

JHeimbach LLC

October 9, 2006

RE: Indirect Food Additive Use of Lauric Arginate

Xavier Rocabayera
Deputy Director, Food Ingredients Department
LAMIRSA (Laboratorios Miret S.A.)
Géminis, 4
Políg. Ind. Can Parellada
08228 Terrassa
Barcelona
Spain

Dear Xavier:

As you are aware, one of your customers intends to use lauric arginate as a component of a spray application for use in keeping food conveyor belts clean and reducing microbial contamination. This use is regarded as an *indirect* food additive use because the lauric arginate is not directly added to the food, but rather is applied to a food-contact surface; any lauric arginate that becomes a component of the food does so through migration; and it has no functional effect in the food.

The intended use is such that, if all of the lauric arginate applied to the conveyor belt were to migrate to the food carried on the belt between applications, the resulting concentration of lauric acid in the food would be less than 2 mg/kg (parts per million). Since lauric arginate is generally recognized as safe (GRAS) for direct addition to food at a concentration of over 200 mg/kg, the added concentration is less than 1% of that resulting from direct application.

The U.S. Food and Drug Administration (FDA) has established a threshold of regulation for substances used in food-contact articles. This regulation is presented in 21 CFR §170.39, which reads in part:

Sec. 170.39 Threshold of regulation for substances used in food-contact articles.

(a) A substance used in a food-contact article (e.g., food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

(1) The substance has not been shown to be a carcinogen in humans or animals, and

(2) The substance presents no other health or safety concerns because:

(i) The use in question has been shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion, or

- (ii) The substance is currently regulated for direct addition into food, and the dietary exposure to the substance resulting from the proposed use is at or below 1 percent of the acceptable daily intake;
- (3) The substance has no technical effect in or on the food to which it migrates; and
- (4) The substance use has no significant adverse impact on the environment.

As can readily be seen, the intended indirect use of lauric arginate fully complies with these provisions. Therefore, the intended use is permitted under the threshold of regulation principle.

Additionally, I sought the opinions of the members of the Expert Panel that evaluated the safety of lauric arginate: Joseph F. Borzelleca, Ph.D., Robert J. Nicolosi, Ph.D., Michael W. Pariza, Ph.D., and John A. Thomas, Ph.D. These individuals, qualified by scientific training and experience to evaluate the safety of foods and food ingredients, concurred in my determination that this additional use of lauric arginate is GRAS.

The intended use of lauric arginate is thus permitted both under threshold of regulation and under the GRAS provisions. The only limitation in this use is that it must be such that the resulting concentration of lauric arginate in the food does not exceed 2 mg/kg.

Sincerely,

A handwritten signature in black ink, appearing to read 'J T Heimbach', written in a cursive style.

James T. Heimbach, Ph.D., F.A.C.N.
President