Statement on the exemption of linolenic acid (CAS 463-40-1) from the obligation to register in accordance with Article 2(7)(b) of Regulation (EC) No 1907/2006 (REACH)

1. Preface

Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) and its amendment by Regulation (EC) No 987/2008 of 8 October 2008 lay down the criteria for the exemption of substances, covered by Annex V from the registration, downstream user and evaluation requirements. The ECHA guidance document "Guidance for Annex V – Exemptions from the obligation to register" (Version 1.1 – November 2012) gives more explanations and background information for applying the exemption.

This statement sets out the position of the manufacturer of linolenic acid on the obligation to register linolenic acid (CAS 463-40-1) with regard to Annex V and the relevant section of the ECHA Guidance document (Guidance for Annex V, Entry 9, p. 29-32). Based on the available information on the substance and our understanding of the legislation, CAS 463-40-1 is exempted from registration through the application of Annex V, Entry 9 of the Regulation (EC) No 1907/2006 (REACH). This document explains the case for the exemption.

2. Legal text: Annex V "Exemptions from the obligation to register in accordance with Article 2(7)(b)", Entry 9

"The following substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):
Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol."

3. Justification for the exemption from the obligation to register for linolenic acid

Linolenic acid is obtained from a natural source and is not further chemically modified once obtained from the natural source. No data are available showing that linolenic acid contains any dangerous properties. The substance is not classified for physico-chemical human health and environmental hazards. Furthermore, there is no evidence that purified linolenic acid is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, Regulation (EC) No 1907/2006. Linolenic acid is a monoconstituent substance and an 18-carbon polyunsaturated fatty acid (C18:3).

4. Conclusion

Based on all available data, it can be concluded that linolenic acid (CAS 463-40-1) satisfies the criteria according to Annex V, Entry 9 of the Regulation (EC) No 1907/2006 (REACH). Thus, linolenic acid (CAS 463-40-1) does not need to be registered according to Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) and its amendment by Regulation (EC) No 987/2008 of 8 October 2008.