

Communication paper – March 2016

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 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 co-product of the manufacture of paper and the Kraft Pulp Process in particular. It is a dark brown viscous substance containing 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 December 2015).
- 4. The substance must be a fatty acid from C6 and C24.** TOFA is considered to be a UVCB¹ substance. UVCB’s are substances of Unknown or Variable composition, complex reaction products or biological materials². As stated above, TOFA is produced by the fractionation of crude tall oil (CTO). The latter contains naturally occurring resin acids, fatty acids, and neutral components as they are present in wood originating from various pine species. The TOFA composition is a function of the originating pine species, and the process parameters used in the CTO fractionation. Generally, TOFA contains 90-99% fatty acids^{3,4,5}. Grades with less than 90% fatty acids and a minimum of 10% rosin acids are often referred to as Distilled Tall Oil³. The fatty acids in TOFA are for the utmost part C16-20 fatty acids and include saturated, unsaturated and polyunsaturated fatty acids. Main components are oleic acid (CASN 112-80-1) and linoleic acid (CASRN 60-33-3)^{3,4,5}.

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 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 at www.cefic.org/harrpa (Joël Wilmot +32 2 676 7288 or e-mail: JWI@cefic.be), or any of the signatories.

References

- 1) USA. Toxic Substances Control Act (TSCA) Chemical Substances Inventory (July 2015): "Fatty acids, tall-oil; This entry is a substance of unknown or variable composition, a complex reaction product, or a biological material (TSCA code "UVCB").
- 2) REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 3) McSweeney, E.E., Arlt, H.G. and Russell, J. 'Tall oil and its uses – II'. Pulp Chemicals Association, Inc. Atlanta, 1987
- 4) High Production Volume (HPV) Chemical Challenge Program, Final Submission for Tall Oil Fatty Acids and related Substances, Submitted to US EPA, 2004
- 5) Tall Oil Fatty Acids, D.P. Duncan, in Naval Stores by D.F. Zinkel and J.R. Russell (eds.), Pulp Chemical Association, New York, 1989.

March 2016: This paper is published by HARRPA, on behalf of the following signatory companies:

Arizona Chemicals B.V.



Forchem Oy.



DRT S.A.



Kemira Oy.



Annex 1

“ANNEX V form Reach Regulation”

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

...

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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