

## Limit values for phenol in food-contact articles and toys are to be updated

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Phenol is used, amongst other things, in the production of plastics and dyes. The substance may be contained in packaging material for food and in toys. In animal experiments a specific minimum dose of the substance is toxic. Hence, there are limit values to prevent any risks to consumer health. These limit values are guided by the Tolerable Daily Intake (TDI), i.e. the amount of a substance that can be consumed daily throughout a lifetime without any health risk. The TDI value for phenol is currently 1.5 milligrams per kilogram body weight and day. This value was established more than 40 years ago on the basis of the data available at the time. A current EU assessment has, however, shown that the value is in the range where harmful effects are still observed in animal experiments, i.e. 1.8 milligrams per kilogram body weight and day (LOAEL). Hence, BfR is of the opinion that the existing limit values for phenol in food-contact articles and toys are not adequate.

At the present time, BfR cannot undertake a health assessment of the risk as no data have been submitted to BfR concerning how much phenol is contained in and can be released from food-contact materials or toys. Hence, the Institute is unable to estimate how much phenol consumers ingest from toys or food to which the substance has migrated from the packaging material or cooking utensils. Yet there are indications that phenol can be released from these. BfR therefore recommends that the competent bodies gather the latest data on the release of phenol which could serve as the basis for an exposure assessment. BfR also recommends that the European Food Safety Authority (EFSA) reassess the TDI and that the German Institute for Standardization (DIN) and the European Committee for Standardization (CEN) use this value for the elaboration of safety standards.

### 1 Subject of the Assessment

The Federal Institute for Risk Assessment (BfR) has reviewed the substance assessment of phenol and thus derived a need for action for food contact materials, toys and other utensils and consumer products.

### 2 Results

The limit values for phenol for food contact materials, toys and other utensils are still based on a TDI (Tolerable Daily Intake) value of 1.5 mg/kg body weight (BW)/ day, which was determined in 1968 by the former SCF (Scientific Committee for Food) based on the data available at the time. This TDI is in the range of the LOAEL (Lowest Observed Adverse Effect Level) value of 1.8 mg/kg BW/day referred to in the 2006 EU Risk Assessment Report. If these values are reached, adverse health effects can no longer be ruled out, and according to the present state of scientific knowledge the limit values are too high. BfR thus emphasises the need to reassess the values for phenol.

### 3 Reasons

Phenol (CAS-Nr. 108-95-2, PM-Nr. 22960) is an important intermediate product for organic synthesis. Phenol is also contained in exhaust emissions and occurs in combustion processes such as smoking cigarettes as well as within human and animal organisms during xenobiotic metabolism.

### 3.1 Hazard potential of phenol

A current EU Risk Assessment Report for phenol summarises the state of knowledge on the subject (ECB 2006). The principal facts are briefly outlined here:

Phenol is absorbed well after oral intake and inhalation as well as following dermal application. A percutaneous absorption of 19% was determined in *in-vitro* experiments with human skin. In the human organism, phenol is metabolised predominantly to its sulfate and glucuronide conjugates and excreted in urine (ECB 2006).

At high dosages, the acute toxicity of phenol is fatal: Animal tests with Wistar rats were used to determine an LD<sub>50</sub> ranging from 340 to 530 mg/kg BW after aqueous phenol preparations were administered orally. A case report of a human poisoning indicates an effective dose of 140 to 290 mg/kg BW following oral intake (ECB 2006).

Several studies have revealed immunotoxicity and hematotoxicity following oral administration as the most sensitive parameters (including a decrease erythrocyte counts) in mice which received phenol in drinking water over a period of 28 days. Even the lowest dose of 1.8 mg/kg BW showed an effect and must therefore be regarded as LOAEL (Hsieh et al. 1992).

Several studies have evaluated the genotoxicity and mutagenicity of phenol. Phenol induced no mutations in bacterial gene mutation tests. Various mammalian cell gene mutation assays are reported to reveal positive effects for chromosomal aberrations, micronuclei and gene mutations. Phenol was classified according to the 29<sup>th</sup> ATP in Annex I of Directive 67/548/EEC as mutagen in Category 3.

Long-term animal studies revealed no carcinogenic effect of phenol following oral administration in rats as well as in mice (ECB 2006).

### 3.2 Phenol concentrations in utensils and toys

In a meeting of the BfR Committee for Toys of the BfR Committee for Consumer Products, BfR was informed of a report by the Bavarian regional authority for health and food safety (*Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit*) concerning the concentration of phenol in consumer products with mucous membrane contact. According to this information, concentration ranged from 400 to 500 mg/kg. A migration test in water (in compliance with EN 71-9) revealed that phenol migrates at amounts of 15 mg/kg to 110 mg/kg into the aqueous preparation. Furthermore, there are indications that suggest that packaging film can be highly contaminated with residual solvents that contain phenol. The packaging of a swim tube was found to have 129 mg/kg phenol migration into an aqueous preparation (1 h, 40°C).

### 3.3 Exposure assessment for consumers

It is not known whether the occurrences listed above are isolated cases. BfR has no further data on the release of phenol from utensils or other consumer products. A realistic exposure assessment for consumers is thus not possible.

### 3.4 Risk characterisation

In the German consumer goods ordinance (*Bedarfsgegenständeverordnung*), phenol is listed without restrictions in Appendix 3, Section 1, Part A. Therefore the migration value of 60 mg/kg foodstuff applies. The source for this classification was the TDI of 1.5 phenol/kg BW/day which was derived in 1968 by the former SCF (Scientific Committee for Food) based on data available at the time.

BfR assumes that this TDI also served as a basis for the deduction of the migration value of 15 mg/kg for toys in accordance with EN 71-9.

BfR is not able to carry out a risk characterisation at this time due to a lack of information regarding exposure.

### 3.5 Discussion

Over the course of the enquiry on phenol, it became apparent that the TDI of the former SCF of 1.5 mg phenol/kg BW/day does not reflect the current assessment in the EU Risk Assessment Report as this report contains a LOAEL of 1.8 mg/kg BW/day for oral administration. Since the limit values are based on a TDI of 1.5 mg/kg BW/day, which lies in the range of the LOAEL of 1.6 mg/kg BW/day, the occurrence of adverse health effects cannot be ruled out if these values are reached. BfR therefore deems a reassessment of phenol necessary.

This has already been carried out for flavourings. The European Food Safety Authority (EFSA) has assessed phenol and phenol compounds based on the EU Risk Assessment Report. The Authority classified an estimated exposure of 0.18 µg phenol/kg BW/day through foodstuffs to constitute no safety concern, and in regard to LOAEL a margin of exposure of 10,000 was calculated (EFSA 2008).

## 4 Scope for action

BfR recommends an enquiry of the competent regional authorities in order to clarify whether or not food contact materials and other consumer goods as well as toys have been tested for the release of phenol and what the results were. In addition to the Federal Office of Consumer Protection and Food Safety (BVL), the technical inspection agencies and other independent testing laboratories that analyse toys in accordance with the German Equipment and Product Safety Act should also be asked to provide their data.

BfR intends to present EFSA the question of reassessment of the TDI for phenol in food contact materials. Furthermore, BfR intends to draw the attention of the German Institute for Standardization (DIN) and the European Committee for Standardization (CEN) to the necessary consequences for the European norm on toy safety (EN 71-9).

## 5 References

ECB. European Union Risk Assessment Report - Phenol. 1-240. 2006.

EFSA (2008). Flavouring Group Evaluation 88. Consideration of Phenol and Phenol Derivatives evaluated by JECFA (55th meeting). Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. *The EFSA Journal* 857, 1-18.

Hsieh, G. C., Sharma, R. P., Parker, R. D., and Coulombe, R. A., Jr. (1992). Immunological and neurobiochemical alterations induced by repeated oral exposure of phenol in mice. *Eur J Pharmacol* 228(2-3), 107-114.