



PRODUZIONE ARTICOLI TECNICI INDUSTRIALI IN POLIURETANO E GOMMA

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Background

With this comment we would like to present the experience and the opinion of a company producing polyurethane based articles.

Hazard assessment

Experimental data clearly document that 4,4'-methylene-bis-(2-chloroaniline) (MOCA) is carcinogenic for animals, leading to the classification as carcinogen 1B according to CLP Regulation.

However, the relevance of this effect for humans is not clearly defined, since human data are conflicting: in spite of isolated case reports of urothelial cancers in workers exposed to MOCA [1, 2, 3, 4], published studies show that the incidence of neoplasms in workers exposed to MOCA is lower than in general population or - at least - it is not increased [5].

We acknowledge that the mentioned studies were conducted on a small number of subjects, with a short follow-up period, and that a "healthy worker effect" can not be excluded. However, the existing uncertainties should be considered in the assessment of the level of concern posed by this substance.

Mechanism of action

The mechanism underlying the MOCA carcinogenic action is not fully understood. MOCA shows some structural similarity to other aromatic amines; moreover, experimental data show a possible mutagenic activity. However, even if the substance is considered a genotoxic carcinogen [6], carcinogenicity studies show a dose-effect relationship [7], suggesting the existence of a non-effect threshold.

Exposure assessment

Available information documents that airborne levels of MOCA can be kept at very low levels (ten fold lower than the occupational exposure limit) [8, 9]. Internal data from our company confirm these observations, with concentrations as low as $< 1 \mu\text{g}/\text{m}^3$.

The published literature rises concern about surfaces contamination and subsequent cutaneous exposure and absorption [10]. However, data on the amounts of MOCA detectable on workplace surfaces fall in a very broad range of concentrations [11], suggesting that proper handling

procedures may limit at very low levels the surface contamination and hence the potential of skin absorption.

Comments on alternatives

According to our knowledge, alternatives to MOCA are 10 to 20 fold more expensive. Moreover the performance of polyurethane products prepared with MOCA alternatives are less than optimal; in some cases this may represent a safety concern, especially when such articles are used in mechanical parts of machinery.

In our opinion the externalization of the market of MOCA-polyurethane articles outside the EU is not likely: according to our experience, most clients require customized items, with an high degree of personalization, each of them in a limited number of pieces. This scenario requires a direct contact between the manufacturer and the customer.

In order to maintain the same performance, a shift to PVC-based articles can be foreseen; therefore, the health consequences (exposure of a larger number of workers to the known carcinogen 1A vinyl chloride monomer) and the socio-economical impact of this market shift should be considered.

Conclusive remarks

As the market is not yet prepared to deal with the substitution of MOCA both from technical and economical point of view, we suggest as ad interim measure the establishment of an occupational exposure limit (OEL) and a related biological exposure index (BEI) able to warrant the reduction of MOCA exposure to the lowest achievable level (based on the best available technologies). The combination of OEL and BEI is proposed in order to warrant that skin exposure is taken in account too.

The suggested strategy (aimed to protect workers from MOCA exposure) is consistent with the remarks discussed in the Annex XV document, where the concern is related to workers but not to consumer exposure.

The substitution of MOCA will be welcome when options with a more favourable toxicological profile and assuring comparable performances will be available.

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