Office for Product Safety & Standards



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

## Opinion on Aniline in Toy Materials.

### 1. Summary

1.1. Aniline (CAS: 62-53-3) has a harmonised classification as a Category 2 carcinogen and a Category 2 mutagen under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended).[1] A comprehensive summary of the physicochemical and toxicological information pertaining to aniline was provided within Annex 1 of SAGCS-092103.

1.2. Aniline is not presently found in Appendix C to Annex II of the Toy Safety Directive, which means it is currently not restricted in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth (Directive 2009/48/EC). Currently, as a substance that is classified as a Category 2 carcinogen and a Category 2 mutagen, the aniline content limit in toys is 1% (10,000 mg/kg) based on the generic exclusion of CMR substances and applicable thresholds under the Toys (Safety) Regulations 2011 Great Britain.

1.3. The Scientific Committee on Health and Environmental Risks (SCHER) considered, in its opinion of 29 May 2007, that compounds that are carcinogenic, mutagenic or a reproductive toxicant (CMR) should not be present in toys or toy materials. Further, the European Union Risk Assessment Report on Aniline concluded that for consumers there is a need for limiting the health risks associated with the use of products containing aniline, due to its CMR classification.

[1] The GB 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. The full consolidated UK text will be available soon.

1.4. The Committee for Risk Assessment of the European Chemicals Agency (RAC) indicated, in its opinion on restriction of substances in tattoo inks and permanent make-up, that aniline is considered a non-threshold carcinogen. Aniline may therefore cause cancer at even the slightest level of exposure. On the basis of its CMR classification, aniline, its salts, and halogenated and sulphonated derivatives are also prohibited for use in cosmetic products under Entry 22 of Annex II to the Cosmetic Products Regulation UK No 1223/2009 (as amended).[2]

1.5. At its meeting in September 2017, the EU's Working group on Chemicals in Toys (subgroup Chemicals) of the Expert Group on Toys Safety recommended the following limits for aniline in textile toy materials, leather toy materials and finger paints should be adopted as outlined in **Table 1**.

1.6. In light of the classification of aniline as a CMR substance, a number of scientific advisory committees provided reports/opinions on a limit to be set. Hence the European Union Risk Assessment Report on aniline, the opinion of RAC and SCHER and the opinions of the Expert Group in Toys Safety and its subgroup on Chemicals as well as the studies on the presence of aniline in textiles and the European Commission found it necessary to set a limit for aniline in textile toy material and leather toy material of 30 mg/kg after reductive cleavage and a limit for aniline in finger paints of 10 mg/kg as free aniline and 30 mg/kg after reductive cleavage. These values are the lowest concentrations that the reductive cleavage test can reliably identify and the lowest concentrations that can reliably be checked in routine tests of finger paints. These values therefore do not appear to have been set using a health-based end point.

1.7. The European Commission hence published Commission Directive (EU) 2021/903 of 3rd June 2021 amending Directive 2009/48/EC in accordance with the limit values stated above and in **Table 1**. This Directive came into force on the 24th June 2021 and the provisions within will apply in the EU on the 5th December 2022.

1.8. The SAG-CS have been asked to provide scientific advice on the risk posed to health by aniline in toy materials.

**Table 1: Proposed limit values for aniline in toy materials from EU's Working group on Chemicals in Toys (subgroup Chemicals) of the Expert Group on Toys Safety.**

| Substance | Toy Material | Limit Value |
|---|---|---|

[2] The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by SI 696/2019 Product Safety and Metrology (EU Exit) Regulations. The full consolidated UK text will be available soon.

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|---|---|---|
| Aniline | After reductive cleavage in textile toy materials and leather toy materials. | 30 mg/kg |
| Aniline | After reductive cleavage in finger paints. | 30 mg/kg |
| Aniline | As free aniline in finger paints. | 10 mg/kg |

## 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 September 2021 meeting, the SAG-CS reviewed a paper which focussed on the risks posed to human health by aniline in toy materials.

2.2. Members confirmed that analysis, detection, and quantification of aniline is well-established and, based on this criterion alone, there is scope to set lower limits than the “as low as reasonably practicable” (ALARP) limits as defined in Table 1. With respect to ALARP limits, members wished to express that such limits are maxima, and that effort must be made to reduce content to levels that are as low as achievable.

2.3. Members asked for clarity on the limit values of the reductive cleavage test. Members noted that the reductive cleavage test helps to identify the potential for aniline to be released and become bioavailable from azo-dye compounds under strongly reductive conditions. As such, the limits are conservative owing to the more moderate conditions found within the body. Additionally, members highlighted that the limit values for reductive cleavage tests are conservative as they are designed to be applied to a wide range of primary amines. It was noted that employment of state-of-the-art analytical equipment would likely be able to detect aniline at much lower levels.

2.4. A primary source of discussion was the conclusion from the RAC as to aniline being a ‘non-threshold’ carcinogen. To this end, members suggested reviewing more fully the available carcinogenicity and genotoxicity data to appraise modes of action of aniline and understand any dose-response behaviour.

2.5. Members agreed that a better understanding of the carcinogenicity and genotoxicity data would aid their ability to assess the risk to human health posed by low concentrations of aniline.

2.6. Members further considered that exposure to aniline in toys and toy materials is likely not limited to the dermal route. It is anticipated that children will chew or mouth textile and leather toy materials which may result in exposure via the oral route. Oral exposure to aniline via the ingestion of finger paints was also considered alongside potential inhalation exposure of powder form and unmixed finger paints.

2.7. Members wished to consider any potential adverse developmental outcomes due to exposure of aniline owing to the young age of those that would be predominantly exposed to such toys or toy materials.

2.8. Members expressed concern that no margin of exposure (MOE) would appear to have been calculated for aniline in toy materials.

2.9. Members stated that any proposed limit should not exceed the occupational exposure level for aniline set by the Health and Safety Executive (HSE), which is currently 1 ppm or 4 mg/m$^3$ over an 8-hour time-weighted average period, as occupational exposure to aniline has been linked with an increased risk of bladder cancer (Case *et al*, 1954; Case and Pearson 1954; Sorahan *et al*, 2000).

## 3. Conclusions

*Members were satisfied that there was sufficient evidence to provide a statement at this stage.*

*Despite a large amount of toxicological data being available, the group agreed that there was insufficient evidence to derive a health-based limit for aniline in toy materials. Members recommended undertaking a further review of the available data and to source further information from the public domain and other advisory and/or regulatory bodies. A better understanding of potential exposure to aniline would also be necessary in any future risk assessment.*

*Members agreed that there is sufficient scientific basis to indicate that aniline use in toys and toy materials may pose a risk to human health and therefore the current status could be updated. They indicated that the limit values adopted by the EU (Table 1) are likely to be adequately protective and could be implemented as an interim measure until health-based limit values can be derived. Provided that reliable analytical methods are available, the group suggests that further work could be undertaken to ascertain whether these levels should be further lowered.*

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

**January 2022**

## References

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