

BfR Opinion No. 010/2012 of 11 April 2012
Contact Allergens in Toys: Health Assessment of Nickel and Fragrances

Nickel Institute Position Paper

The Nickel Institute takes note of the updated German Federal Institute for Risk Assessment (BfR) Opinion No. 010/2012 dated 11 April 2012 on 'Contact allergens in toys: Health assessment of nickel and fragrances'. As the industry association representing nickel producers in the EU and worldwide, the Nickel Institute wishes to express its views on the use of nickel in toys and address the conclusions drawn as well as the recommendations made in the BfR opinion.

The Nickel Institute supports the existing European regulatory framework (European Commission Directive 2004/96/EC amending Directive 94/27/EC on restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress) in order to protect consumers from nickel allergies. As acknowledged by both the European Directive and the BfR Opinion No. 010/2012, the factors related to nickel sensitisation are a relevant release of nickel from products as well as direct and prolonged skin contact.

Various tests, commissioned by the nickel industry and conducted by independent scientists, have shown that nickel releases from products depend on the selected material. The EU Toys Directive (Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys) acknowledges the specific low metal release characteristics of nickel in stainless steel (the major use of nickel) and derogates the use of nickel in stainless steel for toys.

Whether an end-use product is in direct and prolonged contact with skin is of similar importance to that of material selection. Irrespective of the application, the Nickel Institute does not support the use of nickel-containing materials in prolonged and direct skin contact where release rates exceed the maximum permitted levels.

In the BfR Opinion, other sources for nickel releases that might cause sensitisation are mentioned. Model railroad tracks consisting of nickel-containing alloys other than stainless steel are cited as an example. In particular, children under the age of three years are mentioned as at risk of oral exposure. Model railway tracks cannot serve as an adequate example for a source for nickel sensitisation as mentioned in the statement. As such toys are produced for children aged 10 and above, model railway tracks cannot serve as an adequate example of a source for nickel sensitisation for children under the age of three years. Furthermore, other risks would predominate in oral exposure to such model railroad tracks e.g. sharp edges could injure the mouths of small children.

The Opinion also mentions nickel sensitisation rates in the general population which – depending on the reference – either show stagnation or limited increase over the recent years. The BfR interprets the stagnation or limited increases as a need for further and stricter regulatory measures. However, the observed limited changes in nickel allergies are not a result of an insufficient regulatory framework. Instead, it mainly relates to a lack of implementation within the value chain due to insufficient knowledge of the existing regulatory framework and the selection of unsuitable

materials. SMEs and micro enterprises that provide consumers with end-use products are often unfamiliar with the regulatory framework. Such companies may inadvertently supply the market with products e.g. body piercings or jewellery that fail to comply with the release rates specified by Commission Directive 2004/96/EC amending Directive 94/27/EC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress). Thus, the introduction of further measures such as lowering the release rates of nickel or further restriction of the use of nickel-containing materials would not solve the problem.

As part of its stewardship programme, the Nickel Institute continues to communicate along the value chain as well as with consumers on the safe and appropriate use of nickel and nickel-containing products. In fact, the Nickel Institute has published in total eleven advisory notes covering products that may come into direct and prolonged skin contact, including jewellery, body piercings, mobile phones or musical instruments. These advisory notes can be downloaded from the [Nickel Institute website](#).

Further information:

Dr Mark Mistry
Nickel Institute
13 Avenue des Arts
B – 1210 Brussels, Belgium
Tel.: +32 2 2990 3208
mmistry@nickelinstitute.org
www.nickelinstitute.org