

## Customer Information

# Applicable specific migration limits of energy curable multifunctional acrylates from food packaging printed with Siegwirk low migration inks and varnishes

In accordance with the EuPIA Guideline "Printing Inks for Food Packaging"<sup>1</sup>, migrants from printed layers shall be subject to a risk assessment if a migration above 10 ppb is expected. This measure should take into consideration the availability of appropriate toxicological data.

Within the family of crosslinkable acrylates (oligomers, monomers) used for Siegwirk's **Low Migration** UV- and EB-curable printing inks and varnishes, the potential low molecular weight migrants are multifunctional acrylates which are **esters** of acrylic acids with either polyols, or ethoxylated and/or propoxylated polyols.

The European Food Safety Authority (EFSA) provides guidance<sup>2</sup> on the toxicological evaluation of esters: "If the chemical structure suggests ready **hydrolysis of the substance in food and/or the gastrointestinal tract** into components which already have been toxicologically evaluated, the rate of hydrolysis and its degree of completeness will determine the extent of toxicological testing necessary for the evaluation". As part of the guidance, EFSA has published a dedicated analytical method which "allows determination of the **extent of hydrolysis, especially of esters**, in order to assess whether the constituents break down into innocuous substances".

The multifunctional acrylates used in Siegwirk's Low Migration inks and varnishes, covered in this document, are part of the chemical family of **acrylate esters**.

A number of particular acrylate esters have been evaluated by EFSA for listing on the recognized reference positive list in Europe (Directive 2002/72/EC) relating to plastic materials and articles intended to come into contact with foodstuffs. These particular acrylate esters are **monoacrylates** that are used as monomers for plastics. The result of the evaluation was turned into the listing of several monoacrylates in Directive 2002/72/EC, such as "acrylic acid, methyl ester", "acrylic acid, ethyl ester", "acrylic acid, isopropyl ester", "acrylic acid, monoester with ethyleneglycol", "acrylic acid, benzyl ester", "acrylic acid, isobutyl ester", "acrylic acid, n-butyl ester", "acrylic acid, sec-butyl ester", "acrylic acid, tert-butyl ester", and so on. Obviously, EFSA had applied the procedure of their guidance, that is, they made the evaluation on the basis of the hydrolysis properties. Firstly, EFSA recognized that these esters do completely hydrolyse into the specific linear or branched alkyl alcohol and acrylic acid.

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<sup>1</sup> "EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles", [www.eupia.org](http://www.eupia.org).

<sup>2</sup> "Note for Guidance for Petitioners Presenting an Application for the Safety Assessment of a Substance to be used in Food Contact Materials prior to its Authorisation", [www.efsa.europa.eu](http://www.efsa.europa.eu).



Secondly, EFSA did not allocate any toxicological concern to said linear or branched alkyl alcohols<sup>3</sup>; this is substantiated by the fact that they are listed without restriction (without migration limits) in Directive 2002/72/EC. Thirdly, EFSA's toxicological evaluation of acrylic acid resulted in a restriction by a Specific Migration Limit (SML) of 6 mg/kg (6000 ppb). Lastly, EFSA decided on the basis of these considerations that for all said monoacrylates only acrylic acid is the substance both entering the human body via resorption in the intestine and being the toxicologically critical one. Therefore, a **group SML of 6000 ppb, expressed as acrylic acid**, has been allocated in Directive 2002/72/EC for the total migration of said monoacrylates.

In the case of the **multifunctional acrylates** covered by this document, the nature of the ester bond is chemically equivalent to the ester bond of the evaluated monoacrylates, thus the extent of hydrolysis is also equivalent. The difference is that multifunctional alcohols ("polyols") are the reaction partner of acrylic acid instead of the linear or branched alkyl alcohols. However, there is widespread consensus amongst authority and industry toxicologists that the toxicology of the group of polyols, including ethoxylated and/or propoxylated species, is comparably favourable. This is also substantiated by the listing of several polyols, including polyethoxylates and polypropoxylates, in Directive 2002/72 without restriction<sup>4</sup>.

Viewed from the perspective of many toxicological experts, **it could therefore be concluded** that for the multifunctional acrylates covered by this document, a cross-reading from the monoacrylates is acceptable, and consequently **the same Group SML of 6000 ppb, expressed as acrylic acid**, is applicable. Certain officially recognized institutes that are active in the verification and migration testing of food contact materials follow this approach when expressing an opinion on food packaging printed with UV- or EB-curing inks and varnishes.

However, it must be clearly stated that **the competent top authority in Europe, EFSA, never issued any evaluation nor expressed any opinion on the toxicology and on applicable migration thresholds of the multifunctional acrylates** covered by this document. It must be recognized that an allocation of a threshold of 6000 ppb, expressed as acrylic acid, so far remains without backup from the overarching competent toxicological authority.

Consequently, it can be concluded that the printer should strive to achieve, in accordance with the EuPIA Guideline "Printing Inks for Food Packaging", the migration limit target of 10 ppb per multifunctional acrylate substance. Siegwerk's Low Migration energy curable printing inks and varnishes are formulated according to the current state-of-the-art, in order to enable to the printer to meet this target, or to move towards it.

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<sup>3</sup> In particular: Methanol; ethanol; n-propanol; isopropanol; alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22).

<sup>4</sup> In particular the polyols used for synthesis of the major multifunctional acrylates of UV- and EB-curing inks and varnishes for food packaging: Pentaerythritol, dipentaerythritol, trimethylolpropane, polyethylene glycol, polypropylene glycol.

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Finally, the printer is advised to observe Regulation (EC) No 1935/2004<sup>5</sup>, which requires that materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities which could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

This means that the manufacturer of the finished article and the filler have the legal responsibility that it is fit for its intended purpose.

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<sup>5</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on Materials and Articles intended to come into Contact with Food and repealing Directives 80/590/EEC and 89/109/EEC, OJEU L338 of 13.11.2004.