

# Formaldehyde

## Proposed requirements for Appendix C of the Toy Safety Directive

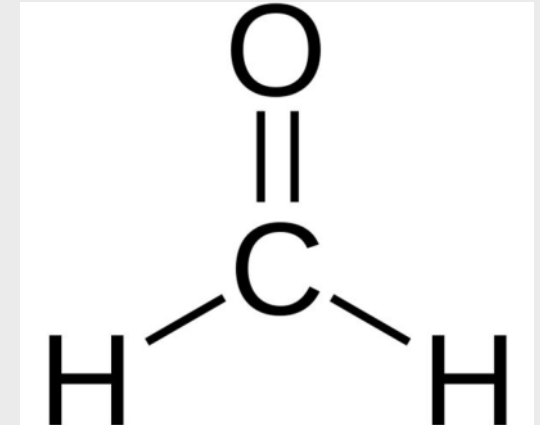
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# Formaldehyde summary

## Proposed limits:

- for **textile** components of toys, a limit of 30 mg/kg in line with EN 71-9;
- for **paper** components of toys, a limit of 30 mg/kg in line with EN 71-9;
- for formaldehyde as a **preservative** an exclusion based on a LOQ;
- for formaldehyde used as a **monomer** a limit of 1,5 mg/l per litre of simulant in in the aqueous migrate in accordance with EN 71-10;
- for formaldehyde **emissions from resin-bonded wood** components of toys the requirement to use wood based panels complying with E1 classification when tested in accordance with the relevant European standard.



# Formaldehyde - skin sensitisation

## Textiles and paper:

- for textile components of toys, a limit of 30 mg/kg in line with requirement included in EN 71-9
- for paper components of toys, a limit of 30 mg/kg in line with requirement included in EN 71-9
- broadly in line with limits in legal and voluntary specifications for small children (i.e. in the range from 16 ppm to 30 ppm)
- corresponds to lowest levels reported for elicitation of skin sensitisation
- possible restriction of formaldehyde based on Article 68(2) of REACH, ongoing consultation, proposed limit 50 ppm for all covered textile products



# Formaldehyde - skin sensitisation

## Liquid toys:

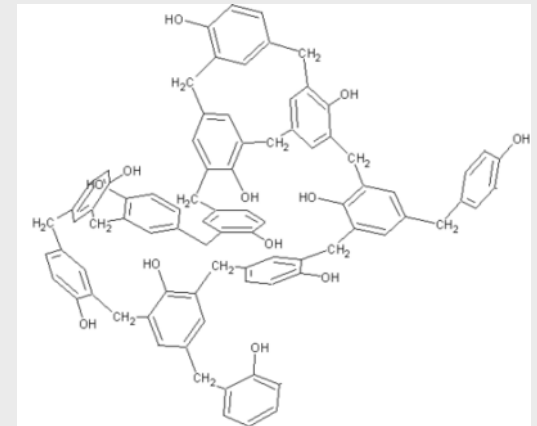
- **for free formaldehyde as a preservative an exclusion based on a LOQ;**
- **EN 71-9 limit for preservatives (other than wood preservatives): 0,05 % free formaldehyde**
- **EN 71-7 limit for free formaldehyde in finger paints 0,1 % (allows paraformaldehyde)**
- **Cosmetics Regulation: products above 0,05 % to be labelled “contains formaldehyde”, limit oral products 0,1%, other 0,2%**
- **Groot et al. 2009: 200-300 ppm for induction, lower levels for elicitation ⇒ 0,05% “is not strict enough and the concentration required for the labelling should be lowered”**



# Formaldehyde – oral exposure

## Polymers:

- **for formaldehyde used as a monomer a limit of 1,5 mg/l per litre of simulant in in the aqueous migrate prepared in accordance with EN 71-10**
- **Regulation on plastic materials and articles intended to come into contact with food: group restriction 15 mg/kg (food) (= 0,25 mg/kg bw\*day)**
- **corresponds to the limit given in EN 71-9 (2,5 mg/l = 0,25 mg/100 ml = 0,25 mg/child\*day)**
- **NOEL identified by WHO for oral long–term exposure: 15 mg/kg bw\*day corresponding to TDI of 0,15 mg/kg bw\*day (safety factor 100)**



# Formaldehyde - inhalation

## Wood-based materials:

- for formaldehyde emissions from resin-bonded wood components of toys the requirement to use wood based panels complying with E1 classification when tested in accordance with the relevant European standard
- current limit in EN 71-9: 80 mg/kg when tested in accordance with EN 717-3 (flask method)
- flask method suitable only for internal production control (presentation Reindl, EXP-WG-2015-016)
- also limit questionable (BfR, 2007) - German limit at the time 110 mg/kg after 24 hours of testing and 30 mg/kg after 5 hours (EN 717-3: 3 hours)
- WHO indoor air limit 0,1 mg/m<sup>3</sup> (sensory irritation), contribution of toys 5% (Maciej)?, 10% (BfR)?





# Formaldehyde - inhalation

## Study initiated by BfR:

- TÜV Rheinland LGA, Nürnberg (Maciej et. al., DLR, 2011)
- bad correlation (deviation from target test mass 20 g up to 20%, different surface/volume ratios)
- proposal: modified EN 717-1 (test chamber)
- 3 size classes of toys and related number of toys per room
  - class 1 (large):  $> 0,1 \text{ m}^3$ , 1 piece/room
  - class 2 (medium):  $0,001 - 0,1 \text{ m}^3$ , size dependent number of pieces
  - class 3 (small):  $< 0,001 \text{ m}^3$ , 20 pieces
- volume means minimum cuboid circumscribing the toy



# Formaldehyde - inhalation

## Study initiated by BfR:

- disadvantages:
  - different limits per area unit of material (unusual), the bigger the article, the more demanding the limit
  - number of items changes – small volume increments may lead to big changes (e.g. 2 items instead of 1)
  - different sizes of pieces – which ones to select for testing?
  - load in test chamber  $\neq$  load in room (prEN 16516 requires that load factor chamber = 50% to 200% of load factor model room, but deviation possible) – in calculation included





# Formaldehyde - inhalation

## Alternative options:

- use complete toys and define room load factor (e.g.  $3 \text{ m}^2/30 \text{ m}^3$  in room =  $0,1 \text{ m}^2/\text{m}^3$ ), adjust test chamber and/or load factor in chamber
  - problem: determination of toy area, different chamber sizes may be required, ....
- use cut toy samples, define load factor in chamber e.g.  $0,1 \text{ m}^2/\text{m}^3$ , use sealed cut areas
- simple solution: require toys made of panels class E1 (EN 13986), i.e. use load factor of  $1 \text{ m}^2/\text{m}^3$  in chamber, but also higher limit of 0,1 ppm, use cut toy samples for market surveillance
- gas analysis method (EN 717-2) inadequate:
  - sample size 5 cm x 40 cm x thickness
  - expensive device – only usable for this test





**For a non-toxic environment!**

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