HARRPA
Hydrocarbon Resins, Rosin Resins and Pine Chemicals Producers Association

Communication paper

REACH: Exemption of Tall Oil Fatty Acids (TOFA) from the Obligation to Register under Annex V.9

The application of European Union (EU) legislation on REACH (Regulation (EC) 1907/2006) to the possible exemption of Tall Oil Fatty Acids (TOFA - CAS #: 61790-12-3; EINECS #: 263-107-3) from the obligation to register under Annex V.9.

Summary

This document sets out the position of the tall oil fatty acids (TOFA) with regard to the possible registration of TOFA and in particular whether an exemption from registration is applicable.

Based on the available information on the substance and our understanding of the legislation we believe that TOFA and certain of its salts are exempt from registration through the application of Annex V.9 of the Regulation. This document explains the case for the exemption.

Exemptions

REACH Annex V (see Commission Regulation (EC) No 987/2008) lists individual substances and groups of substances that are exempt from the obligation to register; criteria usually apply. Annex V.9 sets-out the criteria that certain naturally occurring substances have to satisfy in order to be exempt from registration (see Annex 1 to this letter).

Annex V.9

In order for the exemption under REACH Annex V.9 to apply, a number of criteria have to be met. A summary of these criteria and how these criteria are met by TOFA, as produced by European producers, are set-out below:

1. **The substance must be obtained from natural sources.** TOFA is produced by the fractionation of crude tall oil (CTO). CTO is a by-product of the

manufacture of paper and the Kraft Pulp Process in particular. It is a dark brown viscous mixture of naturally occurring resin acids, fatty acids, and neutral components that are present in the wood of various pine species. TOFA is therefore obtained from natural sources, namely trees.

2. **The substance is not 'chemically modified'.** During the process for extraction of CTO from wood no chemical modification of the constituents takes place other than hydrolysis of esterified constituents (the ECHA guidance on the interpretation of Annex V specifically states that ester hydrolysis to obtain fatty acids is not considered to be a 'chemical modification' and is therefore within the scope of this exemption). Fractionation of CTO to produce TOFA (and the other fractions) is a physical separation by distillation and does not involve any chemical modification.

3. **The substance does not meet the criteria for classification as dangerous nor is it a PBT or vPvB in accordance with the criteria set-out in Annex XIII.** TOFA is not listed on Annex 1 to Directive 67/548/EEC. Reliable test data consistent with that required for a registration of a substance at 10 tonnes or more (i.e. REACH Annex VIII information requirements) are available for TOFA. On the basis of the available data, TOFA does not meet the criteria for classification as dangerous to human health or the environment. TOFA does not meet the criteria in Annex XIII for a PBT or vPvB substance. TOFA is not on the candidate list of 'substances of very high concern' (as of November 2008).

4. **The substance must be a fatty acid from C6 and C24.** TOFA is typically considered to be a multi-constituent substance. There is limited variability in composition from samples of different origin; the constituents present are typically the same although their relative amounts may differ slightly. Arizona Chemicals analysed three samples from different commercial grades in April 2008 using gas chromatography. The full results are available and overall indicate that TOFA is composed of:

   - 96 – 100% fatty acids (of which >99% is C16 – C20, including saturated, unsaturated and polyunsaturated structures)
   - 1 – 4% resin acids (individually not more than ca. 1.1% of any given constituent)
   - 1 – 2% neutrals (individually not more than ca. 0.3% of any given constituent).

The non-fatty acid parts can be considered to be impurities. These results are fully in-line with literature in the public domain which report TOFA as having a fatty acid content >95%, resin acids typically <3% and neutrals typically 1-3%[1].

Conclusion

It is the opinion of the European producers, who have signed this document, based on the information available to us, our understanding of the substance in question, and our understanding of the REACH Regulation, that TOFA and certain of its salts satisfies the criteria under Annex V.9 and is therefore exempt from the obligation to register in accordance with Article 2 (7)(b).

If you have any questions on the above please contact HARRPA www.harrpa.org (Philippe Salémis -Tel: +32 2 676 74 36, e-mail: psa@cefic.be), or any of the signatories.

This paper is published by Harrpa, on behalf of the following signatory companies:

Arizona Chemical; DRT S.A.; Forchem Oy; Kemira GmbH;

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[1] McSweeney, E.E., Arlt, H.G. and Russell, J., 1987, 'Tall oil and its uses – II'. Pulp Chemicals Association, Inc. Atlanta, GA., and US EPA HPV chemical program information.

Annex 1

"ANNEX V form Reach Regulation"

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

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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 bio-accumulative 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."

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