

Position papers

MARINALG INTERNATIONAL POSITION PAPER REGARDING :
European Union : Molecular Weight Specification for Carrageenan (E 407) and Processed Eucheuma Seaweed (E 407a)

Background

In response to a published review article alleging carrageenan to be a carcinogen and in light of its previous reviews of carrageenan, the European Commission's Scientific Committee for Food (SCF) evaluated the publication. In its opinion of March 5, 2003, the SCF concluded that *"there is no evidence of any adverse effects in humans from exposure to food grade carrageenan, or that exposure to degraded carrageenan from the use of food-grade carrageenan is occurring."* However, despite these conclusions, the Committee endorsed the establishment of a specification for carrageenan in which a molecular weight limit of not more than 5% below 50, 000 daltons (50 kDa) would be implemented, *"if feasible"*.

In response to the SCF review, the carrageenan industry initiated two major courses of action :

- Marinalg members commenced a program to determine the feasibility of developing a validated analytical method to measure the low molecular weight tail (LMT) of carrageenan and PES.
- FMC Corporation, a major producer of carrageenan and member of the trade association Marinalg, initiated a 90 day feeding study in rats of a kappa carrageenan just above the current water viscosity specification. Based on the LMT method development program (see below), the test material was believed to be just outside the proposed specification with respect to amount of molar mass below 50kDa.

The results of these programs concluded that :

- Current available analytical methods are deficient in their ability to accurately measure the Lower Molecular Weight Tail of carrageenan on a consistent basis.
- No significant toxicological effects were seen in the 90 day feeding study in rats of a kappa carrageenan, thereby reinforcing the safety of the consumption of carrageenan.

Re: the 90 feeding study in rats :

Groups of Fischer 344 rats (20/sexgroup) received control or treated diets at levels of 0, 2.5 and 5.0% kappa carrageenan (weight average molecular weight range of 196,000 to 257, 000 depending on the laboratory performing the test) for 90 days. (Since no validated analytical method is currently available to measure the LMT of carrageenan, measurement of LMT was in the range of 1.9 % to 12.0 % < 50 kDa using currently available nonvalidated analytical methods).

http://www.marinalg.org/papers/papers_inf.htm

Full histopathological evaluation of organs was conducted on the control groups and groups fed 5.0% carrageenan in the diet. Special microscopic examinations of hematoxylin-eosin stained cross sections of paraffin-embedded rolled colon were conducted in control and high-dose animals. The gastrointestinal tract appeared normal in detailed histopathological evaluation using the colon roll. Thorough histopathological evaluation of the gastrointestinal tract provides no indication of induction of aberrant crypt foci of the colon or any pre-neoplastic changes when kappa carrageenan is fed at the limit dose (5% in the diet).

Dietary administration of up to 50,000 ppm kappa carrageenan (5% in the diet) for 90 days did not result in any treatment-related adverse effects on body weight, body weight gain, food consumption, clinical signs, hematological or clinical chemistry parameters, organ weights or histopathology. There were no treatment-related histopathological findings in this study. Extensive evaluation of the gastrointestinal tract with particular emphasis on the colon was conducted. Since high concentrations of non-nutritional substances in the diet can cause nutritional deficiencies and other non-specific effects, the U.S. FDA recommends 50,000 ppm (5%) of test material in the diet as the highest dose (1982). The results of this study verified the safe use of kappa carrageenan for human dietary use in foods.

Re : method development for measuring the lower molecular weight tail :

Six laboratories participated in the program. The laboratories and methods evaluated by them follow :

■ Degussa Food Ingredients GmbH : SEC/RI/MALLS

Molecular weight determination by size exclusion chromatography with multi-angle laser light scattering and refractive index for each fraction.

■ Danisco A/S : SEC/RI/MALLS

Molecular weight determination by size exclusion chromatography with multi-angle laser light scattering and refractive index for each fraction.

■ Viscotek, Ltd., SEC/RI/LALLS/RALLS/Viscosity

Molecular weight determination by size exclusion chromatography with low- and right angle laser light scattering and refractive index for each fraction, with the additional use of intrinsic viscosity to monitor molecular size and shape.

■ Polymer Standards Services, GmbH; SEC/RI/MALLS

Molecular weight determination by size exclusion chromatography with multi-angle laser light scattering and refractive index for each fraction

■ San-Ei Gen FFI Ltd.: SEC/RI /ICP

Molecular weight determination by size exclusion chromatography refractive index and inductively coupled plasma-atomic emission spectroscopy (sulphur) for each fraction.

■ North East Wales Institute/NEWI. - SEC/RI/MALLS

Molecular weight determination by size exclusion chromatography with multi-angle laser light scattering and refractive index for each fraction.

The program involved testing multiple samples of various types of carrageenan (kappa, lambda, iota) and Processed Eucheuma Seaweed (PES) in a "round robin" format. The intent was to establish a primary validated method that could be used for enforcement purposes. The analytical equipment and methods would be validated against the agreed method and equivalence established.

However, before industry's work was completed, the Commission published Directive 2004/45/EC of 16 April 2004 amending the purity criteria for carrageenan (E 407) and Processed Eucheuma Seaweed (E 407a) to establish the aforementioned specification, even though at the time a validated analytical method for measuring the lower molecular weight fraction of carrageenan and PES was neither available nor known to be feasible.

Current status of method development

At its meeting of October 18, 2005, Marinalg members reviewed the study results and concluded that while the several methods that were screened using identical samples gave good consistency on weight average molecular weight (Mw), the results were inconsistent with respect to measuring the LMT. Furthermore, correlations of Mw to viscosity were determined to be good, but poor with respect to the LMT. Overall, no current analytical methodology is suitable for validation for measuring the lower molecular weight tail of carrageenan. Given these findings, Marinalg holds in abeyance further work to establish a method to measure the LMT of carrageenan until such technology should be developed and available.

An in depth discussion of the results of the program for developing a test method for measuring the LMT of carrageenan can be found in the related document that appears on this website.

Current status of 90 day feeding study in rats

The 90 day feeding study in rats was presented in part at the March, 2005 Society of Toxicology meeting in New Orleans, Louisiana (USA). Publication of the study in a peer reviewed scientifically reputable journal is pending.

Conclusion :

Presently, there is no validated analytical method available to accurately measure the low molecular weight tail of carrageenan, thereby rendering the European Commission's molecular weight specification very difficult to enforce in a consistent manner. However, in light of the recent 90 day feeding study in rats, the data continue to

support the conclusion of the SCF that *"there is no evidence of any adverse effects in humans from exposure to food grade carrageenan, or that exposure to degraded carrageenan from the use of food-grade carrageenan is occurring."* The results of the recent 90 day dietary study on kappa carrageenan in rats support long held positions on the safety of consumption of carrageenan and does not support the establishment of a LMT specification for carrageenan. Marinalg maintains that viscosity remains a practical index of carrageenan molecular weight and functionality. Extracts below the current specification of 5cP simply do not function as carrageenan and are essentially useless in food application.