Can coatings safety assessment

Safety assessment of Tetramethyl bisphenol F diglycidyl ether (TMBPF-DGE) and a literature review for methacrylic acid, 2-hydroxypropyl ester (synonym: 2-hydroxypropyl methacrylate - (HPMA)) for use in can coatings.

TMBPF-DGE

TMBPF-DGE is a coating intended as an acceptable and alternative replacement for bisphenol A (BPA) and bisphenol F (BPF) to use in epoxy linings of aluminium cans and steel cans used in the food industry. Several global brands already market cans coated with TMBPF-DGE.

In 2022, the Dutch Authorities included TMBPF-DGE in their revision of the Dutch Commodities Act (Warenwet), allowing it to be used as a coating in canned food packaging subject to the specific restrictions. In accordance with mutual recognition principles, goods lawfully placed on the single market within an EU member state can also be freely placed on the market within Northern Ireland under the Windsor Framework.

A decision was therefore required to determine whether TMBPF-DGE could be allowed to be used in products for the GB market under similar conditions.

Safety assessment summary

The application was evaluated by:

- the independent Advisory Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)
- the Committee on Mutagenicity (COM)
- and the Joint Expert Working Group on Food Contact Material (FCMJEG)

The FSA/FSS safety assessment was published on 20 September 2024 and can be found here on the Food Contact Materials Joint Expert Group (FCMJEG) and COT website. The assessment of available data did not identify any safety concern for the usage of TMBPF-DGE in can coatings. Hence, the Committees did not see any scientific reason to apply restrictions to the use of TMBPF-DGE. Based on the Committees' conclusions the FSA and FSS concluded that TMBPF-DGE is safe under the expected conditions of use.

FSA/FSS Risk Management Recommendations

The FSA/FSS concludes that TMBPF-DGE, is safe and is not liable to have any adverse effects on human health or on environmental safety at expected levels and intended conditions of use. The below guidelines on specific migration limits (SML) are set out on the Dutch Commodities Act.

Tetramethyl-bis(4-hydroxyphenyl) methane, reaction product with epichlorohydrin (TMBPF-DGE):

- SML (T) = 0.2 mg/kg (sum of TMBPF, TMBPF-DGE, TMBPF-DGE.H_2O and TMBPF-DGE .2H_2O) [4]

- SML(T) = 0.05 mg/kg (sum of TMBPF-DGE.HCl, TMBPF-DGE.2HCl and TMBPF-DGE .HCl.H_2O) [4]

2-hydroxypropyl methacrylate (HPMA)

A literature review was carried out to identify any reports, data or evidence regarding HPMA since the publication of the EFSA Opinion in 2012. HPMA is used in acrylic resin coatings for food cans for all types of food.

EFSA published a positive opinion on HPMA in 2012 (EFSA, 2012). Given that time has elapsed since the EFSA Opinion, a literature search was conducted on HPMA to identify whether any new evidence or data may have been published which would change or raise concerns regarding the conclusions of the EFSA assessment.

Safety assessment summary

Based upon the literature review, no new evidence/data on the toxicity of HPMA, following oral exposure, has been published since the EFSA 2012 Opinion. It is not clear whether these monomers are used in the industrial manufacture of can-coating(s) which are in contact with food and thus there is considerable uncertainty surrounding the final mixture/coating. Therefore, it is not clear whether or how potential sensitisation may relate to the use of HPMA in FCMs.

FSA/FSS Risk Management Recommendations

Given that no new evidence was identified that raised a safety concern or the validity of the original EFSA Opinion, there is no safety concern if HPMA is used as a monomer in acrylic resin coatings for food cans under the appropriate conditions of use (at use levels up to 20%).

More information

See the latest updates from the Committee on Toxicity (COT) of Chemicals in Food, Consumer Products and the Environment