PD CEN/TR 13387-2:2015

BSI Standards Publication

# Child use and care articles — General safety guidelines

## Part 2: Chemical hazards

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**National foreword**

This Published Document is the UK implementation of CEN/TR 13387-2:2015. Together with PD CEN/TR 13387-1:2015, PD CEN/TR 13387-3:2015, PD CEN/TR 13387-4:2015 and PD CEN/TR 13387-5:2015, it supersedes PD CEN/TR 13387:2004, which is withdrawn.

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# Child use and care articles - General safety guidelines - Part 2: Chemical hazards

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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**



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# European foreword

This document (CEN/TR 13387-2:2015) has been prepared by Technical Committee CEN/TC 252 “Child use and care articles”, the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TR 13387:2004.

CEN/TR 13387 comprises the following five parts:

— Safety philosophy and safety assessment (CEN/TR 13387-1);

— Chemical hazards (CEN/TR 13387-2);

— Mechanical hazards (CEN/TR 13387-3);

— Thermal hazards (CEN/TR 13387-4);

— Product information (CEN/TR 13387-5).

CEN/TR 13387-2 should be used in conjunction with CEN/TR 13387-1.

The chemical part has been completely rewritten compared to the previous edition.

# 1 Scope

This Technical Report provides guidance information on chemical hazards that should be taken into consideration when developing safety standards for child use and care articles. In addition, these guidelines can assist those with a general professional interest in child safety.

# 2 Regulatory, normative and policy background

## 2.1 General

In Europe child use and care articles are covered by the Directive on general product safety (GPSD, Directive 2001/95/EC). This directive contains a general safety requirement and does not address chemical substances in particular. However, article 13 of the GPSD provides for the opportunity to adopt temporary “emergency” measures which may include limit values for chemical substances in consumer products. Such measures had been adopted for phthalates in toys and child use and care articles and for dimethylfumarate (DMF) and both have been later incorporated into REACH. In addition, Member States can impose actions on products found unsafe.

Restrictions for several specific chemical substances can be found in Annex XVII of the Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH, Regulation (EC) No 1907/2006) “relating to restrictions on the marketing and use of certain dangerous substances and preparations” as amended. If applicable to their type of product or material used, these provisions are to be followed by manufacturers of child care articles.

The Regulation on persistent organic pollutants (POP, Regulation (EC) No 850/2004) restricts production, placing on the market and use of chemical substances listed in Annex I of the regulation including constituents of articles. The provisions apply also to child care products.

Other regulatory provisions relating to chemicals may apply to certain products. For instance, drinking equipment is subject to the Regulation on materials and articles intended to come into contact with food (Regulation (EC) No 1935/2004) and plastics components of drinking equipment are regulated by the Regulation relating to materials and articles intended to come into contact with foodstuffs. A Directive covers the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Directive 93/11/EEC). Applicable regulation will have to be identified where relevant.

Another example of chemical provisions applicable to child care articles is the Directive on packaging and packaging waste (94/62/EC) which establishes among others limits for lead, cadmium, mercury and hexavalent chromium in packaging.

While not directly applicable to child care articles the Directive on the safety of toys (TSD, 2009/48/EC) is an important reference document addressing a product group with similar exposure characteristics and providing a high standard of safety in the field of products intended for children. Hence, specific guidance seems appropriate on how to make use of toys related chemical rules.

It is the intention of the present guidelines to complement existing legal obligations by providing some practical recommendations keeping in mind legal minimum requirements.

Environmental issues are moving in the spotlight. CEN has adopted a policy: the “CEN Approach on addressing environmental issues in product and service standards” calls for incorporation of environmental considerations when product or service standards are elaborated. These aspects are highly relevant in particular for chemicals as far as child care articles are concerned. Hence, this guide incorporates also recommendations in this regard.

## 2.2 REACH - Short summary

### 2.2.1 Registration

All chemical substances manufactured or imported in quantities greater than 1 tonne per year per manufacturer or importer shall be registered at the European Chemicals Agency (ECHA) unless they are exempted from the scope of registration. The registration obligations apply to the individual chemical substances, independently of whether they are on their own, in a mixture or in an article (when the chemical substance is intended to be released).

### 2.2.2 Authorization

Chemical substances with properties of very high concern may be subject to authorization before being allowed to be manufactured or used in the European Union. These are CMRs (carcinogenic, mutagenic and toxic for reproduction), PBTs/vPvBs (persistent, bio accumulating and toxic/very persistent and very bio accumulating chemical substances) and chemical substances identified as causing serious and irreversible effects to humans or the environment equivalent to the effects mentioned above. As a first step such chemical substances are incorporated in a so-called “candidate list” which is published and periodically updated by ECHA (twice a year in June and December). The candidate list is also known as the “SVHC list”. Finally, chemical substances identified as requiring authorization will be taken up in Annex XIV or REACH. These chemical substances cannot be placed on the market or used for manufacturing in Europe after a given date, unless an authorization is granted for their specific use, or the use is exempted from authorization.

For the current list of SVHC please consult the ECHA website.

### 2.2.3 Restrictions

REACH Annex XVII contained specific restrictions on 64 chemical substances or groups of substances by the end of 2014. These may apply to all uses of the substance or more specifically to certain product types or exposure scenarios. Some restrictions have particular relevance to child care and use articles such as the limits on total content for certain phthalate based plasticisers and total content limits for certain flame retardants in textiles where there is prolonged skin contact. Some entries, such as the total content restriction for cadmium in certain materials, may apply to child care and use articles where that material is used to make the finished product.

### 2.2.4 Articles

Articles within REACH are defined as an object, which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition (Article 3(3)). This means that most consumer products including child use and care articles can be defined as articles. Chemical substances in articles do not need to be registered under REACH, except chemical substances in articles that are intentionally released if present in quantities greater than 1 tonne per manufacturer annually. This could be for example a product with a perfume scent. Chemical substances that are unintentionally released during use are not in scope for registration, like plasticizers migrating out of a product over time.

If articles contain chemical substances on the “candidate list” (SVHC list) in a concentration above 0,1 % (w/w), the supplier has to provide sufficient information (as a minimum the name of the chemical substance) to the recipient of the article to allow for safe use of the article. For consumers the information about these chemical substances in the article shall only be given upon request and within 45 days of the request. (Article 33 of REACH). This requirement is independent of the total tonnage of the chemical substance. No such requirement exists for other dangerous chemical substances in articles.

If a SVHC substance is present in a concentration above 0,1 % in the article and its import or manufacturing quantities are above 1 tonne in total per year per company, EU producers or importers of articles shall notify the ECHA of the presence of the SVHC substance. Such notification requirement does not exist for other dangerous substances in articles.

Chemical substances integrated in articles are neither subject to registration nor to authorization with the exception of chemical substances intended to be released. However, SVHC substances used in or for the manufacturing of articles in Europe may require authorization. Restricted chemical substances (REACH Annex XVII) cannot be used in articles in the EU, nor can they be present in any article imported into the EU.

#### 2.2.5 Recommendations

Manufacturers and standardization bodies involved with child care and use articles should be aware of the developments in REACH and how they apply to the product category. Where the developments are deemed sufficiently protective of children there is generally no further need to elaborate a current or future standard unless the development of new scientific knowledge indicates otherwise. Where REACH covers child care and use articles in a limited way (in particular, imported articles) REACH should not be considered as a replacement for product specific chemical rules.

### 2.3 Toy Safety Directive and related standards

#### 2.3.1 Short summary of Toy Safety Directive

The Toy Safety Directive (TSD) was published in June 2009 (Directive 2009/48/EC). Part III of Annex II contains the chemical requirements and are summarized below.

Chemical substances that are carcinogenic, mutagenic or toxic to reproduction (CMR) substances of category 1A, 1B or 2 under the Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008) are only allowed in toys if certain conditions are met:

— If the use and presence of the chemical substance is allowed according to Appendix A of Annex II;

— these chemical substances are inaccessible to children in any form, including inhalation;

— the concentration of the chemical substances does not exceed the concentration limits as set for the classification of mixtures containing these chemical substances in the CLP regulation.

55 listed allergenic fragrances shall not be used in toys only if the presence is technically unavoidable under good manufacturing practice and does not exceed 100 ppm. Another 11 allergenic fragrances shall be declared on a product label if they are present in concentrations above 100 ppm.

Requirements on migration of 19 elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc) replacing the previous migration restrictions on 8 elements (antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium). The migration limits are set for three different types of materials:

1) dry, brittle powder-like or pliable toy material,

2) liquid or sticky toy material and

3) scraped-off toy material.

For the elements arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, the limits have been set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.

Furthermore, N-nitrosamines and N-nitrosatable substances are prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. Specific migration limit values are set.

According to article 46 the Commission may adopt specific limit values for chemical substances used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account food contact material legislation (Regulation (EC) No 1935/2004).These specific limit values are listed in Appendix C of Annex II. By end of 2014 the substances tris (2-chloroethyl) phosphate (TCEP, CAS No 115-96-8), tris-monochloro-propyl phosphate (TCPP, CAS No 13674-84-5) and tris(1,3-dichloropropyl-2)phosphate (TDCP, CAS No 13674-87-8) are listed with a specific limit value of 5 mg/kg (content limit). In addition, bisphenol A (CAS No 80-05-7) is included with a limit of 0,1 mg/l (migration limit).

According to article 18 manufactures shall, before placing a toy on the market, carry out analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards. This is also called a safety assessment. The manufactures shall furthermore, demonstrate that the toy complies with the requirements set in Annex II. The assessment shall be kept in the technical documentation.

### 2.3.2 Toy standards

The following standards dealing with chemical substances in toys relevant for child use and care articles are currently available:

#### 2.3.2.1 Harmonized standards

— EN 71-3:2013, Safety of toys - Part 3: Migration of certain elements.

This standard contains migration limits and test methods for 19 elements (aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc).

— EN 71-12:2013, Safety of toys - Part 12: N-Nitrosamines and N-nitrosatable substances.

This standard contains limits and test methods for N-nitrosamines and N-nitrosatable substances for toys and parts of toys made from elastomers and intended for use by children under 36 months or intended to be placed in the mouth and finger paints for children under 36 months.

#### 2.3.2.2 Non-harmonized standards

— EN 71-9:2005+A1:2007, Safety of toys - Part 9: Organic chemical compounds – Requirements;

— EN 71-10:2005, Safety of toys - Part 10: Organic chemical compounds - Sample preparation;

— EN 71-11:2005, Safety of toys - Part 11: Organic chemical compounds - Method of analysis;

The standards EN 71-9, EN 71-10 and EN 71-11 which do not provide a presumption of conformity to TSD requirements include limit values and test methods for certain organic chemical compounds such as:

— flame retardants;

— colorants;

— primary aromatic amines;

— monomers (migration);

— solvents (migration and inhalation);

— wood preservatives;

— preservatives;

— plasticizers (migration).

It should be noted, however, that EN 71-9, EN 71-10 and EN 71-11 cover only a small number of organic chemical substances. Consequently, the introduction of EN 71-9 includes the following sentence: “This document, therefore, supports but does not reduce the responsibility of toy manufacturers, importers and suppliers for ensuring that the use of other substances will not endanger the health whilst playing with toys as intended or in a reasonably foreseeable way”.

### 2.3.3 Recommendations

The applicable requirements in the Directive including generic CMR exclusions and standards dealing with chemical substances in toys should be considered when establishing requirements for child use and care articles. However, the limits should be checked and different values should be considered when e.g. the exposure and use profile is different compared to toys or if new scientific evidence suggests that the limits need to be changed.

It is also recommended to carry out an analysis of the chemical hazard that a child use and care article may present, as well as an assessment of the potential exposure to such a hazard.

Manufacturers and importers of as well as standard setting bodies for child use and care articles should monitor the revisions of the limit values given in the Toy Safety Directive and the adoption of specific limits for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. In addition, the developments within CEN/TC 52 should be taken into account. Manufacturers should consider the latest versions of limit values and test methods in the toys field if referenced in child use and care standards, as these are normally updated with some delay.

## 2.4 CEN Approach on addressing environmental issues in product and service standards

### 2.4.1 Short summary

The key objective of the “CEN approach on addressing environmental issues in Product and Services Standards” is to put in place a general framework to systematically address environmental issues in standardization in order to reduce the environmental impacts of products and services.

The document defines roles and responsibilities for the various parties involved including technical bodies of CEN, its Strategic Advisory Body on Environment (SABE) including the Environmental Helpdesk (EHD) and the Team on Environmental Issues in Standardization (ENIS), stakeholders and national standards bodies.

The framework consists of supporting tools (guidance documents, checklists, trainings, tailored environmental programmes for technical bodies, etc.) and mandatory elements (review of titles and scopes of TCs, inclusion of environmental issues in business plans, new work item proposals, formatted resolutions, agenda item on environmental issues). It is envisaged to provide specific guidance to TCs/WGs on specific issues including *inter alia* advice on the coverage of chemicals in product standards.

The functioning of the above is subject to monitoring by the relevant CEN groups and will be periodically reviewed.

### 2.4.2 Recommendations

If specific guidance on addressing chemical substances in product standards is made available by CEN’s advisory bodies on environmental issues it should be taken into consideration. Environmental concerns should be taken on board in the development of standards for child use and care articles, i.e. also environmental effects of chemical substances should be addressed. This means to not only consider human health but also environmental impacts, e.g. to eliminate PBTs or vPvB substances.

# 3 Basics of Chemical Safety Assessment (CSA)

## 3.1 General

The scope and limit of chemical substance restrictions in regulations and standards are most often based on a chemical safety assessment (CSA). This assessment determines the scope relevancy of the restriction (e.g. type of material, accessibility etc) and provides recommended safe limit value based on the exposure profile and use of a product or product group. To be able to adopt and adapt chemical substance restrictions for different types of child use and care articles it is important to understand the key aspects of a chemical safety assessment.

CSA is the process that identifies and describes the conditions under which the use and/or presence of a chemical substance could be considered safe. There are three major steps in the CSA process. These are:

— Hazard assessment;

— Exposure assessment;

— Risk characterization.

The **hazard assessment** requires the collection and evaluation of all available and relevant information on the intrinsic properties of the chemical substance. The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe (the so called no-effect levels).

The **exposure assessment** is the process of measuring or estimating the dose or concentration of the chemical substance to which humans and the environment are or may be exposed, depending on the use of the chemical substance and the use of products in which it is present.

Within the exposure assessment, the definition of the conditions under which the chemical substance is used and present, as well as how a product or product group containing the chemical substance is used is critical in order to determine the potential level of exposure. The information on the conditions under which a chemical substance and the product or product group containing the chemical substance is used is called the **exposure scenario**. For each exposure scenario, the potential exposure levels of humans and if relevant the environment need to be determined.

The third step in the CSA process is the **risk characterization**. For the risk characterization, the levels of exposure are compared with the threshold levels for each relevant effect.

Risks are regarded as controlled when the potential exposure levels to the chemical substance are below the threshold levels which are considered as safe. For effects with no threshold levels, emissions and exposures have to be minimised or avoided for risks to be considered to be controlled.

In the following parts the main steps of a CSA are briefly explained and complemented by specific considerations for chemicals used in child use and care articles in particular.

## 3.2 Hazard assessment

The hazard assessment normally comprises the following steps:

1) Hazard Identification

Hazard identification is the determination of what hazards are associated with the chemical substance. The information on the types of hazard can come from the classification and labelling of the chemical substance or other available relevant toxicological and ecotoxicological information.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) provides criteria to classify substances and preparations as dangerous (e.g. very toxic, toxic, harmful) based on their intrinsic properties. The classification of a substance as dangerous is a critical input for the hazard identification.

ECHA has published a database which contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonized EU classifications.

Other relevant and available toxicological and ecotoxicological information on the intrinsic properties of a chemical substance not covered by the classification and labelling information can be found, for instance, in the publically available REACH registration dossiers as published on the ECHA website.

For example the toxicological properties of the chemical substance when exposed via dermal (skin) contact, oral contact or inhalation and the effect of the chemical substance if the exposure is short-term (acute) or long term (chronic) can be found in these dossiers.

2) Derivation of threshold levels

The derivation of threshold levels is the determination of the relationship between the hazard and the dose (exposure amount). In principle for almost every hazard there is a minimum dose under which no effect is expected anymore, a threshold level.

Several thresholds are available to be used in a chemical safety assessment.

Derived-No-Effect Level (DNEL)

The Derived No-Effect Level or DNEL is the level of exposure to the substance above which humans should not be exposed. The DNEL is typically based on the NOAEL(No-Observed-Adverse-Effect-Level) of a chemical substance, The NOAEL is the greatest concentration or amount of a substance, found by observation or experiment, which causes no statistically significant detectable adverse effect in the exposed population. The NOAEL is scaled by a safety factor, conventionally but not always of 100, to account for the differences between test animals and humans (factor of 10) and possible differences in sensitivity between humans (another factor of 10).

The lowest value available (for the most sensitive end point) is used for risk characterization. However, in some cases (e.g. for mutagenic carcinogens) no safe threshold level can be obtained. In such cases, a semiquantitative value, known as the DMEL or Derived Minimal Effect level may be developed. DMELs can be used later on in the risk characterization process in the same way as DNELs.

DNELs and DMELs can be found in publically available REACH dossiers or can be calculated based on available toxicological information.

Predicted-No-Effect Concentration (PNEC)

The environmental counterpart of the DNEL is the Predicted No Effect Concentration or PNEC – it is the concentration of a substance in any environment below which adverse effects will most likely not occur during long term or short-term exposure. The PNEC needs to be determined for each environmental sphere (aquatic, terrestrial, atmospheric, sewage treatment, food chain).

PNECs can be found in publically available REACH dossiers or can be calculated based on available ecotoxicological information.

Tolerable Daily Intake (TDI)

In the field of consumer products limits are often based on TDI (Tolerable Daily Intake) values which indicate the amount of a substance that can be taken in daily over a lifetime without appreciable health risk. They are a special form of a DNEL.

Important is that before a TDI is used in the risk assessment, the underlying data are checked to determine if it up-to-date and relevant for the type of exposure.

No threshold chemical substances

Chemical substances, especially when carcinogenic, mutagenic or toxic for the reproduction, without a threshold value, should be eliminated as far as possible, i.e. banned using a low level of detection unless any exposure can be excluded.

## 3.3 Exposure assessment

An exposure assessment entails the following two steps:

1) Development of exposure scenarios

Exposure scenarios provide a quantitative estimate of an exposure associated with the use of a chemical substance or a product containing the substance. The qualitative characteristics of the use of the child use and care article should be identified and used to determine the relevant exposure.

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 expected exposure to the article; and

— likely route(s) of exposure to the article, e.g. ingestion, skin contact or inhalation.

2) Exposure estimation

When estimating exposure, there are three major routes by which chemicals can enter the body: oral (ingestion and licking/sucking), dermal (skin) and inhalation.

For child care articles the oral contact route (biting off particles, mouthing, licking and sucking) and dermal contact are the most relevant. Depending on the properties of certain chemical substances inhalation could also be a factor.

3) Prolonged contact with the skin

Sometimes limits are established for “prolonged” contact with the skin. No definition is given for the interpretation of such contact. An appropriate time of contact depends on the chemical substance and needs to be determined on a case-by-case basis.

## 3.4 Risk characterization

A quantitative risk characterization is carried out by comparing the estimated exposure level for a given exposure pattern with the lowest threshold value, i.e. the critical DNEL/DMEL, for that exposure pattern. The comparison needs to be done for each exposure pattern resulting from a given exposure scenario.

The risk also needs to consider risks from combined exposures via different routes or via different sources. This may be the case where the same person is potentially exposed to the same substance via different routes of entry into the body.

The risk will be considered to be adequately controlled if the estimated exposure levels do not exceed the appropriate threshold levels. If there is no threshold it is therefore recommended to reduce the levels of the substances as far as technically feasible using a precautionary approach.

Child use and care articles are usually not the only potential source of exposure to a chemical substance. When assessing the safe use of a chemical substance in a child use and care article, exposure should contribute only to a fraction of the TDI. In the field of toys normally a 10 % allocation is made. However, for some elements (see 2.3.1) only half of this value was used. This approach is also appropriate for child use and care articles. In case of (non-threshold) mutagenic carcinogens the product is safe if any exposure of a child is avoided, i.e. when the substances are below the levels of detection using sensitive analytical methods.

## 3.5 Example – PAHs

The example below is based on the German proposal for the REACH Annex XVII restriction of PAHs in consumer products, including child use and care articles. The example is given to provide insight in how a chemical safety assessment can be used to determine a safe limit for non-threshold substances.

It is known for a long time that certain PAHs are very hazardous and have been shown to have carcinogenic and mutagenic properties. All PAHs discussed in the proposal are classified carcinogens of category 1B. Benzo[a]pyrene and chrysene are also legally classified as mutagens. These PAHs were found in a variety of different consumer products including strollers. More than 5300 samples from consumer articles were analysed for their PAH content.

It was judged that safe thresholds cannot be established for these substances. However, based on available data a whole range of DMELs using different approaches was calculated (0,004 – 30 ng/kg bw/d) for the risk characterization.

In the risk characterization potential PAH exposure from consumer products was compared against derived DMELs. For children, comparably high exposure estimates up to ca. 70 µg/kg bw/d (assuming 10 % migration/h) and 1,3 µg/kg bw/d Benzo[a]pyrene (0,2 %/h) were used. The corresponding risk characterization ratios (exposure divided by threshold level) were respectively ca. 2 300 and 43 (meaning that exposure even when least conservative assumptions were made exceeds the derived DMELs) showing a risk for children.

The proposed limit of 0,2 mg/kg (Limit of Quantitation, LOQ) exceeds the acceptable risk characterization ratios. However, the current LOQ does not allow reducing the limit further.

NOTE Following an evaluation at EU level a restriction was adopted under REACH (see A.1.8 Policyclic Aromatic Hydrocarbons (PAHs))

## 3.6 Example – Migration limit values in Toy Safety Directive

The migration limit values in the toy safety directive (2009/48/EC) are different depending on the material of the toy or the component in question. The materials in question are:

a) Dry, brittle, powder-like or pliable toy materials;

b) Liquid and sticky toy materials, and

c) Scraped-off toy materials.

These limits are based on a chemical safety assessment as described in the RIVM study “Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on elements”.

This report describes a risk based methodology that can be used to assess the safety of exposure to chemicals in toys. In the report five exposure scenario categories have been identified that may be relevant for toys: direct ingestion, mouthing, inhalation via evaporation, inhalation via dust or spray and skin contact. In considering these scenarios for elements in particular, only the oral ingestion route has been included. Limit values for elements have only been derived for toys intended for children < 36 months as older children are not likely to mouth toys for prolonged periods.

Based on the conclusion above the following exposure scenario and assumptions have been used:

Toys intended for children aged 0-3 years

— Body weight: 7,5 kg (based on 6-9 months of age);

— Duration: 3 h/day (worst case based on literature);

— Mouthing area 10 $cm^2$;

— Amount ingested:

  — Toys consisting of liquid or sticky material: 400 mg/day;

  — Toys consisting of dry, brittle, powder-like or pliable material: 100 mg/day;

  — Toy material scraped off: 8 mg/day.

— Absorption: 100 % over the intestinal tract of the amount of element migrated out of the toy.

With the above exposure scenario and the basic rule that a toy should not contribute more than x% of the TDI, specific migration limits can be calculated using the following formula:

$$\frac{X\,\%\,\mathrm{TDI}\,(\mathrm{mg/kg\,bw/day}) \times \mathrm{Body\ weight\ (kg)}}{\mathrm{Amount\ of\ toy\ ingested\ (mg/day)}}$$

To illustrate, the following example can be given. The TDI for boron is 160 µg/kg bw/day. A toy should not contribute more than 10 % of the TDI and it is assumed that a small child ingests 8 mg of scraped off toy material per day. The migration limit for boron in this material therefore is:

10 % x 0,16 mg/kg bw/day x 7,5 kg / 8 mg = 0,015 mg/mg toy or 15 000 mg/kg toy.

In the same way migration limit values have been derived for all elements in the Toy Safety Directive. Similarly this method can also be applied to other exposure scenarios and use profiles of for example child use and care articles.

### 3.7 Recommendations

Manufacturers and importers of as well as standard setting bodies for child use and care articles should regularly review ongoing risk assessments and developments to impose restrictions of chemicals in (consumer) articles, most notably at the European level (e.g. REACH restriction path). These processes may be directly applicable to child use and care articles or may provide a useful basis for establishing limits for child use and care articles. Further, it is recommended to regularly review other sources such as published

test results, reports of enforcement agencies, etc. to identify substances of concern for which limit values may have to be set.

# 4 Child use and care articles specific approaches

## 4.1 General aspects

The following sub clauses highlight regulatory and normative provisions and other information covering different groups of chemicals which are not applicable to child use and care articles but which seem useful in identifying possible requirements for child use and care articles.

Specific recommendations for child-use and care articles are also given. However, the limits should be checked and lower values should be considered when e.g. new scientific evidence suggests that the limits are outdated.

NOTE A summary of regulatory requirements contained in Annex XVII of REACH and some other legislation that are applicable to child use and care articles can be found in Annex A. Existing regulatory requirements applicable to child care articles do not need to be incorporated in standards for child care articles.

In order to ensure consistent application of normative references in child care articles standards generally the normative requirements should be included in the relevant standard and only the test methods should be referenced. Preference should be given to undated references.

Model requirements recommended to be used in a standard are provided in Annex B of this TR.

To limit the amount of testing for compliance purposes it is suggested to incorporate a normative requirement in the relevant standard stating that the manufacturer or importer may replace the testing by providing a compliance declaration providing details as regards the chemical requirements. The declaration is based on an analysis of the chemical substances present or likely to be present in the article or knowledge of the production process.

## 4.2 Substances of Very High Concern (SVHC)

It can be anticipated that only a few SVHC substances will be granted authorization to be used in the manufacturing of child care articles. Although the process of authorization will take some time (possibly years) it is advisable and beneficial from a precautionary perspective to eliminate chemical substances from products intended to come into contact with children once included in the “candidate list”. At the latest the SVHC which are not CMRs should be eliminated after the sunset date given for the substance in Annex XIV of REACH unless an authorization is granted for child care articles.

## 4.3 CMR substances

The limits for CMR substances in the TSD are based on classification of mixtures containing these chemical substances in the CLP regulation. At a maximum the limits for child use and care articles should be:

— for carcinogenic and mutagenic substances 0,1 %, 0,1 % and 1 % (for cat. 1A, 1B and 2);

— for substances toxic to reproduction 0,3 %, 0,3 % and 3 % (for cat. 1A, 1B and 2);

— in accordance with the specific limits included in Annex VI, Table 3.1 of Part 3 of the CLP Regulation,

unless a lower limit seems warranted.

These limits have been questioned among others by the scientific committee SCHER. It is therefore recommended to reduce the levels of CMR substances as far as technically feasible. In case of (non-threshold) mutagenic carcinogens the product is safe if any exposure of a child is avoided, i.e. when the substances are below the levels of detection using sensitive analytical methods.

These chemical substances may be present if there is no likely exposure to children in any form, including inhalation.

## 4.4 Certain elements

### 4.4.1 Regulatory and normative background

The limits for elements in scraped-off toy material in the Toy Safety Directive are shown in Table 1.

**Table 1 — Migration limits, from toys or components of toys, scraped-off toy materials**

| Element | mg/kg |
|---|---|
| Aluminium | 70 000 |
| Antimony | 560 |
| Arsenic | 47 |
| Barium | 18 750 |
| Boron | 15 000 |
| Cadmium | 17 |
| Chromium (III) | 460 |
| Chromium (VI) | 0,2 |
| Cobalt | 130 |
| Copper | 7 700 |
| Lead | 160 |
| Manganese | 15 000 |
| Mercury | 94 |
| Nickel | 930 |
| Selenium | 460 |
| Strontium | 56 000 |
| Tin | 180 000 |
| Organic tin | 12 |
| Zinc | 46 000 |

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin.

NOTE Limits for dry, brittle, powder-like or pliable or liquid or sticky toy material are not considered relevant for child use and care articles

Test methods for elements in Table 1 are included in EN 71-3.

### 4.4.2 Specific child use and care articles considerations

The requirements concerning elements included in the TSD should be considered as regards components of child use and care articles which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin.

## 4.5 Flame retardants

### 4.5.1 Regulatory and normative background

The following substances are restricted at 5 mg/kg (content limit) in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth:

— Tris (2-chloroethyl) phosphate (TCEP, CAS No 115-96-8);

— Tris(1,3-dichloropropyl-2)phosphate, Tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP, TDCPP, CAS No 13674-87-8);

— Tris-monochloro-propyl phosphate, Tris(2-chloro-1-methylethyl) phosphate (TCPP, CAS No 13674–84–5).

EN 71-9:2005+A1:2007, Table 2A includes action limits (defined as routinely-achievable limit of quantification for a particular substance using the specified method of analysis) for flame retardants as shown in Table 2.

**Table 2 — Flame retardants with action limits from EN 71–9**

| Compound | CAS Number | Limit |
|---|---|---|
| Tri-o-cresyl phosphate | 78–30–8 | Action limit |
| Tris(2-chloroethyl) phosphate | 115–96–8 | Action limit |

The action limits apply to textile toys and accessible components of toys intended for children under 3 years of age.

Test methods for flame retardants in Table 2 are provided in EN 71-10 and EN 71-11.

#### 4.5.2 Specific child use and care articles considerations

Requirements for flame retardants for combustible materials in child use and care articles should at a minimum consider to eliminate substances found not to be acceptable in toys.

### 4.6 Colourants

#### 4.6.1 Regulatory and normative background

EN 71-9:2005+A1:2007, Table 2B includes action limits for colourants as shown in Table 3.

**Table 3 — Colourants with action limits from EN 71–9**

| Colour Index Name | CAS Number | Limit |
|---|---|---|
| Disperse Blue 1 | 2475–45–8 | Action limit |
| Disperse Blue 3 | 2475–46–9 | Action limit |
| Disperse Blue 106 | 12223–01–7 | Action limit |
| Disperse Blue 124 | 61951–51–7 | Action limit |
| Disperse Yellow 3 | 2832–40–8 | Action limit |
| Disperse Orange 3 | 730–40–5 | Action limit |
| Disperse Orange 37/76 | 12223–33–5<br>13301–61–6 | Action limit |
| Disperse Red 1 | 2872–52–8 | Action limit |
| Solvent Yellow 1 | 60–09–3 | Action limit |
| Solvent Yellow 2 | 60–11–7 | Action limit |
| Solvent Yellow 3 | 97–56–3 | Action limit |
| Basic Red 9 | 569–61–9 | Action limit |
| Basic Violet 1 | 8004–87–3 | Action limit |

| | | |
|---|---|---|
| Basic Violet 3 | 548–62–9 | Action limit |
| Acid Red 26 | 3761–53–3 | Action limit |
| Acid Violet 49 | 1694–09–3 | Action limit |

The action limits apply to a broad range of toys including those intended for children under 3 years of age made of textile and leather.

Test methods for colourants in Table 3 are provided in EN 71-10 and EN 71-11.

A first-action method for colourants is described in EN 71-10. An assessment of whether any colourants can be transferred from textile materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A of EN 71-10, they shall be tested by the final-action method for colourants.

#### 4.6.2 Specific child use and care articles considerations

The requirements concerning colourants included in EN 71-9 and EN 71-10 should be considered as regards components of child use and care articles made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin.

### 4.7 Primary aromatic amines

#### 4.7.1 Regulatory and normative background

EN 71-9:2005+A1:2007, Table 2C includes action limits for primary aromatic amines as shown in Table 4.

**Table 4 — Primary aromatic amines with action limits from EN 71–9**

| **Compound** | **CAS number** | **Limit** |
|---|---|---|
| Benzidine | 92–87–5 | Action limit |
| 2-Naphthylamine | 91–59–8 | Action limit |
| 4-Chloroaniline | 106–47–8 | Action limit |
| 3.3'-Dichlorobenzidine | 91–94–1 | Action limit |
| 3,3'-Dimethoxybenzidine | 119–90–4 | Action limit |
| 3.3'-Dimethylbenzidine | 119–93–7 | Action limit |
| o-Toluidine | 95–53–4 | Action limit |
| 2-Methoxyaniline (o-Anisidine) | 90–04–0 | Action limit |
| Aniline | 62–53–3 | Action limit |

The action limits apply to a broad range of toys including those intended for children under 3 years of age made of textile and leather.

Test methods for primary aromatic amines Table 4 are provided in EN 71-10 and EN 71-11.

A first-action method for primary aromatic amines is described in EN 71-10. An assessment of whether any colourants can be transferred from textile materials to the mouth, mucous membranes or skin. If textiles are found not to be colourfast when tested in accordance with the test procedure described in Annex A of EN 71-10, they shall be tested by the final-action method for primary aromatic amines.

#### 4.7.2 Specific child use and care articles considerations

The requirements concerning primary aromatic amines included in EN 71-9 and EN 71-10 should be considered as regards components of child use and care articles made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin.

### 4.8 Monomers

#### 4.8.1 Regulatory and normative background

Bisphenol A is restricted at 0,1 mg/l (migration limit) in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth .

EN 71-9:2005+A1:2007, Table 2D includes limits for monomers as shown in Table 5.

**Table 5 — Monomers with limits from EN 71–9**

| **Compound** | **CAS Number** | **Limit**[a] |
|---|---|---|
| Acrylamide | 79–06–1 | Action limit |
| Bisphenol A | 80–05–7 | 0,1 mg/l |
| Formaldehyde | 50–00–0 | 2,5 mg/l |
| Phenol | 108–95–2 | 15 mg/l |
| Styrene | 100–42–5 | 0,75 mg/l |
| [a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11). | | |

Table 5 Monomers with limits from EN 71-9:2005+A1:2007, Table 2D.

The limits apply to certain kinds of toys, particularly those with intended mouth contact or likely mouth contact for prolonged periods.

Test methods for monomers in Table 5 are provided in EN 71-10 and EN 71-11.

#### 4.8.2 Specific child use and care articles considerations

The requirements concerning monomers included in EN 71-9 should be considered as regards child use and care articles which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

### 4.9 Solvents (migration)

#### 4.9.1 Regulatory and normative background

EN 71-9:2005+A1:2007, Table 2E includes limits for solvents (migration) as shown in Table 6.

**Table 6 — Solvents (migration) with limits from EN 71–9**

| Compound | CAS Number | Limit[a] |
|---|---|---|
| Trichloroethylene | 79–01–6 | Action limit |
| Dichloromethane | 75–09–2 | 0,06 mg/l |
| 2-Methoxyethyl acetate | 110–49–6 | 0,5 mg/l (total) |
| 2-Ethoxyethanol | 110–80–5 | |
| 2-Ethoxyethyl acetate | 111–15–9 | |
| Bis(2-methoxyethyl) ether | 111–96–6 | |
| 2-Methoxypropyl acetate | 70657–70–4 | |
| Methanol | 67–56–1 | 5 mg/l |
| Nitrobenzene | 98–95–3 | Action limit |
| Cyclohexanone | 108–94–1 | 46 mg/l |
| 3,5,5-Trimethyl-2-cyclohexene-1-one | 78–59–1 | 3 mg/l |
| Toluene | 108–88–3 | 2 mg/l |
| Ethylbenzene | 100–41–4 | 1 mg/l |
| Xylene (all isomers) | various | 2 mg/l (total) |

[a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11).

The limits apply to certain kinds of toys, particularly with intended mouth contact or likely mouth contact for prolonged periods.

Test methods for solvents (migration) in Table 6 are provided in EN 71-10 and EN 71-11.

#### 4.9.2 Specific child use and care articles considerations

The requirements concerning solvents (migration) included in EN 71-9 should be considered as regards child use and care articles which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

### 4.10 Solvents (inhalation)

#### 4.10.1 Regulatory and normative background

EN 71-9:2005+A1:2007, Table 2F includes limits for solvents (inhalation) as shown in Table 7.

**Table 7 — Solvents (inhalation) with limits from EN 71–9**

| Compound | CAS Number | Limit[a] |
|---|---|---|
| Toluene | 108–88–3 | 260 µg/m3 |
| Ethylbenzene | 100–41–4 | 5 000 µg/m3 |
| Xylene (all isomers) | Various | 870 µg/m3 (total) |
| 1,3,5-Trimethylbenzene (mesitylene) | 108–67–8 | 2 500 µg/m3 |
| Trichloroethylene | 79–01–6 | Action limit |
| Dichloromethane | 75–09–2 | 3 000 µg/m3 |
| n-Hexane | 110–54–3 | 1 800 µg/m3 |
| Nitrobenzene | 98–95–3 | Action limit |
| Cyclohexanone | 108–94–1 | 136 µg/m3 |
| 3,5,5-Trimethyl-2-cyclohexene-1-one | 78–59–1 | 200 µg/m3 |
| [a] Conformity with these limits cannot easily be assessed analytically pending further validation of the methods for volatile solvents described in EN 71–11. | | |

The limits apply to certain toys made of polymeric or textile materials, e.g. for inflatable toys with a surface greater than 0,5 $m^2$ when fully inflated, toys worn over the mouth or nose or toys which the child can enter.

Test methods for solvents (inhalation) in Table 7 are provided in EN 71-10 and EN 71-11. However, the methods have not been validated.

#### 4.10.2 Specific child use and care articles considerations

For some child use and care products with large areas or which are close to the child's nose for prolonged periods, inhalation of certain solvents may be relevant. In particular, this holds true for child use and care articles made of polymeric materials which can surround the child, for example a rain cover.

The requirements concerning solvents (inhalation) included in EN 71-9 should be considered as regards to components of child use and care articles made of polymeric materials which can surround the child.

### 4.11 Plasticizers

#### 4.11.1 Regulatory and normative background

EN 71-9:2005+A1:2007, Table 2l includes action limits for plasticizers as shown in Table 8.

**Table 8 — Plasticizers with limits from EN 71–9**

| Compound | CAS Number | Limit[a] |
|---|---|---|
| Triphenyl phosphate | 115–86–6 | Action limit |
| Tri-o-cresyl phosphate | 78–30–8 | Action limit |
| Tri-m-cresyl phosphate | 563–04–2 | Action limit |
| Tri-p-cresyl phosphate | 78–32–0 | Action limit |
| [a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11). | | |

The limits apply to certain kinds of toys, particularly with intended mouth contact or likely mouth contact for prolonged periods made of polymeric materials.

Test methods for plasticizers in EN 71-9:2005+A1:2007, Table 8 are provided in EN 71-10 and EN 71-11.

#### 4.11.2 Specific child use and care articles considerations

The requirements concerning plasticizers included in EN 71-9:2005+A1:2007, Table 8 should be considered as regards to child use and care articles made of polymeric articles which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

### 4.12 Sensitizers – Fragrances

#### 4.12.1 Regulatory and normative background

According to the TSD toys shall not contain allergenic fragrances as listed in Table 9. However, the presence of traces of these fragrances shall be allowed, provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

**Table 9 — Allergenic fragrances not allowed to be used in toys**

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (1) | Alanroot oil (Inula helenium) | 97676–35–2 |
| (2) | Allylisothiocyanate | 57–06–7 |
| (3) | Benzyl cyanide | 140–29–4 |
| (4) | 4 tert-Butylphenol | 98–54–4 |
| (5) | Chenopodium oil | 8006–99–3 |
| (6) | Cyclamen alcohol | 4756–19–8 |
| (7) | Diethyl maleate | 141–05–9 |
| (8) | Dihydrocoumarin | 119–84–6 |
| (9) | 2,4-Dihydroxy-3-methylbenzaldehyde | 6248–20–0 |
| (10) | 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) | 40607–48–5 |
| (11) | 4,6-Dimethyl-8-tert-butylcoumarin | 17874–34–9 |
| (12) | Dimethyl citraconate | 617–54–9 |
| (13) | 7,11-Dimethyl-4.6,10-dodecatrien-3-one | 26651–96–7 |
| (14) | 6,10-Dimethyl-3.5,9-undecatrien-2-one | 141–10–6 |
| (15) | Diphenylamine | 122–39–4 |
| (16) | Ethyl acrylate | 140–88–5 |
| (17) | Fig leaf, fresh and preparations | 68916–52–9 |
| (18) | trans-2-Heptenal | 18829–55–5 |
| (19) | trans-2-Hexenal diethyl acetal | 67746–30–9 |
| (20) | trans-2-Hexenal dimethyl acetal | 18318–83–7 |
| (21) | Hydroabietyl alcohol | 13393–93–6 |

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (22) | 4-Ethoxy-phenol | 622–62–8 |
| (23) | 6-Isopropyl-2-decahydronaphthalenol | 34131–99–2 |
| (24) | 7-Methoxycoumarin | 531–59–9 |
| (25) | 4-Methoxyphenol | 150–76–5 |
| (26) | 4-(p-Methoxyphenyl)-3-butene-2-one | 943–88–4 |
| (27) | 1-(p-Methoxyphenyl)-1-penten-3-one | 104–27–8 |
| (28) | Methyl trans-2-butenoate | 623–43–8 |
| (29) | 6-Methylcoumarin | 92–48–8 |
| (30) | 7-Methylcoumarin | 2445–83–2 |
| (31) | 5-Methyl-2,3-hexanedione | 13706–86–0 |
| (32) | Costus root oil (Saussurea lappa Clarke) | 8023–88–9 |
| (33) | 7-Ethoxy-4-methylcoumarin | 87–05–8 |
| (34) | Hexahydrocoumarin | 700–82–3 |
| (35) | Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch) | 8007–00–9 |
| (36) | 2-Pentylidene-cyclohexanone | 25677–40–1 |
| (37) | 3.6,10-Trimethyl-3.5,9-undecatrien-2-one | 1117–41–5 |
| (38) | Verbena oil (Lippia citriodora Kunth) | 8024–12–2 |
| (39) | Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene) | 83–66–9 |
| (40) | 4-Phenyl-3-buten-2-one | 122–57–6 |
| (41) | Amyl cinnamal | 122–40–7 |
| (42) | Amylcinnamyl alcohol | 101–85–9 |
| (43) | Benzyl alcohol | 100–51–6 |
| (44) | Benzyl salicylate | 118–58–1 |
| (45) | Cinnamyl alcohol | 104–54–1 |
| (46) | Cinnamal | 104–55–2 |
| (47) | Citral | 5392–40–5 |
| (48) | Coumarin | 91–64–5 |
| (49) | Eugenol | 97–53–0 |
| (50) | Geraniol | 106–24–1 |

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (51) | Hydroxy-citronellal | 107–75–5 |
| (52) | Hydroxy-methylpentylcyclohexenecarboxaldehyde | 31906–04–4 |
| (53) | Isoeugenol | 97–54–1 |
| (54) | Oakmoss extracts | 90028–68–5 |
| (55) | Treemoss extracts | 90028–67–4 |

In addition, the names of the allergenic fragrances in Table 10 shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof.

**Table 10 — Allergenic fragrances to be labelled if used in toys**

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (1) | Anisyl alcohol | 105–13–5 |
| (2) | Benzyl benzoate | 120–51–4 |
| (3) | Benzyl cinnamate | 103–41–3 |
| (4) | Citronellol | 106–22–9 |
| (5) | Farnesol | 4602–84–0 |
| (6) | Hexyl cinnamaldehyde | 101–86–0 |
| (7) | Lilial | 80–54–6 |
| (8) | d-Limonene | 5989–27–5 |
| (9) | Linalool | 78–70–6 |
| (10) | Methyl heptine carbonate | 111–12–6 |
| (11) | 3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one | 127–51–5 |

#### 4.12.2 Specific child use and care articles considerations

The requirements concerning allergenic fragrances included in the TSD should be considered as regards scented child use and care articles.

### 4.13 N-Nitrosamines and N-Nitrosatable substances

#### 4.13.1 Regulatory and normative background

According to TSD N-nitrosamines and N-nitrosatable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for N-nitrosamines and 1 mg/kg for N-nitrosatable substances.

Test methods for N-Nitrosamines and N-nitrosatable substances in toys and parts of toys made from elastomers are provided in EN 71-12 “Safety of toys – Part 12: N-Nitrosamines and N-nitrosatable substances”.

#### 4.13.2 Specific child use and care articles considerations

The requirements concerning N-Nitrosamines and N-Nitrosatable substances included in the Toy Safety Directive and EN 71-12 should be considered as regards child use and care articles made of elastomers which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006”.

NOTE This does not apply to soothers or teats for drinking equipment made of elastomers.

### 4.14 Other

#### 4.14.1 Formaldehyde (other than monomer or preservative)

##### 4.14.1.1 Regulatory and normative background

EN 71-9:2005+A1:2007 contains the following requirements for formaldehyde in 4.3 in addition to the requirements for formaldehyde used as monomer or preservative:

Accessible textile components of toys intended for children under 3 years of age shall not contain free and hydrolyzed formaldehyde in excess of 30 mg/kg when tested in accordance with EN ISO 14184-1.

Accessible resin-bonded wood components of toys intended for children under 3 years of age shall not release formaldehyde in excess of 80 mg/kg when tested in accordance with EN 717-3.

Test methods are given in the standards referenced above.

##### 4.14.1.2 Specific child use and care articles considerations

The requirements concerning formaldehyde included in EN 71-9 should be considered as regards components of child use and care articles:

— made of textiles, which due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin;

— made of resin-bonded wood, which due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to inhalation.

# Annex A
(informative)

# Brief description of EU regulatory chemical requirements applicable to child use and care articles

## A.1 Cadmium

According to Annex XVII of REACH cadmium (entry 23) shall not be used in articles manufactured from certain plastics materials including e.g. PVC, PUR, ld PE, PP. A limit of 0,01 % applies.

## A.2 Nickel

According to Annex XVII of REACH nickel (entry 27) shall not be used in products intended to come into direct and prolonged contact with the skin (examples include e.g. rivet buttons, zippers, tighteners) if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm$^2$/week.

Nickel shall not be used in articles intended to come into direct and prolonged contact with the skin where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm$^2$/week for a period of at least two years of normal use of the article.

Test methods are included in:

— EN 1811 “Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin”, and

— EN 12472 “Method for the simulation of wear and corrosion for the detection of nickel release from coated items”.

## A.3 Flame retardants

According to Annex XVII of REACH the following substances are banned in textile articles with skin contact:

— Tris (2,3 dibromopropyl)phosphate (entry 4, CAS No 126-72-7);

— Tris(aziridinyl)phosphinoxide (entry 7, CAS No 545-55-1);

— Polybromobiphenyls (entry 8, CAS No 59536-65-1).

## A.4 Colourants

According to Annex XVII of REACH Azocolourants and Azodyes (entry 43) are banned in a broad range of textile and leather articles including toys. This refers to Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8 (it includes currently 22 substances), in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) which may come into direct and prolonged contact with the human skin or oral cavity.

## A.5 Wood preservatives

The Biocidal Products Regulation (Regulation (EU) No 528/2012) includes provisions for articles treated with biocides which apply also to child care articles. Only approved substances and biocidal products are allowed to be used in articles and labelling requirements for treated articles apply.

## A.6 Preservatives (other than wood preservatives)

According to Annex XVII of REACH articles or any parts thereof containing Dimethylfumarate (DMF) (entry 61, CAS No 624-49-7) in concentrations greater than 0.1mg/kg shall not be placed on the market.

The Biocidal Products Regulation (Regulation (EU) No 528/2012) includes provisions for articles treated with biocides which apply also to child care articles. Only approved substances and biocidal products are allowed to be used in articles and labelling requirements for treated articles apply.

## A.7 Plasticizers

According to Annex XVII of REACH toys and childcare articles containing the following phthalates (entry 51) in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market:

— Bis (2-ethylhexyl) phthalate (DEHP) (CAS No 117-81-7);

— Dibutyl phthalate (DBP) (CAS No 84-74-2);

— Benzyl butyl phthalate (BBP) (CAS No 85-68-7).

According to Annex XVII of REACH toys and childcare articles which can be placed in the mouth by children containing the following phthalates (entry 52) in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market:

— Di-“isononyl” phthalate (DINP) (CAS No 28553-12-0 and 68515-48-0);

— Di-“isodecyl” phthalate (DIDP) (CAS No 26761-40-0 and 68515-49-1);

— Di-n-octyl phthalate (DNOP) (CAS No 117-84-0).

A “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” is available.

## A.8 N-Nitrosamines and N-Nitrosatable substances

Specific regulation applies to the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers (Directive 93/11/EEC). It establishes the following limits:

— 0,01 mg in total of N-nitrosamines released/kg (of the parts of teat or soother made of elastomer or rubber);

— 0,1 mg in total of N-nitrosatable substances/kg (of the parts of teat or soother made of elastomer or rubber).

Test methods are included in:

EN 12868 “Child use and care articles - Methods for determining the release of N-Nitrosamines and N-Nitrosatable substances from elastomer or rubber teats and soothers” provides a test method for the regulatory requirements for elastomer or rubber teats and soothers.

## A.9 Policyclic Aromatic Hydrocarbons (PAHs)

According to Annex XVII of REACH (entry 50) toys, including activity toys, and childcare articles, shall not be placed on the market, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 0,5 mg/kg (0,00005 % by weight of this component) of any of the listed PAHs (Benzo[a]pyrene, Benzo[e]pyrene, Benzo[a]anthracene, Chrysen, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene and Dibenzo[a,h]anthracene).

NOTE The regulation applies from 27 December 2015.

## A.10 Persistent Organic Pollutants (POPs)

The objective of Regulation (EC) No 850/2004 is to protect human health and the environment from persistent organic pollutants by prohibiting, phasing out as soon as possible, or restricting the production, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants. Annex I includes substances subject to prohibitions.The provisions apply also to child use and care articles.

## A.11 Food contact materials

Certain child use and care articles such as drinking equipment are subject to Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. Of particular importance is Commission Regulation (EC) No 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs.

## A.12 Packaging

Directive 94/62/EC on packaging and packaging waste establishes among other things limits for lead, cadmium, mercury and hexavalent chromium in packaging which apply also to packaging of child use and care articles.

# Annex B
(informative)

# Model requirements for use in a standard

## B.1 Introduction

This annex contains model requirements which can be copied and pasted into a draft standard.

## B.2 General chemical requirements

The chemicals mentioned below do not represent a definitive list. The following requirements cover the current known issues. In addition, grades of materials with quality standards that ensure that there is no increased risk from chemicals either specified or not in this standard are recommended to be used.

A compliance declaration containing details as regards the chemical requirements may replace the testing. The declaration shall be based on an analysis of the chemical substances present or likely to be present in the article or knowledge of the production process.

## B.3 Substances of Very High Concern (SVHC)

Substances other than CMRs included in Annex XIV of REACH shall not exceed 0,01 % after the sunset date given for the substance unless an authorization is granted for child care articles.

## B.4 CMR substances

Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in any part which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin if exceeding the following limits:

— for carcinogenic and mutagenic substances 0,1 %, 0,1 % and 1 % (for cat. 1A, 1B and 2);

— for substances toxic to reproduction 0,3 %, 0,3 % and 3 % (for cat. 1A, 1B and 2);

— in accordance with the specific limits included in Annex VI, Table 3.1 of Part 3 of Regulation (EC) No 1272/2008.

## B.5 Certain elements

The migration of elements from any parts which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin shall not exceed any of the limits given in Table B.1.

When testing is performed the method described in EN 71-3 shall be used.

**Table B.1 — Migration limits of certain elements**

| Element | mg/kg |
|---|---|
| Aluminium | 70 000 |
| Antimony | 560 |
| Arsenic | 47 |
| Barium | 18 750 |
| Boron | 15 000 |
| Cadmium | 17 |
| Chromium (III) | 460 |
| Chromium (VI) | 0,2 |
| Cobalt | 130 |
| Copper | 7 700 |
| Lead | 160 |
| Manganese | 15 000 |
| Mercury | 94 |
| Nickel | 930 |
| Selenium | 460 |
| Strontium | 56 000 |
| Tin | 180 000 |
| Organic tin | 12 |
| Zinc | 46 000 |

## B.6 Flame retardants

Fire-resistance treated materials shall not contain any flame-retardants exceeding the limit given in Table B.2.

When testing of Tri-o-cresyl phosphate is performed the method described in EN 71-10 and EN 71-11 shall be used.

NOTE There are no standardised test methods for the other flame retardants listed.

**Table B.2 — Flame retardant limits**

| Compound | CAS Number | Limit |
|---|---|---|
| Tri-o-cresyl phosphate | 78–30–8 | 50 mg/kg |
| Tris(2-chloroethyl) phosphate | 115–96–8 | 5 mg/kg |
| Tris(1,3-dichloropropyl-2)phosphate | 13674–87–8 | 5 mg/kg |
| Tris-monochloro-propyl phosphate | 13674–84–5 | 5 mg/kg |

## B.7 Colorants

The migration of colourants from parts made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin shall not exceed any of the limits given in Table B.3.

When testing is performed the first action method for colourants and primary aromatic amines described in EN 71-10 shall be used. If colour fastness to water or to perspiration results is less than 3-4 on the grey scale as defined in EN 20105-A03 then the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.3 — Colourants limits**

| Colour Index Generic Name (CIGN) | Colour Index Constitution Number (CICN) | CAS Number | Limit |
|---|---|---|---|
| Disperse Blue 1 | 64500 | 2475–45–8 | Action limit |
| Disperse Blue 3 | 61505 | 2475–46–9 | Action limit |
| Disperse Blue 106 | 111935 | 12223–01–7 | Action limit |
| Disperse Blue 124 | 111938 | 61951–51–7 | Action limit |
| Disperse Yellow 3 | 11855 | 2832–40–8 | Action limit |
| Disperse Orange 3 | 11855 | 730–40–5 | Action limit |
| Disperse Orange 37/76/59 | 11132 | 12223–33–5<br>13301–61–6 | Action limit |
| Disperse Red 1 | 11110 | 2872–52–8 | Action limit |
| Solvent Yellow 1 | 11000 | 60–09–3 | Action limit |
| Solvent Yellow 2 | 11020 | 60–11–7 | Action limit |
| Solvent Yellow 3 | 11160 | 97–56–3 | Action limit |
| Basic Red 9 | 42500 | 569–61–9 | Action limit |
| Basic Violet 1 | 42535 | 8004–87–3 | Action limit |
| Basic Violet 3 | 42555 | 548–62–9 | Action limit |
| Acid Red 26 | 16150 | 3761–53–3 | Action limit |
| Acid Violet 49 | 42640 | 1694–09–3 | Action limit |

## B.8 Primary aromatic amines

The migration of primary aromatic amines from parts made of textiles and leather which, due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, or prolonged contact with skin shall not exceed any of the limits given in Table B.4.

When testing is performed the first action method for colourants and primary aromatic amines described in EN 71-10 shall be used. If colour fastness to water or to perspiration results is less than 3-4 on the grey scale as defined in EN 20105-A03 then the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.4 — Primary aromatic amines limits**

| Compound | CAS number | Limit |
|---|---|---|
| Benzidine | 92–87–5 | Action limit |
| 2-Naphthylamine | 91–59–8 | Action limit |
| 4-Chloroaniline | 106–47–8 | Action limit |
| 3.3'-Dichlorobenzidine | 91–94–1 | Action limit |
| 3,3'-Dimethoxybenzidine | 119–90–4 | Action limit |
| 3.3'-Dimethylbenzidine | 119–93–7 | Action limit |
| o-Toluidine | 95–53–4 | Action limit |
| 2-Methoxyaniline (o-Anisidine) | 90–04–0 | Action limit |
| Aniline | 62–53–3 | Action limit |

## B.9 Monomers

The migration of monomers from parts made of polymeric materials which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” shall not exceed the limits in Table B.5.

When testing is performed the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.5 — Monomers limits**

| **Compound** | **CAS Number** | **Limit**[a] |
|---|---|---|
| Acrylamide | 79–06–1 | Action limit |
| Bisphenol A | 80–05–7 | 0,1 mg/l |
| Formaldehyde | 50–00–0 | 2,5 mg/l |
| Phenol | 108–95–2 | 15 mg/l |
| Styrene | 100–42–5 | 0,75 mg/l |
| [a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11). | | |

## B.10 Solvents (migration)

The migration of solvents from parts made of polymeric or textile material which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006 ” shall not exceed the limits in Table B.6.

When testing is performed the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.6 — Solvents (migration) limits**

| **Compound** | **CAS Number** | **Limit**[a] |
|---|---|---|
| Trichloroethylene | 79–01–6 | Action limit |
| Dichloromethane | 75–09–2 | 0,06 mg/l |
| 2-Methoxyethyl acetate | 110–49–6 | 0,5 mg/l (total) |
| 2-Ethoxyethanol | 110–80–5 | |
| 2-Ethoxyethyl acetate | 111–15–9 | |
| Bis(2-methoxyethyl) ether | 111–96–6 | |
| 2-Methoxypropyl acetate | 70657–70–4 | |
| Methanol | 67–56–1 | 5 mg/l |
| Nitrobenzene | 98–95–3 | Action limit |
| Cyclohexanone | 108–94–1 | 46 mg/l |
| 3,5,5-Trimethyl-2-cyclohexene-1-one | 78–59–1 | 3 mg/l |
| Toluene | 108–88–3 | 2 mg/l |
| Ethylbenzene | 100–41–4 | 1 mg/l |
| Xylene (all isomers) | Various | 2 mg/l (total) |
| [a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11). | | |

## B.11 Solvents (inhalation)

The inhalation of solvents from parts made of polymeric materials which can surround the child shall not exceed the limits in Table B.7.

When testing is performed the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.7 — Solvents (inhalation) limits**

| **Compound** | **CAS Number** | **Limit**[a] |
|---|---|---|
| Toluene | 108–88–3 | 260 µg/m3 |
| Ethylbenzene | 100–41–4 | 5 000 µg/m3 |
| Xylene (all isomers) | Various | 870 µg/m3 (total) |
| 1,3,5-Trimethylbenzene (mesitylene) | 108–67–8 | 2 500 µg/m3 |
| Trichloroethylene | 79–01–6 | Action limit |
| Dichloromethane | 75–09–2 | 3 000 µg/m3 |
| n-Hexane | 110–54–3 | 1 800 µg/m3 |
| Nitrobenzene | 98–95–3 | Action limit |
| Cyclohexanone | 108–94–1 | 136 µg/m3 |
| 3,5,5-Trimethyl-2-cyclohexene-1-one | 78–59–1 | 200 µg/m3 |
| [a] Conformity with these limits cannot easily be assessed analytically pending further validation of the methods for volatile solvents described in EN 71–11. | | |

## B.12 Plasticizers

The migration of plasticizers from parts made of plasticized polymeric materials which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006 ” shall not exceed the limits in Table B.8.

When testing is performed the method described in EN 71-10 and EN 71-11 shall be used.

**Table B.8 — Plasticizers limits**

| Compound | CAS Number | Limit[a] |
|---|---|---|
| Triphenyl phosphate | 115–86–6 | Action limit |
| Tri-o-cresyl phosphate | 78–30–8 | Action limit |
| Tri-m-cresyl phosphate | 563–04–2 | Action limit |
| Tri-p-cresyl phosphate | 78–32–0 | Action limit |
| [a] Limits are expressed as amount of substance per litre of simulant (see EN 71–11). | | |

## B.13 Sensitizers – Fragrances

Any scented part or material shall not contain any of the allergenic fragrances as listed in Table B.9. However, the presence of traces of these fragrances shall be allowed, provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the allergenic fragrances in Table B.10 shall be listed on the article, on an affixed label, on the packaging or in an accompanying leaflet, if added to any scented part or material at concentrations exceeding 100 mg/kg.

**Table B.9 — Allergenic fragrances not allowed to be used**

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (1) | Alanroot oil (Inula helenium) | 97676–35–2 |
| (2) | Allylisothiocyanate | 57–06–7 |
| (3) | Benzyl cyanide | 140–29–4 |
| (4) | 4 tert-Butylphenol | 98–54–4 |
| (5) | Chenopodium oil | 8006–99–3 |
| (6) | Cyclamen alcohol | 4756–19–8 |
| (7) | Diethyl maleate | 141–05–9 |
| (8) | Dihydrocoumarin | 119–84–6 |
| (9) | 2,4-Dihydroxy-3-methylbenzaldehyde | 6248–20–0 |
| (10) | 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) | 40607–48–5 |
| (11) | 4,6-Dimethyl-8-tert-butylcoumarin | 17874–34–9 |
| (12) | Dimethyl citraconate | 617–54–9 |
| (13) | 7,11-Dimethyl-4.6,10-dodecatrien-3-one | 26651–96–7 |
| (14) | 6,10-Dimethyl-3.5,9-undecatrien-2-one | 141–10–6 |
| (15) | Diphenylamine | 122–39–4 |
| (16) | Ethyl acrylate | 140–88–5 |
| (17) | Fig leaf, fresh and preparations | 68916–52–9 |
| (18) | trans-2-Heptenal | 18829–55–5 |
| (19) | trans-2-Hexenal diethyl acetal | 67746–30–9 |
| (20) | trans-2-Hexenal dimethyl acetal | 18318–83–7 |
| (21) | Hydroabietyl alcohol | 13393–93–6 |
| (22) | 4-Ethoxy-phenol | 622–62–8 |
| (23) | 6-Isopropyl-2-decahydronaphthalenol | 34131–99–2 |
| (24) | 7-Methoxycoumarin | 531–59–9 |
| (25) | 4-Methoxyphenol | 150–76–5 |
| (26) | 4-(p-Methoxyphenyl)-3-butene-2-one | 943–88–4 |
| (27) | 1-(p-Methoxyphenyl)-1-penten-3-one | 104–27–8 |

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (28) | Methyl trans-2-butenoate | 623–43–8 |
| (29) | 6-Methylcoumarin | 92–48–8 |
| (30) | 7-Methylcoumarin | 2445–83–2 |
| (31) | 5-Methyl-2,3-hexanedione | 13706–86–0 |
| (32) | Costus root oil (Saussurea lappa Clarke) | 8023–88–9 |
| (33) | 7-Ethoxy-4-methylcoumarin | 87–05–8 |
| (34) | Hexahydrocoumarin | 700–82–3 |
| (35) | Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch) | 8007–00–9 |
| (36) | 2-Pentylidene-cyclohexanone | 25677–40–1 |
| (37) | 3.6,10-Trimethyl-3.5,9-undecatrien-2-one | 1117–41–5 |
| (38) | Verbena oil (Lippia citriodora Kunth) | 8024–12–2 |
| (39) | Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene) | 83–66–9 |
| (40) | 4-Phenyl-3-buten-2-one | 122–57–6 |
| (41) | Amyl cinnamal | 122–40–7 |
| (42) | Amylcinnamyl alcohol | 101–85–9 |
| (43) | Benzyl alcohol | 100–51–6 |
| (44) | Benzyl salicylate | 118–58–1 |
| (45) | Cinnamyl alcohol | 104–54–1 |
| (46) | Cinnamal | 104–55–2 |
| (47) | Citral | 5392–40–5 |
| (48) | Coumarin | 91–64–5 |
| (49) | Eugenol | 97–53–0 |
| (50) | Geraniol | 106–24–1 |
| (51) | Hydroxy-citronellal | 107–75–5 |
| (52) | Hydroxy-methylpentylcyclohexenecarboxaldehyde | 31906–04–4 |
| (53) | Isoeugenol | 97–54–1 |
| (54) | Oakmoss extracts | 90028–68–5 |
| (55) | Treemoss extracts | 90028–67–4 |

**Table B.10 — Allergenic fragrances to be labelled**

| No | Name of the allergenic fragrance | CAS number |
|---|---|---|
| (1) | Anisyl alcohol | 105–13–5 |
| (2) | Benzyl benzoate | 120–51–4 |
| (3) | Benzyl cinnamate | 103–41–3 |
| (4) | Citronellol | 106–22–9 |
| (5) | Farnesol | 4602–84–0 |
| (6) | Hexyl cinnamaldehyde | 101–86–0 |
| (7) | Lilial | 80–54–6 |
| (8) | d-Limonene | 5989–27–5 |
| (9) | Linalool | 78–70–6 |
| (10) | Methyl heptine carbonate | 111–12–6 |
| (11) | 3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one | 127–51–5 |

## B.14 N-Nitrosamines and N-Nitrosatable substances

The migration of N-Nitrosamines and N-nitrosatable substances from parts made of elastomers which can be placed in the mouth, particularly those with intended mouth contact or likely mouth contact for prolonged periods and taking into account the “Guideline on the interpretation of the concept “which can be placed in the mouth” as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006” shall not exceed 0,05 mg/kg for the sum of N-nitrosamines and 1 mg/kg for the sum of N-nitrosatable substances.

When testing is performed the method described in EN 71-12 shall be used.

NOTE 1 The method for other toys or parts of toys than balloons applies.

NOTE 2 This does not apply to soothers or teats for drinking equipment made of elastomers.

## B.15 Formaldehyde (other than monomer or preservative)

Free and hydrolysed formaldehyde contained in parts made of textile materials, which due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin shall not exceed 30 mg/kg.

When testing is performed the method described in EN ISO 14184 shall be used.

The release of formaldehyde from parts made of resin-bonded wood which due to their accessibility, function, volume or mass, can reasonably lead to a exposure due to inhalation shall not exceed 80 mg/kg.

When testing is performed the method described in EN 717-3 shall be used.

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[7] EN 1811, *Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin*

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[11] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD)

[12] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys

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[14] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

[15] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

[16] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

[17] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

[18] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

[19] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[20] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

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