# Ensuring safe plastic food contact materials.

## Polyamide oligomer migration testing – an essential factor for accessing profitable EU markets.

Plastics have revolutionized our life – from medicine to transportation and even the way we eat. But they have also created regulatory and safety challenges.

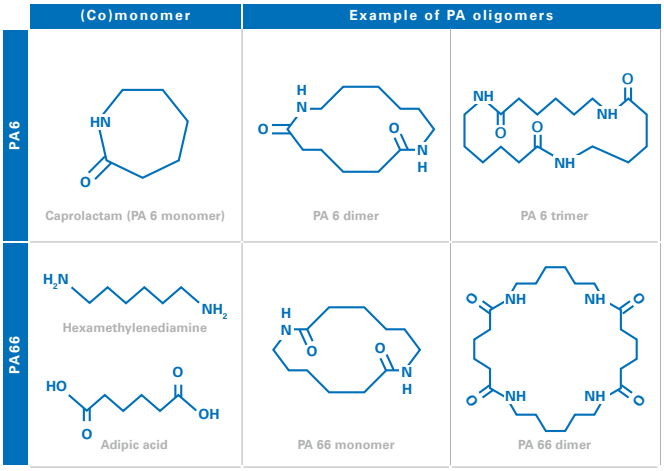
For plastic food contact materials imported into the European Union (EU), any monomer, additive or polymer production aid intentionally added to the formulation of a plastic food contact material placed on the market in the European Union (EU) must be listed in Annex I of EU regulation No. 10/2011. All of these are subject to specific compliance checks. The EU regulation also covers "NIAS" – Non-Intentionally Added Substances – which may be found in plastics, even if they are not added directly or on purpose.

### PINPOINTING POLYAMIDES

Polyamide (PA) plastics (such as PA6 and the copolymer PA66) are the most frequently used materials in food contact products like cooking utensils and spatulas where high heat-resistance is needed. However, PA-based kitchen utensils can contain traces of cyclic monomers and oligomers.

Oligomer molecules consist of 2 to 40 repeating (co) monomer units (i.e. dimer, trimer, tetramers, etc.), depending on the chemical composition of the monomers. PA oligomers can occur as side-products during the polymerization process, or are generated via thermal or hydrolytic degradation of longer polymer chains.

### EXAMPLES OF PA MONOMERS AND PA OLIGOMER




- PA6 oligomers consist of a few repeated caprolactam units
- PA66 oligomers consist of a few repeated co-monomer units of hexamethylenediamine and adipic acid

Oligomers with a molecular weight below 1000 Da are generally recognized as toxicologically-relevant migrants, because they can be absorbed through the gastrointestinal tract after being consumed in food. Since they are not intentionally added to the plastic materials, these substances may be considered as NIAS.

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Recent studies published by the German Federal Institute for Risk Assessment (BfR) have shown that kitchen utensils made of PA6 and PA66 can release high levels of PA oligomers into food. Under Article 19 of EU regulation No. 10/2011, manufacturers are required to conduct a risk assessment on these substances in order to prove compliance with article 3 of EC Regulation 1935/2004.

## TESTING FOR PA OLIGOMERS

Although not giving specifications for a comprehensive assessment, Article 3 of Regulation (EC) No. 1935/2004 does requires all plastic materials coming into contact with food to be safe.

That's where TÜV Rheinland comes in. Our experienced technicians and advanced testing services can help you get a picture of the level of PA oligomers migrating from your products, and, more importantly, help you understand whether this amount could potentially pose a risk to human health. The testing under Regulation (EU) No. 10/2011 includes migration tests using food simulants, which are then carefully analyzed using high-performance liquid chromatography (HPLC). The German Federal Institute for Risk Assessment (BfR) has analyzed the toxicological data on the evaluation of cyclic PA6 oligomers (n = 2 to 8, i.e. dimer to octamer) and cyclic PA66 oligomers (n = 1 to 4, i.e. monomer to tetramer). Based on the data, BfR has set a specific migration limit (SML) of 5 mg per kg of food simulant. This maximum migration level is considered to be toxicologically acceptable for the sum of migration values for the aforementioned oligomers.

TÜV Rheinland recommends customers to meet this PA oligomers requirement announced by BfR in order to support compliance under Article 3 of Regulation (EC) No. 1935/2004.

## OUR SERVICES

TÜV Rheinland's services include:

- Designing tailor-made testing programs for international buyers and manufacturers
- Continuous expansion of coverage in FCM chemical safety requirements
- Conducting seminars and providing training to buyers and manufacturers
- Delivering support worldwide to your local, regional and global requirements

## BENEFITS AT A GLANCE

PA Oligomers tests carried out by TÜV Rheinland laboratories allow you to:

- Prevent instead of react to NIAS concerns raised by industries and authorities
- Provide consumers with safe and tested products
- Boost confidence in the quality and safety of your products
- Document implementation of legal requirements with test reports

**OUR EXPERTS WILL BE HAPPY TO ASSIST YOU WITH ANY FURTHER QUESTIONS. PLEASE GET IN TOUCH WITH US!**

ONLINE CONTACT


**REFERENCES**

1. Abe Y., Mutsuga M., Ohno H., Kawamura Y., and Akiyama H. (2016): Isolation and Quantification of Polyamide Cyclic Oligomers in Kitchen Utensils and Their Migration into Various Food Simulants. (https://doi.org/10.1371/journal.pone.0159547)
2. BfR Opinion No. 014/2018 Polyamide oligomers: plastic ingredients from kitchen utensils (https://www.bfr.bund.de/cm/343/polyamid-oligomere-kunststoffbestandteile-aus-kuechenutensilien.pdf)
3. European Food Safety Authority (EFSA) Threshold of Toxicological Concern (http://www.efsa.europa.eu/en/topics/topic/threshold-toxicological-concern)
4. M. Hoppe a, et al. (2016): Identification and quantification of oligomers as potential migrants in plastics food contact materials with a focus in polycondensates – A review.
5. O. Kappenstein, et al. (2018): Validation and application of an LC-MS/MS method for the determination of cyclic oligomers originating from polyamide 6 and polyamide 66 in food simulant
6. 21st BfR committee meeting minutes (https://www.bfr.bund.de/cm/343/21-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf)



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