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Reviewed by FEICA. B.Ghyoot, July 16th 2010

Migration Modelling, Theoretical Migrates from Adhesives in Food Packaging and Adverse Press Comment.

The lack of a uniform regulation across Europe for food packaging and the use of substances in packaging adhesives led the European adhesives industry to propose a study to evaluate the adoption of a mathematical modelling approach to identifying any potential migration into the food from the substances used in the adhesive formulations. The three-year project was welcomed by the Commission, which agreed to partly fund the programme to develop a pragmatic, science based tool to support existing and future EU regulation for adhesives, used in food packaging.

This 3 million € project, involving 21 partners across 8 countries, has been successful and produced a mathematical modelling tool for predicting migration and software which can be used across the food packaging supply chain. The interim results and the modelling tool have been presented to industry by national adhesive associations throughout Europe with plans for the full results to be made publicly available later this year. The findings show that the study has been highly successful in demonstrating that a Migration modelling tool will prove effective to meet probable future regulatory requirements as it was recognised by the Commission on the closing conference.

One of the project partners the Spanish University of Zaragoza (UNIZAR) published the results of its part of the project in several papers, one of them submitted to the Royal Society of Chemistry's learned *Journal of Materials Chemistry*. This paper, entitled "*Partition and diffusion of volatile compounds from acrylic adhesives used for food packaging multilayer manufacturing*" describes one small part of the results.

UNIZAR's contribution was to compare and validate the predicted results of the mathematical modelling software conducted by other partners, with analytical experiments, on various food-packaging adhesives and packaging configurations. The UNIZAR paper must be reviewed in the context of this project. Since publication the researchers have confirmed that their reported findings of the estimated daily intake in their studies were above the exposure value recommended by Cramer¹ but below the US Environmental Protection Agency values most widely referenced by the European and US food industry.

¹ G. M. Cramer, R. A. Ford and R. L. Hall, *Food Cosmetic Toxicology* 1978, 716, 255–276.

UNIZAR's paper was widely reported in the British press, however, the reports were both inaccurate and misleading and we would like to correct the impressions that have been created.

Several of the reports focused upon the detected migration of one particular chemical in these experiments, 2,4,7,9-tetramethyl-5-decyne-4,7-diol, CAS No. 126-83-3 (TMDD) and sensationally compared the substances detected to hydrochloric acid, asbestos etc ². TMDD was detected in one adhesive material used in a limited number of indirect food contact applications. TMDD is a substance that when classified according to Cramer rules, is suspected to exhibit high toxicity requiring further investigation.

The following are the salient points to be considered when reviewing the UNIZAR paper:

- The adhesive samples supplied by manufacturers for this study were the same composition as those supplied in the market. However, the laboratory samples prepared were made for scientific experiment only and were not representative of the actual commercial food packaging applications (for more technical details see Annex 1).
- Classification according to Cramer rules makes a theoretical evaluation of toxicity based upon the chemical structure of the molecules, but it does not take into account the experimental toxicity determinations. It is a method used by biochemists to identify if a chemical requires toxicological testing rather than rules that determine the actual toxicity of that chemical. TMDD in fact has a very low toxicity based upon testing on aquatic organisms and animals (for more technical details see Annex 2).
- It is also important to highlight that the cytotoxicity of these adhesives and the laminates produced from them have been experimentally evaluated in the MIGRESIVES Project; none of the adhesive formulations tested, exhibited cytotoxicity.

Background

This paper was issued to a number of journalists in February 2010.

The Royal Society of Chemistry, UK published in May 2010 the paper an abstract of which can be found on the Internet:

[http://www.rsc.org/delivery/ArticleLinking/DisplayHTMLArticleforfree.cfm?JournalCode=JM&Year=2010&ManuscriptID=c0jm00514b&Iss=Advance Article](http://www.rsc.org/delivery/ArticleLinking/DisplayHTMLArticleforfree.cfm?JournalCode=JM&Year=2010&ManuscriptID=c0jm00514b&Iss=Advance+Article).

FEICA

FEICA, the European Adhesive & Sealant Manufacturing Association, is a multinational association representing the European Adhesive and Sealant Industry. With the support of 14 national associations and over 16 direct members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA aims at establishing a constructive dialogue with legislators in order to act as a reliable partner to resolve issues affecting the European Adhesive and Sealant Industry.

For Further information: contact Mr. Bernard Ghyoot, FEICA General Secretary.

Telephone: +32 476 53 53 78

E-mail: b.ghyoot@feica.eu

Website: www.feica.eu

Annex

Annex 1:

- The coat weight of the TMDD containing adhesive is typically used with a maximum of 5% of the surface to be bonded. However, 100% coverage was required for the laboratory diffusion experiments, and it was from these laboratory samples that the migration of TMDD was found. The actual exposure is significantly below the laboratory determined level and is estimated to be 0,013 mg/person/day, which is significantly below the maximum established as potentially toxic by the Cramer study. It therefore represents no risk to consumers.
- The manufacturer of the adhesive concerned does not add TMDD to the product, however, a surfactant containing ethoxylated TMDD (CAS No. 9014-85-1) is used in the formulation and it has been demonstrated that the TMDD detected, was a result from the decomposition of this surfactant. Nevertheless, the Spanish manufacturer of the adhesive has removed this surfactant from the adhesive formulation as a precaution.

Annex 2:

- TMDD has been reviewed by the U.S. Environmental Protection Agency (US EPA)² which determined in 2008 that TMDD was a low priority for further review in the chemical assessment and management program. US EPA recognized the potential for the general population to be exposed from environmental releases due to the commercial use of TMDD and its low biodegradation rate. Based upon the low human health hazard, there was a low concern for potential risks to the general population from environmental releases, which means a lowest observed adverse effect level (LOAEL) of 200 mg /kg body weight/day. Considering an average value of 60 Kg/person, the estimated daily intake (EDI) value from the experimental data of migration obtained by the University of Zaragoza for 2,4,7,9-tetramethyldec-5-yne-4,7-diol (TMDD) will be 0.004 mg /Kg body weight/day. This value is very significantly below the recommended LOAEL value.
- Furthermore, both TMDD (CAS No. 126-83-3) and ethoxylated TMDD (CAS No. 9014-85-1) are listed in the US Food and Drug Administration (FDA) Code of Regulations in section 175.105: Indirect food additives: Substances for use only as components of adhesives, without limitation.
- Additional data on TMDD will become available through REACH. This will include exposure assessments developed by industry based on commercial uses and additional toxicological data may be required.

² US EPA, Initial Risk-Based Prioritization of High Production Volume Chemicals 2,4,7,9-Tetramethyl-5-decyne-4,7-diol (CASRN 126-86-3), September 2008