

Statement on the exemption of fatty acids, C16-22 and C18-22-unsatd. (CAS 95912-82-6) 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 fatty acids, C16-22 and C18-22-unsatd. on the obligation to register fatty acids, C16-22 and C18-22-unsatd. (CAS 95912-82-6) 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 95912-82-6 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 fatty acids, C16-22 and C18-22-unsatd.

Fatty acids, C16-22 and C18-22-unsatd. is obtained from a natural source and is not further chemically modified once obtained from the natural source. The substance is not classified for physico-chemical and environmental hazards. For human health endpoints fatty acids, C16-22 and C18-22-unsatd. has also been shown to be not toxic with the exception of possible skin irritating properties depending on its content of erucic acid (C22:1) (CAS 112-86-7). The substance meets the criteria as a skin irritant [Xi, R38] according to Directive 67/548/EEC, if C22:1 is $\geq 20\%$. There is no evidence that purified fatty acids, C16-22 and C18-22-unsatd. 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.

Fatty acids, C16-22 and C18-22-unsatd. is a UVCB substance and represents a group of fatty acids, which are saturated and/or unsaturated fatty acids having a range from C6 to C24.

4. Conclusion

Based on all available data, it can be concluded that fatty acids, C16-22 and C18-22-unsatd. (CAS 95912-82-6) satisfies the criteria according to Annex V, Entry 9 of the Regulation (EC) No 1907/2006 (REACH). Thus, fatty acids, C16-22 and C18-22-unsatd. (CAS 95912-82-6) 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.

Disclaimer

Please note that it is the responsibility of the company issuing this FATAC statement to ensure that their specific product meets the requirements listed for REACH Annex V exemption.

Please be aware that this paper is based on an understanding in good faith of the legal requirements as of today, and may be subject to change if the law, or any official guidance on its interpretation issued by the Commission, ECHA or a Competent Authority in a Member State, should change in the future.

Nothing in this paper should be taken as limiting the ability of any company, whether a Fatty Acids Consortium Member or not, to apply a different interpretation.

Neither the Consortium nor any of its Members or its Secretariat can be held liable for any damage, loss or penalty resulting from its use.