Scientific Committee on Health and Environmental Risks

SCHER

Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys

The SCHER adopted this opinion at its 17th plenary on 25 September 2012

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat. They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

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Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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http://ec.europa.eu/health/scientific_committees/environmental_risks/index_en.htm

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All Declarations of working group members are available at the following webpage:
http://ec.europa.eu/health/scientific_committees/environmental_risks/members_wg/index_en.htm

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1. BACKGROUND

Under the new Toys Safety Directive (TSD)[1], CMR substances or mixtures of category 1A, 1B and under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

By way of derogation, CMR substances or mixtures can be used in toys under very strict conditions. This is the case if the CMR substances or mixtures are contained in toys and micro-structurally distinct parts of toys in individual concentrations equal to or smaller than the relevant concentrations limits established for the classification of mixtures containing these substances.

Another possibility to derogate from the ban is when the substance or mixture is inaccessible to children in any form, including inhalation.

Thirdly, a decision of the Commission can exempt the substance or mixture from the ban. The Commission can take this decision if the three following conditions are met: the substance or mixture has been evaluated by a Scientific Committee and found safe for children; there are no suitable alternative substances or mixtures available (this only applies to CMR of category 1A and B); and the substance or mixture concerned is not prohibited under Regulation (EC) 1907/2006 (REACH).

In this framework, a request concerning the exemption from the CMR ban for the use of metallic nickel in the manufacture of toys was referred to the Commission. The request concerns more specifically metallic nickel in materials where its use is necessary for the correct electrical function of toys.

Nickel is classified as a CMR category 2 under Regulation (EC) 1272/2008 and thus subject to the CMR ban provisions. By way of derogation, it can be used in toys when inaccessible in any form, or when used in individual concentrations equal to or smaller than 1%. The use of nickel in stainless steel is already permitted by the Directive as from the 20 July 2013. Further exemptions can be foreseen, following an evaluation by a Scientific Committee where the use of nickel is found to be safe.

In addition, REACH Regulation 1907/20063 bans the use of nickel in articles intended to come in direct and prolonged contact with the skin if the rate of nickel release from the parts of these articles coming in direct and prolonged contact with the skin is greater than 0.5 µg/cm^2/week.

Please, find enclosed the request for an opinion on the risk to health from the use of metallic nickel in toys for the Committees you consider appropriate.

2. TERMS OF REFERENCE

DG Enterprise would like to seek the opinion of SCHER on the risk to the health from the presence of metallic nickel in materials allowing the correct function of electric toys (i.e. plating, coating and alloys enabling electrical conductivity).

[1] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170, 30.06.2009, p.1.

The EU Risk Assessment Report on nickel, which was carried out under the "Existing Substances" Regulation 793/93, is available at:

http://esis.jrc.ec.europa.eu/doc/existingchemicals/risk_assessment/REPORT/nickelreport311.pdf

DG Enterprise would therefore like an opinion on the followings questions:

1. Is there sufficient scientific information available to evaluate the risk to children's health from the presence of metallic nickel in materials allowing the correct electrical function of toys?

2. On the basis of the available scientific information, is it possible to conclude that the presence of metallic nickel in materials allowing the correct electrical function of toys would not pose a risk to the health of children? If so, please specify the specific use of metallic nickel where no risk on health is expected.

For the aforementioned questions, the Committee is asked to take into account the particularity of the consumer, who is under fourteen years old, and the various possible exposure scenarios (inhalational, dermal and oral exposure).

The Committee is invited to make any additional comments it considers relevant to the presence of metallic nickel in toys.

3. SCIENTIFIC RATIONALE

3.1. Sources of Nickel

Humans are exposed to nickel (Ni) from a variety of sources. The consumer ingests Ni with drinking water and the diet, by contact with consumer products including metal containing tools, kitchenware and toys. Very low concentrations of Ni are present in ambient air and will thus be inhaled. For the general population, including children, oral exposure is the predominant route of exposure (EU, 2006); Ni is naturally present in many plants and is considered an essential element in a variety of microorganisms.

Due to its resistance to corrosion and high electrical conductivity, Ni is widely used for a variety of industrial applications. Ni is present in a variety of alloys and used as surface coating for other metals such as tools and coins. Ni may be released from such materials by skin contact (EU, 2006).

Ni-containing metal alloys are also used in a variety of toys. In toys, Ni is used in wire plugs and connectors and contained in model railroad tracks and electric contacts in model locomotives and cars. Ni is also contained in metal alloys in a variety of other toys and a survey of toys on the market in Germany has indicated a considerable release of Ni from this variety of toys (BVL, 2011). However, release of Ni from toys is now restricted by the REACH regulation to 0.5 µg/cm^2/week in a standardized release assay.

3.2. Toxicological profile of Nickel

Occupational exposure to high concentrations of Ni-containing dusts and fumes by inhalation has increased the incidence of lung tumours in workers; inhalation of respirable Ni containing dusts in rodents also produced lung tumours. Therefore, several Ni salts and metallic Ni are classified as a class 1 or 2A carcinogen (according to GHS). However, in contrast to the results of inhalation exposures, several studies with oral application of Ni to rodents do not indicate a potential for carcinogenicity by this route of

administration. The EU RAR concluded that oral exposure to Ni does not induce a cancer risk. As other metal ions, high concentrations of Ni-ions give positive responses in short-term tests for genotoxicity, probably due to the redox-chemistry of Ni and the formation of Ni-complexes with proteins and nucleic acids inhibiting DNA-repair.

Dermal contact with Ni releasing jewellery has been demonstrated to cause sensitisation to Ni. Non-occupational exposures to Ni is the major cause of Ni-sensitisation and up to 20 % of the EU-population has been reported to be sensitive to Ni. Piercing of the ear lobes with Ni-releasing alloys is considered the major cause for Ni-sensitisation. An allergic contact eczema may be induced in sensitized individuals by a direct and prolonged contact with materials even with low Ni-releases. The sensitizing agent is the Ni ion released from the alloys. Ni release is increased by contact with sweat and biological fluids and thus a direct contact with skin or blood. Ni-release is also depending on temperature and humidity. Ni-induced contact dermatitis occurs often at the direct site of contact with the Ni-containing jewellery.

OPINION

Specific responses to the questions raised:

1. Is there sufficient scientific information available to evaluate the risk to children's health from the presence of metallic nickel in materials allowing the correct electrical function of toys?

Response: The toxicology database for Ni is comprehensive and has been recently evaluated in detail (EU RAR). Ni only causes tumours in the respiratory tract after inhalation exposures to Ni-containing dusts and fumes, but not after oral intake as demonstrated by several studies summarized in the EU RAR. Inhalation of Ni in the form of fumes or dusts released from toys is extremely unlikely in non-occupational setting (e.g. for children) due to the very low vapour pressure of Ni. In order to produce Ni available for inhalation, toys need to be subjected to abrasive or thermal treatment of the Ni-containing parts using very specific equipment and high temperatures. Malfunction of electric motors is not considered as a source of metal fumes in the occupational setting (EU RAR) and malfunction of the small electric motors in model cars and railroad locomotives is thus not expected to release inhalable Ni under reasonably foreseeable conditions.
Therefore, the classification of Ni as a CMR, which is based on effects after inhalation of Ni-containing dusts and fumes, has no relevance for risk assessment of the oral or dermal exposures to Ni expected from handling of toys.

Ni induced sensitisation by skin contact is addressed by the REACH regulation limiting Ni-release (0.5 microg/cm^2/week in a standardized release assay) from materials with potential frequent skin contact.

2. On the basis of the available scientific information, is it possible to conclude that the presence of metallic nickel in materials allowing the correct electrical function of toys would not pose a risk to the health of children? If so, please specify the specific use of metallic nickel where no risk on health is expected.

Response: Since inhalation of Ni from toys is extremely unlikely from toys, a tumor risk due to Ni exposure when handling toys is not present. Intake of Ni by oral or skin contact with Ni-containing parts of toys is also expected to be very limited due to the restrictions on Ni-release applicable to metal-containing parts in toys, the limited accessibility of the metal-containing parts, and the small surface area of the Ni-containing parts in the Ni-application considered here. The EU RAR concluded large Margins-of-safety for all oral Ni exposures including Ni exposures from food contact materials (3 µg/kg bw/d) and did not consider dermal exposures to Ni from coins (which release more Ni under standard conditions as compared to toys) as health risk. SCHER therefore concludes that the use

of Ni in parts of toys allowing the correct electric function of toys will result in a very low potential for exposure to Ni by oral and dermal intake. Thus, health risks are not expected.

4. ABBREVIATIONS

Ni	Nickel
CMR	carcinogenic, mutagenic, and reprotoxic

5. REFERENCES

BLV, 2011: Berichte zur Lebensmittelsicherheit 2010; Bundesweiter Überwachungsplan 2010

EU, 2006: European Union Risk Assessment of NICKEL (CAS-NO.: 7440-02-0, EINECS-NO.: 231-111-4); NICKEL CARBONATE (CAS-NO.: 3333-67-3, EINECS-NO.: 222-068-2); NICKEL CHLORIDE (CAS-NO.: 7718-54-9, EINECS-NO.: 231-743-0), NICKEL DINITRATE (CAS-NO.: 13138-45-9, EINECS-NO.: 236-068-5); NICKEL SULPHATE (CAS-NO.: 7786-81-4, EINECS-NO.: 232-104-9)