Toys Safety Directive 2009/48/EC chemical requirements

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Point 1: The general chemical safety requirement

Toys shall be designed and manufactured in such a way that:

- They present no risk of adverse health effects due to exposure to chemical substances/mixtures in toys during foreseeable use
- They comply with the relevant Community legislation relating to certain products or restrictions for certain substances/mixtures

Until 20 July 2013, the chemical requirements in 88/378/EEC apply.

The general chemical safety requirement is practically the same in the two directives but the particular safety requirements change.
Specific chemical safety requirements

Point 2: Toys that are substances and mixtures

Toys that are themselves substances or mixtures must comply with

- Directive 67/548/EEC (dangerous substances Directive, DSD), and
- Directive 1999/45/EEC (dangerous preparations Directive, DPD), and
- Regulation 1272/2008 (CLP – Classification, labelling and packaging of substances and mixtures)
- The CLP regulation will replace the two directives by 1 June 2015 after a period of transitional provisions
Toys that are substances or mixtures must comply with CLP. Hence, the toy (the substance or the mixture) must be labelled accordingly if it fulfils the criteria for classification.

- Eg. finger paint, crayon, slime and play dough

- If such products contain dangerous substances they might need to be labelled.
Toy safety directive, 2009/48/EC

Cosmetic directive, 76/768/EEC

CLP, EC/1272/2008

National restrictions

REACH, EC/1907/2006

RoHS directive, 2002/95/EC

Food contact materials, 2002/72/EC
Point 3: Prohibition of CMRs

Substances classified as CMR (Carcinogenic, Mutagenic or toxic for Reproduction) of category 1A, 1B or 2 as specified in CLP (Regulation (EC) No 1272/2008) shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

“Structurally distinct part”:
- ≈ “homogenous material”
- Can be visually distinguished from its surroundings: a bicycle has several “parts” (saddle, fork etc) but each of them can have several homogenous materials

“Micro-structurally “:
- e.g. a thin coating on a base material

Note: CLP defines categories 1 A, 1 B and 2. Classification in DPD refers to category 1, 2 and 3
Point 4: Exemptions to the CMR-prohibition for Category 1A and 1B

Substances and mixtures classified as CMR category 1A and 1B (according to CLP) are exempted from the prohibition in point 3 if:

- The individual concentration is below the limits specified in CLP
- The substance/mixture is inaccessible in any form incl. inhalation
- The substance/mixture is listed in Appendix A to Annex II.

Such listing requires that three criteria are fulfilled:
- Scientific Committee found it safe and reviews this every 5 years
- There are no suitable alternatives (documented analysis needed)
- Not prohibited by REACH for use in consumer articles

Note: In comparison to the limits in CLP, until 1 June 2015 other concentration limits may apply in DPD

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Point 5: Exemptions to the CMR-prohibition for Category 2

Same conditions as for CMRs category 1 A and B with one difference:

The Commission decision to list it in Appendix A to Annex II can be taken based on the following two criteria:

- Scientific Committee has found it to be safe
- Not prohibited by REACH for use in consumer articles

Note: The criterion that there no suitable alternatives are available does not apply for listing of a CMR category 2 (applies for category 1 A and 1 B)

Note: An application will be made to list in Appendix A (before 20 July 2013) “Nickel in electrically conductive surfaces”
Point 6: Exemption for Nickel in stainless steel from points 3, 4 and 5

“Points 3, 4 and 5 shall not apply to nickel in stainless steel”

Note: The derogation for nickel in stainless steel does not apply to nickel in coatings.
Point 7: Exemptions to the CMR-prohibition for approved Food contact materials and materials complying with limits in Appendix C

Stricter concentration limits can be listed in Appendix C of Annex II:

- Requires a Commission Decision
- Applies to chemicals in toys intended for children under 36 months and toys intended to be placed in the mouth
- Stricter limit values can be justified due to the higher exposure for these categories of toys

Materials covered by and complying with Food Contact Material legislation are allowed in toys until 20 July 2017
Point 8: Prohibition of nitrosamines in certain toys

Scope:
N-nitrosamines and N-nitrosatable substances in toys for children under 36 months or in other toys intended to be put in the mouth.

Migration limits are:

- 0.05 mg/kg for N-nitrosamines
- 1 mg/kg for N-nitrosatable substances

“Intended to be placed in the mouth" refers to teethers, balloons etc but not to e.g. bicycle tyres. Particular relevance for rubber material and finger paints.
Point 9: Requires the Commission to systematically and regularly evaluate the occurrence of hazardous substances of materials in toys.

Point 10: Cosmetic toys shall comply with the compositional and labeling requirements of the cosmetics directive 76/768/EEC.

- Cosmetic toys shall comply with both TSD and the cosmetic directive (76/768/EEC). E.g. make up for a doll.

Attention on:
Appendix with allowed preservatives and colours.
Cosmetic shall for example have a list of ingredients and a “best before” date.
Point 11: Prohibition for fragrances and marking requirements

- Toys shall not contain any of 55 listed allergenic fragrances
  - Traces are allowed if technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg
- 11 other allergenic fragrances shall be labeled if added to a toy at concentrations exceeding 100 mg/kg

Guidelines for interpretation of the cosmetics directive:

Point 12: Derogations from the fragrance prohibition

An exemption to the prohibition of the 15 “extra” fragrances (41 – 55) applies to:

- Olfactory board games (learn to recognize different odours/flavours)
- Gustative games (allow children to make sweets or dishes)
- Cosmetic kits (a toy the purpose of which is to assist a child to learn to make products such as fragrances, soap, make-up, etc)

Provided that:

- The fragrances are labeled on the packaging and a warning is present “contains fragrances that may cause allergies”
- The resulting products, made in accordance with the instructions, comply with the requirements of Cosmetics directive, if applicable, and the fragrances comply with the relevant legislation on food, if applicable
- The toy carries a warning “Not suitable for children under 3 years” with indication of the hazard
Point 13: Migration limits

- Migration limits apply to 19 elements:
  Aluminium, Antimony, Arsenic, Barium, Boron, Cadmium, Chromium, Chromium (VI), Cobalt, Copper, Lead, Manganese, Mercury, Nickel, Selenium, Strontium, Tin, Organic tin, Zinc

- The requirements apply in addition to the CMR-prohibition

- Apply to accessible toys/components (after foreseeable use test)

- Limits for arsenic, cadmium, chromium VI, lead, mercury and organic tins are set at 50% of what is considered safe by the scientific committee

- Different limits for different material types
  - Dry, brittle, powder-like or pliable toy materials
  - Liquid and sticky toy materials
  - Scrapped-off toy materials.
Requirements in the TSD

• The chemical requirements enters into force 20 July 2013
• Migration limits can be changed via committee procedures, when new scientific data are available
• Specific limits for substances in toys intended for children under 36 months or toys intended to be put in the mouth can be amended via committee procedure

New limits for different substances can be expected!
Migration limits

Cadmium

Migration limits

Lead

Migration limits

Barium

*Opinion SCHER:*

*Aim: new limits a factor of 3 lower*
CMR substances

TCEP, TCPP, TDCP


Aim: amend appendix C with a limit value of 5 mg/kg (tbd)
CMR substances

Metallic Nickel:

*Opinion SCHER:*
http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_163.pdf

*Aim: allow the presence of metallic nickel in materials allowing the correct electrical function of toys*
Expert WG chemicals and Committee

Under consideration to set specific limit values for chemicals used in toys intended for use by children < 36 months or in toys intended to be placed in the mouth:

- Kathone
- Formamide, phenol and formaldehyde
- BPA
- 22 non treshold CMRs
Requirement in REACH (1)

- DEHP, DBP and BBP are restricted in all toys and childcare articles at concentrations higher than 0.1%.
- DINP, DIDP and DNOP are restricted in toys and childcare articles at concentrations higher than 0.1% in toys and childcare articles which can be placed in the mouth.

Guidance documents on articles which can be put in the mouth:
Requirement in REACH (2)

- Cadmium is restricted as stabiliser in polymers and shall not be used to give colour to finished articles in concentrations above 100 ppm
- Benzene is restricted in toys in concentration above 5 ppm
- From 2017, 5 specific phenylmercury compounds are restricted in articles, substances and mixtures in concentrations above 100 ppm
 Requirement in REACH (3)

- **Tri-substituted organic tin compounds like TBT and TPT shall not be used in articles in concentration above 0.1 % by weight of tin**
- **DBT shall not be used in articles in concentration above 0.1 % by weight of tin**
  
  For some uses the ban will apply from January 2015

- **DOT shall not be used in concentrations above 0.1 % in:**
  
  Textiles intended to come into contact with the skin
  Childcare articles
  Nappies
  Other articles that are not relevant for toys
Restriction of azocolourants, annex XVII

Requirement in REACH (4)

- Azodyes which may release one or more of 22 specific aromatic amines in concentrations above 30 ppm, shall not be used in textile or leather articles which may come in prolonged contact with human skin or oral cavity.
- A test method is given in appendix 10 of REACH
- Restriction is made to limit the exposure to carcinogenic substances
- Toys which have higher concentrations of one or more of the aromatic amines will pose a serious risk to the children.
Restriction on the use of certain hazardous substances in electrical and electronic equipment

**RoHS directive**

- **Electrical and electronic equipment shall not contain:**
  - Lead (1000 ppm)
  - Mercury (100 ppm)
  - Cadmium (100 ppm)
  - Chromium VI (1000 ppm)
  - Polybrominated biphenyls (PBB) (1000 ppm)
  - Polybrominated dephenyl ethers (PBDE) (1000 ppm)
Food contact material

- Toys that are food contact material shall comply with both the legislation for food contact material and the TSD
- Compliance with the legislation for food contact material does not necessarily ensure safe toys
- Limit for chemicals in food contact materials are not based on the articles are used as toys
National restrictions

Phthalates, mercury, lead, phenol, formaldehyde, formamide...
Chemical safety assessment
Safety assessment in 2009/48/EC

The requirement:

The requirement is found in 2009/48/EC, article 18:

Manufacturers shall, before placing a toy on the market, carry out an 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.

The aim of a safety assessment is to identify and minimize risks. Can be done at any point before the toy is placed on the market.

The requirement is in place since 20 July, 2011 also for chemical hazards although new chemical requirements do not come into force until 20 July, 2013. Chemical requirements in 88/378/EEC apply until then (including the general chemical requirement).
Available standards
(some new and some revised will be published during 2013)

- EN 71-3 “Migration of certain elements”
- EN 71-4 “Chemical experimental sets”
- EN 71-5 “Chemical toys other than chemical sets”
- EN 71-7 “Fingerpaints”
- EN 71-12 “N-Nitrosamines and Nitrosatable substances”
- EN 71-13 “Olfactory board games, cosmetic kits and gustative games”
- EN 71-9 “Organic chemical compounds” (not referenced in the OJEU – does not give presumption of conformity)

Note: The assessment can reduce and/or target testing. Testing only needs to be considered for substances that can reasonably be expected to appear in the toy in question.
Relevant links

Guidance documents from the Commission:

The two most important are:
TSD explanatory guidance document and
Technical documentation guidance document