



Nickel: triply regulated in toys

18 March 2015

Nickel is a substance that is subject to several restrictions in toys, which sometimes leads to misunderstandings. The following three rules apply separately and all three must be met.

Requirements for migration in the Toy Safety Directive and the EN 71-3 standard

Nickel is one of the nineteen substances covered by migration limits in the Directive (2009/48/EC), i.e. a limit on how much nickel may migrate (or 'leak') from a toy material when tested using the method specified in the EN 71-3 standard on the 'migration of certain elements'.

In certain cases, nickel migration limits do not apply:

- When the part of the toy containing nickel is not accessible to children
- When the function, volume or mass of the toy or one of its components does not allow children to suck, lick or swallow it. The child's behaviour must be taken into consideration, therefore this limit does not apply to toys intended for children over six years of age unless they are:
 - For use in or near their mouth, e.g. the mouthpiece of a toy flute
 - A cosmetic toy
 - Pencils, crayons, etc. that are classified as toys
- When the part containing nickel is so big it will not fit in the small parts cylinder

Requirements for nickel as a CMR in the Toy Safety Directive

Substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) are banned in toys by the Toy Safety Directive. However, exceptions are made for:

- Substances that are not accessible
- Substances used in concentrations below the limits specified in the Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP, 1272/2008)
 - Nickel is classified as a category 2 carcinogenic. According to the CLP Regulation, the concentration of nickel in a toy may therefore not exceed 1% of the total concentration of substances in the toy or its components.
- Substances listed in Appendix A of the Directive
 - Nickel is listed in Appendix A for its use in stainless steel. This means that nickel in stainless steel is not covered by the CMR limit of 1% total concentration.
 - This is also the case for nickel used in materials intended to conduct electricity, e.g. a rail track for an electric model train or a USB port. Nickel is considered to be safe for these uses.

Requirements for nickel allergenicity according to the REACH Regulation

The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, 1907/2006) contains a restriction on the release of nickel from products intended to come into direct and prolonged contact with the skin.

The European Chemicals Agency (ECHA) defines prolonged skin contact with products containing nickel, as a period of time exceeding:

- 10 minutes on three or more occasions within two weeks or
- 30 minutes on one or more occasions within two weeks

In both cases, it is a matter of 10 or 30 minutes of more or less continuous skin contact and not many shorter periods that total 10 or 30 minutes.

For toys or parts of toys that meet the criteria of direct and prolonged contact with the skin, the limit for nickel release is established in the REACH Regulation and the associated EN 1811 standard.

About TIE

Toy Industries of Europe (TIE) is the trade association for the European toy industry. The toy industry is highly international and is one of the most dynamic business sectors in Europe. Over 99% of the sector is composed of small and medium sized enterprises (SMEs), which have less than 50 employees. Members of TIE include corporate companies as well as national associations from Bulgaria, France, Germany, Italy, the Netherlands, Spain, Sweden, the UK and the Nordic region. TIE membership is open to both corporate companies with a presence in Europe and national associations from European Union Member States (including candidate countries).

Readers are reminded that the text of the original directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice. Toy Industries of Europe (TIE) does not accept any liability with regard to the contents of this document.