Raising standards for consumers

POSITION PAPER

Formamide:

no need for additional content-based limits in Appendix C of the Toy Safety Directive

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Summary

The present paper discusses the need for possible content limits for formamide for toys intended for use by children under 36 months or in other toys intended to be placed in the mouth to be inserted in Appendix C (in accordance with Article 46 of the TSD) to address possible health risks following ingestion of toy materials.

Based on available literature it arrives at the conclusion that it is very unlikely that formamide is present in such toys in relevant amounts and that, as a consequence, additional limits for formamide in Appendix C are not needed.

Background

Commission Directive (EU) 2015/2115 of 23 November 2015 introduced specific emission limits for formamide in Appendix C: 20 µg/m3 after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content).

According to Annex II Part III point 7 of the TSD the generic provisions regarding the use of CMR substances (points 3, 4 and 5 of Annex II Part III) shall not apply to materials that comply with the specific limit values set out in Appendix C. This means in case of formamide that the general content-based limit of 0,3% (for substances classified as toxic to reproduction category 1B) is superseded by the emission limit stated above. In other words, no content-based threshold for formamide applies to toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. Hence, the question was raised whether this could constitute a safety gap, whether formamide could be present in such toys complying with the emission limit in Appendix C in amounts that could constitute a health hazard.

1. Key considerations

1.1 Relevant thresholds for oral exposure

In its opinion "on the uses of formamide in consumer goods and health risks related to formamide in children's foam puzzle mats"[1] ANSES identified an applicable NOAEL of 20 mg/kg/d formamide for effects on haematological parameters observed in animals and used an uncertainty factor of 500 resulting in a limit for long term internal exposure dose of 0.04 mg/kg/d.

Assuming a body mass of a child of 10 kg and a daily intake of 8 mg toy the maximum formamide concentration in a (solid) toy material to address ingestion would be 50 g/kg (i.e. 5%). The maximum allowed migration (from 10 cm^2) would be 0.4 mg/d for a child of 10 kg.

1.2 Measured formamide content values in puzzle mats

The maximum concentration of formamide in puzzle mats reported in the ANSES report (page 26) was 1,3 g/kg. The maximum concentration reported by Istituto Superiore di Sanità (EXP-WG-2011-038) was 2,8 g/kg. No higher value could be identified in the reports made available to the Chemicals Subgroup. These values are far below any concern – even the highest value is below the acceptable level of 50 g/kg. In addition, foams complying with the TSD emission threshold would have content levels far below the maximum values measured.

1.3 Migration of formamide from puzzle mats

ANSES commissioned also measurements of formamide migration from puzzle mats and calculated the exposure following mouthing (and ingestion based on content measurements). They stated in their opinion: "The data collected during this expert assessment indicate that exposure of children and adults occurs almost exclusively by inhalation; the ingestion exposure route (mouthing, direct ingestion of pieces) is negligible".

1.4 Migration of formamide from other toys

The Danish EPA published a report entitled "Migration and health assessment of chemical substances in surface treated wooden toys"[2] in 2005. It identified two toys containing formamide at levels of 18 and 69 µg/g using a migration method. Using a NOAEL of 50 mg/kg bw/day a Margin of Safety (MOS) of more than 2300 was calculated for the higher value. Using the NOAEL of 20 mg/kg/d mentioned above would still result in a MOS of 920.

[1] https://www.anses.fr/sites/default/files/documents/CHIM2010sa0302Ra-2EN.pdf
[2] http://www2.mst.dk/Udgiv/publications/2005/87-7614-712-6/pdf/87-7614-713-4.pdf

1.5 Other consumer products

According to the ECHA database formamide is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year. This substance is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has not been registered for any consumer use or for the production of articles in Europe. However, this does not preclude its use in the manufacture of consumer articles outside of Europe.

Annex VII of the ANSES report summarises existing reports about (few) consumer-relevant uses. This includes, in particular, the (former?) use of formamide in certain writing instruments such as felt pens. ANSES concluded that these evaluations have shown little concern ("En conclusion, les différentes évaluations réalisées ont statué que l'exposition au formamide présente un niveau faible de préoccupation (US EPA, 1986; OEHHA, 1997; OCDE, 2007; Santé Canada, 2009)").

The most recent assessment mentioned was conducted by Environment/Health Canada in 2009[3]. The assessment states: "Due to its primary use in industrial settings, the general population is not expected to be exposed to formamide. Exposure is possible from ink in marking pens, where it has been used as a solvent" (with a formamide content of the ink of up to about 30%). In the risk assessment model, it was assumed that an individual may be exposed to an estimated 25 cm of ink line per day resulting in an estimated uptake of 22.2 to 56.4 µg/kg bw per day for a child aged 0.5–4 years via dermal exposure. Using the lowest dermal LOAELs of 300 mg/kg bw per day resulted in MOEs of 5 300 to 13 500.

NOTE 1: If the NOAEL of 20 mg/kg bw per day had been used (as e.g. by ANSES) the MOE would have been only 353 which may not be sufficient (below the uncertainty factor of 500 used in the ANSES risk assessment).

Environment/Health Canada concluded "that formamide should be considered as a substance that is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health".

NOTE 2: A felt pen (or the like) is considered as a combination of an article (functioning as a container or a carrier material) and a substance/mixture in REACH (see ECHA Guidance on requirements for substances in articles, 2017). From this follows that the use of formamide in a felt pen would have to be registered under REACH. Given that this has not been the case it can be assumed that it is not used for this purpose.

NOTE 3: According to entries 28-30 of Annex XVII of REACH it is not allowed to place CMRs cat. 1A and 1B on the market for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

[3] https://www.ec.gc.ca/ese-ees/AD68092D-857E-47FC-9FB9-91810449C249/batch5_75-12-7_en.pdf

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008.

Assuming that a felt pen (or the like) is considered as a combination of an article and a substance/mixture the concentration of formamide in the mixture would be limited to 0,3%.

Conclusions

It can be concluded from existing data that the oral exposure (ingestion as well as licking/chewing) from formamide included in puzzle mats (or similar foam materials used in toys) is negligible. There is little indication that oral exposure from other toys is relevant. The only consumer products identified containing higher amounts of formamide were writing instruments such as marker or felt pens. Whilst the formamide exposure from such products would merit further investigation regarding associated risks it is unlikely that such products can be found on the European market because the use for this purpose would require REACH registration. However, no such use has been registered. In addition, according to entry 30 of REACH the concentration of formamide in the mixture would have to be limited to 0,3%. A content based threshold in Appendix C does not seem necessary.

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About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

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