Corrigendum

Scientific Committee on Health, Environmental and Emerging Risks

SCHEER

Opinion on the
safety of the presence of cobalt in toys

The SCHEER adopted this document by written procedure on 16 December 2022

CORRIGENDUM adopted at the plenary meeting on 9 March 2023

ABSTRACT

The Toy Safety Directive 2009/48/EC prohibits the use of substances in toys if those substances are classified as carcinogenic, mutagenic or toxic for reproduction. To permit the use of a CMR substance, a derogation of this rule is possible when the substance is evaluated by a relevant Scientific Committee and found to be safe in particular in view of exposure. Another possibility for derogation is that there are no suitable alternative substances or mixtures available. Cobalt has been classified as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B and is present in toys as an impurity in nickel and nickel-containing alloys, or cobalt may be used intentionally e.g. in cobalt-containing colourants. The SCHEER evaluated the safety of the use of cobalt in toys based on a report provided by Toy Industries of Europe (TIE) and additional information from publicly available literature. The SCHEER identified possible sources for exposure to cobalt from toys which need to be considered. With the exception of few cases (e.g. cobalt-containing metals for conduction of electric current), information and data essential for an adequate exposure assessment were lacking. In these cases, therefore, no quantitative exposure and hence risk assessment was possible.

Risk due to cobalt inhalation associated with the use of cobalt-containing metals can be considered negligible; a potential risk can be associated for inhalation exposure to cobalt from chalks and chalk bombs as well as from powder-like toy materials, containing cobalt-based pigments/colourants: for such toys, cobalt-free pigments should be used. Specific attention should be given to the 'emerging' use of cobalt-containing materials in 3D pens and 3D-printers.

For the oral exposure, based on available toxicological reference values, the SCHEER calculated new migration limits for cobalt in toys, in relation to oral exposure. However, due to the uncertainties regarding the carcinogenic properties for cobalt after oral exposure the SCHEER recommends reducing migration limits to the lowest technically achievable levels.

For the dermal exposure, the restrictions proposed in the ECHA-RAC Opinion on cobalt content of textiles and leather can be assumed to also protect children from sensitization from all toy materials that are in contact with the skin.

The analysis of alternatives as performed so far by TIE, is considered insufficient.

Due to their availability the SCHEER recommends that cobalt-free pigments should be used.

Keywords:
Cobalt, toys, pigments, risk assessment, inhalation, oral, carcinogenicity

Opinion to be cited as:

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https://ec.europa.eu/transparency/regexpert/index.cfm

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1. SUMMARY

The SCHEER evaluated the safety for the use of cobalt in toys. Information was provided by the Toys Industries of Europe (TIE) as well as retrieved from a literature search. In many toys and toy materials, cobalt is present as an impurity in nickel and in alloys that contain nickel, or cobalt salts as impurities in colourants. Cobalt may play a role as a precursor for some plastic materials or as an auxiliary agent in paints. Regarding the intentional use, the SCHEER identified cobalt-based pigments/colourants, specific hard metals, batteries and materials for 3-D pens/3-D printing as possible sources for exposure to cobalt from toys or toy materials.

The weight of evidence for the presence of cobalt in toys is strong. However, due to the limited information available, the SCHEER considers the evidence for specific data on potential exposure, necessary for the risk assessment (e.g. cobalt content in toys, data on migration) in general as weak. This does not account for some specific uses in toys addressed in the TIE report. These data are considered to contribute to a strong weight of evidence.

Alternatives

The SCHEER is of the opinion that the information on possible alternatives for the use of cobalt in toys in the TIE report is limited and insufficient. The TIE analysis of alternatives is not considered satisfactory for the safety evaluation requested.

The weight of evidence for information about possible alternatives is considered to be weak to moderate.

Exposure assessment

Children may be exposed to cobalt from different toy types and toy materials. Based on the information available, the SCHEER considers the following scenarios (each including one or more exposure mode: inhalation, oral and dermal) as relevant for the exposure assessment:

1. cobalt-containing metals included to allow conduction of electric current;
2. cobalt-containing metals that serve a function other than electrical conductance like for toys of metal, toy jewellery, fidget spinners, magnets;
3. kids make-up;
4. 3-D pens, materials for toy printers and printed toys;
5. cobalt-containing paintings, inks and coatings used for toys, chalks and chalk bombs and toys made of leather or textiles;
6. toys containing batteries.

TIE provided information on the cobalt content and exposure for exposure scenarios 1 and partially 2 as listed above. For other cobalt- containing toys this information was scant or not available.

Indeed, information and data essential for an adequate exposure assessment, were mostly lacking, except for cobalt-containing metals included to allow conduction of electric current, one example for cobalt-containing metals that serve a function other than electrical conductance (a slot car magnet) and for 3-D pens. Therefore, for the remaining scenarios no quantitative exposure assessment was possible. In addition, it has to be noted, that children

are exposed to cobalt not only from many different kinds of toys at the same time, but also from sources other than toys like their diet, soils and consumer products made from cobalt-containing materials or coated with cobalt-containing colourants or products with batteries. All the different sources can contribute to the aggregate exposure of cobalt for children.

Weight of evidence

In general data needed for exposure assessments (i.e. content of cobalt, migration rates) are limited for the different toy types, except for specific groups of toys as provided by TIE (scenarios 1 and partially 2). For some scenarios, therefore no quantitative exposure assessment was possible. The evidence therefore is considered to be weak to moderate. Exposure estimates based on data provided by TIE are considered to contribute to a strong weight of evidence.

Risk assessment

The SCHEER evaluated the assessment from TIE and performed the risk assessment for inhalation and for oral and dermal exposure. The focus is on risks related to carcinogenic properties of cobalt.

Inhalation

For cobalt-containing metals included to allow conduction of electric current, the SCHEER agrees that the inhalation pathway is associated with negligible exposure to cobalt from this type of metallic material and therefore unlikely to be associated with a risk for children playing with such toys.

There is a potential risk for inhalation exposure to cobalt from powder-like toy materials like kids' cosmetics or creative art toys containing cobalt-based pigments/colourants including chalks and chalk bombs, which are expected to produce dust and should have a potential high risk of inhalation exposure. For such toys, cobalt-free pigments should be used.

There is a potential risk for inhalation exposure to cobalt form materials to be used in context with 3-D pens/3-D printing. The calculated exposure for 3-D pens is low, but there is limited data for other applications and the use is increasing. Cobalt-containing materials should therefore be avoided for 3-D printing.

Oral exposure

Risk assessment provided by TIE.

Based on the exposure estimates performed for swallowing a slot car magnet once in lifetime, TIE used three approaches for the risk assessment:

Threshold approach using TDI of 1.5 µg/kg bw/day
Threshold approach using a DNEL of 29.8 µg/kg bw/day
Non-threshold approach calculating the life-time cancer risk

All approaches resulted in an acceptable additional risk for the exposure to cobalt from toys.

SCHEER assessment

The SCHEER is of the opinion that a risk assessment based on the uptake of a slot car magnet once in lifetime is not appropriately addressing all possible oral exposure sources from toys. The SCHEER assumes that there are toys and toy materials for which an oral exposure to cobalt is possible. This assessment takes into account the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user. Taking into account the behaviour of children, also some degree of misuse of the toy has to be considered as foreseeable use and therefore it needs to be considered when designing and manufacturing the toy. Additional sources like other metal toys (such as toy jewellery), kids cosmetics, chalks and chalk bombs, batteries (especially the small ones) or coloured materials have also to be considered for the risk assessment. Some of these toys can be also used together at the same time. As data on cobalt content and cobalt release in most cases are missing, the SCHEER could not perform a quantitative risk assessment. However, based on available toxicological reference values, the SCHEER calculated migration limit values for cobalt using a threshold approach and a TDI of 1.6 µg/kg bw/d.

Migration limit values are:

Scraped-off toy materials (8 mg)	150mg/kg toy material
Dry, powder like or pliable toy materials (100 mg)	12 mg/kg toy material
Liquid or sticky toy materials (400 mg)	3 mg/kg toy material

Although these migration limits should prevent from risk associated to the oral exposure, the SCHEER acknowledges the uncertainties regarding the carcinogenic properties for cobalt after oral exposure as well as the questions remaining with regard to the mode of action. Therefore, the SCHEER recommends reducing migration limits to the technically achievable lowest levels.

Dermal Exposure

Dermal exposure is considered possible from metal toys, toy jewellery, kids cosmetics, materials with cobalt containing coatings or batteries as well as from materials for 3-D pens/printings.

Due to low migration of cobalt to artificial sweat, and the very limited dermal absorption, the risk after dermal exposure is considered to be low/negligible by the SCHEER. The migration limit values derived for oral uptake are considered to be also protective with regard to sensitisation and possible allergic skin reactions. The restrictions as proposed in the ECHA-RAC Opinion (ECHA/RAC/RES-O-0000006785-62-01/F)(2020) on cobalt content of 70 mg/kg w/w in textile and 20 mg/kg w/w in leather, hides and furs (after extraction, expressed as cobalt metal that can be extracted from the material) can be assumed to also protect children, when is applied to all toy materials that are in contact with the skin.

Overall weight of evidence

Regarding inhalation, the overall weight of evidence is strong for the risk assessment of cobalt-containing metals included to allow conduction of electric current. There is a potential risk for the use of 3-D pens and powder-like toy materials like kids cosmetic or creative art toys containing cobalt-bases pigments/colourants and 3-D printing with a moderate weight of evidence.

The overall weight of evidence is considered moderate after oral exposure and strong after dermal exposure.

2. MANDATE FROM THE EU COMMISSION SERVICES

2.1. Background

The Toy Safety Directive 2009/48/EC[1] prohibits the use of substances in toys if those substances are classified as carcinogenic, mutagenic or toxic for reproduction (CMR)[2, 3]. Under certain conditions, however, the use of such substances may be permitted.

To permit the use of a CMR substance of category 1B, the substance has to be evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure. An additional condition is that there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives. Finally, the substance must not be prohibited for use in consumer articles under REACH[4, 5].
Cobalt (CAS number 7440-48-4) has been classified as carcinogenic category 1B, mutagenic category 2 and toxic for reproduction category 1B, among other hazard classes[6, 7]. The toy industry has signalled the presence of cobalt in toys and toy materials, as an impurity in nickel and in alloys that contain nickel, up to slightly exceeding 0.3% for example in toy materials

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[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.
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589882074178&uri=CELEX:02009L0048-20191118

[2] Annex II, Part III, point 3 of the Toy Safety Directive.

[3] 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. OJ L 353, 31.12.2008, p. 1.
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589288952589&uri=CELEX:32008R1272

[4] Annex II, Part III, point 4 (c) of the Toy Safety Directive.

[5] REACH: 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. OJ L 396, 30.12.2006, p. 1.
https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1589281141090&uri=CELEX:32006R1907

[6] Committee for Risk Assessment (RAC), Opinion proposing harmonised classification and labelling at EU level of cobalt. 22.9.2017.
https://echa.europa.eu/documents/10162/23665416/clh_opinion_cobalt_6858_en.pdf/b7316b11-ae65-1dd0-2e64-bb6ad3efbd82

[7] Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation. OJ L 44, 18.2.2020, p. 1.
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.044.01.0001.01.ENG&toc=OJ:L:2020:044:TOC

intended to conduct an electric current not made of stainless steel[8]. TIE has also undertaken an analysis of alternatives[9].

Cobalt was further found in consumer products other than toys when they were made of or with leather[10]. A study on the bio-accessibility of (nickel and) cobalt in stainless steel, alloys and artificial sweat has been made available[11].

2.2. Terms of reference

SCHEER is asked:

1. to review the available data on the presence of cobalt in particular in toys and toy materials;
2. to assess whether the use of cobalt in toys and toy materials can lead to exposure;
3. to assess whether the TIE analysis of alternatives referred to in the background above can be considered sufficiently complete for the safety evaluation requested in point 4 below;
4. to evaluate whether the presence of cobalt in toys and toy materials can be considered to be safe in light of the exposure identified, and in light of the classification of cobalt as outlined in the background above. Safe toys and toy materials should be indicated.

2.3. Timeline

The deadlines were adapted according to restrictions related to the Covid-19 crisis:
Preliminary Opinion – summer 2022
Final Opinion – autumn 2022

Annexes to the mandate:

1. Toy Industries of Europe (TIE), Background document … [on the] uses of cobalt (EC N° 231-158-0, CAS N° 7440-48-4) in certain toy materials. 8 July 2020.
2. Toy Industries of Europe (TIE), Cobalt in certain toy materials - Analysis of alternatives as required by the Toy Safety Directive in the framework of a request for an Appendix A derogation for CMR 1A and 1B substances. 5 May 2020.
3. Swedish Chemicals Agency: Enforcement project on Co and CrVI. 2019.
4. X. Wang, et al. (2019) Bioaccessibility of nickel and cobalt in powders and massive forms of stainless steel, nickel- or cobalt-based alloys, and nickel and cobalt metals in artificial sweat. Regulatory Toxicol. and Pharmacol. 106:15-26; and its Supplemental Material.

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[8] Toy Industries of Europe (TIE), Background document … [on the] uses of cobalt (EC N° 231-158-0, CAS N° 7440-48-4) in certain toy materials. 8 July 2020.

[9] Toy Industries of Europe (TIE), Cobalt in certain toy materials - Analysis of alternatives as required by the Toy Safety Directive in the framework of a request for an Appendix A derogation for CMR 1A and 1B substances. 5 May 2020.

[10] Swedish Chemicals Agency, Enforcement project on Co and CrVI. 2019.

[11] X. Wang, *et al.* (2019) Bioaccessibility of nickel and cobalt in powders and massive forms of stainless steel, nickel- or cobalt-based alloys, and nickel and cobalt metals in artificial sweat. Regulatory Toxicol. and Pharmacol. 106:15-26.

3. OPINION or CONCLUSIONS

The SCHEER is asked to review the available data on the presence of cobalt in particular in toys and toy materials

To address the terms of reference of this Opinion, the SCHEER evaluated information on the use of Cobalt in toys provided by the Toys Industries of Europe (TIE) as well as information retrieved from a literature search. In addition, literature provided by the working group members was considered.

In many toys and toy materials, cobalt is present as an impurity in nickel and in alloys that contain nickel, or cobalt salts are present as impurities in colourants. Cobalt may play a role as a precursor for some plastic materials or as an auxiliary agent in paints. Regarding the intentional use, the SCHEER identified cobalt-based pigments/colourants, specific hard metals, batteries and materials for 3-D pens/3-D printing as possible sources for exposure to cobalt from toys or toy materials.

The weight of evidence for the qualitative presence of cobalt in toys is strong. However, due to the limited information available, the SCHEER noticed a lack of specific data on cobalt content in many toys and/or materials used for the manufacturing of toys, including data on cobalt migration from toys, that are necessary for a quantitative risk assessment. Based on the data available for the quantitative aspects the evidence is weak. For those few toys data on content and migration were provided by TIE that are considered to contribute to a strong weight of evidence.

The SCHEER is asked to assess whether the use of cobalt in toys and toy materials can lead to exposure

Children may be exposed to cobalt from different toy types and toy materials. Based on the information available, the SCHEER considers the following scenarios as relevant for the exposure assessment:

1. cobalt-containing metals included to allow conduction of electric current;
2. cobalt-containing metals that serve a function other than electrical conductance like for toys of metal, toy jewellery, fidget spinners, magnets;
3. kids make-up;
4. 3-D pens, materials for toy printers and printed toys;
5. cobalt-containing paintings, inks and coatings used for toys, chalk and chalk bombs and toys made of leather or textiles;
6. toys containing batteries.

In the TIE report, exposure estimates for (1) cobalt-containing metals that allow conduction of electric current and (2) partially cobalt-containing metals that serve a function other than electrical conductance were addressed. For other cobalt containing toys, this information was scant or unavailable.

Exposure Scenario 1

For the exposure scenario (1) the TIE report includes an exposure estimate for metallic material intended to conduct an electric current. Possible exposure for inhalation as well as for dermal and oral routes were considered for these sources. The SCHEER agrees with TIE conclusions that the inhalation pathway is associated with negligible exposure to cobalt from this type of metallic material and therefore unlikely to be associated with increased risk. This assumption is supported by the SCHER (2012) Opinion that concludes that inhalation of Ni from toys is extremely unlikely. For cobalt present in toys as a contaminant of nickel (50:1), these conclusions will also apply.

Concerning the dermal route, the TIE report includes a migration study carried out according to the harmonised standard EN71-3:2019 for a Rail Track and a Slot Car Magnet showing no detection of cobalt. In addition, a study on Ni and Co release from toys indicated that none of the toys released cobalt (Jensen *et al.,* 2014). The SCHEER is, therefore, of the opinion that dermal exposure to cobalt can be considered negligible when handling model rail track and model rail track joiners during play or assembly.

The SCHEER agrees that no direct oral exposure is expected to occur through intended use of these products, as it is unlikely that metal parts will be ingested from these toy types. Mouthing is considered not to be of concern for the age group of users most likely to play with model railways with metal track. Scrape off during mouthing would not be relevant because of the hardness of the material.

However, a possible indirect route of exposure may occur through ingestion of dust present on hands or settling on nearby objects, particularly by children’s hand to mouth contact as also indicated by the exposure assessment as presented in the TIE report. The SCHEER agrees with the exposure determinants and assumptions used in the development of this exposure assessment, however, a play time of 3 h/week is not considered as a worst case. The calculated cobalt intake for 3 hours play time per week is 0.083/7 = 0.012 µg/day. The SCHEER is of the opinion that a play time of 7 h/week is more appropriate for toys that require setting up and preparation. This is corresponding to a cobalt intake of 0.028 µg/day.

Exposure Scenario 2

For the exposure scenario (2) in the TIE report, an exposure estimate was carried out on “Other metallic materials - cobalt included in toys within metal components that serve a function other than electrical conductance” which include stainless-steel ball bearings, slot car magnets and car set rollers (TIE, 2021). As release of cobalt from these contaminated metals is negligible, for these toys the inhalation pathway for cobalt, as a contaminant of nickel, is associated with negligible risk.

Concerning the dermal route, Wang *et al.* (2019) reported that based on a modified EN1811 test, dermal exposure to cobalt from stainless-steel was negligible, with the bio-accessible concentration reported as <0.01µg cobalt/cm^2/week. In addition, migration of cobalt from a slot car magnet determined according to the harmonised standard EN71-3:2019 was not detectable (Test Report Bureau Veritas (Dec. 2020), in app. A of the TIE report). Therefore, the SCHEER supports the view that exposure to cobalt via the dermal route for these toy types is negligible and unlikely to be associated with any risk.

The SCHEER considers the oral exposure as most relevant. In the TIE report, the worst-case assumptions included oral exposure in children through the unintentional ingestion of a metallic foreign body like a small screw or stainless-steel ball bearing, which was calculated as representing an oral intake of 0.1 – 0.6 µg/kg bw. If 5% absorption from the GIT is assumed, the intake is 0.78 µg; if 30% absorption from the GIT is assumed, the intake is 4.68 µg.

The SCHEER is of the opinion that the exposure assessment for a stainless-steel ball is appropriate. However, the unintentional ingestion of such a ball once in a life is not considered as a worst-case scenario. Moreover, the SCHEER is of the opinion that oral exposure from other metallic toys, including toy jewellery, needs to be considered in order to assess possible health risks for children.

Due to a lack of data - among others related to cobalt concentration in the product, initial leaching rate and density of the individual toy material - the SCHEER cannot perform a quantitative exposure assessment for these toys.

The SCHEER recommends migration analysis (“Migration to artificial sweat” according to DS/EN 1811:2000 and migration analysis to saliva simulant) for dermal and oral exposure.

Exposure Scenario 3

Exposure scenario 3 (kids’ cosmetics) is not considered within the TIE report. The Cosmetic Regulation 1223/2009/CE (EC, 2009) prohibits the use of many metals as ingredients but tolerates their presence in traces (art. 17) provided that 1) these are "technically unavoidable", also by observing Good Manufacturing Practices for Cosmetics and 2) the product is safe for human health (art. 3). At the moment, there are no European or international standards that define the levels of heavy metals (including cobalt) identifiable as unavoidable traces, and as such tolerated in cosmetics.

No data are available on the amount of cobalt (as impurity or as part of a colourant) in kids cosmetics or toy make-up. Therefore, the SCHEER cannot provide a quantitative exposure assessment. However, regarding safety evaluations, the SCHEER is of the opinion that when children are the target population, it is necessary to consider specific exposure scenarios, referring to typical behaviour of children. Based on the RIVM report 612810012/2002 Children's toys fact sheet to assess the risks for the consumer a total daily intake of 30 mg for eye shadow and for lipstick each is assumed and considered sufficiently conservative. Depending on the $CoCl_2$ or any other Co-impurity content (here migration is not relevant), the daily exposure could then be calculated.

Exposure scenario 4 (3-D pens, toy printers).

The Danish Environmental Protection Agency has performed a survey and risk assessment for 3-D pens (Danish EPA, 2018). The SCHEER agrees with the exposure scenario used in this report. Based on this data, in a room with a volume of 17.4 m^3, the concentration of Co will be 0.043 ng/m^3 when a 3- to 6-year-old is playing and 0.086 ng/m^3 when a 6 to 11-year-old is playing in the room.

Although the room concentrations calculated on the information available are low, the SCHEER is of the opinion that these toy types have to be considered when assessing possible health risks from cobalt for children, especially in view of their increasing use. In addition, also material for the 3-D printing of toys and the printed toy may be a source of cobalt exposure.

Exposure scenario 5

Cobalt-containing paintings, inks and coatings used for toys, chalk and chalk bombs and toys made of leather or textiles were not included in the TIE report. The SCHEER is of the opinion that i) chalk and chalk bombs which are expected to produce dust are relevant for both inhalation and depending on the particles dimensions also for the oral exposure; and ii) cobalt-containing paintings, inks and coatings used for toys as well as toys made of leather or textiles are relevant for the assessment of oral exposure. The SCHEER furthermore is of the opinion that the possibility of accidental ingestion of small pieces of toys and of painted toy material, or migration after mouthing, need to be taken into account when assessing the exposure of children to cobalt from toys. Due to the lack of data on other Co compounds or on materials other than painted toys, no quantitative assessment can be performed.

Exposure scenario 6

For exposure scenario 6 (batteries), TIE states that the batteries are in general inside the toy and no contact is possible (TIE, 2021). Batteries may contain cobalt in the contacts but also inside the batteries itself. However, unintentional destroying of toys while exploring them, is a foreseeable use taking into account the behaviour of children, and therefore, exposure to cobalt from batteries cannot be excluded. Cases of battery ingestions by children notified by poison centres (e.g. https://www.poison.org/battery/stats#20161) demonstrate that batteries (especially the small button batteries) are a realistic source for possible exposure to cobalt. However, due to limited data, the SCHEER cannot provide a quantitative exposure scenario.

Some of the above-described toys can be also used together at the same time. Therefore, cumulative scenarios are reasonably foreseen. In addition, children may be exposed to cobalt sources other than toys and toys materials, as reported below.

Other sources

Exposure of children to cobalt from other sources than toys occur frequently, as the main route of exposure to cobalt in children is via their diet (0.52 µg cobalt/kg/day for infants and 3.93 µg/day for a child of 7.5 kg). In communities where soils are contaminated with cobalt, certain behaviours in children can also contribute to overall exposure to cobalt. In addition, children may be exposed to cobalt from consumer products other than toys made from cobalt-containing materials or coated with cobalt-containing colourants or products with batteries, as well as to Co-containing medical devices (e.g. implant and dental materials).

Weight of evidence

In general, data needed for exposure assessments (i.e. content of cobalt, migration rates) are limited for the different toy types, except for specific data provided by TIE. For that reason, no quantitative exposure assessment was possible for some scenarios. The evidence therefore is considered to be weak to moderate.

For exposure estimates based on data provided by TIE, the evidence is considered to be strong.

The SCHEER is asked to assess whether the TIE analysis of alternatives referred to in the background information could be considered sufficiently complete for the safety evaluation requested in point 4 below

The SCHEER considers that in the TIE report provides insufficient information on possible alternatives. The TIE analysis of alternatives is not considered satisfactory for the requested safety evaluation.

Research efforts have been focussing on the elimination of cobalt oxide from the cathodes of Li-ion batteries (Kim *et al.,* 2021) or its replacement with manganese oxide ($LiMn_2O_4$) both due to its cost and toxicity (Pender *et al.,* 2020).

Samarium-cobalt (SmCo) magnets have a stronger tendency for corrosion and exert considerable cytotoxicity compared to other type of rare earth magnets, i.e., neodymium-iron-boron (NdFeB) magnets, as shown in studies, where both types of magnets had been used for magnetic prosthetic devices (Hopp *et al.*, 2003). Therefore, SmCo could be replaced by NdFeB magnets in toys. Alternatively, the use of SmCo magnets could be restricted to toys with irremovable coatings, in order to minimise exposure.

In conclusion, all alternatives need to be evaluated for potential toxicity resulting in health risks and a risk-benefit analysis should be performed where appropriate.

For colourants, dyes and coatings products without cobalt could be used (Hamann *et al.*, 2018).

The weight of evidence for information about possible alternatives is considered to be weak to moderate.

The SCHEER is asked to evaluate whether the presence of cobalt in toys and toy materials could be considered to be safe in light of the exposure identified, and in light of the classification of cobalt as outlined in the background information. Safe toys and toy materials should be indicated.

The SCHEER evaluated/performed the risk assessment for inhalation and for oral and dermal exposure corresponding to all the 6 exposure scenarios listed above. The main focus is on risks related to carcinogenic properties of cobalt.

Inhalation

For cobalt-containing metals included to allow conduction of electric current the SCHEER agrees that the inhalation pathway is associated with negligible exposure to cobalt from this type of metallic material and therefore unlikely to be associated with a risk for children playing with these toys.

The SCHEER is of the opinion that there is a risk of inhalation exposure to cobalt from powder-like toy materials like kids cosmetic or creative art toys, chalk and chalk bombs containing cobalt-based pigments/colourants. For such toys, cobalt-free pigments/colourants should be used.

There is a risk for inhalation exposure to cobalt form materials used in context with 3-D pens/3-D printing. The calculated external exposure for 3-D pens is low, but there is limited data for other applications and in view of a foreseeable increase in their use, the SCHEER recommends that cobalt-containing materials is avoided for 3-D printing.

Oral exposure

In the TIE report (2020), the potential for carcinogenicity risk related to the inclusion of cobalt containing metals in toys was characterised for the oral route and based on the toxicity data and uncertainties regarding the mode of action.

Based on the exposure estimates performed for swallowing a slot-car magnet once in a lifetime, TIE used three approaches for the risk assessment:

Threshold approach using TDI of 1.5 µg/kg bw/day
Threshold approach using a DNEL of 29.8 µg/kg bw/day
Non-threshold approach calculating the life-time cancer risk

All approaches resulted in an acceptable risk for the exposure to cobalt from toys.

The SCHEER is of the opinion that a risk assessment based on the uptake of a slot-car magnet once in a lifetime is not addressing all possible oral exposure sources from toys appropriately. The SC assumes that there are toys and toy materials for which an oral exposure to cobalt is possible. Therefore, additional sources like other metal toys, toy jewellery, kids' cosmetics, chalk and chalk bombs generating non respirable dust, batteries or coloured materials have to be considered for the risk assessment. As data on cobalt content and cobalt release in most cases are missing, the SCHEER cannot perform a quantitative risk assessment. However, based on available toxicological reference values, the SCHEER calculated migration limits for cobalt (according to the TSD):

For a threshold approach, the TDI of 1.6 µg/kg bw/d is used.

Calculation of migration limit ML according to the following formula:

ML = [(PTDI * TDI * BW)/(AMT * 100)] * K mg/kg toy material

where:
ML = migration limit (mg/kg product)
PTDI = percentage of TDI allocated to toys (10)
TDI = mg/kg bw/d
BW = body weight (default 7.5 for children one year of age)
AMT = amount of toy material (8, 100, or 400 mg)
100 = conversion factor from percentage to fraction
K = conversion factor from mg/mg toy material to mg/kg toy material (10^6).

Migration limit values:

Scraped-off toy materials (8 mg)	150 mg/kg toy material
Dry, powder like or pliable toy materials (100 mg)	12 mg/kg toy material
Liquid or sticky toy materials (400 mg)	3 mg/kg toy material

Although these migration limits should prevent from risk associated to the oral exposure, the SCHEER acknowledges the uncertainties regarding the carcinogenic properties for cobalt after oral exposure as well as the open questions regarding the mode of action. Therefore, in addition to the migration limits proposed above, the SCHEER recommends reducing the migration of cobalt from toys to the lowest technically achievable amount.

Dermal Exposure

Dermal exposure is considered possible from metal toys, toy jewellery, kids' cosmetics, materials with cobalt-containing coatings or batteries as well as from materials for 3-D pens/printings.

Due to low migration of cobalt to artificial sweat, the risk after dermal exposure is considered to be low/negligible by the SCHEER. The restrictions on cobalt content of textiles and leather, as proposed in the ECHA-RAC Opinion (ECHA/RAC/RES-O-0000006785-62-01/F) (2020), can be assumed to also protect children, when the threshold of 0.44 µg/cm² is applied to all toy materials that are in contact with the skin.

Overall weight of evidence

Regarding inhalation, the overall weight of evidence is strong for the risk assessment of cobalt-containing metals included to allow conduction of electric current; it is moderate for 3-D pens and for powder-like toy materials like kids cosmetic or creative art toys containing cobalt-bases pigments/colourants and 3-D printing.

The overall weight of evidence is considered moderate for the risk assessment after oral exposure and strong for the risk assessment after dermal exposure.

4. MINORITY OPINIONS

None

5. DATA AND METHODOLOGIES

5.1. Data/Evidence

The SCHEER, on request of Commission services, provides scientific opinions on questions concerning health, environmental and emerging risks. Besides the documents submitted with the mandate and cited in 2.1, the SCHEER received an extended TIE report on cobalt in toys dated March 2021[12], which was the version used for this assessment.

The scientific assessments carried out should always be based on scientifically accepted approaches, and be transparent with regard to the data, methods and assumptions that are used in the risk assessment process. They should identify uncertainties and use harmonised terminology, where possible, based on internationally accepted terms. In its scientific work, the SCHEER relies on the Memorandum on Weight of Evidence (WoE) and uncertainties (SCHEER, 2018), i.e. the search for relevant information and data for the SCHEER comprises of identifying, collecting and selecting possible sources of evidence in order to perform a risk assessment and/or to answer the specific questions being asked. For each line of evidence, the criteria of validity, reliability and relevance need to be applied and the overall quality has to be assessed.

5.2. Methodologies

To address the terms of reference of this Opinion, scientific data on the toxicity and assessments of cobalt as well as information regarding approaches to derive NOAEL values were collected from available open literature, websites and from documents of other Scientific Committees and International Organisations (e.g. WHO, EPA, EFSA, ECHA, JECFA). In addition, information on the use of cobalt in toys, provided by the Toys Industries of Europe (TIE), was evaluated and included in the Opinion where appropriate. TIE's approaches of to assess exposure of children to cobalt from toys and the risk characterisation performed were evaluated.

The Commission library service performed a literature search in April 2021 covering publications from 01/01/2009 until 30/04/2021. The search terms used and results are presented in Annex 1. In addition, the SCHEER made use of reports by other organisations on this topic (EFSA, ECHA and SCCS), as well as information provided by the Commission. Additional literature provided by the working group members was considered and information provided by the Toys Industries of Europe (TIE) was evaluated.

Each document used for the Opinion is assessed for relevance, validity and reliability. As the information from the TIE only contained relevant information, the submitted information was only assessed for validity and reliability. The overall WoE is assessed following the WoE document (SCHEER, 2018) and expressed as weak, moderate or strong accordingly.

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[12] TIE. Final Report. Support in the preparation of a proposal by Toy Industries of Europe (TIE) for a possible derogation laid down in Appendix A of the Toy Safety Directive 2009/48/EC for presence of residual cobalt (EC No 231-158-0, Cas No 7440-48-4) in certain toy metallic materials. March 2021.

5.3. Interpretation of Terms of Reference

The SCHEER is asked to review the available data on the presence of cobalt in particular in toys and toy materials (see Terms of Refence in the Mandate). In agreement with the Commission, in particular with the mandating DG (DG for Internal Market, Industry, Entrepreneurship and SMEs; Unit F2 – Bioeconomy, Chemicals, Cosmetics) the SCHEER included the different forms of cobalt that could be present in any toy material as a source of foreseeable exposure for children, and therefore does not restrict its Opinion on the presence of elemental cobalt in toy metallic materials.

The SCHEER included toy jewellery in its assessment. The Explanatory Guidance Document on the Toy safety Directive distinguishes jewellery and toy jewellery as follows[13] : '… *fashion accessories, in particular jewellery for children, which are not for use in play are not considered as toys. Jewellery with play value, in contrast, is a toy, for instance jewellery sold with toy disguise costumes and (imitation) jewellery to be assembled by the child himself*'.

With regard to oral exposure to cobalt from toys, the SCHEER considers the general safety requirement in Article 10.2 of the Toy Safety Directive specifying that toys have to be safe when used as intended or in a foreseeable way bearing in mind the behaviour of children. Therefore, it is not enough for the toy to be safe when used as intended by the manufacturer, but it needs to be safe also when used in a foreseeable way. When assessing what can be regarded as foreseeable, account has to be taken of the behaviour of children, who normally do not show the same care as an average adult user.

In addition, although SCHEER is aware that the relevant harmonised standard supporting the Toy Safety Directive 's requires that the compartments of small batteries for toys are not accessible by children (EN IEC 62115 :2020/A11:2020, clauses 13.4.1 and 13.4.2.), the SCHEER considers unintentional destroying toys by children, while exploring them, as a foreseeable use. Therefore, the SCHEER considers the possible exposure of children to cobalt from batteries in toys as within the ToR of this opinion.

6. ASSESSMENT

6.1. Introduction

In order to answer the questions addressed in the terms of reference, the SCHEER reviewed the available information on the presence of cobalt in toys and toy materials and assessed the release and potential exposure from different toys and toy materials. The SCHEER evaluated the data and information provided by the association Toy Industries of Europe (TIE, 2021) and information from a literature search. In its risk assessment, the SCHEER focussed on possible carcinogenic effects (relevant for addressing the ToR) after inhalation and oral uptake (identified as the relevant exposure routes associated to toys containing Co). In addition, non-carcinogenic systemic effects after oral cobalt uptake and local effects like sensitisation after dermal contact were considered within this Opinion. Respiratory

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[13] https://ec.europa.eu/docsroom/documents/16183/attachments/1/translations

sensitization was not considered because this has only been observed from high levels of exposure in occupational settings.

6.2. Physico-Chemical characterisation of cobalt compounds

Cobalt (CAS No. 7440-48-4) is a naturally occurring element (atomic number 27) in the first transition series of Group 9 of the periodic chart of elements.^{59}Co is the only stable isotope. Cobalt occurs in the 0, +2, and +3 valence states. Cobalt(II) is more stable than cobalt(III), which is a powerful oxidizing agent that can oxidize water and liberate oxygen. Cobalt has a relative molecular mass of 58.93 and is a silvery grey solid at room temperature. Its melting point is 1493 C. At room temperature (20 C), the density of cobalt is 8.9 g/cm^3. Cobalt is soluble in dilute acids, and ultrafine metal cobalt powder is soluble in water at 1.1 mg/l. Selected chemical and physical properties of cobalt and several inorganic cobalt compounds are presented in Table 1, with further details contained in the International Chemical Safety Cards[14].

Table 1: Physical and chemical properties of selected cobalt compounds

Species	**CAS No.**	**Relative molecular mass**	**Molecular formula**	**Melting point**	**Solubility**
Cobalt	7440-48-4	58.93	Co	1493 °C	Insoluble in water
Cobalt(II) acetate	71-48-7	177.03	$Co(C_2H_4O_2)_2$	No data	Soluble in water, 2.1 g/100 g methanol
Cobalt(II) acetate tetrahydrate	6147-53-1	249.1	$Co(C_2H_4O_2)_2 \cdot 4H_20$	140 °C	Very soluble in water
Cobalt(III) acetate	917-69-1	236.07	$Co(C_2H_4O_2)_3$	Decomposes at 100 °C	Soluble in water, alcohol, acetic acid
Cobalt(II) carbonate	513-79-1	118.94	$CoCO_3$	Decomposes	0.18 g/100 g water
Cobalt carbonyl	10210-68-1	341.9	$Co_2(CO)_8$	51 °C	Insoluble in water; soluble in ether
Cobalt(II) chloride	7646-79-9	129.84	$CoCl_2$	724 °C	450 g/l water, 544 g/l ethanol, 86 g/l acetone
Cobalt(II) hydroxide	21041-93-0	92.95	$Co(OH)_2$	No data	0.0032 g/l water
Cobalt(II) nitrate	10141-05-6	182.96	$Co(NO_3)_2$	Decomposes at 100–105 °C	Soluble in water (133.8 g/l), ethanol, acetone
Cobalt(II) nitrate hexahydrate	10026-22-9	291.03	$Co(NO_3)_2 \cdot 6H_2O$	55 °C	133.8 g/100 ml water at 0 °C
Cobalt(II) sulfate	10124-43-3	154.99	$CoSO_4$	Decomposes at 735 °C	36.2 g/100 ml water at 20 °C
Cobalt(II) sulfate heptahydrate	10026-24-1	281.1	$CoSO_4 \cdot 7H_2O$	96.8 °C	60.4 g/100 ml water at 3 °C

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[14] International Chemical Safety Cards (ICSCs) (ilo.org)

[https://inchem.org/documents/cicads/cicads/cicad69.htm#2.0]

Impurities in cobalt compounds comprise zinc oxide, copper, iron, cobalt sulphate and nickel powder. The cobalt percentage of different cobalt compounds ranges from 100% (cobalt) to 20.95% for cobalt sulphate heptahydrate.

Alloys and stainless steel

The United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) defines an alloy as "… a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means" (United Nations, 2017). Alloys, which are specific mixtures of metals, are produced to have unique physico-chemical properties, including hardness, toughness, and corrosion resistance (amongst others) that differ from those of their pure ingredients.

Stainless steel is a ferrous alloy containing 10 to 30% chromium to achieve resistance to corrosion and heat. Other elements, such as nickel, molybdenum, titanium, aluminium, niobium, copper, nitrogen, sulphur, phosphorus, or selenium, may be added to increase corrosion and oxidation resistance, and to give special physicochemical characteristics to the alloy. There are more than 100 grades of stainless steel. Most of them are classified into five major groups in the family of stainless steels: austenitic, ferritic, martensitic, duplex, and precipitation-hardening (Table 2).

Table 2: Major groups of stainless steels

Group	Composition	Properties	Applications
Austenitic	16-26% chromium < 35% nickel	not hardenable by heat treatment, highest corrosion resistance, nonmagnetic	aircraft, dairy, food-processing industries
Ferritic	10.5-27% chromium nickel-free <0.2% carbon	hardenable by heat treatment, less critical corrosion resistance	Architectural and auto trim
Martensitic	11.5-18% < 1.2% carbon may contain nickel	hardenable by heat treatment, modest corrosion resistance	cutlery, surgical instruments, wrenches, turbines
Duplex stainless	21-27% chromium 1.35-8% nickel 0.05-3% copper 0.05-5% molybdenum	stronger and more resistant to corrosion than austenitic and ferritic	storage-tank construction, chemical processing, containers for transporting chemicals
Precipitation-hardening	15-17.5% chromium 3-5% nickel 3-5% copper < 0.5% aluminium, copper, and niobium	high corrosion resistance	construction of long shafts

[https://www.britannica.com/technology/stainless-steel]

The largest proportion (75% of total) of manufactured stainless-steel is classified as austenitic, which contains nickel, with cobalt as an impurity. Austenitic steel has excellent corrosion resistance and is easily formed into a variety of products and shapes. Nickel contributes to the corrosion resistance through promotion of an austenitic microstructure which is more resistant than the ferritic structure, and through decreasing current flow. Cobalt mining is concentrated in large scale copper and nickel mines across the world (Schmidt *et al.,* 2016) and, therefore, can be found in the alloys wherever these mines are located (Ahmed *et al.*, 2021).

For non-ferrous alloys, nickel may be also added as melting grade nickel, giving alloys with a nickel content of between 93 and 97%, with a corresponding cobalt content of between 1 and 1.6% Nickel-silver is the most commonly used alloy and has a typical composition of 55% copper, 27% zinc and 18% nickel, with a cobalt content in the region of 0.3%. Where high purity nickel briquettes are used as a raw material, cobalt content is reduced to 0.1%. Cobalt is also present in nickel plating and DIN 50970 (Electroplated coatings. Nickel chemicals for nickel baths - Requirements and testing) sets a maximum limit of 5000 ppm for cobalt. It is possible therefore that nickel plating may contain cobalt above 0.1% (TIE, 2021). As the cobalt content of nickel is not constant, it is likely that cobalt levels could vary both within and between batches of components, depending on their origin. Cobalt levels are only required to be specified for stainless-steel used in the nuclear power industry, with a limit of 0.2% permitted for use. It is therefore impractical to source low cobalt materials for consumer applications (TIE, 2021).

In addition, cobalt is used in hard metal (alloy of Cobalt and tungsten carbide[15]). Tungsten carbide cobalt hard metals are the standard among hard metals, measured by the quantity produced, with cobalt contents between 3 and 30 %. The SCHEER, however, has no information whether this material is used for toys.

6.3. Presence of cobalt in toys

Cobalt as an impurity

Cobalt may be present in toys as an impurity of nickel used in toys and toy parts and in alloys containing nickel (e.g., nickel/copper-containing alloys, nickel-plated materials and stainless steel like battery contacts, electricity conducting parts, magnets, USB ports, nickel-plated toy jewellery, keychains etc.).

In addition to its corrosion resistance as a component of stainless-steel**,** nickel is used for its conducting properties when electricity is necessary for the correct functioning of the toy. Uses of nickel alloys include connectors such as jack plugs, model railway tracks and battery contacts; also, USB ports may be nickel plated (TIE, 2021). The use of conducting components containing nickel are also essential in meeting the requirements of other Directives such as the Electromagnetic Compatibility Directive 2014/30/EU (EMC Directive).

Furthermore, toys are often made of rubber or other elastic material, textiles, plastic, cardboard or wood, some of which are painted with – or contain colourants that may contain cobalt compounds as impurities (see table 3 for references).

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[15] https://www.hardening-of-stainless-steel.com/glossar/hard-metal/

Intentional use of cobalt

The SCHEER identified cobalt-based pigments/colourants, specific hard metals, batteries and materials for 3-D pens/3-D printing as possible sources for exposure to cobalt.

Examples of cobalt present in toys

Cobalt usually exists in form of inorganic derivatives, which could be identified in different materials that may be used for toys (Table 3).

In the TIE report, the sources considered for exposure to cobalt are restricted to non-stainless steel electric current conducting components in toys and non-conducting metallic toys or toy parts. In addition, in the TIE report the only mention of cobalt presence in batteries refers to battery contacts. However, as shown in Table 3, cobalt is contained in the cathode of several types of lithium-ion batteries. Although children do not come into contact with the inner components of batteries under normal operation of toys, chemical leakage (e.g., due to short-circuit overheating) cannot be excluded. In such a case, children might be exposed to cobalt through several routes, although inhalation of lithium cobalt oxide ($LiCoO_2$) particles seems to present the most critical toxicity (Sironval *et al.*, 2018). In addition, the cases of battery ingestions by children notified by poison centers (e.g. https://www.poison.org/battery/stats#20161) demonstrate that batteries (especially small button batteries) are a realistic source of exposure to cobalt.

The SCHEER identified further toys/toy materials from which exposure to cobalt for children might be possible, like toy make-up sets, chalks and chalk bombs, 3-D pens and toy printers, and toy materials coated with cobalt-containing colourants including toys made of leather or textiles (see also Table 3).

Table 3: Examples of cobalt presence in toys

Toy/Toy part/ Product/Material	**Impurity/Function**	**Substance name**	**Reference**
non-stainless steel electric current-conducting component	impurity in nickel and in alloys that contain nickel	cobalt	TIE (2020)
non-conducting metallic toys (e.g. fidget spinners, toy jewellery, magnets)	impurity in nickel and in alloys that contain nickel	cobalt	Ahlström *et al.* 2018, TIE (2020)
toy makeup sets (eye shadows eye liners toy makeup sets)	impurity or intentionally	Cobalt	*Corrazza et al., 2009*
3-D pens and 3-D toys printers and printed toys	impurity or intentionally	cobalt particles	Jinghai *et al.* 2019

toys with batteries lithium-ion batteries rechargeable sodium batteries	impurity or intentionally	$LiCoO_2$ $LiNi_{1-x-y} Mn_x Co_y O_2$ $LiNi_{1-x-y} Co_x Al_y O_2$ $Na_2Ni_{2-x}Co_xTeO_6$ $LiNi_{0.33}Co_{0.33}Mn_{0.33}O_2$	*Sironval, et al., 2018] Li et al., 2020 Quintero-Almanza, et al., 2019* *Chen, et al., 2020]. Choubey et al., 2020*
toy cloths (nylon, wool, and silk textile products)	colourant agent	mordant dyes	*Tsuyoshi et al., 2020*
Plastic or paper/cardboard surfaces wood stains, paints and toy jewellery	Drying agent in paints, as a colourant / decolourant	cobalt dichloride cobalt (II) dinitrate, cobalt (II) carbonate cobalt (II) diacetate	Guney, at al., 2012
polymers	colourant	Cobalt naphthenate	Clariant.com/plastics
alkyl-based paints in paints, varnishes, and inks	drier catalysts or drying agents	cobalt carboxylates (cobalt soaps)	Simpson *et al.*, 2019 Boer et al., 2013.
paints	paint and varnish drier, adhesion additive, whitener and catalyst	cobalt bis(2-ethylhexanoate)	https://echa.europa.eu/
glass, ceramics, inks, paints and varnishes.	Colourant (e.g. deep blue)	cobalt silicate cobalt aluminate ($CoAl_2O_4$, cobalt blue)	https://www.culturalheritage.org/docs/default-source/resource-guides/chart-of-heavy-metals-their-salts-and-other-compounds-nbsp-.pdf
mobile phones, laptops, tablets, toys, medical equipment, electric cars	lithium-ion batteries rechargeable sodium batteries	$LiFePO_4$ $Li_4Ti_5O_{12}$ $LiCoO_2$ $LiNi_{1-x-y} Mn_x Co_y O_2$ $LiNi_{1-x-y} Co_x Al_y O_2$ Na2Ni2-xCoxTeO6 $LiNi_{0.33}Co_{0.33}Mn_{0.33}O_2$	*Sironval, et al., 2018] Li , et al., 2020 Quintero-Almanza, et al., 2019* *Chen, et al., 2020]. Choubey et al., 2020*
pigments	colourant	cobalt blue (cobalt aluminate); cerulean blue (cobalt (II) stannate); cobalt green (a mixture of cobalt(II) oxide and zinc oxide); cobalt violet (cobalt phosphate) Aureolin (cobalt yellow)	https://www.culturalheritage.org/docs/default-source/resource-guides/chart-of-heavy-metals-their-salts-and-other-compounds-nbsp-.pdf

Weight of evidence

The weight of evidence for the qualitative presence of cobalt in toys is strong. However, the SCHEER considers the evidence for quantitative data, necessary for the risk assessment (e.g. cobalt content in toys, data on migration) in general as weak. This does not account for the toys addressed in the TIE report, for which the weight of evidence is considered strong.

6.3.1. Possible alternatives to cobalt for use in toys

The SCHEER considers that in the TIE report insufficient information is given on possible alternatives and the TIE analysis of alternatives is not considered satisfactory for the safety evaluation requested.

Research efforts have focused on the elimination of cobalt oxide from the cathodes of Li-ion batteries (Kim *et al.,* 2021) or its replacement with manganese oxide ($LiMn_2O_4$) both due to its cost and toxicity (Pender *et al.,* 2020).

Samarium-cobalt (SmCo) magnets have a stronger tendency for corrosion and exert considerable cytotoxicity compared to other type of rare earth magnets, i.e., neodymium-iron-boron (NdFeB) magnets, as shown in studies, where both types of magnets had been used for magnetic prosthetic devices (Hopp *et al.*, 2003). Therefore, SmCo could be replaced by NdFeB magnets in toys. Alternatively, the use of SmCo magnets could be restricted to toys with unremovable coatings, in order to minimise exposure.

In conclusion, all alternatives need to be evaluated for potential toxicity resulting in health risks and a risk-benefit analysis should be performed, where appropriate.

For colourants, dyes and coatings without cobalt could be used (Hamann *et al.*, 2018).

The **weight of evidence** for information about possible alternatives is considered to be weak to moderate.

6.4. Toxicity and health effects

Cobalt metal has high acute toxicity via inhalation (LC50 of between 50 to 165 mg cobalt/m^3 in rats). Acute toxicity is lower via the oral route, with variation seen between cobalt compounds and test species (LD50 of between 42.4 to 317 mg/kg bw/day in rats and 89.3 to 123 mg/kg bw/day in mice) (ECHA, 2017).

Cobalt metal is classified as a Category 1 skin and respiratory sensitiser according to CLP regulation.

After oral exposure the increase in erythrocytosis is the effect observed at the lowest dose. in OECD- and GLP-compliant studies. The principal target organ for non-cancer effects is the male reproductive system and cobalt metal is classified as a Category 1B reproductive toxicant (presumed human reproductive toxicant) based on male reproductive effects in animal studies following both oral and inhalation exposure, generally at quite high doses (close to the MTD). Overall, no mode of action (MOA) has been clearly identified to explain the reproductive toxicity of cobalt. Although a hypothesis related to induction of hypoxia leading to polycythaemia/erythrocytosis and decrease in body weight has been proposed, ECHA did not consider the reproductive toxicity to occur as a secondary effect to general toxicity.

The principal target organ for cancer effects following inhalation of cobalt metal is the lung. Cobalt metal is a suspected mutagen and is classified as a Category 1B carcinogen (presumed human carcinogen) based on induction of lung tumours in experimental species (rats and mice) following inhalation. For lung carcinogenicity, although the MOA remains uncertain, it may be linked to threshold mechanisms at high doses (ECHA, 2017), including induction of alveolar proteinosis, chronic inflammation and hyperplasia.

Cobalt has been shown to be absorbed from the lungs and, as discussed in the toxicokinetics chapter, absorption from the gastrointestinal tract is also likely (ECHA, 2017, 2019).

The CLH classification relates to all physical forms of cobalt metal (i.e., massives, granules and powders) using a read-across approach to different cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)). However, the RAC Opinion (ECHA, 2017) also notes that, when assessing classification of cobalt metal for carcinogenicity, mutagenicity and reproductive toxicity (CMR properties), consideration of the toxicokinetics of the metallic cobalt is needed to evaluate the applicability of data read-across from other cobalt compounds. However, there are no specific in vivo animal toxicokinetic studies on cobalt metal itself.

As there are no animal studies on the carcinogenicity of cobalt metal or cobalt compounds via routes of exposure other than inhalation, it is difficult to definitely exclude the possibility of cancer induction by cobalt via routes of exposure other than inhalation. Indeed, local carcinogenicity in the gastrointestinal tract after oral exposure cannot be excluded, especially when taking into account that repeated dose studies with cobalt and cobalt chloride affect the gastro-intestinal tract and Kirkland *et al.* (2015) demonstrated nuclear anomalies (apoptotic changes) in the gastrointestinal-tract after single dose oral exposure. On this basis, ECHA (ECHA, 2017) proposed to classify cobalt a Carcinogenic Category 1B (H350), without specifying the route of exposure.

ECHA proposed a restriction targeted only at lung cancer risk, on 5 water soluble cobalt salts, namely cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate), having a harmonised classification as Carcinogenic 1B, Mutagenic 2 and skin and respiratory sensitisers category 1. This REACH restriction proposal was triggered by the ECHA assessment on the uses of cobalt salts in 2017: by using the RAC dose-response for carcinogenicity (ECHA, 2017) excess cancer risks in all sectors involving mainly occupational exposure to these cobalt salts are in the range of 10^{-3} to 10^{-2}. The proposal would restrict the placing on the market, manufacture and use of the 5 above-mentioned cobalt salts on their own or in mixtures in a concentration equal to or above 0.01% by weight in industrial and professional applications (ECHA-RAC, 2020).

However, as the Commission was preparing to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds according to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, it took the view that there was no need to address those risks under the REACH Regulation as well.

Accordingly, the REACH restriction procedure was terminated without adopting a restriction[16].

Toxicological Mode of Action (MoA)

According to the ECHA CLH Opinion (2017) on cobalt metal and to the ECHA restriction-Opinion (ECHA-RAC/SEAC, 2020) on cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)) there were uncertainties regarding the

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[16] DocsRoom - European Commission (europa.eu)

carcinogenicity mode of action, which is considered to be threshold-based at high doses, and non-threshold-based at low doses. Nevertheless, the overall data were not sufficient to identify a specific threshold level for the genotoxicity and carcinogenicity of cobalt (Lison *et al.*, 2018).

At high exposure doses, cobalt carcinogenicity was generally considered to be secondary to mechanisms like the induction of alveolar proteinosis, chronic inflammation and hyperplasia. In addition, the systemic carcinogenicity of cobalt metal after the inhalation exposure in connection with pheochromocytomas, and pancreatic cancers occurring close to or above the maximum tolerated dose also supports a threshold mechanism at high doses.

Cobalt is a suspected genotoxic agent, but Co(II) ions have a role in mediating indirect genotoxicity through interaction with proteins involved in the DNA repair and maintenance systems, phenomena being expected to follow threshold dose-response relationships. In addition, the Fenton-like activity of Co(II) ions appears to be limited for their genotoxicity activity in vivo. The capacity of cobalt compounds to release these ions and their bioaccessibility (see chapter 6.5.1) is a key dimension for interpreting and predicting their genotoxic and carcinogenic activities. Surface corrosion in biological fluids is considered by Lison *et al.*, (2018) as a relevant source for Co exposure (cobalt metal, Tungsen-Carbid-Co and Co-based alloys) which, along with the solubilisation of Co(II) ions, is driving their genotoxic and carcinogenic properties through a burst of ROS production and oxidative stress resulting in DNA damage and contributing to genotoxicity and inflammatory reactions, which again are considered to be thresholder regulated.

Nevertheless, uncertainties remain, as to the possibility of non-threshold mechanisms for genotoxicity possibly involved at low doses and whether inflammation is indeed a prerequisite for the observed carcinogenicity.

In ECHA Restriction (ECHA-RAC/SEAC, 2020) targeting lung cancer risk, a residual cancer risk at low exposure levels could not be totally excluded and a non-threshold approach for the dose-response analysis was adopted based on lung inflammatory effects as the marker for the genotoxicity and carcinogenicity of cobalt with a sub-linear approach and the selection of a LOAEC of 0.3 mg/m³ as cobalt sulphate hexahydrate, corresponding to 0.067 mg/m³ cobalt, as the point of departure (PoD).

EFSA (2009) considered a threshold mode of action for oral systemic toxicity of cobalt which potentially entails a number of adverse effects in humans, e.g. cardiac effects, effects on erythropoiesis, effects on thyroid, developmental effects and effects on the immune system (allergic dermatitis). A Minimal Risk Level of 0.01 mg Co/kg body weight/day has been derived for intermediate duration (≤ 365 days) of cobalt exposure based on a LOAEL of 1 mg/kg for polycythaemia (ATSDR, 2004). EFSA (2012) considered this value with an assessment factor of 600 (10 for inter human variability, 10 for extrapolation from subacute to chronic and 6 for extrapolation from LOAEL to NOAEL) resulting in a TDI value of 1.6 µg/kg bw/day.

Toxicokinetics

The oral bioavailability of cobalt and cobalt compounds varies depending on substance, species, age and dose. Studies with dissolved cobalt compounds show a bioavailability ranging from 13- 34%, with the highest values for water-soluble cobalt salts (ECHA, 2019; EFSA, 2012).

For insoluble cobalt compounds like Co_3O_4, bioavailability is determined by the dissolution rate in gastric fluid: indeed, although cobalt metal is poorly soluble in water and in other neutral fluids, it seems to be solubilised at low pH conditions (Stopford *et al.*, 2003). The speciation is also an important factor: Co^0 and Co^{3+} compounds need to be transformed into Co^{2+} as the first step. The oral bioavailability of cobalt is expected to be higher after dietary exposure compared to gavage exposure, due to the potential involvement of active transport in the cellular uptake.

The bioavailability of cobalt and cobalt compounds after inhalation exposure also varies depending on substance, particle size and dose. There are no specific in vivo animal toxicokinetic studies on cobalt metal itself, but the bioavailability of cobalt metal after inhalation has been demonstrated in many inhalation toxicity studies in animals and in biomonitoring studies of occupationally exposed workers (Lison *et al.* 1994), in which similar regression coefficients between air and urinary cobalt levels were obtained for both cobalt metal and its salts (ECHA, 2017).

The bioavailability of water soluble and lysosomal fluid soluble cobalt and cobalt compounds is estimated at 20 – 30% (ECHA, 2019).

The available data on human volunteers indicate that the dermal bioavailability of cobalt and cobalt compounds on the undamaged skin occurs but is low (ECHA, 2017).

About 43 % of body cobalt is stored in muscles. However, kidneys and liver are the edible tissues containing the highest cobalt concentrations (EFSA, 2012). After inhalation some retention in the lungs is noted. Cobalt can be transferred to the foetus via the placenta. Absorbed Co^{2+} is rapidly (highest t ½=19h) excreted mainly via the urine (88%), hence urinary cobalt is considered a good indicator of exposure to soluble cobalt, but not to insoluble cobalt compounds (EFSA, 2012). Unabsorbed cobalt is predominantly excreted via the faecal route.

The International Commission on Radiological Protection (ICRP) has developed two physiologically based pharmacokinetic/pharmacodynamic models that are applicable to cobalt: a human respiratory tract model for radiological protection (ICRP, 1994) and a biokinetic model of ingested cobalt in humans (ICRP, 1979, 1994). A study on the urinary cobalt levels in a group of exposed workers was used to calibrate a population toxicokinetic model, taking into account both the measurement uncertainty and intra- and interindividual variability (Martin *et al.*, 2010). More recently an updated biokinetic model for human exposures to cobalt (Co) was developed based on a comprehensive set of human pharmacokinetics data collected from five male and five female volunteers who ingested ~1 mg Co/day of a Co supplement for 3 months (Unice *et al.*, 2014).

6.4.1. Health Effects to humans

Although cobalt has a biologically necessary role as a metal constituent of vitamin B12, excessive exposure has been shown to induce various adverse health effects, like neurological (e.g. hearing and visual impairment), cardiovascular and endocrine effects.

In a biokinetic model the dose-response relationship and effects of chronic exposure have been described. According to the model, health effects are unlikely to occur at blood Co concentrations under 300µg/l (100µg/l respecting a safety factor of 3) in healthy individuals; hematological and endocrine dysfunctions are the primary health endpoints.

However, toxic reactions at lower doses have been described in several cases of malfunctioning hip implants, which may be explained by certain underlying pathologies that increase the individual susceptibility for Co-induced systemic toxicity. This may be associated with a decrease in Co bound to serum proteins and an increase in free ionic Co2+ which is suspected to be the toxic form (Leyssens *et al.*, 2017).

Available data have not clearly defined about whether children are at greater risk from exposure to cobalt than adults are. Data on effects of cobalt in children following inhalation exposures are lacking.

Enlarged thyroid glands have been reported in children who were orally given cobalt chloride for treatment of anaemia; the effect is reversible, since stopping the cobalt therapy resulted in a return to normal thyroid size. Offspring of mice intravenously injected with approximately 1.2 mg cobalt/kg at day 8 of gestation, but not at day 3, showed delayed ossification, as evident in the post-mortem of their skeletons. Other studies, however, have not shown developmental effects of stable cobalt compounds, or have shown effects only at maternally toxic doses (ATSDR, 2004).

6.4.2. Immunological effects: sensitisation

Cobalt is a known sensitiser in humans (Thyssen *et al.*, 2021), and skin contact sensitisation and elicitation of contact dermatitis has been documented in children (Goossens *et al.*, 2021; Simonsen *et al.*, 2018). Respiratory sensitisation is only relevant in occupational settings. Sensitisation and elicitation occur mostly upon skin contact with cobalt ions released from solid materials.

Although there are no data on the prevalence in the general children population, the prevalence of contact allergy to cobalt among children can assumed to be very low. The causative exposures among patients (also children) sensitised to cobalt are often unknown, although there is increasing evidence that sensitisation may arise from contact with leather products (Alinaghi *et al.*, 2019).

The ECHA-RAC Opinion (ECHA/RAC/RES-O-0000006741-74-01/F) (2020) on skin sensitizing substances proposes that cobalt compounds with CLH classification as skin sensitisers in category 1, 1A or 1B in individual concentrations greater than 70 mg/kg w/w in textile and 20 mg/kg w/w in leather, hides and furs (after extraction, expressed as cobalt metal that can be extracted from the material) shall not be placed on the market for the general public (ECHA, 2020). The RAC, while taking into account skin surface contact parameters, agreed to use a default migration factor of 10% to derive a concentration limit of 70 mg/kg for cobalt in textile articles and 15 mg/kg for cobalt in leather articles. For their Opinion, an elicitation threshold of 0.44 µg/cm² was applied, derived from patch-test elicitation studies (Fischer *et al.*, 2011, 2016). This elicitation threshold is also considered to be appropriate as the threshold for induction of sensitisation.

The RAC agreed to use a default migration factor of 10% to derive a concentration limit of 70 mg/kg for cobalt in textile articles and 15 mg/kg for cobalt in leather articles.

For household products (mostly products for washing / cleaning), it has been proposed that these should not contain more than 5 ppm cobalt. Based on a quantitative risk assessment, a ‘safe’ target level of exposure to nickel, chromate and cobalt from such products should be 1 ppm (Basketter *et al.*, 2003).

6.4.3. Weight of evidence

The weight of evidence for carcinogenicity of cobalt is considered strong for inhalation exposure but weak for the oral route. Due to uncertainties about the mechanism (threshold vs. non-threshold mechanism), the evidence for the mode of action is considered moderate. For sensitisation the weight of evidence is strong.

6.5. Exposure Assessment

6.5.1. Cobalt release from different materials

Metals in the alloy are organised within a matrix, and the strength of binding of the metal to the matrix is one of the main factors determining the release of metal ions from the alloy (described also as migration, leaching or bioaccessibility in the different references).

The reason why metal ion releases are important is that for metal-containing materials in general, including alloys, the free metal ion is usually considered to be responsible for the observed systemic toxicity and also considered to play a role in local effects (e.g. skin or respiratory tract effects): Co is not an exception (Goyer, 1996). To exert their toxicity, the metals species (in whatever form they exist upon release, e.g. complex, hydrated ions, etc.) (Hedberg and Odnevall Wallinder, 2015) must be taken up into the organism and reach their site of action; i.e. the metal species must become bioavailable.

In addition, existing group classifications of metal-containing substances, e.g. European Union (EU), International Agency for Research on Cancer (IARC)) highlight the assumption that metal ions drive the toxicity of these substances for systemic effects.

The first step allowing the release is the capability for the metal to be oxidised (corrosion process). If corrosion is minimal then so is metal ion release. As a result, alloys that are corrosion-resistant will also not release significant amounts of metal ions. By contrast there are other alloys where the matrix effect may result in the increased release of one particular metal ingredient above what one would expect based on the release from the pure metal, even after considering the concentration of the ingredient in the alloy.

Migration or bioaccessibility is defined as the fraction of a substance that dissolves under surrogate physiological conditions. Since the free metal ion is generally the toxic agent, it is essential to know its migration, and then the potential absorption and bioavailability into systemic circulation are essential data to assess the actual exposure (Midander *et al.*, 2016; Heim *et al.*, 2020; Wang *et al.*, 2020).

The chemical speciation of the released ions, affecting the absorption and bioavailability, is dependent on pH, temperature, redox potential, concentration of the ions released, and time (Hedberg and Odnevall Wallinder, 2015). The composition of the simulant can also be relevant, but not for the oral bioaccessibility of highly soluble cobalt (Stopford *et al.*, 2003; Stefaniak *et al.*, 2010).

For metallic cobalt and cobalt salts, *in vitro* testing with artificial fluid (intestinal, alveolar, lysosomal, serum, synovial, gastric and interstitial) at different times demonstrated that cobalt is poorly soluble in water and in other neutral fluids whereas it is solubilised at low pH conditions (Stopford *et al.*, 2003). Some cobalt salts such as cobalt(II) sulfate heptahydrate were highly soluble, whereas cobalt alloys used in medical implants and cobalt aluminate used as pigments, showed minimal dissolution over 72 hours at 37°C (Stopford *et al.*, 2003). These in vitro tests are known as bioelution tests and are able to measure the relative bioaccessible concentration that is the fraction of a substance that dissolves into liquid-mimicking physiological conditions (e.g. simulated gastric fluid, artificial sweat, lung fluids).

It has been reported in an inter-laboratory validation of bioaccessibility testing for metals that while gastric and lysosomal fluids had reasonably good reproducibility, other fluids did not show as good concordance between laboratories (Henderson *et al.*, 2014).

In a study, powders and massive forms of Co and stainless steel 316L were tested in gastric fluid, while only powder forms of Co-containing alloys were also tested in lung fluids (interstitial and lysosomal) (Heim *et al.*, 2020). The results indicated that the type of alloy, the fluid used, and the physical form of the alloy all affect metal ion release: due to the much larger surface area of the powders per gram of sample with respect to other forms, metals are apparently more easily released from powders. Indeed, when results are expressed per surface area, the massive forms have higher releases per m^2 than the powders. Overall, the study results showed that the relative bioaccessible concentration of cobalt in the alloy cannot be predicted a priori, since matrix effects can increase or decrease the metal ion release, depending on the metal ingredients, alloy type, and fluid, consistent with results obtained by other authors. Very recently, a study reported the bioaccessibility of cobalt ions from twelve cobalt substances tested in three artificial lung fluids (interstitial, alveolar and lysosomal) (Verougstraete *et al.,* 2022). It evidences strong differences in the dissolution behaviour of the test items in the different fluids, with the cobalt substances generally being less soluble in neutral pH fluids and more soluble in the acidic pH fluid. Results from this in vitro study can help in grouping different Co ions with similar bioaccessibility behaviour (Verougstraete *et al.,* 2022). The bioelution test results may be a better surrogate than the bulk content for alloys classification (according to CLP), after looking at correlations with acute toxicity data. For inhalation, although with a high degree of uncertainty, it seems that bioaccessibility in interstitial lung fluid is more predictive of acute inhalation toxicity than in lysosomal fluid (Heim *et al.*, 2020).

A good correlation between in vitro bioaccessibility with in vivo bioavailability and subsequent in vivo oral repeated toxicity has been described for six cobalt substances with inorganic ligands, tested with gastric and intestinal fluids simulants (Danzeisen et al, 2020). The study concludes that in vitro bioelution in simulated gastric fluid is a good, yet conservative, predictor of in vivo bioavailability and oral systemic toxicity of inorganic cobalt substances, identifying two groups of cobalt substances, i.e. highly bioavailable/ bioaccessible ones (e.g. cobalt metal, some cobalt salts, cobalt monoxide and dihydroxide, cobalt lithium dioxide, cobalt propionate, cobalt octoate, cobalt borate octoate, cobalt acetyl acetonate and cobalt oxalate) and poorly bioavailable/bioaccessible cobalt substances (tricobalt tetraoxide, cobalt sulphide and cobalt oxyhydroxide CoOOH) (Danzeisen *et al.,* 2020). Indeed, since in vivo information on the bioavailability of cobalt and its compounds is limited, bioaccessibility data are sometimes used to support read-across between tested and untested cobalt compounds (ECHA, 2019).

Very similar results were obtained in another paper, where cobalt release from chromium-alloy powders (different stainless steels and a nickel-based Inconel alloy), consisting of particles sized within the respirable range, was measured at simulated human exposure scenarios (ingestion, skin contact, and inhalation) between 2 and 168 h (Wang *et al.*, 2020). The results indicated a relatively high corrosion resistance of the alloys, with Co released at much lower levels than the pure metal. Similar results were also obtained when the release was measured in simulating sweat fluid was tested (0.00003–0.6 wt% in the tested alloy compared to corresponding bulk alloy contents 0.02–65 wt% Co) (Wang *et al.*, 2019). A comparison among the surrogate fluids indicated that the relative bioaccessible concentration is higher in the acidic gastric fluid than in the artificial lysosomal fluid, simulating the inhalation exposure.

Co bioavailability has also been shown to be relatively low when ingested incidentally in the forms found in the environment (e.g. in soil or dust), compared to when exposure occurred to freely soluble forms (ionic salts used as the basis for oral toxicity criteria). Indeed, bioavailability of cobalt in soil and dust contaminated by Co-containing alloys measured in swine in vivo was around 1% (Suh *et al.*, 2019).

After oral exposure, cobalt and cobalt compounds may dissolve in the stomach due to the low pH depending on their solubility and solubility rate. When the dissolved Co^{2+} is moved to the intestine, it has been suggested that it does not precipitate also when the pH is raised to normal: therefore, the dissolution in gastric fluid is considered determinative for the oral bioavailability (ECHA, 2019). For inhalation, the respirable particles will be transported into the alveoli: when they do not dissolve in the alveolar fluid they will be taken up by cells and transported into the lysosomes.

The ECHA CLH report on Cobalt (2017) describes the procedure for deriving a relation between external oral dose and internal concentration in the stomach, based on information about dissolution in the gastric fluid and consideration about inhalation exposure in order to apply the read across to evaluate different cobalt compounds.

In conclusion, since the type of alloy and the physical form of the alloy affects metal ion release, the relative bioaccessible concentration of cobalt in the alloy cannot be predicted a priori.

Weight of evidence

Based on limited data on release of cobalt from different materials and their dependence on various factors, the evidence is considered weak to moderate, except for the examples provided by TIE.

6.5.2. Exposure scenarios for children playing with cobalt-containing toys

Children may be exposed to cobalt from different toy types and toy materials. Based on information available, the SCHEER considers the following sources as relevant for the exposure assessment:

1. cobalt-containing metals included to allow conduction of electric current;
2. cobalt-containing metals that serve a function other than electrical conductance like for toys of metal, toy jewellery, fidget spinners, slot car magnets;

3. kids make-up;
4. 3-D pens, materials for toy printers and printed toys;
5. cobalt-containing paintings, inks and coatings used for toys, chalks and chalk bombs and toys made of leather or textiles;
6. toys containing batteries.

The TIE report exposure estimates for cobalt-containing metals addressed scenario (1) conduction of electric current and partially scenario (2) cobalt-containing metals that serve a function other than electrical conductance. The other sources were not considered in the TIE report. The SCHEER addresses the additional other toy types as appropriate.

6.5.2.1 Cobalt-containing metals included to allow conduction of electric current

The TIE report includes an exposure estimate for metallic material intended to conduct an electric current (model rail track and model rail track joiners as an example of a potential exposure to cobalt in metals that are included in toys to allow conduction of electric current which is essential to the toy's function) (TIE, 2021).

Possible exposure for inhalation as well as for dermal and oral routes were considered for these sources. The SCHEER agrees with TIE conclusions that the inhalation pathway is associated with negligible exposure to cobalt from this type of metallic material and therefore unlikely to be associated with increased risk. This assumption is supported by the SCHER (2012) Opinion which concludes that inhalation of Ni from toys is extremely unlikely. For cobalt present in toys as a contaminant of nickel (50:1), these conclusions will also apply.

Concerning the dermal route, the TIE report (Appendix A) includes a migration study carried out according to the harmonised standard EN71-3:2019 for a Rail Track (2 samples) and a slot-car magnet showing no detection of cobalt. In addition, a study on Ni and Co release from toys indicated that none of the toys released cobalt (Jensen *et al.*, 2014). By means of a spot-test that becomes positive when more than 8 ppm cobalt is released, 212 toys purchased in 18 different retail and on-line shops in the USA and Denmark were screened. Only toys with exposed metal components were selected. For all of these toys the spot-test was negative.

The SCHEER is, therefore, of the opinion that dermal exposure to cobalt can be considered negligible, when handling model rail track and model rail track joiners during play or assembly.

The SCHEER agrees that no direct oral exposure is expected to occur through intended use of these products, as it is unlikely that metal parts will be ingested from these toy types. Mouthing is considered not to be of concern for the age group of users most likely to play with model railways with metal track. Scrape off during mouthing would not be relevant because of the hardness of the material.

However, a possible indirect route of exposure may occur through ingestion of dust present on hands or settling on nearby objects, particularly by children's hand-to-mouth contact and the TIE report includes the following estimate:

> Based on the experimental testing undertaken to determine the mass loss from rail track during operation of a toy train, where a total mass loss of 4.9 mg was found during 40 hours of operation (alloy with a nickel content of 13% and estimated

> respective cobalt content of 0.26%), the estimated mass of nickel would be 0.637 mg with associated cobalt level of 0.013 mg. Assuming that the 0.637 mg was released at a constant rate and that the amount released each day was the result of an extreme case of 3 hours of use each day, then the release per day would be 0.637 x 3/40 = 0.048 mg/day[17]. If all this mass lost from the rail track was ingested, assuming the maximum migration limits (130 mg/kg = 0.13µg/mg), the amount of exposure to releasable cobalt from nickel for uptake would be 0.13 x 0.637=0.083µg/day. If the amount of play time were a more typical 3 hours per week, then the release would occur over seven times longer period and the exposure to releasable cobalt would thus be 0.083/7 = 0.012 µg/day.

The SCHEER agrees with the exposure determinants and assumptions used in the development of this exposure assessment; however, a play time of 3 h/week is not considered as a worst case. As presented in the TIE report, no more than 10% dust is ingested. The calculated cobalt intake for 3 hours play time per week is 0.083/7 = 0.012 µg/day. The SCHEER is of the opinion that a play time of 7 h/week is more appropriate for toys that require setting up and preparation. This is corresponding to a cobalt intake of 0.028 µg/day.

6.5.2.2 Cobalt-containing metals that serve a function other than electrical conductance

In the TIE report, an exposure estimate was carried out on “Other metallic materials - cobalt included in toys within metal components that serve a function other than electrical conductance” which include stainless-steel ball bearings, slot car magnets and car set rollers (TIE, 2021).

Based on the negligible inhalation exposure related to the use of these toys, the inhalation pathway for cobalt, as a contaminant of nickel, is associated with negligible risk.

Concerning the dermal route, Wang *et al.* (2019) reported that based on a modified EN1811 test, dermal exposure to cobalt from stainless-steel was negligible, with the bio-accessible concentration reported as <0.01µg cobalt/cm^2/week. In addition, migration of cobalt from a slot car magnet determined according to the harmonised standard EN71-3:2019 was not detectable (Test Report Bureau Veritas (Dec. 2020), in app. A of the TIE report). Therefore, the SCHEER supports the view that exposure to cobalt via the dermal route for these toy types is negligible and unlikely to be associated with increased risk.

The SCHEER considers the oral exposure as most relevant. In the TIE report, the worst-case assumptions included addresses oral exposure in children through the unintentional metallic foreign body ingestion of a small screw or stainless-steel ball bearing, with the following exposure determinants (TIE, 2021):

Object:	Stainless-steel ball bearing
Material:	316 stainless-steel

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[17] The calculation from TIE was corrected by the SCHEER

Diameter: 3 mm
Density: 7.98 g/cm^3
Mass: 0.12 g (approximate)
Migration: 130 mg/kg toy material [A]
Soluble cobalt [0.12 / 1000] x 130 = 0.0156 mg or 15.6 µg.

[A] – legal limit value (EN71-3) for cobalt migration (assuming pH 1.1-1.3, 2 hours migration time).

Frequency: 1/lifetime
Absorption % (GIT): 5% -30%
Body weight: 7.5 kg

Oral intake: **0.1 – 0.6 µg/kg bw**

The SCHEER is of the opinion that the exposure assessment for a stainless-steel ball is appropriate, taking 30% absorption as the most likely value (ECHA, 2019). However, the unintentional ingestion of such a ball once in a life is not considered as a worst-case scenario. Moreover, the SCHEER is of the opinion that oral exposure from further metallic toys, including toy jewellery, leads to aggregate exposure and needs to be considered in order to assess possible health risks for children due to ingestion of cobalt containing metallic toys containing cobalt.

The SCHER Final Opinion on Estimates of the amount of toy materials ingested by children (2016) states that children can ingest parts of toys when they put them into the mouth. Therefore, it is necessary to conduct a risk assessment starting from migration data in gastric fluids simulants. For toys used by children under the age of 3 years, in addition, mouthing has to be considered.

Parameters for these additional exposure assessments are laid down in the above mentioned SCHER Opinion (SCHER, 2016) as well as in the RIVM Report on Chemicals in toys (RIVM, 2008).

Due to data gaps, among others in areas related to cobalt concentration in the product, initial leaching rate and density of the individual toy material, the SCHEER cannot perform a quantitative exposure assessment for these toys.

Toy jewellery

Cobalt, in its pure form, cannot be used in jewellery. As a result, cobalt is alloyed with other metals to make it stronger, more malleable and more wearable and in jewellery is often alloyed with metals such as chromium (Wennervaldt *et al.*, 2021), tungsten and iron.

As children play with toy jewellery, the SCHEER considers that this is an additional source of exposure both via the skin as well as via the oral route, due to the habits of children to put objects into their mouth. No specific data on cobalt contained in toys have been found, but the lack of data does not mean cobalt is not present, it simply can reflect it has not been searched for, so far. If a survey has to be conducted, the SCHEER recommends following the indications given by SCHER for the evaluation of lead in jewellery (SCHER, 2010). The SCHEER recommends the following methodology:

Part of the jewellery should be selected to cover the different product types (rings, necklaces, watches, bracelets etc.) where the primary criterion should be to represent a part of the jewellery coming in contact with skin. The migration analysis method to be used should be “Migration to artificial sweat” according to DS/EN 1811:2000, when the dermal contact should be analysed.

For the oral route, the extrapolation from artificial sweat to saliva cannot be made due to differences in chemical composition such as pH and presence of chelating agents, therefore the detection limit (LOD) of the method to quantify the metal should be sufficient to allow conclusions on potential health risks.

The SCHER (2010) recommended performing of an optimised migration study with repeated extractions. Indeed, a repeated discontinuous extractions separated by a ‘dry spell’ of the metal may better mimic this exposure situation. Corrosion kinetics of metals or alloys often show that metal-release rates in biological fluids or water slow down after an initial fast release, commonly denoted as the “first flush” (Skeaff *et al.*, 2000; Herting *et al.*, 2007). This decrease is a consequence of the time-related formation of a more corrosion-resistant surface (Herting *et al.*, 2007).

These migration studies might also be appropriate for other metal-containing toys.

6.5.2.3 Exposure scenarios for kids’ cosmetics: cobalt in toy make up sets

As shown in Table 3, Co has been found in toy make-up sets, mainly eye shadows, which are frequently used by children of various age, namely, in the age groups 3-6 and 6-11 years old. While prohibiting the use of many metals as ingredients (e.g. the ones included in the list of CMR substances as cobalt), the Cosmetic Regulation 1223/2009/CE (EC, 2009) tolerates their presence in traces (art. 17) provided that 1) these are "technically unavoidable", also by observing Good Manufacturing Practices for Cosmetics and 2) the product is safe for human health (art. 3). The definition of "technically unavoidable traces" is however vague and depends on the quality of raw materials and production technology, especially for products from non-European countries, where the Good Manufacturing Practices for cosmetic products do not correspond to that applied in Europe to comply with Regulation no. 1223/2009. This applies also to cobalt in cosmetics.

At the moment, there are no European or international standards that define the levels of heavy metals (including cobalt) identifiable as unavoidable traces, and as such tolerated in cosmetics. The results of specific survey of products on the market carried out by the German BfR (2017), Health Canada (2012), and FDA (2020) indicate the levels of metals considered as "technically unavoidable" in cosmetics. These values do not represent health-based data, but are derived from the above-mentioned monitoring activities, taking the lower values found as "technically achievable”. These values have been demonstrated to decrease over time, due to the improvement of the producing techniques.

In any case, to comply with art. 3 of the Regulation, a case-by-case assessment based on actual exposure is recommended to establish the risk associated with these products. To characterise the risk of the presence of substances in cosmetic products, the MOS (Margin of Safety) is used, which indicates the level of safety. It is expressed as the ratio between the NOAEL or BMDL of the critical effect and the estimated systemic dose of exposure (SED = Systemic Exposure Dosage).

MOS values equal to or greater than 100 should suggest that the use of one ingredient/contaminants pose no significant health risk for humans. With reference to children, it is the opinion of the SCCS (SCCS 2012 and further updates till 2021) that it is not always necessary to add safety factors for cosmetic products for children (e.g. products for daily hygiene), since the difference between adults and children is already included in the safety factor for intraspecific differences: consequently, a minimum MOS of 100 takes this aspect into account. Nevertheless, the SCHEER considers that when children are the target population, it is necessary to consider specific exposure scenarios, referring to typical behaviours (for example, the habit of frequently putting their hands and other objects into the mouth).

In addition, cosmetics for children can be considered as toys, and for a toy, according to the SCHER Opinion (2010), the maximum % of TDI (or other reference value) attributable to the exposure associated with their use is 10%, so the minimum MOS in this case is 1000. Since cobalt is generally present as $CoCl_2$, which is a soluble compound, the content other than migration values is relevant. For the MOS calculations, in order to obtain the SED value, it should be considered that soluble cobalt compounds show an oral absorption of about 30%, while the dermal absorption is much lower (below 1%).

Eye shadow

As for eye shadows, the estimated amount used is 30 mg (8 cm^2 exposed area), 3 times the amount applied by an adult woman, as indicated by the RIVM; the increased values are justified by the inexperience in the application. As a precaution for children in the lower age group, 3-6 years, who are much more likely to apply eye shadow with their fingers rather than with the applicator, the special case in which 15% remains on the fingers and can be ingested is also considered (RIVM report 612810012/2002 Children's toys fact sheet: OECD 2019). For the age group 6-11 years, only the skin absorption of the product is expected. Considering that use is not daily, a total daily intake of 30 mg product is considered sufficiently conservative. Then, depending on the cobalt content, daily exposure can be calculated. For powder eye-shadow the possibility for dust inhalation can be also possible, but data on exposure are not available.

Lipstick

It is estimated that children are exposed to the product via the skin and mouth; since the ingested quantity is much more relevant, the dermal route for this type of product can generally be neglected. The total ingestion of the product is considered as the worst case, including the fraction applied to the lips and that left on the fingers, both for the lipsticks/lip glosses present in the tray and for those in stick form.

As reported in the SCCS Note for Guidance (2012, 2016), the total amount of lipstick applied by an adult woman for each application is about 30 mg for 2 applications, for a total daily dose of about 60 mg per day. The RIVM Report 320104001 also reports that a woman uses 0.01 g of product 2-6 times a day and it is assumed that the entire product can be ingested. For children aged>3 years, the single application is considered equal to 30 mg per application and that it is completely ingested (RIVM report 612810012/2002). Considering that use is not daily, a total daily intake of 30 mg product is considered sufficiently conservative. Then, depending on the cobalt content, daily exposure can be calculated.

No or scant data are available on the amount of cobalt (as impurity or as part of a colourant) in kids cosmetics or toy make up. Therefore, the SCHEER cannot provide a quantitative exposure assessment on a representative sample.

6.5.2.4 Exposure scenario for 3-D pens and toy printers

The Danish Environmental Protection Agency has performed a survey and risk assessment for 3-D pens (Danish EPA, 2018). The SCHEER agrees with the exposure scenario used in this report which are as follows:

The frequency that a child plays with a 3-D pen is assumed to be lower than for playing with play dough. RIVM, to which the Danish EPA refers to, assumes one weekly use of play dough (indicated in the RIVM document as ‘modelling clay’) and a contact time of 60 min (RIVM, 2002). Therefore, for the 3-D pen it is assumed that the product is used for 30 minutes for the 3-6-year old and for 60 minutes for the 6-11-year-old, respectively. The time of use is expected to be shorter for children in the lower age group, due to their shorter attention span, compared to the older children. The 3-D pen is assumed to be used once a month on average and maximum once per day, because of the cost of the materials for 3-D pens and 3-D printers, which is substantially higher than for play dough.

In the 3-D pen, the material is extruded and led through a small opening. Tests with the 3-D pens have shown that the extrusion rate in average is 1.7 g/minute. It is assumed that the child will not extrude material the entire time the 3-D pen is used, because the child will need time for mounting material, changing material colours and possibly shaping the extracted material with the hands without using the 3-D pen. The amount of applied material on the printed object will vary with age (older children play longer and create larger objects) and pen (various extrusion rates). Assuming the measured average extrusion rate of 1.7 g/min and that the extrusion occurs during half of the total play time, an amount of applied material of 25 g for 3-6-year-olds and 50 g for 6-11-year-olds, respectively, appears a realistic worst-case scenario.

According to Jinghai *et al.* (2019), the cobalt emission yield for aerosol released by PLA filaments extruded with a 3-D pen can reach 0.03 ng/g printed. Based on this data, in a room with a volume of 17.4 m^3 and without air change, the concentration of Co will be 0.043 ng/m^3 when a 3-6-year-old is playing and double this value (0.086 ng/m^3) when a 6-11-year-old is playing in the room for longer times. By considering the inhalation rate and the body mass, these values would correspond to an inhalation of 0.00566 and 0.0129 ng/kg per day for 3-6 and 6-11 years old children respectively (assuming that all the emitted Co is respirable and hence bioavailable). Intake due to oral exposure is 1-2 order of magnitude lower; the level associated with external dermal contact is similar to the inhaled dose, but the dermal absorption is limited, making the corresponding internal dose very low. Details of the calculations are given in Annex 2, where an air change rate of 0.3 hr^{-1} is assumed for the room. The calculation parameters for the older group in Annex 2 are taken as the average of a 6.5-year-old and a 12.5-year-old, assuming that the play time for the 6.5-12.5-year-old group (used in Annex 2) is the same with that of the 6-11-year-old group.

Although the exposure calculated based on the available information are low, the SCHEER is of the opinion that these toy types have to be considered when assessing possible health risks from cobalt for children. In addition, material for 3-D printing of toys and the printed toy may also be a source for cobalt exposure.

6.5.2.5 Cobalt-containing paintings, inks and coatings used for toys and toys made of leather or textiles

The SCHEER is of the opinion that cobalt-containing paintings, inks, chalks and chalk bombs and coatings used for toys as well as toys made of leather or textiles are relevant for the assessment of oral exposure. The SCHEER furthermore is of the opinion that the possibility of ingestion, and mouthing needs to be taken into account when assessing the exposure of children to cobalt from toys. In case of chalks and chalks bomb and the other types of toys originating dust also the inhalation exposure should be considered. Due to the lack of data, no quantitative assessment can be performed.

6.5.2.6 Toys containing batteries

Batteries may contain cobalt in the contacts but also inside the batteries itself. TIE states that since the batteries are inside the toy, no contact is possible (TIE, 2021). However, destroying toys while exploring them is a foreseeable use taking into account the behaviour of children and therefore, exposure to cobalt from batteries cannot be excluded. Cases of battery ingestions by children notified by poison centres (e.g. https://www.poison.org/battery/stats#20161) demonstrate that batteries (especially the small button ones) are a realistic source for possible exposure to cobalt. However, the SCHEER cannot provide a quantitative exposure scenario.

6.5.2.7 Exposure of children to cobalt from other sources than toys

The main route of exposure to cobalt in children is via their diet, as for adults. Infants (0 – 12 months of age) have an estimated average intake from food and water of 0.52 µg cobalt/kg/day and 3.93 µg/day for a child of 7.5 kg. Actual intakes were reported to be influenced by whether the infant was breast or milk-based formula fed, with higher intakes associated with formula feeding (Dabeka and McKenzie, 1995 – cited in ATSDR, 2004). In communities where soils are contaminated with cobalt, certain behaviours in children can also contribute to overall exposure to cobalt. These include crawling on a floor where soil has been tracked in from outside, and hand-to-mouth behaviour contributing to unintentional or intentional ingestion of soil. In addition, children may be exposed to cobalt from consumer products other than toys made from cobalt-containing materials or coated with cobalt-containing colourants or products with batteries as well as to Co-containing medical devices (e.g. implant and dental materials).

6.5.3. Weight of evidence

In general, data needed for exposure assessments (i.e. content of cobalt, migration rates) are limited for the different toy types, except for specific data provided by TIE for some scenarios. Therefore, no quantitative exposure assessment was possible.

For exposure estimates based on data provided by TIE, the weight of evidence is considered strong.

6.6 Risk Assessment

The SCHEER performed the risk assessment for inhalation and for oral and dermal exposure. The main focus is on risks related to carcinogenic properties of cobalt.

Inhalation

For cobalt-containing metals included to allow conduction of electric current the inhalation pathway is associated with negligible exposure to cobalt from this type of metallic material and therefore unlikely to be associated with any risk for children using these type of toys.

There is a potential risk for inhalation exposure to cobalt from powder-like toy materials like kids cosmetic or creative art toys, chalks and chalk bombs containing cobalt-based pigments/colourants. For such toys, cobalt-free pigments should be used.

There is a potential risk for inhalation exposure to cobalt form materials to be used in context with 3-D pens/3-D printing. The calculated external exposure for 3-D pens is low, but there is limited data for other applications and their use is increasing. Cobalt-containing materials should therefore be avoided for 3-D printing.

Oral exposure

In the TIE report (2020), the potential for additional carcinogenicity risk related to the inclusion of cobalt-containing metals in toys (for the specific use considered here) in the TSD derogation was characterised for the oral route and based on the following rational:

A Specific Concentration Limit (SCL) was derived for cobalt based on the T25 of 0.1 mg/kg bw, which falls in the category of high potency carcinogens according to EC (1999). The starting assumption for this potency grouping is an assumption of a linear dose response relationship. However, the three main modes of action proposed for the carcinogenic effects of cobalt ion (ROS and oxidative stress, inhibition of DNA repair and upregulation of HIF-1ɑ) are mechanisms, which are likely to have a threshold, although there are some uncertainties related to the threshold for oxidative damage.
A possible threshold mode of action (and therefore lower potency at low exposure levels) could partly explain the lack of clear evidence from epidemiological studies on the carcinogenicity of cobalt regardless of its long-term use.
In conclusion, though epidemiological data seems to indicate a lower concern there is insufficient data to lower the carcinogenic potency of cobalt and therefore the current SCL is based on the calculated T25 of 0.01% using the animal data.

No data are available in the open literature on the potential carcinogenicity of cobalt following the exposure via the oral route either in humans or in experimental animals. The exposure to cobalt via the oral route may potentially entail a number of adverse effects in humans (cardiac effects, effects on erythropoiesis, effects on thyroid, developmental effects, and allergic dermatitis). A daily oral intake of 60 mg Co (based on a LOAEL of 1 mg/kg for polycythaemia) appears a minimum risk level for humans that would protect from the known threshold-related adverse effects (EFSA, 2009). Considering the population exposure to cobalt, which is about 4–10 times lower than the health-based guidance value, no safety concern for the consumer is expected for threshold effects of oral cobalt at the current intake level. However, considering the toxicological profile of cobalt(II) and its salts, and the uncertainties regarding the deposition and the speciation of cobalt (cobalt(II) or vitamin B12) in foodstuffs of animal origin, the FEEDAP Panel confirms its previous position that it would be prudent to limit the cobalt (cobalt(II) cation) supplementation of feeding stuffs to a level lower than the current maximum authorised (EFSA, 2012).

Based on the exposure estimates performed for swallowing a slot car magnet once in a lifetime, TIE used three approaches for the risk assessment

Threshold approach using TDI of 1.5 µg/kg bw/day
Threshold approach using a DNEL of 29.8 µg/kg bw/day
Non-threshold approach calculating the life-time cancer risk

All approaches resulted in an acceptable risk for the exposure to cobalt from toys.

SCHEER approach

The SCHEER is of the opinion, that a risk assessment based on the uptake of a slot-car magnet once in a lifetime does not appropriately address possible oral exposure sources from toys. The SC assumes that there are toys and toy materials for which an oral exposure to cobalt is possible. Therefore, additional sources like other metal toys, toy jewellery, kids' cosmetics (i.e. lipstick), batteries or coloured materials have to be considered for the risk assessment. As data on cobalt content and cobalt release in most cases are missing, the SCHEER cannot perform a quantitative risk assessment. However, based on available toxicological reference values, the SCHEER calculated the following migration levels (according to the TSD) for cobalt:

For a threshold approach the TDI of 1.6 µg/kg bw/d is used.

Calculation of migration limit ML according to the following formula:

$ML = [(PTDI * TDI * BW)/(AMT * 100)] * K$ mg/kg toy material

where:
ML = migration limit (mg/kg product)
PTDI = percentage of TDI allocated to toys (10)
TDI = mg/kg bw/d
BW = body weight (default 7.5 for children one year of age)
AMT = amount of toy material (8, 100, or 400 mg)
100 = conversion factor from percentage to fraction
K = conversion factor from mg/mg toy material to mg/kg toy material (10^6).

Migration limit values:

Scraped-off toy materials (8 mg)	150 mg/kg toy material
Dry, powder-like or pliable toy materials (100 mg)	12 mg/kg toy material
Liquid or sticky toy materials (400 mg)	3 mg/kg toy material

The SCHEER acknowledges the uncertainties regarding the carcinogenic properties for cobalt after oral exposure as well as the open questions regarding the MoA. Therefore, the SCHEER recommends reducing migration of cobalt from toys to the lowest technically achievable amount.

Dermal Exposure

Dermal exposure is considered possible from metal toys, toy jewellery, kids' cosmetics, materials with cobalt containing coatings or batteries as well as from materials for 3-D pens/printings.

Due to low migration of cobalt to artificial sweat and the very limited dermal exposure, the risk after dermal exposure is considered to be low/negligible. The migration limit values derived for oral uptake are considered to also be protective with regard to sensitisation and possible allergic skin reactions. The restrictions on cobalt content of textiles and leather, as proposed in the ECHA-RAC Opinion (ECHA/RAC/RES-O-0000006741-74-01/F), can be assumed to also protect children, when the threshold of 0.44 µg/cm² is applied to all toy materials that are in contact with the skin.

Overall weight of evidence

Regarding inhalation, the overall weight of evidence is strong for the risk assessment of cobalt-containing metals included to allow conduction of electric current; it is moderate for 3-D pens and moderate for powder-like toy materials like kids cosmetic or creative art toys containing cobalt-bases pigments/colourants and materials for 3-D printing.

The overall weight of evidence is considered moderate for the risk assessment after oral exposure and strong for the risk assessment after dermal exposure.

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8. LIST OF ABBREVIATIONS

CAS	Chemical Abstract Service
CMR	carcinogenic, mutagenic or toxic to reproduction (materials)
EC	European Commission
ECDC	European Centre for Disease prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medical Agency
EPA	Environmental Protection Agency
ES1	metallic material intended to conduct an electric current
EU	European Union
FDA	Food and Drug Administration (US)
GHS	United Nations Globally Harmonized System of Classification and Labelling of Chemicals
JECFA	Joint FAO/WHO Expert Committee on Food Additives
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SCCS	Scientific committee on consumer safety
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
TDI	Tolerable Daily Intake
TIE	Toy Industries of Europe
WHO	World Health Organization
WoE	Weight of Evidence

ANNEX 1

LITERATURE REVIEW ON SAFETY OF COBALT IN TOYS

The Scientific Committee on health, environmental and emerging risks, has received from the Commission a request for a scientific opinion on safety of cobalt in toys.

In order to ensure that all relevant scientific information is available to the Scientific Committee for its assessment, we performed a literature search.

The terms used in the searches were:

1. Cobalt AND toy OR toy materials

2. Cobalt AND nickel OR alloy AND toy OR toy materials

3. Cobalt AND migration OR release AND toy materials

4. Cobalt AND toxicokinetics

5. Cobalt AND bioavailability

6. Cobalt AND bioelution

6. Cobalt AND sensitisation AND toy OR toy material

8. Cobalt AND exposure AND toy OR toy materials

9. Cobalt AND nickel AND substitution OR alternatives

10. Nickel alloy AND cobalt

The types of documents:

- peer reviewed articles (the period covered: 01/01/2009 – 30/04/2021)
- journal entries (the period covered: 01/01/2009 – 30/04/2021)
- book chapters (the period covered: 01/01/2009 – 30/04/2021)
- government and non-government funded publications (the period covered: no time limitation)

Note 1: most articles are full-text available via the IP of the Commission. A few of them might only be available in abstract, but the library would be able to get the full text.

Note 2: different keywords can result in the same article being displayed several times

ANNEX 2

Calculation of the exposure scenario for 3-D pens and toy printers

Inhalation Scenario					
Toy					Notes
Ink extrusion rate	1,7	g/min			Most common extrusion rate for the ink
Emission of Co per printed toy mass	0,03	ng/g			
Age	3 - 6	yr	6.5 - 12.5	yr	
Exposure (play) time	30	min	60	min	
Extrusion time	15	min	30	min	Printing occurs only half of the time of play.
Printed toy mass	25,5	g	51	g	
Total Co mass emitted	0,765	ng	1,53	ng	
Room					
Volume of room	17,4	m^3			
Air change rate	0,3	hr^{-1}			Worst case from opinion on squishy toys
Age	3 - 6	yr	6.5 - 12.5	yr	
Co air concentration in room	0,15	ng/m^3	0,29	ng/m^3	
Child					
Age	3 - 6	yr	6.5 - 12.5	yr	
Body weight	16,3	kg	30	kg	For the 3-6yr group, weight of the 4.5yr (RIVM). For the 6.5-12.5yr, average weight.
Inhalation rate	1,26	m^3/hr	1,32	m^3/hr	Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure (ECHA) - short term inhalation rates
Exposure (play) time	0,5	hr	1	hr	
Frequency of play per day	1	/dy	1	/dy	The first days after purchase, at least once per day playing with the toy

Inhaled intake per day and body weight $\mathrm{Dinh}\left[\frac{\mathrm{mg}}{\mathrm{kg\ day}}\right]=\frac{\mathrm{Cinh}\left[\frac{\mathrm{mg}}{\mathrm{m}^3}\right]*\mathrm{IH\ air}\left[\frac{\mathrm{m}^3}{\mathrm{t}}\right]*\mathrm{T\ [t]}*\mathrm{n}[\frac{1}{\mathrm{day}}]}{\mathrm{BW\ [kg]}}$					
D_{inh}	**0,00566**	**ng/kg/dy**	**0,01290**	**ng/kg/dy**	Assuming all inhaled Co becomes bioavailable

Skin Contact Scenario					
Toy					Notes
Emission of Co per printed toy mass	0,03	ng/g			
Concentration of Co in toy mass	0,03	ng/g			It is assumed that all Co was emitted during the analytical test. Not the worst case approach, but no info available on w/w concentration of Co in 3D printing inks.
Age	3 - 6	yr	6.5 - 12.5	yr	
Printed toy mass	25,5	g	51	g	See "Inhalation" spreadsheet in this workbook
Mass of printed artefact in contact with child's skin	5,1	g	5,1	g	This is 20% of the mass of the printed artefact for the smaller age group and 10% for the older age group, due to finer motoric skills of the latter.
Child					
Age	3 - 6	yr	6.5 - 12.5	yr	
Body weight	16,3	kg	30	kg	For the 3-6yr group, weight of the 4.5yr (RIVM). For the 6.5-12.5yr, average weight.
Frequency of play per day	1	/dy	1	/dy	The first days after purchase, at least once per day playing with the toy
Dermal intake per day and body weight					
$Lder\left[\frac{mg}{cm^2}\right] = \frac{Qprod\,[g]*Fc\,prod\left[\frac{mg}{g}\right]}{Ader[cm^2]}$ $Dder\left[\frac{mg}{kg\,day}\right] = \frac{Lder\left[\frac{mg}{cm^2}\right]*Ader\,[cm^2]*n\left[\frac{1}{day}\right]}{BW\,[kg]}$					
D_{der}	**0,00939**	**ng/kg/dy**	**0,00510**	**ng/kg/dy**	Assuming all leached Co becomes bioavailable

Oral (Ingestion) Scenario					
Toy					Notes
Emission of Co per printed toy mass	0,03	ng/g			
Concentration of Co in toy mass	0,03	ng/g			It is assumed that all Co was emitted during the analytical test. Not the worst case approach, but no info available on w/w concentration of Co in 3D printing inks.
Age	3 - 6	yr	6.5 - 12.5	yr	
Printed toy mass	25,5	g	51	g	See "Inhalation" spreadsheet in this workbook
Mass of printed artefact ingested	0,1	g	0,1	g	According to European Commission (2016), Directive 2009/48/EC on the safety of toys
Child					
Age	3 - 6	yr	6.5 - 12.5	yr	
Body weight	16,3	kg	30	kg	For the 3-6yr group, weight of the 4.5yr (RIVM). For the 6.5-12.5yr, average weight.
Frequency of play per day	1	/dy	1	/dy	The first days after purchase, at least once per day playing with the toy
Dermal intake per day and body weight $D_{Oral} = \frac{Q_{prod} * FC_{prod\,intake} * n * 1000}{BW}$					
D_{oral}	**0,00018**	**ng/kg/dy**	**0,00010**	**ng/kg/dy**	Assuming all ingested Co becomes bioavailable

Summary of Intakes				
Age	3 - 6	yr	6.5 - 12.5	yr
D_{inh}	0,00566	ng/kg/dy	0,01290	ng/kg/dy
D_{der}	0,00939	ng/kg/dy	0,00510	ng/kg/dy
D_{oral}	0,00018	ng/kg/dy	0,00010	ng/kg/dy