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Consultation Document on Health Canada's Proposal to Enable the Use of a New Food Additive, Ethyl Lauroyl Arginate, as a Preservative in Various Standardized and Unstandardized Foods

Notice of Proposal – *Lists of Permitted Food Additives*

December 9, 2013

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

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Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations*. Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada received a food additive submission seeking approval for the use of ethyl lauroyl arginate, also known as lauric arginate ethyl ester, lauramide arginine ethyl ester, ethyl-N-alpha-lauroyl-L-arginate hydrochloride or ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride, as a preservative in a variety of standardized and unstandardized foods, namely water-based non-alcoholic beverages at a maximum level of use of 50 parts per million (p.p.m.), and soups, cheese products, sauces and dips, ketchup, pie fillings, and meat, poultry and fish products, all at a maximum level of use of 200 p.p.m.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of ethyl lauroyl arginate when used as described. Therefore, it is the intention of Health Canada to modify the [List of Permitted Preservatives](#) by adding the following entries to Part 2 - Class 2 Preservatives of the list. Part 2 of the *List of Permitted Preservatives* comprises preservatives that act as antimicrobials.

Text of Proposed Modifications to the *List of Permitted Preservatives*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
E.1	Ethyl lauroyl arginate	(1) Unstandardized non-alcoholic water-based beverages (2) Cheddar cheese; Meat by-product loaf; Meat loaf; (naming the variety) Cheese; (naming the variety) Whey cheese; Pie fillings; Potted meat; Potted meat by-product; Prepared fish	(1) 50 p.p.m. calculated as ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (2) 200 p.p.m. calculated as ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride

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		<p>or prepared meat (Division 21); Prepared meat; Prepared meat by-product; Prepared poultry meat; Prepared poultry meat by-product; Preserved fish or preserved meat (Division 21); Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Sausage; Soups; Tomato catsup; Unstandardized dips; Unstandardized sauces; Whey cheese</p>	
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Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of ethyl lauroyl arginate when used as described above. The assessment considered the microbiological, toxicological and technical aspects of the proposal.

Ethyl lauroyl arginate is a cationic surfactant¹ that can be used as an antimicrobial preservative to protect food against microbiological contamination and spoilage due to its ability to disrupt the integrity of cell membranes in a broad spectrum of Gram positive and Gram negative bacteria, and yeasts and moulds at low and near-neutral pH. Data on the ability of ethyl lauroyl arginate to inhibit the growth of microorganisms were evaluated and found to support the efficacy of the additive as an antimicrobial preservative in the requested food categories.

¹ Surfactant is a substance which reduces the surface tension of a liquid (Canadian Oxford Dictionary, Second Edition).

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The active ingredient in ethyl lauroyl arginate is ethyl-N-alpha-lauroyl-L-arginate hydrochloride. The name assigned to the active ingredient by the IUPAC² is ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride. The Chemical Abstracts Service Registration Number (CAS number) for the active ingredient is 60372-77-2. Ethyl lauroyl arginate contains a minimum of 85% of ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride. The remaining components are by-products and residuals generated from the manufacturing process: N-alpha-lauroyl-L-arginine, ethyl laurate, lauric acid, arginine hydrochloride, and ethyl arginate dihydrochloride.

Studies were assessed on the stability of ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride, under various storage temperatures throughout a range of pH levels, and in different food products. These studies demonstrated that the active ingredient is stable in different products and at the storage temperatures and range of pH levels to which this preservative may be exposed.

No microbiological concerns have been identified with respect to the proposed use of the active ingredient and no evidence was found that any of the metabolites produced following ingestion of ethyl lauroyl arginate can cause allergies or food intolerances.

Health Canada reviewed the results of a number of safety studies with experimental animals that were designed to specifically examine whether ethyl lauroyl arginate could cause harmful health effects on metabolism, acute and short-term oral toxicity, genetic and reproductive toxicity. The results of these studies were considered in relation to an estimate of total dietary exposure to ethyl lauroyl arginate if present in all foods as described in the above table.

Based on the results of the assessment, Health Canada's Food Directorate considers that the data support the safety and efficacy of ethyl lauroyl arginate when used under the conditions set out in the table above. The Department is therefore proposing to enable the use of ethyl lauroyl arginate as set out in that table.

Other Relevant Information

- As a food additive, ethyl lauroyl arginate would be required to meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC), a compendium of standards for the purity and identity of food ingredients, including food additives, which is published by United States Pharmacopeial Convention. A key specification of the FCC monograph is that ethyl lauroyl arginate contains not less than 85% of the active ingredient ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride.
- Ethyl lauroyl arginate is listed under the synonym lauric arginate ethyl ester (INS 243) in the Codex General Standard for Food Additives (GSFA). The GSFA contains provisions for its use in a wide range of food categories at a maximum level of use of 200 mg/kg (p.p.m.), except for carbonated and non-carbonated water-based flavoured drinks (food

² IUPAC: International Union of Pure and Applied Chemistry

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categories 14.1.4.1 and 14.1.4.2) and concentrates for water-based flavoured drinks (food category 14.1.4.3) for which the maximum level of use is 50 mg/kg. However, there are no provisions in the GSFA for the use of ethyl lauroyl arginate in meat, poultry and fish products.

- In the European Union, the assessment for ethyl lauroyl arginate is ongoing.
- In the United States, one Generally Recognized as Safe (GRAS) notice (GRN000164) for lauramide arginine ethyl ester (i.e., ethyl lauroyl arginate), comprised of 89-95% ethyl-N-alpha-lauroyl-L-arginate hydrochloride (dehydrated), was submitted in 2005 to the US Food and Drug Administration (FDA) for review. The US FDA did not raise any objections regarding the petitioner's determination of GRAS status for the use of lauramide arginine ethyl ester as an antimicrobial in a wide range of foods at levels up to 200 mg/kg (p.p.m.) ethyl-N-alpha-lauroyl-L-arginate hydrochloride.
- Australia and New Zealand permit the use of ethyl lauroyl arginate in a wide variety of food categories, many of which have a maximum level of use of 200 p.p.m. (calculated as ethyl- N-alpha-lauroyl-L-arginate·HCl). However, it is permitted in beverages (i.e., water-based flavoured drinks, fruit and vegetable juices and fruit and vegetable juice products) up to a level of 50 p.p.m.; processed comminuted meat and poultry products up to a level of 315 p.p.m.; and in semi-preserved fish and fish products, cheese (soft/cream/processed and mozzarella), dairy and fat based desserts, dips and snacks at a level up to 400 p.p.m. All of these maximum use levels are calculated as ethyl- N-alpha-lauroyl-L-arginate·HCl.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the [List of Permitted Preservatives](#). This will be announced via a Notice of Modification which will be published on the [Food and Nutrition - Public Involvement and Partnerships](#) section of Health Canada's Website.

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

[Bureau of Chemical Safety, Food Directorate](#)

If communicating by e-mail, please use the words “**ethyl lauroyl arginate**” in the subject line of your e-mail. Health Canada is able to consider information received by **February 21, 2014**, 75 days from the date of this posting.