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FEICA carried out a risk assessment on cyclic esters potentially present in polyester adhesives intended to be used in food contact materials. By Jana Cohrs- Rahmoun, FEICA.

RISK ASSESSMENT OF CYCLIC ESTERS

In the European Union, all polyesters used in food contact applications should be based on monomers authorised to be used in plastic materials and articles intended to come into contact with foodstuffs according to the Plastics Regulation (EU) No. 10/2011.

Cyclic esters are of interest in these applications because small quantities of non-reactive cyclic esters are created as by-products during production of the high molecular weight chain polyesters used in the manufacture of laminating adhesives intended for use in food contact applications.

FEICA, the Association of the European Adhesive and Sealant Industry, published a summary report of a risk assessment it carried out on cyclic esters potentially present in polyester adhesives intended to be used in food contact materials. The FEICA risk assessment aims to provide downstream users with the information they need to help them carry out their own risk assessments. The recently published summary report outlines the main findings of the risk assessment and explains that human exposure to cyclic esters from polyester pre-polymers in food packaging adhesives is not relevant from a toxicological point of view.

Whilst the long-chain polymers of the polyester do not have a migration potential, the smaller cyclic esters could potentially migrate into the food. These cyclic esters are non-intentionally added substances (NIAS) and therefore require a risk assessment. The European Food Safety's Note for guidance for petitioners states that migratable substances from food packaging with a molecular weight of less than 1000 Da are important from the toxicological point of view as they could be absorbed in the gastrointestinal tract.

BUILDING A TASK FORCE

FEICA created a Cyclic Esters Task Force comprising several member companies* who shared relevant study results and expertise. Chem-Safe, an independent consulting company, facilitated the sharing of data and the development of the risk assessment. Subsequently, the Cramer classification scheme was used to estimate the threshold of toxicological concern, which is a screening and prioritisation tool for the safety assessment of chemicals when hazard data are incomplete and human exposure can be estimated.

An overestimate for human daily exposure level was deduced and the resulting calculations indicate that human exposure to cyclic esters potentially present in food packaging originating from polyester-based adhesives will be several orders of magnitude below the relevant thresholds of toxicological concern. It can be concluded that exposure to cyclic esters representing NIAS from polyester pre-polymers in adhesives in food packaging applications does not present a risk to consumers.

Attention should be paid to food packaging systems that generate cyclic esters containing ortho-phthalic acids because they don't seem to hydrolyse and exposure to these NIAS could be different than to other cyclic esters since they exhibited different behaviour in the studies. More investigation is needed to better understand the impact of ortho-phthalic esters from food packaging.

BRIEFING STAKEHOLDERS

To brief stakeholders about its risk assessment of cyclic esters, FEICA organised a webinar on 4 June 2020, which was attended by more than



The FEICA risk assessment undertook the following steps:

- Identify the species of cyclic esters potentially present in the food packaging
- Review the available published data
- Evaluate in silico data
- Evaluate in vitro mutagenicity/genotoxicity data
- Evaluate in vivo genotoxicity data
- Evaluate in vitro metabolism studies, which demonstrated that cyclic esters, other than those containing ortho-phthalic acids, undergo hydrolysis rates of at least 95% under metabolic conditions
- Estimate the threshold of toxicological concern
- Deduce an overestimate for human daily exposure

The results suggest that exposure to cyclic esters representing NIAS from polyester pre-polymers in adhesives in food packaging applications does not present a risk to consumers.

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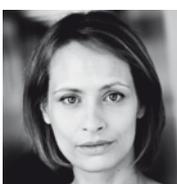
100 participants. Dr Matthias Frischmann, food chemist and Head of Corporate Analytics at Henkel in Düsseldorf, introduced the topic of cyclic esters, explained the risk assessment that was carried out and the responsibilities of each actor in the supply chain of polyurethane and heat seal adhesives polyester-based adhesives.

Dr Frischmann also presented on the topic of “Risk assessment of cyclic esters in adhesives for food contact applications” at the 9th International Akademie Fresenius Conference, which should have taken place in Cologne in June, but now has taken place online, on 18 and 19 November 2020 (<https://www.akademie-fresenius.com/events/detail/produkt/9th-international-akademie-fresenius-conference-residues-of-food-contact-materials-in-food-onli/>).

Dr Frischmann stated ‘The Summary Report is based on the current state of knowledge. Further evaluation will be possible in the case that new data becomes available. More investigation is needed to better understand the impact of ortho-phthalic esters from food packaging.’

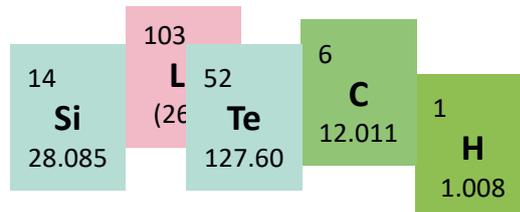
In the meantime, the Cyclic Esters Task Force hopes that the document will assist downstream users in their risk assessment activities. FEICA would like to thank Dr Frischmann and the Cyclic Esters Task Force for their dedication to this project. 

* FEICA member companies of the Cyclic Esters Task Force: Henkel, Dow, Coim, H.B. Fuller, Bostik



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Heisenberg is Certain for Once:
Siltech Specialty Silicones Help
You Break Today's Tougher
Problems



Your Technology
- Our Chemistry

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