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FEICA recommendation to substitute GLYMO by the end of 2020 in applications intended for food contact

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard FEICA aims to establish a constructive dialogue with legislators in order to act as a reliable partner to resolve issues affecting the European adhesive and sealant industry.

Introduction

GLYMO ([3-(2,3-epoxypropoxy)propyl]trimethoxy silane, CAS No 2530-83-8, FCM 1068) has been used by the adhesives industry as an adhesion promoter for polyurethane adhesives for flexible packaging for decades. It is used mostly for high performance packaging such as sterilisation, pasteurisation, retort conditions, etc.

As explained in the respective FEICA guidance¹, adhesives may contain non-listed substances, provided the adhesive manufacturer has carried out an internal risk assessment, and provided the adhesive allows the final food contact article to comply with Article 3 of the framework Regulation (EC) No. 1935/2004.

In June 2018, GLYMO was added to the union list of the Commission Regulation (EU) No. 10/2011² as a component of a sizing agent to treat glass fibres. Although this application does not represent adhesives, the conclusion of the related EFSA opinion³ that the substance has genotoxic potential is relevant.

The EFSA guidance on the review of the threshold of toxicological concern (TTC)⁴ concept from March 2016 advocates an exposure threshold of 0.0025 µg/kg.bw/day for genotoxic substances, which for a 60 kg person would translate into an exposure threshold of 0.15 µg/person/day. Although GLYMO still has no—harmonised classification under Regulation CLP 1272/2008, adhesives manufacturers and the supply chain have to take into account the migration limit of 0.15 ppb for the risk considerations due to the genotoxic potential of the substance.

FEICA recommendation to member companies

With regards to the suspicion that GLYMO ([3-(2,3-epoxypropoxy)propyl]trimethoxy silane, CAS No 2530-83-8, FCM 1068) has genotoxic potential and taking into account the continuous effort of FEICA companies to ensure the safety of their products, FEICA recommends that its members substitute

¹ FEICA guidance for a food contact status declaration for adhesives : <http://www.feica.eu/our-priorities/key-projects/food-contact.aspx>

² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0831&from=EN>

³ EFSA opinion on GLYMO

⁴ EFSA guidance on TTC from 2016, last updated 06.2019

GLYMO by end 2020 in applications intended for food contact (i.e. food packaging) and assist customers in implementing alternative solutions for food contact applications.

In the meantime, we recommend strong collaboration along the value chain to assist customers in ensuring that their applications meet the recommended limit.

Contact

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