

Leachables/Extractables: Trace analysis of organic and inorganic compounds

Leachable and extractable chemicals may undermine the safety of a wide range of products, particularly in the field of plastics, metals and alloys. The use of such additives cannot always be avoided as they are often responsible for the specific properties needed in a product.

The RMS Foundation has a wide range of analytical tools at its disposal to determine the chemical nature and content of such leachable and extractable compounds down to the lowest concentration ranges.

Extraction of additives or contaminations

A leachables/extractables (L&E) study begins with the extraction of additives or contaminations from the product materials. Various extraction methods with suitable solvents are available, such as reflux, Soxhlet, ultrasound, incubation at defined temperatures, etc. The choice of the solvent or extraction method is often critical to the validity of an L&E study. The potentially critical additives or contaminations do not necessarily have to originate from the product materials themselves, but can also be introduced into the actual product from the packaging or through treatments such as sterilization.

Screening/quantitative analysis of extracts

The extraction solutions are then analyzed using appropriate analytical methods. Depending on the product, specific limits must be obeyed for potentially critical additives or contaminations. These are specified by standards such as ISO 10993 (biocompatibility), RoHS/Reach (heavy metals, plasticizers, flame retardants) and others. In addition to established methods such as ICP-MS (detection of heavy metals), TOC/TN (organic contaminants in aqueous solutions) and others, a large

number of trace organic compounds can now be identified and quantified at the RMS using highly sensitive GC-MS/MS.

Close and efficient cooperation

The most important aspect of an L&E study is the close cooperation between the client and the RMS Foundation experts, as the procedure has to be planned individually depending on the product and the study. We maintain a friendly and straightforward relationship with our clients and strive to meet their needs as efficiently and promptly as possible.



Figure 1: GC-MS/MS: A method for identification and determination of trace organic elements.

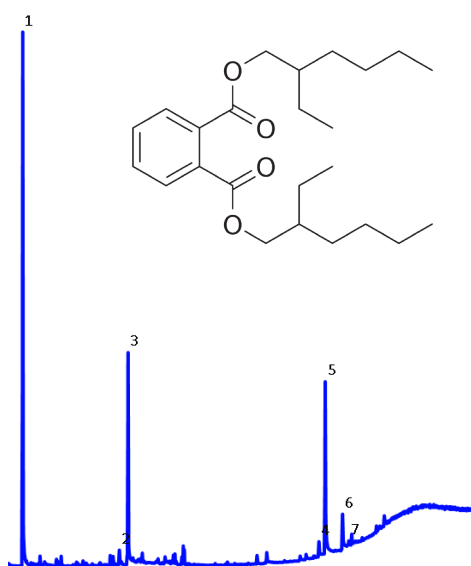


Figure 2: Chromatogram of a PVC sample containing a significant amount of bis (2-ethylhexyl) phthalate plasticizers (peak 5).

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Applications:

- Heavy metals: Pb, Hg, As, Cd etc. (USP 232/233, ISO 10993, RohS/Reach)
- Softeners (Phthalate) in polymers (RoHS)
- Flame retardants (PBBs, PBDEs) in polymers (RoHS)
- Sterilization residues
- Volatile und semi-volatile organic compounds (VOC, sVOC)
- Solvent residues

Methods:

- ICP-Mass spectrometry (ICP-MS)
- Gaschromatography coupled mass spectrometry (GC-MS/MS)
- FT infrared spectroscopy (FT-IR)
- X-ray fluorescence spectroscopy (XRF)
- Total hydrocarbon (TOC)
- Total nitrogen (TN)

Discuss your questions with us! We are happy to advise you.

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More information as well as our service catalogue can be found on our website.

RMS Foundation has been certified according to ISO 9001 and is an ISO/IEC 17025 (type C) accredited laboratory.

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