits using the risk assessment approach already identified, for some of the more common chemicals likely to be encountered with child use and care articles. They specifically recommend test methodology (and test equipment) that should be applied to ensure conformance with specified limits:

- migration of certain elements (2.5);
- migration of vinyl chloride monomer (2.6);
- total content and migration of nickel (2.7);
- total content and migration of plasticisers (2.8);
- total content and migration of formaldehyde (2.9);
- total content of flame retardants (2.10);
- migration of *N*-Nitrosamines and *N*-Nitrosatable substances (2.11);
- migration of vulcanisation accelerators (and antioxidants) (2.12);
- total content of volatile compounds (2.13);
- total content and migration of certain dyes, azo-colourants and disperse dyes (2.14);
- migration of bisphenol A (2.15);
- total content of organotin compounds (2.16);
- total content of pentachlorophenol (2.17).

Additional clauses, e.g. for preservatives, non-ionic surfactants and volatile solvents, are planned for subsequent revision of this document. Standardisers should review current practice in all cases; e.g. work on organic chemical compounds in toys is well underway in CEN/TC 52/WG9 (Safety of toys).

2.5 Migration of certain elements

2.5.1 Rationale

The rationale for setting limits for the release of certain elements from child use and care articles is that, in general, they are accepted to be cumulative poisons that may pose health risks following relatively low levels of exposure, primarily through the oral route. The aim is therefore to set the strictest limit that can reasonably be achieved and measured, whilst maintaining the desired level of safety.

2.5.2 Limits

For guidance, two sets of standard limits are given below for application to general and specific cases of child use and care articles. These are maximum allowable migration levels; for both environmental and health reasons, the lowest practicable level of incorporation and/or migration should be considered. Articles intended to be mouthed by children should not exceed the specific limits given in Table 2.5A.

Table 2.5A — Specific limits for migration of certain elements

Antimony, Sb	60 mg/kg
Arsenic, As	25 mg/kg
Barium, Ba	250 mg/kg
Cadmium, Cd	50 mg/kg
Chromium, Cr	25 mg/kg
Lead, Pb	90 mg/kg
Mercury, Hg	25 mg/kg
Selenium, Se	500 mg/kg

All other child use and care articles should not exceed the general limits given in Table 2.5B.

Table 2.5B — General limits for migration of certain elements

Antimony, Sb	60 mg/kg
Arsenic, As	25 mg/kg
Barium, Ba	1 000 mg/kg
Cadmium, Cd	75 mg/kg
Chromium, Cr	60 mg/kg
Lead, Pb	90 mg/kg
Mercury, Hg	60 mg/kg
Selenium, Se	500 mg/kg

2.5.3 Requirements

When tested in accordance with the methodology shown in 2.5.4, the migration of certain elements should not exceed the specific or general limits indicated in 2.5.2.

2.5.4 Test methodology

These guidelines have been based on existing work in the field of toy safety. The test method applicable for the determination of the migration of these elements from child use and care articles is that specified in EN 71-3 Safety of toys - Migration of certain elements. The method has been validated within specified concentration ranges for the individual metals to be determined. Areas of testing (accessibility) are considered in EN 71-1 Safety of toys – Mechanical and physical properties.

For some child use and care articles, there is likely to be an added safety margin built in to the recommended limits when compared to toy safety. EN 71-3 assumes that particles of a toy product (e.g. paint) will become detached and ingested; migration into hydrochloric acid solution (stomach acid simulant) is therefore determined. Whilst some child use and care articles, e.g. babies' soothers, may be mouthed for relatively long periods, the likelihood of ingestion of detached particles is low. Furthermore, migration of certain elements into artificial saliva simulant has been shown to be generally similar to, or lower than, stomach acid simulant.

2.6 Migration of vinyl chloride monomer

2.6.1 Rationale

The rationale in setting limits for residual vinyl chloride monomer (VCM) in child use and care articles is that it is listed as a known carcinogen (Fourth Annual Report on Carcinogens, NTP 85-002, 1985). The exposure of most concern is through the oral route. The aim is therefore to set the strictest limit that can reasonably be achieved and measured.

2.6.2 Limits

Child use and care articles should meet the limit for VCM release set for food contact materials of 1 mg/kg.

2.6.3 Requirements

When tested in accordance with the method indicated in 2.6.4, the amount of migrated VCM should not exceed the limit indicated in 2.6.2.

2.6.4 Test methodology

The test method for determining the migration of VCM from child use and care articles is that specified in the official Community method of analysis for Directive 78/142/EEC and its amendments - Materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.

2.7 Total content and migration of nickel

2.7.1 Rationale

Nickel is a well-known sensitiser, which may cause serious allergic reactions when in direct and prolonged contact with the skin, e.g. nickel-coated metal clips or metal studs/zippers on clothing or equipment.

The 12th amendment to Directive 76/769/EEC - Restrictions on the marketing and use of certain dangerous substances and preparations, provides restrictions on the use of nickel in jewellery and other items intended to come into direct and prolonged contact with the skin. No definition is given for the interpretation of such contact. However, products intended for very young children should be treated as special cases and prolonged contact should be interpreted as being potentially in contact with the nickel-releasing surface for ≥ 1 h/day for a period of ≥ 4 weeks.

2.7.2 Limits

Nickel should not be used in products intended to or likely to come into direct and prolonged contact with the skin if the rate of nickel release from the part of the product in direct and prolonged contact with the skin is $> 0.5 \mu\text{g}/\text{cm}^2/\text{wk}$.

Nickel should not be used in products intended to or likely to come into direct and prolonged contact with skin which have a non-nickel coating, unless the coating is sufficient to ensure that the rate of nickel release is not $> 0.5 \mu\text{g}/\text{cm}^2/\text{wk}$ for a period of at least 2 years of normal use of the product.

2.7.3 Requirements

When tested in accordance with the appropriate methodologies shown in 2.7.4, the total content or migration of nickel should not exceed the limits indicated in 2.7.2.

2.7.4 Test methodology

Three test methods and a draft for development have been developed by CEN/TC 283/WG4 - Precious metals, to demonstrate compliance with Directive 76/769/EEC:

- EN 1810, *Body-piercing post assemblies - Reference test method for the determination of nickel content by flame atomic absorption spectrometry*;
- EN 1811, *Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin*;
- EN 12472, *Method for the simulation of wear and corrosion for the detection of nickel from coated items (followed by EN 1811)*; and
- CR 12471:2002, *Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin*.

2.8 Total content and migration of plasticisers

2.8.1 General

Plasticisers are added to polymers to give them specific properties, e.g. flexibility. They are used extensively in PVC, polyvinylidene chloride (PVDC), cellulose-acetate and unsaturated polyesters, etc. Plasticiser levels can be as high as 40 + %. They may also be present in glues and varnishes. They may also be used in lubricants at far lower levels, e.g. 2 %. Exposure to these substances can occur through both the oral and, to a lesser extent, dermal routes.

Guidelines concerning plasticiser migration have traditionally been based on static tests to assess migration from materials and articles in contact with food. However, it is now widely accepted that testing which provides data under more realistic (dynamic) conditions of exposure is more appropriate for assessing indicative plasticiser release from child use and care articles that are intended to be, or which may be, mouthed.

Achieving a predictive laboratory-based (*in vitro*) method for plasticiser migration has been limited by the lack of validated oral contact time and *in vivo* migration data as reference points. Adult data, rather than that for children, represents the only practical and ethical means for deriving such data. Since its derivation through child observation and *in vivo* adult 'chew and spit' studies, two methods have been developed and validated, albeit to differing extents. The more validated of the two is currently only applicable to determining one of the potential phthalate plasticisers (di-isononylphthalate) increasingly being found in soft PVC child use and care articles (Dutch Consensus Report, September 1998 and JRC/RIVM EUR 19899 EN, 2001). The other method has wider applicability for all commonly-used phthalate plasticisers as well as other plasticisers (A.O. Earls, I.P. Axford and J.H. Braybrook, *J.Chrom.A*, **983** (2003) 237-246 and LGC/1999/DTI/002&3, 1999). Hence both are provided in 2.8.5, in addition to a static test, to allow appropriate selection, depending on the likely usage of the article and the plasticiser(s) present.

2.8.2 Rationale

Discussions as to the potential levels of plasticiser migration from certain child use and care articles, have led the CSTEE to review currently available toxicological, migration and exposure data for six phthalate plasticisers (and certain common citrate and adipate plasticisers) and, where possible, set appropriate TDIs.

An additional potential risk is identifiable with highly plasticised PVC articles where pieces of the PVC itself may be ingested. Plasticiser migration from the PVC in the stomach can lead to sharp, rigid PVC that can cause serious injury. Manufacturers should be aware of this potential problem and take precautions to minimise the risk of ingestion of such materials.

2.8.3 Limits

The following guidance in setting total content limits in child use and care articles made from soft PVC is now available. For total plasticiser release from articles **intended** to be mouthed (e.g. soothers and feeding equipment and utensils), the Commission Decision of 7th December 1999 (1999/815/EC) prohibits the placing on the market toys and childcare articles made of soft PVC containing specified phthalates. This ruling applies only to those articles intended to be placed in the mouth by children under three years of age. The limit is 0,1 % (w/w) in the article of one or more of six specified phthalates: di-butyl phthalate (DBP), di-n-octyl phthalate (DNOP), di-(2-ethylhexyl) phthalate (DEHP), di-isononyl phthalate (DINP), di-iso-decyl phthalate (DIDP), and butylbenzyl phthalate (BBP).

The following general guidance in setting migration limits is currently as follows, but the most up-to-date information should be sought when addressing this issue. For migration release of plasticisers from articles that **may be** mouthed (e.g. cot rails and upholstery of a highchair or pushchair), the CSTEE (http://europa.eu.int/comm/dg24/health/sc/sct/out19_en.html) recommends the following guideline values for maximum permissible extracted amounts (for a child of 8 kg BW) of 0,8 mg DBP, 3,0 mg DNOP, 0,3 mg DEHP, 1,2 mg DINP, 2,0 mg DIDP, and 1,6 mg BBP per 10 cm² of article mouthed over a 3 hour time period. These values do not take into consideration the fact that children may be exposed to additional sources of phthalates.

The CSTEE also recommends that the insufficient toxicological and exposure data for certain citrate and adipate plasticisers (tri-ethylcitrate, tri-butylcitrate, acetyl triethylcitrate and acetyl tributylcitrate, and di-(2-ethylhexyl) adipate) does not make it possible to support their current use as alternatives to phthalates in toys and childcare articles intended to be, or which may be, mouthed. They do however suggest that guidance migration limits could be set, assuming satisfactory data becomes available.

Tri-cresylphosphate and tris-(2-chloroethyl)phosphate are considered under flame retardants (2.10), but are not recommended for use as plasticisers in child use and care articles.

2.8.4 Requirements

When tested in accordance with the appropriate methodologies shown in 2.8.5, the total content or migration of phthalates should not exceed the limits indicated in 2.8.3.

When tested in accordance with the appropriate methodologies shown in 2.8.5, the certain citrate and adipate plasticisers shown in 2.8.3 should not be present.

2.8.5 Test methodology

2.8.5.1 Static test method

A suitable static migration test method is similar to that used for the testing of materials and articles in contact with food. The suggested migration conditions are:

Migration solution:	artificial saliva (as BS 6684).
Extraction period:	3 hours.
Sample shape/size:	sample prepared with minimum cutting; surface area accurately measured (ignore thickness of sample if > 1 mm).
Sample:liquid ratio:	10 cm ² :20 ml.
Temperature:	37 °C.

The migrated phthalate should be extracted into a suitable solvent (e.g. hexane) before quantification. A suitable gas chromatography (GC) method is:

Column:	CPSil 5CB, 2 m × 0,222 mm or equivalent.
Carrier gas:	nitrogen.
Flow rate:	0,4 ml/min.
Oven temperature	250 °C.
Injector temperature:	270 °C.
Detector:	flame ionisation (FID).
Detector temperature:	300 °C.
Split ratio:	approx. 1:70.
Internal standards:	trimethylhexylphthalate for the determination of DEHP and dibutylphthalate for DINP and DIDP.

A calibration curve for DEHP can be prepared in the usual way using an internal standard. However, since DINP and DIDP are complex isomeric mixtures, quantification is more complicated. The graph may be prepared by plotting the ratio of the sum of the height of the internal standard peaks against concentration. As the isomeric mixtures vary between samples, a new calibration curve should be prepared for each sample.

2.8.5.2 Total content test method

The method described primarily extracts, identifies and quantifies monomeric phthalates (with wider application to other types of plasticisers) contained in PVC samples. The extraction method uses Soxhlet extraction with diethylether or other suitable solvent. The total solvent extractable plasticiser content is calculated by weight with GC-mass spectroscopy (GC-MS) detection to identify and quantify individual phthalates.

Pre-heat a 150 ml flat-bottomed flask in an oven at $(105 \pm 5) ^\circ\text{C}$ for (30 ± 5) min and allow it to cool in a dessicator prior to accurately weighing. Add approx. 50 ml solvent to the flask. Accurately weigh $(2 \pm 0,2)$ g of the article cut into small pieces (<5 mm $\varnothing$). Place in a Soxhlet thimble, adding cotton wool to prevent the sample escaping, in a Soxhlet extractor. Connect the flask, extractor and condenser together. Reflux gently on a heating mantle for (360 ± 30) min. After cooling, completely evaporate the solvent and place in an oven for (30 ± 5) min prior to cooling in a dessicator. After (30 ± 5) min, accurately weigh the flask and record the weight. Repeat until the difference between two consecutive weights is $\leq 0,0005$ g.

To the weighed extract, add (50 ± 2) ml of n-hexane or other suitable solvent. Swirl the flask to completely dissolve the plasticiser extract. Decant the solution into a 200 ml volumetric flask. Repeat, adding the rinses to the flask. Make up to the mark. As appropriate, prepare further diluted solutions so that the final concentration in solution is within the linear calibration concentration for phthalate present. Transfer a portion of solvent into a capped vial for GC-MS analysis.

The following GC-MS conditions for phthalate determination have been found to be suitable (see also Table 2.8A):

Model:	5890 GC with a HP5971A MSD with scan range 50 amu to 500 amu.
Column:	30 m, 0.25 mm I.D. & 0.15 μm film thickness, 50 % dimethyl-50 % diphenyl-polysiloxane, e.g. DB-17HT.
Carrier gas:	He.
Flow rate:	0.8 ml/min.
Injector temp:	290 $^\circ\text{C}$.
Injection volume:	2 μl .
Injection type:	splitless.
Detector:	MSD.
Transfer line temp:	280 $^\circ\text{C}$.
MSD mode:	electron impact (EI).
Temp. programme:	40 $^\circ\text{C}$ for 4 mins, 40 $^\circ\text{C}$ to 300 $^\circ\text{C}$ @ 10 $^\circ\text{C}/\text{min}$, isothermal 4 mins. total run time, 34 mins.

Table 2.8A — Typical quantitation ions for phthalate plasticisers

Typical quantitation ions for :	Tgt ion	Q1	Q2	Q3
Di-butylphthalate (DBP)	149	223	278	
Butylbenzyl phthalate (BBP)	149	206	238	
Di-(2-ethylhexyl)phthalate (DEHP)	149	167	279	
Di-n-octyl phthalate (DNOP)	149	279	261	
Di-isononyl phthalate (DINP)	149	293	127	167
Di-isodecyl phthalate (DIDP)	149	307	167	141

Compare the obtained GC-MS spectra to known spectra or phthalate ester standards to allow qualitative identification of phthalate ester plasticisers or any other compounds. Plot a calibration graph of the response against known standard concentrations and determine the response of phthalate ester found in the sample.

This method may have to be modified for other branched chain phthalates or other plasticisers.

2.8.5.3 Migration test methods

2.8.5.3.1

A suitable method for determining the release of di-isononylphthalate in saliva simulant from toys (and child use and care articles) using a head-over-heels dynamic agitation device is described in JRC/RIVM EUR 19899 EN, 2001 at www.jrc.cec.eu.int.

In this procedure, the test sample is mechanically treated with a saliva simulant of aqueous salt solution. After 30 mins of dynamic mechanical treatment, the saliva extract is removed for subsequent extraction. The flask and sample are replenished with fresh saliva simulant and subjected to a further mechanical treatment. The pooled saliva simulant extracts are subjected to two successive extractions using cyclohexane in a separation funnel. The amount of DINP in the cyclohexane solution is determined by normal phase high performance liquid chromatography (HPLC) using ultra-violet (UV) detection at 225 nm and validated by GC-MS using a non-polar column. Quantification is achieved using an external standard calibration procedure as well as an internal standard.

The migration levels observed using Dutch PVC reference material containing DINP clearly shows the migration levels for DINP to correlate to the *in vivo* mean value reported by the human volunteer studies and not the maximum value recommended by the CSTEE as the target value for any methodology. Caution is therefore required when comparing observed migration values with the guidance migration levels recommended by the CSTEE in 7.4.2.

2.8.5.3.2

A suitable method for determining the release of all commonly-used phthalates (including the six CSTEE-specified phthalates) as well as other plasticisers in saliva simulant from (toys and) child use and care articles using a linear horizontal (transverse) shaking water bath is described in A.O. Earls, I.P. Axford and J.H. Braybrook, *J.Chrom.A*, **983** (2003) 237-246 and LGC/1999/DTI/002&3 (stringent method), 1999 at www.lgc.co.uk.

In this procedure, the test sample is mechanically treated using a transverse shaking water bath with saliva simulant of aqueous salt solution at elevated temperature (60 °C to 65 °C) in the presence of 10 stainless steel balls (approx. 12 mm diameter). After 30 mins of dynamic mechanical treatment, the saliva extract is removed for subsequent extraction. The flask and sample are replenished with 50 ml fresh saliva simulant and subjected to a further mechanical treatment. The pooled saliva simulant extracts are subjected to two successive extractions using dichloromethane in a separation funnel. The amount of DINP in the dichloromethane solution is determined by GC-MS using a non-polar column. Quantification is achieved using an external standard calibration procedure as well as an internal standard.

The migration levels observed using LGC PVC reference material containing DINP clearly shows the migration levels for DINP to correlate to the *in vivo* maximum value reported by the human volunteer studies and recommended by the CSTEE as the target value for any methodology. The migration results may therefore be compared directly with the guidance migration levels recommended by the CSTEE in 7.4.2.

2.9 Total content and migration of formaldehyde

2.9.1 General

Formaldehyde and its aqueous solution, formalin, may be used in clothing and textile product finishes to give cotton and cotton-containing fabrics 'easy care' characteristics, crease resistance and dimensional stability; in urea-, phenol-, acetal- and melamine-formaldehyde resins for the manufacture of plastics, paper and rubber products; and as adhesives in the manufacture of plywood, particle board and other pressed wood products commonly used to manufacture furniture, cabinets, wall panelling and shelves.

Under certain conditions formaldehyde may be released from these items, creating the potential for human exposure either by inhalation, skin contact or ingestion. 'Off-gassing' from products into the air is most commonly observed in products such as plywood, particle board and other pressed wood products. It is greatest when the product is new and at higher temperature and humidity, but decreases over time.

2.9.2 Rationale

Formaldehyde is listed in Annex I of Directive 67/548/EEC - Classification, packaging and labelling of dangerous substances, as a Category 3 carcinogen. Such a substance is one that causes concern for people because of possible carcinogenic effects (in this case associated with sites of chronic irritation) observed from animal (in this case inhalation) studies, although the available information is not adequate for making a satisfactory assessment and higher categorisation.

Formaldehyde is also listed as being toxic by inhalation, skin contact and ingestion. It may cause an irritant effect and sensitisation on direct and prolonged skin contact, especially of children, where its concentration is approx. 1 %. If inhaled, emitted formaldehyde may also cause inflammation of the respiratory tract. It is also believed to be one of the most significant allergy-causing agents.

2.9.3 Limits

The maximum content of free and hydrolysable formaldehyde in certain textile and leather products should be 30 mg/kg for textiles for babies, 750 mg/kg for textiles in direct skin contact, and 300 mg/kg for all other products.

For food-contact items, such as bowls and cups, the recommended migration limit for formaldehyde is given in Directive 2002/72/EC - Plastics materials and articles intended to come into contact with foodstuffs, as 15 mg/kg migration liquid (2,5 mg/dm² sample).

For child use and care articles other than food-contact items, it is recommended that the following migration limits should not be exceeded; 80 mg/kg for wood-based items and 30 mg/kg for articles other than those which are wood-based.

2.9.4 Requirements

When tested in accordance with the appropriate methodologies shown in 2.9.5, the total content or migration of formaldehyde should not exceed the limits indicated in 2.9.3.

2.9.5 Test methodology

For food-contact articles, e.g. feeding bowls and cups, a suitable test method is described in EN ISO 4614:1999, Plastics - Melamine-formaldehyde mouldings - Determination of extractable formaldehyde (ISO 4614:1977), methods 462A and 462B.

Suitable test methods for the determination of formaldehyde release from items that can be cut up, e.g. soothers and textiles, are described in EN ISO 14184-1, Textiles - Determination of formaldehyde - Part 1:

Free and hydrolysed formaldehyde (water extraction method) and EN ISO 14184-2, Textiles - Determination of formaldehyde – Part 2: Release of formaldehyde (vapour absorption method).

The European Disposables and Non-Wovens Association (EDANA) recommended test methods (ERT) for the determination of free formaldehyde: I, 210.1-99; II, 211.1-99 (under stressed conditions); III, 212.0-96 (determination by HPLC); and IV, 213.0-96 (in processing), are available on http://www.edana.org/story.cfm?section=|edana_nonwovens&story=testmethods.xml.

There are specific requirements for wooden/chipboard items including particle board, plywood and fibre boards. Reference should be made to the following standards, which cover the determination of the content and release of formaldehyde:

- EN 717-2, *Wood-based panels – Determination of formaldehyde release – Part 2: Formaldehyde release by the gas analysis method*;
- EN 1084, *Plywood: formaldehyde release classes determined by the gas analysis method*;
- EN 645, *Paper and boards intended to come into contact with foodstuffs - Preparation of a cold water extract*; and
- EN 1541, *Paper and board intended to come into contact with foodstuffs – Determination of formaldehyde in an aqueous extract*.

NOTE results from gas analysis will not directly correlate with those produced by liquid extraction.

2.10 Total content of flame retardants

2.10.1 General

The most common flame retardant chemicals are generally brominated and/or phosphorus compounds. The reader is referred to section 4 of these guidelines which provides advice on dealing with thermal hazards. The specific selection of materials that inherently meet this advice offers an alternative to the inclusion of flame retardant chemicals.

2.10.2 Rationale

Some flame retardant chemicals are considered to be unsuitable for use in child use and care articles due to the severity of the toxicological endpoint reported for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitisation or severe organ toxicity and are therefore presumed to offer a human health hazard.

2.10.3 Limits

In considering chemical safety it is advised to avoid the addition of certain flame retardants to specifically reduce flammability. Tri-cresylphosphate and tris-(2-chloroethyl)phosphate have been toxicologically assessed and determined not to be acceptable for use in child use and care articles (CEN/TC52/WG9/TG3 - organic chemical release from toys). Limits of detection are therefore to be applied.

Penta- and octa-bromodiphenyl oxide and short-chain chlorinated paraffins are currently being restricted through Directive 2003/11/EC and Directive 2002/45/EC respectively, and amendment to Directive 76/769/EEC.

Deca-bromodiphenyl oxide and intermediate-chain chlorinated paraffins are currently under review and it is suggested that the most up-to-date information be sought when addressing this issue.

Certain compounds are prohibited in textiles in contact with skin by the EC Directives indicated:

- Tris-(2,3-dibromopropyl)phosphate (79/663/EEC);
- Tris-(aziridinyl)phosphine oxide (83/264/EEC); and
- Polybromobiphenyls (83/264/EEC).

Some brominated flame retardants are to be restricted in electrical and electronic equipment under the Restriction on Hazardous Substances (RoHS) Directive.

2.10.4 Requirements

When tested in accordance with the methodology shown in 2.10.5, the flame retardants in 2.10.3 should not be detected.

2.10.5 Test methodology

An appropriate screening method is outlined in M.Reiss and R.Eldvik, 'Identification of brominated flame retardants in polymeric materials by reversed phase liquid chromatography with UV detection', *J. Chrom. A*, **827** (1998) 65-71.

In brief, sample solutions in propan-2-ol are analysed using HPLC with the following conditions:

Column:	RP-18, 250 mm x 4 mm Hichrom
Mobile phase:	3 % buffered methanol
Column temp:	25 °C
Injection volume:	10 µl
PDA Scan:	190-350 nm

The method has been shown to be suitable for penta- and octa-bromodiphenyl oxide, tetrabromobisphenol A (TBBPA) and its ethers (TBBPA-bis-(2-hydroxyethylether) and TBBPA-bis-allylether), tetrabromophthalic anhydride and 2,4,6-tribromophenol. The penta- and octa-bromodiphenyl oxides do not give good single peak responses but are quantifiable. The suitability of the method for other flame retardants should be demonstrated.

NOTE experience shows that analysis for decabromodiphenyl oxide is likely to require GC-MS-MS. Methodology is under investigation by CEN/TC52/WG9 on organic chemical release from toys.

2.11 Migration of *N*-Nitrosamines and *N*-Nitrosatable substances

2.11.1 General

It has been shown that certain child use and care articles made of elastomer or rubber, i.e. feeding bottle teats and soothers, may release *N*-Nitrosamines and substances capable of being converted into *N*-Nitrosamines (*N*-Nitrosatable substances).

2.11.2 Rationale

The EC SCF has indicated that *N*-Nitrosamines and *N*-Nitrosatable substances may endanger human health owing to their genotoxicity. Levels of such genotoxic carcinogens are to be reduced to as low a level as practically achievable.

Commission Directive 93/11/EEC regulates the release of *N*-Nitrosamine and *N*-Nitrosatable substances from elastomer or rubber teats and soothers.

2.11.3 Limits

The limits shown in Table 2.11A apply:

Table 2.11A — Limits specified through Directive 93/11/EEC

Analyte	Limit (mg/kg)	Analytical tolerance (mg/kg)
<i>N</i> -Nitrosamines	0,01	0,01
<i>N</i> -Nitrosatable substances	0,1	0,1

2.11.4 Requirements

When tested in accordance with the appropriate methodologies shown in 2.11.5, the migration of *N*-Nitrosamines and *N*-Nitrosatable substances should not exceed the limits indicated in 2.11.3.

2.11.5 Test methodology

The analytical methods used to determine the migration of *N*-Nitrosamines and *N*-Nitrosatable substances are set out in EN 12868 - Methods for determining the release of *N*-Nitrosamines and *N*-Nitrosatable substances from elastomer or rubber teats and soothers. Detailed analytical tolerances are shown such that compliance with the requirements of Directive 93/11/EEC can be determined.

2.12 Migration of vulcanisation accelerators (and antioxidants)

2.12.1 General

Vulcanising agents are utilised in both food-contact and non-food contact applications of rubber child use and care articles, e.g. food-contact rubber seals, feeding bottle teats and soothers, to provide maximum resistance to thermal oxidation and prevent surface cracking caused by atmospheric ozone attack.

2-mercaptobenzothiazole (MBT) was the major vulcanising accelerator in use, but dialkyldithiocarbamate and dialkylthiuram compounds are now being used more widely as alternative vulcanising accelerators. The major route of exposure for these agents is through the oral route, with the dermal route providing an alternative, albeit lesser, contact route.

2.12.2 Rationale

Health concerns have centred on the potential carcinogenicity of compounds structurally similar to 2-mercaptobenzothiazole (MBT), although the SCF have accepted new toxicological studies that do not show a carcinogenic effect (SCF/CS/PM/GEN/M83). Nonetheless levels of MBT incorporation and hence potential migration can be controlled better than was previously the case. The alternative vulcanising accelerators (dialkyldithiocarbamates) are currently less well defined toxicologically.

2.12.3 Limits

The migration of MBT should not exceed 8 mg/kg after a 24 hour extraction period.

The migration of antioxidant 2,6-bis-(1,1-dimethylethyl)-4-methylphenol (BHT) should not exceed 30 µg/100ml or 60 µg/dm². The migration of antioxidant 2,2-methylene-bis-(6-(1,1-dimethylethyl)-4-methylphenol)) (Antioxidant 2246) should not exceed 15 µg/100ml or 30 µg/dm².

Acceptable migration levels for the alternative vulcanising accelerators (dialkyldithiocarbamates) have not yet been agreed. Any measured extraction levels should be considered on a case-by-case basis.

2.12.4 Requirements

When tested in accordance with the appropriate methodologies shown in 2.12.5, the migration of vulcanisation accelerators and antioxidants should not exceed the limits indicated in 2.12.3.

2.12.5 Test methodology

2.12.5.1 MBT and antioxidants

A suitable method for determining the migration of certain vulcanising accelerators and antioxidants is provided in EN 1400-3 - Soothers for babies and young children: Safety requirements and test methods.

The method has been shown to be applicable to determining the migration limits for MBT, and the antioxidants BHT and Antioxidant 2246.

2.12.5.2 Dialkyldithiocarbamates

A further method, based on existing literature methods for rubber gloves and foam rubber carpet backing, has been found to be suitable for determining the migration of the alternative vulcanising accelerators shown in 2.12.5.1.

The principle of the method is the exchange-reaction of the metal-cation in a dithiocarbamate salt complex by a cobalt (II) cation, which results in an increase in stability of the compound. The vulcanising accelerators are removed from the sample, over a defined time period, whilst immersed in an artificial simulant. They are concentrated by solid phase extraction before back extraction of the solid phase with dichloromethane. The dichloromethane extract is treated with cobalt (II) chloride to form the cobalt (II) salt. The solution is re-concentrated and made up in acetonitrile/tetrahydrofuran for HPLC analysis using conditions similar to those specified in EN 1400-3 for the determination of MBT.

This extraction method has shown to be suitable for both zinc diisononyldithiocarbamate and zinc dibenzylthiocarbamate, but is restricted to one class of dithiocarbamate in the sample because of the potential formation of mixed ligand complexes.

2.13 Total content of volatile compounds

2.13.1 Rationale

Currently validated methodology for determining individual volatile compounds in child use and care articles, which correlates with 'real' exposure scenarios, does not exist. The volatility of these chemicals makes inhalation the major contact route of concern.

EN 1400-3 Child use care articles – Soothers for babies and young children – Part 3: Chemical requirements and tests, specifies allowable total volatile content for silicone rubber teats & soothers.

NOTE Methodology is being investigated under the work of CEN/TC52/WG9 on organic chemical release from toys.

2.13.2 Limits

The total content of volatile compounds from elastomer or rubber teats and soothers should not exceed 0,5 % (m/m).

2.13.3 Requirements

When tested in accordance with the methodology shown in 2.13.4, the content of volatile compounds should not exceed the limit indicated in 2.13.2.

2.13.4 Test methodology

Samples from reusable products should be immersed in boiling water for 10 min without touching the walls of the container.

NOTE 1 This is to remove the surface coating arising from the manufacturing processes and ensure that the materials used are stable in boiling water.

Drain excess water from the sample. Place approximately 10 g of the whole sample into a pre-heated (approx. 1 h) open, shallow container and place the container with the sample in a drying oven at $(100 \pm 5) ^\circ\text{C}$ with fresh air inlet. After 1 h, cool the container with the sample in a dessicator for at least 2 h and weigh (accuracy $\pm 0,1$ mg). Replace the container with the sample in a drying oven at $(200 \pm 5) ^\circ\text{C}$ with fresh air inlet. After 4 h, cool the container with the sample in a desiccator for at least 2 h and re-weigh (accuracy $\pm 0,1$ mg). The content of volatiles is calculated from percentage weight difference.

NOTE It is recommended that the test be carried out at least in duplicate.

2.14 Total content and migration of certain dyes, azo-colourants and disperse dyes

2.14.1 Rationale

Certain dyes are known to be carcinogenic, mutagenic or toxic to reproduction. Others may be assigned any of the risk phrases R45 (may cause cancer), R46 (may cause heritable genetic damage), R60 (may impair fertility) or R61 (may cause harm to the unborn child) as defined in Directive 67/548/EEC.

The ability to chemically reduce certain azo-colourants, one of the most popular types of organic colorants used by the textile and leather industries, to certain primary aromatic amines is well established. Several of these aromatic amines have been recognised as potential carcinogens for many years and since the 1980s the use of many dyes manufactured from these amines has been withdrawn voluntarily by industry, at least in the western world.

There is also extensive literature on the sensitising potential of disperse dyes. Human patch testing indicates that disperse dyes elicit positive reaction in individuals following exposure through textiles containing these dyes, although the clinical manifestations of the dermatitis are variable.

2.14.2 Limits

The dyes shown in Table 2.14A should not be used.

Table 2.14A — Carcinogenic or mutagenic dyes or dyes toxic to reproduction

C.I. Solvent Yellow 1
C.I. Solvent Yellow 2
C.I. Solvent Yellow 3
C.I. Basic Red 9
C.I. Disperse Blue 1
C.I. Acid Red 26

Additional dyes considered to be carcinogenic or mutagenic dyes or dyes toxic to reproduction by CEN/TC52/WG9/TG3 are shown in Table 2.14B.

Table 2.14B — Additional dyes considered to be carcinogenic or mutagenic dyes or dyes toxic to reproduction

C.I. Basic Violet 1
C.I. Basic Violet 3
C.I. Acid Violet 49

Azo-colourants are restricted by Directive 2002/61/EC and amendment for the 19th time of Directive 76/769/EEC (COM[2000]785). Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Table 2.14C in detectable concentrations (i.e. 30 µm/g) in the finished articles or dyed products thereof, should not be used in textile and leather articles which may come into direct and prolonged contact with human skin or oral cavity.

Table 2.14C — Restricted aromatic amines

Number	Aromatic amine	CAS No
1	o-toluidine (2-aminotoluene)	(95-53-4)
2	o-anisidine (2-methoxyaniline)	(90-04-0)
3	4-chloroaniline	(106-47-8)
4	6-methoxy-m-toluidine (p-cresidine)	(120-71-8)
5	2,4,5-trimethylaniline	(137-17-7)
6	4-chloro-o-toluidine	(95-69-2)
7	4-methyl-m-phenylenediamine	(95-80-7)
8	4-methoxy-m-phenylenediamine	(615-05-4)
9	2-naphthylamine	(91-59-8)
10	Biphenyl-4-ylamine (4-amino-biphenyl) (xenylamine)	(92-67-1)
11	4,4'-oxydianiline	(101-80-4)
12	Benzidine	(92-87-5)
13	4,4'-methylenedianiline (4,4'- diaminodiphenylmethane)	(101-77-9)
14	4,4'-methylenedi-o-toluidine	(838-88-0)
15	3,3'-dimethylbenzidine (4,4'-bi-o- toluidine)	(119-93-7)
16	4,4'-thiodianiline	(139-65-1)
17	3,3'-dichlorobenzidine (3,3'- dichlorobiphenyl-4,4'-ylenediamine)	(91-94-1)
18	3,3'-dimethoxybenzidine (o-dianisidine)	(119-90-4)
19	4,4'-methylene-bis-(2-chloroaniline) (2,2'-dichloro-4,4'-methylene-dianiline)	(101-14-4)
20	5-nitro-o-toluidine	(99-55-8)
21	4-amino azobenzene	(60-09-3)
22	o-aminoazotoluene (4-amino-2',3- dimethylazobenzene) (4-o-tolylazo-o- toluidine)	(97-56-3)

Directive 2003/03/EC and adaptation for the 12th time of Directive 76/769/EEC restricts blue colourant Index No. 611-070-00-2 (commonly known as navy blue) for placing on the market or for use for colouring textile and leather articles as a substance or constituent of preparations in concentrations higher than 0,1 % by mass.

The potentially sensitising (disperse) dyes shown in Table 2.14D should only be used if the fastness to (acid and alkaline) perspiration of the dyed yarn or fabric is at least 4.

Table 2.14D — Potentially sensitising dyes

C.I. Disperse Blue 3
C.I. Disperse Blue 35
C.I. Disperse Blue 106
C.I. Disperse Blue 124
C.I. Disperse Yellow 3
C.I. Disperse Orange 3
C.I. Disperse Orange 37/76
C.I. Disperse Red 1

Due to the migration limits for certain heavy metals, the use of after-chromed dyes is not recommended.

2.14.3 Requirements

The dyes known to be, or proposed as, carcinogenic or mutagenic or toxic to reproduction in 2.14.2 should not be present in textile and leather articles.

When tested in accordance with the appropriate methodologies shown in 2.14.4, the total content and migration of certain azo-colourants and disperse dyes should not exceed the limits indicated in 2.14.2.

Potentially sensitising dyes should not exceed the limits indicated in 2.14.2.

2.14.4 Test methodology

The following methods have been found to be suitable for the determination of aromatic amines arising from the use of certain azo-colourants in leather/textiles:

- CEN ISO/TS 17234, *Leather – Chemical tests - Determination of certain azo colourants in dyed leathers (ISO/TS 17234:2003)*.
- EN 14362-1, *Textiles - Methods for the determination of certain aromatic amines derived from azo colourants – Part 1: Detection of the use of certain azo colourants accessible without extraction*.
- EN 14362-2, *Textiles - Methods for the determination of certain aromatic amines derived from azo colourants – Part 2: Detection of the use of certain azo colourants accessible by extracting the fibres*.

NOTE False positives may be possible with respect to the presence of 4-aminoazobenzene and confirmation is recommended.

Test method for determining colour fastness is ISO 105-E04 .