

Excellence in Extractables & Leachables Testing

VR Analytical is a leading provider of extractables and leachables (E&L) testing services.

Founded in 2001, VR Analytical is one of the leading contract research laboratories providing extractables and leachables testing for the bio/pharmaceutical industry.

Using a science-based, partnership-driven approach, and supported by one of the industry's largest extractables databases, we help our customers find the most efficient paths to regulatory approval. Our knowledge of the E&L regulatory landscape is based on years of direct contribution to the industry, through participation in standards setting organizations, and presentation of novel research conducted in our labs.

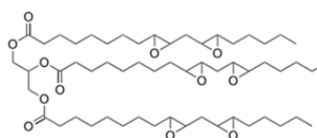
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Epoxidized soybean and linseed Oils are marketed as low cost, biodegradable nontoxic plasticizer replacement options for the more traditional phthalates in PVC formulations. Although, an obvious alternative for plastic formulators, this additive provides quite the challenge for analytical chemists.

Epoxidized soybean oil (ESBO) is in fact a much less toxic and a greener solution than traditionally used phthalate plasticizers such as DEHP. Because of this, we can expect to see these alternative PVC plasticizers in E&L for many years to come as they continue to gain traction in PVC plastic formulations utilized in healthcare applications.

So, what is ESBO and the like? These additives that are derived from polyunsaturated vegetable oils, where the unsaturated double bonds on the carbon chain are converted to epoxide groups. The results are a mixture of mono, di and tri-epoxidized glycerides. An example structure is provided below.



Traditional phthalate PVC formulations contained a single compound as primary plasticizer and a single compound as a secondary plasticizer. Thus, when extracting and analyzing these PVC test articles, E&L experts could expect to see two intact plasticizers compounds and likely a small subset of degradation products. Since the alternative ESBO plasticizer is a mix of numerous compounds, E&L experts now can expect to detect multiple EBSO compounds and multiple degradation products that need to be identified for safety assessment. This causes some E&L analytical workflow challenges making it hard to perform these extraction studies in a reasonable timeline at a reasonable cost for the sponsor. Although E&L companies find themselves being challenged with more renewable additives such as ESBO, it gives opportunity for advancement in analytical knowledge and workflows.

Hot Topics....

Do you work with extractables and leachables? Here is one recent and challenging addition to the plasticizer's category

One way to do this is utilizing deconvolution software to mine extracted ions above a specified threshold. Deconvolution software helps further separate these compounds out for quantitation and will help reduce time by minimizing manual interpretation during data analysis. When performing compound identifications, rather than completely elucidating the structure, linking compounds to being a part of ESBO additive is often enough for the toxicological assessment. This can be more easily achieved by looking at the carbon number of an unknown's molecular formula and the fragment ions it generates. Often ESBO associated compounds will have carbon numbers equivalent to the fatty acid, mono, di and triglycerides. For example, a stearin glyceride would show a carbon number of C18 (for acid product), C21 (for monoglyceride product), C39 (for diglyceride product) and C57 (for triglyceride product).

For more information;

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