



SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Cobalt in specific toy materials.

1. Summary

1.1. Cobalt metal (CAS: 7440-48-4) in all forms has a harmonised classification as a Category 1B carcinogen, Category 2 mutagen, and a Category 1B reproductive toxicant *via* all routes of exposure (Table 1) under the [GB Classification, Labelling and Packaging \(CLP\) regulation](#) No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. Additionally, cobalt metal is classified as a Category 1 skin and respiratory sensitiser.

Table 1: Classification of cobalt CMR categories under GB CLP regulations with hazard phrases and relevant comments.

Endpoint	Category	Hazard Phrase	Comment
Carcinogenicity	1B	H350	Presumed human carcinogen (proven in animals); for all routes of exposure (inhalation, oral, dermal).
Mutagenicity	2	H341	Suspected of causing genetic defects.
Reproductive Toxicity	1B	H360F	Presumed human reproductive toxicant; effects on fertility.

1.2. Owing to its classification as a Category 1B carcinogen and a Category 1B reproductive toxicant, the presence of cobalt is currently prohibited in toys or



toy materials when accessible at concentrations exceeding 0.1% or 0.3%, respectively, unless a derogation is laid down in Appendix A of the [Toys \(Safety\) Regulations 2011: Great Britain](#) (henceforth the Toy Safety Regulations). Cobalt is also subject to restricted migration limits which must be respected in addition to the Carcinogenicity, Mutagenicity, and Reproductive Toxicity (CMR) prohibition and any derogations; these limits are detailed in Table 2.

Table 2: Current migration levels for cobalt from toys or components of toys as listed in Annex II (Part III, Point 13) of the Toy Safety Regulations.

Element	Migration Limits (mg/kg)		
Cobalt	Dry, brittle, powder-like or pliable toy material	Liquid or sticky toy material	Scraped-off toy material.
	10.5	2.6	130

- 1.3. A dossier has been submitted to OPSS which aims to justify derogation for cobalt under exemption in accordance with the Toy Safety Regulations (Annex II, Section III, Point 4c) and listing in Appendix A of the Toy Safety Regulations. OPSS have hence requested that the SAG-CS review and provide a scientific opinion on the safety information provided within the submitted dossier.
- 1.4. The applicant has requested a derogation for cobalt in “toys and toy components made from stainless steel” and in “toy components which are intended to conduct an electric current”. The SAG-CS have considered these uses and the potential exposures from these uses only.

2. Presentation and Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

- 2.1. At their April 2022 meeting, the SAG-CS discussed a paper which focussed on risks posed to health by cobalt in toy materials. Following this meeting, further discussion was held specifically in relation to the [draft SCHEER opinion](#) on cobalt in toys and the text has been updated to reflect the specificity of the derogation for cobalt in stainless steel and components used for conducting electricity. The committee noted that the SCHEER Opinion on cobalt in toys covers the full range of toys that may contain cobalt (including those that will no longer be available because no derogation has been applied for) and that SCHEER have been unable to draw conclusions on these uses.



- 2.2. Discussions were held around the safety and risk of cobalt regarding its various carcinogenic, mutagenic, and reprotoxic classifications.
- 2.3. The group considered cobalt to exhibit a clear mutagenic potential. The group agreed that there was supporting evidence for a threshold-based mutagenic effect of cobalt, possibly as a result of an oxidative stress-based effect.
- 2.4. Members requested clarification on the migration limits for cobalt listed in the Toys (Safety) Regulations 2011 Great Britain. Members questioned the relationship between the migration limits in Annex II of the Toys Safety Regulations and chemicals listed under derogation in Appendix A. After the meeting, OPSS clarified that migration limits set in Annex II of the Toys Safety Regulation must still be adhered to, regardless of the status of a substance being included under derogation in Appendix A.
- 2.5. Exposure scenarios provided by the applicant were considered. These calculated a total exposure from three different scenarios of exposure – namely metallic material intended to conduct an electric current (such as a model rail track and joiners); other metallic material (such as ingestion of a small screw or ball-bearing); and nickel coated components. The table below gives exposure estimates as determined by the applicant which were considered reasonable by the SAG-CS.

Source	Population group	Route		
		Oral	Inhalation	Dermal
Metallic material intended to conduct electric current	Children 8+ and adults	0.93 $\mu\text{g}/\text{day}^1$	-	0.6 ng/week
Other metallic materials: ball bearing ingestion	Children, 2-8 years (bodyweight >12 kg)	15.6 $\mu\text{g}/\text{event}$	-	<0.01 μg cobalt/ cm^2/week
Nickel-coated components	Adults and Children	-	-	0.06 ng/week

- 2.7 These exposures were compared to the Tolerable Daily Intake (TDI) used by [RIVM in 2008](#) in relation to toy exposures of 1.4 $\mu\text{g}/\text{kg}$ bw/day. This was based on results from a human study in beer drinkers consuming cobalt

¹ This is a worst-case scenario assuming a maximal migration of cobalt from the toy and that all ingested household dust comes from use of the toy – which is unlikely.



sulphate which is used as a stabiliser in beer. This TDI would be equivalent to 98 µg/day for a 70-kg adult or 19.6 µg/day for a 14-kg child. Exposures from the defined scenarios were all significantly below the TDI.

2.8 Members agreed that exposure to cobalt through toys and toy materials is probable but that this exposure would be expected to be limited in its extent and can be considered likely to be below its potential capacity for mutagenic, carcinogenic and reproductive toxicity from the presence of cobalt within toy materials.

2.9 In summary the assessment by the SAG-CS of Cobalt in toys has not taken into account any cobalt exposures from sources other than the two specific types namely *“toys and toy components made from stainless steel”* and in *“toy components which are intended to conduct an electric current”*.

3. Conclusions

Members were satisfied that there was sufficient evidence to form an opinion at this stage.

The group agreed that cobalt presented a tolerable level of risk in light of the exposures identified when used in “toys and toy components made from stainless steel” and in “toy components which are intended to conduct an electric current” providing that migration levels listed in the Toys Safety Regulation are not exceeded.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

September 2022