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Food Safety in flexible packaging

What you need to know about primary aromatic amines (PAA)

Food safety has been very high on the agenda of the primary packaging material manufacturers and the packaging and food industry for many years. In addition to plasticizers and mineral oils, special attention has to be paid to primary aromatic amines (PAA). In our expert discussion, Dr. Dennis Bankmann, Product Development Loctite Liofol Europe at Henkel AG & Co. KGaA, will be telling us about PAA. He explains where risks exist in flexible packaging and what steps the packaging and food industry can take to ensure highest safety.

First things first: What exactly are PAA and why are they an important factor for food safety?

PAA are a group of chemical substances from the wider group of amines. PAA specifically carry an aromatic residue. They are used industrially, for example to manufacture azo dyes and certain polymers. We know that certain PAA present a toxicological concern as they have been identified as carcinogenic. Because of this specific hazard, PAA stand out among the non-intentionally added substances (NIAS) found in flexible packaging. This means that special attention must be paid to ensure that they do not migrate into food at detectable levels.

Where do PAA become an issue, specifically when talking about flexible packaging?

While azo dyes are used in inks for packaging materials made of paper, board, wood and plastics, when it comes to flexible packaging polyurethane (PU)-based materials have received the highest attention.

Polyurethanes are common components of adhesives, inks and coatings used to produce flexible packaging. Currently, about 90 percent of all adhesives used to produce flexible packages are PU adhesives. In other words, they are based on or contain polyurethanes.



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The reason why PAA are relevant in this context does call for an explanation, since the formulations of adhesives such as those from Henkel's Loctite Liofol product line do not, of course, contain any PAA themselves.

There is however a possibility that PAA can be formed if an unsuitable adhesive is selected, processing parameters are not adequate or laminates are thermally stressed. To prevent formation of PAA as undesirable by-products, it is of crucial importance not only to ensure that the adhesive has been appropriately formulated, but also that the finished packaging is only used within its limits.

How can PAA occur during the manufacture and use of laminates? Could you explain this in more detail and give us a concrete example?

PAA can form if the adhesive has not fully cured before the laminate is filled with food. In such a case, residual isocyanate monomers in the adhesive that have not reacted will react with the moisture that is found in practically all foods and PAA will be formed. These can migrate and then remain in the foodstuff and be incorporated by the consumer.

There are several reasons why laminates may, typically in adverse conditions, not fully cure. It could be that the temperature or ambient humidity is too low during curing, and certain types of laminating materials also play a role. If these insufficiently cured laminates were to get into the packaging process, this would present a risk for the filled foodstuffs.

The packaging industry is aware of the importance of adequate curing conditions since many years and manages the PAA topic professionally through good manufacturing practices and monitoring of the produced laminates. Therefore, the question today is not so much whether our foods are safe but how packaging manufacturers can maximize their productivity and minimize waste with the help of fast-curing adhesives. This is where we help the industry, by providing continuously improved adhesive solutions.

How about thermal stress, for example in sterilization processes?

Thermal stress on laminates is indeed a factor that always has to be considered – and not just in retort processes, as for example used in pet food or baby food, but also for packages that are to be heated in a household oven. With respect to the adhesive selection, inappropriately high temperatures for a given adhesive can cause PAA to form, even when the adhesive had fully cured. Chemically, at temperatures above 100 degrees Celsius certain polyurethanes begin to degrade. In this process the nature of the adhesive as well as the temperature and time play an essential role. Ultimately, the question will always remain: Will PAA be formed as a result? Regarding thermal stress, the correct choice of adhesive is crucial. It has to withstand the foregoen conditions and offer a degree of telegope in order to assure process

the foreseen conditions and offer a degree of tolerance in order to assure process safety in industrial retort processes and to withstand any deviations from the recommended heating instructions that may happen in a household use.

What can producers and users do to be on the safe side?

The industry has two important levers it can employ to maximize the safety of packaging: choosing the best possible adhesive and applying good manufacturing practice, as mentioned earlier.

By selecting a good adhesive, I can make sure as a producer that I am starting out with the best possible conditions. With its PU-based Loctite Liofol adhesives, Henkel can offer the right solution for every scenario. We can cover the most varied of requirements in terms of production process, performance, storage time or temperature and provide solutions for all kinds of foods – from snacks, coffee and fruit juices to sterilized foods and convenience foods for cooking in the microwave and the oven.

For exposure to temperatures up to 100 degrees Celsius, our Low Monomer and Ultra Low Monomer adhesives are an excellent choice. They contain only a minimum amount of free isocyanate monomers and thus reduce from the outset the amount of PAA that could be formed. Moreover, they considerably shorten the curing time with respect to PAA, often to less than three days. For example, in certain laminates, Henkel's Ultra Low Monomer adhesive LA 7777/LA 6137 will cure enough in just one day that there is no PAA risk any more.

Regarding proper use, controls on the produced laminate are a vital step before using it for packaging. As a packaging material manufacturer, I have to check how many days my laminate needs to cure, as this can vary widely according to climate, the structure that is to be produced and the inks used. In addition to the initial validation, consistency and good manufacturing practice are essential. If I don't have temperature controlled storage facilities, I may get different results in winter than in summer.

Another point to consider is choice of test method. Do I choose a simple method that I can carry out myself on site? Or do I contact an external institute or go directly to Henkel? We support our customers in many ways, not just in selecting the right adhesives. We can help to select the most appropriate test methods, to set them up on site and to validate them. If the questions or the circumstances are more challenging than usual, we can support with our own in-house accredited test laboratory.

What is the regulatory situation regarding PAA? Are any changes foreseeable?

The European regulations regarding primary aromatic amines are probably the most clearly defined in the world. There are two main regulations that have been harmonized Europe-wide.

The Framework Regulation (EC) No 1935/2004 states that substances may not migrate from food contact materials in a quantity that would present a risk to health. This regulation naturally also covers PAA, even if no explicit limit is mentioned. EU regulations require that generally recognized scientific methods be used to carry out the assessment and risk analysis.

Regarding the question of which limits to apply, since there is no Europe-wide regulation dealing specifically with adhesives, the industry generally refers to Regulation (EC) No 10/2011 which governs plastic materials and articles. This regulation specifies that the sum of all migrating aromatic amines must not exceed

10 μ g per kg of foodstuff – which may also be expressed as 10 ppb, or parts per billion.

These limits may be tightened in the future. In a position paper prepared by BfR, the German Federal Institute for Risk Assessment, on aromatic amines migrating from printing inks an individual limit of 2 ppb per specific PAA is recommended in addition to the overall limit of 10 ppb. We are still waiting for an answer from the European authorities, but the BfR position paper gives a clear indication of which way the discussion is heading.

What consequences would the new limits have?

We can expect that in many cases, adhesives in laminates would have to cure for longer time to ensure compliance with the new limits. Obviously, the option of switching to an adhesive that cures faster and allows faster PAA decay presents itself here. As mentioned earlier, Henkel has a wide range of solutions to offer.

Retort applications are a special case. It should be remembered that faster curing or a lower monomer content in polyurethane adhesives cannot automatically be equated with higher heat resistance. If the regulations were tightened, there would likely result a greater interest in aliphatic adhesives. Important reasons influencing that decision would be questions of process safety and the major challenge of actually being able to reliably detect such small quantities of PAA after retort.

This is where aliphatic adhesive solutions such as Henkel's Loctite Liofol LA 2760/LA 7371 (solvent based) or LA 7772/LA 6172 (solvent free) step in. Since aliphatic adhesives employ different raw materials, PAA will not occur at all, no matter what the temperature exposure is. Our modern aliphatic adhesives also have none of the major disadvantages that earlier aliphatic products had. LA 2760/LA 7371 and LA 7772/LA 6172 do not use tin-based catalysts, nor do they require a tempering chamber for curing. This makes them highly attractive solutions for the high performance range.

We have only been able to skim the surface of the PAA topic in this interview. Where and how can market participants gain in-depth information?

We offer extensive information online in our Food Safe Packaging Portal at <u>www.henkel.com/foodsafety</u> where visitors can find webinars, white papers, a glossary on important topics in food safety, and more.

The webinars are interactive, and deal with both overarching topics such as the relevant legislation. Further, specific technical issues such as plasticizers and mineral oils, how to perform migration as well as how to run PAA tests correctly are addressed. We inform participants about the basic background and on current or forthcoming changes, for example in regulations or methods.

In the webinars, participants have the possibility to communicate directly with the Henkel experts. Many of our customers as well as food companies, institutes, consultants and our own employees in all regions around the world have been taking advantage of the campaign since its inception in 2013. They have successfully gained access to the topic of safety of food contact materials and been able to learn as they go.

Participation in the webinars is free of charge, by the way. Neither do we charge for the white papers. This year, we will be holding a total of 16 webinars, mostly in English. They are also held at different times during the day to accommodate participants in different time zones. I can highly recommend them to anyone involved in any way in the subject of food safety.

Henkel offers 360° expertise for the whole value chain in food packaging

Henkel's Food Safe Packaging webinars address food safety officers, quality managers, packaging developers, buyers and other stakeholders from the food packaging industry and food-related sectors wishing to learn more about the details and developments relating to this important subject.

Integral to this initiative is Henkel's commitment to sharing knowledge, interacting and collaborating with all partners along the value chain. The company is constantly expanding its in-house competence, leveraging its activities in its analytical center, toxicology and product development departments. This is a team of diverse specialists, ideally composed to support any kind of regulatory question.

For an overview of Henkel's webinar offerings, visit the Henkel knowledge portal at www.henkel.com/foodsafety. To participate, you will need to register online in advance. The webinars are free of charge. There are currently four dates fixed for sessions on primary aromatic amines:

Primary Aromatic Amines – Everything you need to know

April 5, 2016: 09:00 and 16:00 (CEST) November 30: 09:00 and 16:00 (CET)

Registration is done online. To do this, visit <u>www.henkel.com/foodsafety</u> and select *Webinars* in the menu bar on the left.

About Dr Dennis Bankmann

Dennis Bankmann studied physical chemistry and radiochemistry in Cologne, then gained a doctorate in physico-organic chemistry. In 2007, he joined Henkel in Düsseldorf as a researcher in the Adhesive Technologies business unit. After three years in Germany, he moved to Barcelona to help establish a joint research center with the "Universitat Autònoma de Barcelona". Returning from the assignment, Dennis Bankmann joined Industrial Adhesives product development in 2012 and has since taken over responsibility for the development of the Loctite Liofol range of laminating adhesives, cold seal and heat seal materials. For the year 2014, Dennis Bankmann also held overall responsibility for industrial adhesives development in the IMEA region.

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Henkel operates worldwide with leading brands and technologies in three business units: Laundry & Home Care, Beauty Care and Adhesive Technologies. Founded in 1876, Henkel holds globally leading market positions, both in the consumer and in the industrial businesses, with well-known brands such as Persil, Schwarzkopf and Loctite. Henkel employs about 50,000 people and reported sales of 18.1 billion euros and adjusted operating profit of 2.9 billion euros in fiscal 2015. Henkel's preferred shares are listed in the German stock index DAX.

Photo material is available at http://www.henkel.com/press

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The following material is available:



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