

Safety assessment of tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) for use in coating in canned food packaging materials

Conclusions

In this guide

[In this guide](#)

1. [Summary and Introduction](#)
2. [Assessment of non-toxicological data](#)
3. [Assessment of toxicological data](#)
4. [Exposure Assessment /Risk characterisation](#)
5. [Conclusions](#)

Conclusions

61. The FCMJEG, COM and COT considered all available information at their respective meetings. It should be noted, that while testing was performed on TMBPF-DGE, as well as the epoxy resin, the following conclusions are on the safety of TMBPF-DGE only, and do not include evaluation of any of the other chemicals included in the manufacture of the epoxy resin or final product.

62. The migration of TMBPF-DGE and its derivatives was based on extraction in acetonitrile, which Members of the Committees agreed was the worst-case extraction and hence would be the worst-case migration of TMBPF-DGE. The anticipated migration of 1 mg/kg food is low and within the specific migration limit. The anticipated migration is also below the restriction of 9 mg/kg food applied to BADGE and bisphenol F diglycidyl ether (BFDGE), its closest comparators.

63. The Committees considered TMBPF-DGE to be genotoxic in vitro. However, while some uncertainties remain, specifically around the potential of TMBPF-DGE to induce polyploidy, the in vivo genotoxicity data were negative and provided a sufficient margin of safety. Overall, the Committees agreed that it is unlikely that there would be a risk to human health from any mutagenic effect of TMBPF-DGE.

64. Members concluded that the available, albeit screening-level, data on non-genotoxic endpoints did not indicate any reproductive or developmental effects at a concentration of 300 mg/kg or raise any other toxicological concerns at exposures of ≤ 100 mg/kg.

65. While not a requirement for the assessment, the endocrine data available for TMBPF-DGE epoxy resin were of good quality with the Committees concluding that there was no concern over endocrine effects of TMBPF-DGE at the expected exposure levels.

66. Members did not consider it appropriate to establish a HBGV due to the lack of a long term/chronic toxicity study and other database deficiencies.

67. Whilst uncertainties remain over the toxicological significance of the polyploidy induced by TMBPF-DGE and any potential long-term effects a chronic study may have revealed, the Committees concluded that there was sufficient information available to assess the safety of TMBPF-DGE under the proposed conditions of use.

68. When considering all available information, including a comparison of TMBPF-DGE with bisphenol A diglycidyl ether (BADGE), its closest comparator, the available data did not identify any safety concerns for the usage of TMBPF-DGE in can coatings. The MOE was at least 67,000, well above the value of 1000 considered to indicate a lack of any safety concern. In addition, the TTC approach provided re-assurance, given its in-built conservatism and supported the conclusion that the estimated exposure to TMBPF-DGE would be below any level of potential concern. Hence, the FCMJEG and COT did not see any scientific reason to apply restrictions to the proposed usage of TMBPF-DGE.

COT/FCMJEG

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