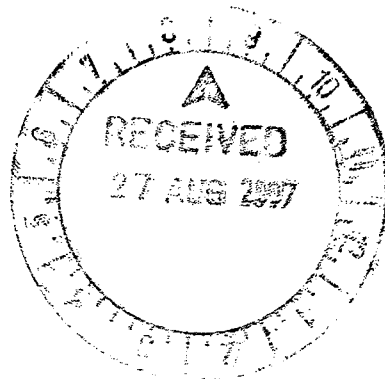


22 August 2008



Standards Management Officer  
Food Standards Australia New Zealand  
Boeing House  
55 Blackall Street  
Barton, ACT 2600

Dear Madam,

**Application for Listing in Schedule 1 of Standard 1.3.3 (Food Additives)**

**Substance:** Lauric Arginate

**Applicant:** Laboratorios Miret, S.A.

---

Laboratorios Miret, S.A. is applying for inclusion of lauric arginate in Schedule 1 of Standard 1.3.3 of the Food Standards Code.

Lauric arginate is a new substance developed by Laboratorios Miret, S.A. for controlling microbial contaminants in a broad range of foods. The substance has demonstrated activity against bacteria, fungi and yeasts that contaminate foods.

In addition to demonstrated efficacy, the product has low toxicity.

The combination of good efficacy and low toxicity makes lauric arginate a valuable tool in the prevention of food poisoning caused by contaminated foods.

The foods that can be protected include beverages, cheeses, meats, fruits and vegetables, breads and bakery products, fish products, savoury toppings, certain deserts and others.

In support of the application, please find enclosed:

1. Two hard copies of the application plus two CDs containing an electronic copy of the application. The application includes confidential information that has been separated from the rest of the application. Confidential information is included on a separate CD to the non-confidential information. Justification for the confidential information is provided below.
2. The applicant will derive exclusive capturable commercial benefit. A declaration is attached to this letter and is included in the appendices (Appendix 69).
3. A statutory declaration as required in 3.1.10 of the Application Handbook is included in the appendices (Appendix 69).
4. A completed Checklist is enclosed with this letter and is included in the appendices (Appendix 70).

Confidential information has been enclosed in separate volumes marked confidential. The confidential information relates to manufacturing of the

substance and to specific studies done to confirm efficacy of the product. Justification for claiming confidentiality for each study is listed below:

1. Confidential Appendix 1: While information is included in the Confidential Appendices, no confidentiality is claimed for the information as it has been separately provided in the non-confidential section. The information is provided to simplify referencing.
2. Confidential Appendix 2: While information is included in the Confidential Appendices, no confidentiality is claimed for the information as it has been separately provided in the non-confidential section. The information is provided to simplify referencing.
3. Confidential Appendix 3: While information is included in the Confidential Appendices, no confidentiality is claimed for the information as it has been separately provided in the non-confidential section. The information is provided to simplify referencing.
4. Confidential Appendix 4: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers.
5. Confidential Appendix 5: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
6. Confidential Appendix 6: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
7. Confidential Appendix 7: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
8. Confidential Appendix 8: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
9. Confidential Appendix 9: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from

their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.

10. Confidential Appendix 10: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
11. Confidential Appendix 11: The data contained in this appendix were obtained in cooperation with a potential named customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
12. Confidential Appendix 12: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
13. Confidential Appendix 13: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
14. Confidential Appendix 14: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
15. Confidential Appendix 15: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
16. Confidential Appendix 16: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.

17. Confidential Appendix 17: The data contained in this appendix were obtained in cooperation with a potential named customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
18. Confidential Appendix 18: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
19. Confidential Appendix 19: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
20. Confidential Appendix 20: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
21. Confidential Appendix 21: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
22. Confidential Appendix 22: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
23. Confidential Appendix 23: The information provided in this appendix includes reference to customers or potential customers. The identity of these customers/potential customers is considered to be commercially sensitive and should not be disclosed to third parties as such disclosure could adversely impact commercial arrangements with those customers/potential customers. Furthermore, the presence of identified microbial contaminants in product from a named producer could be misinterpreted and could adversely affect the business of that producer.
24. Confidential Appendix 24: The data contained in this appendix were obtained in cooperation with a potential named customer who has requested the information not be made available to competitors who have not invested in

helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.

25. Confidential Appendix 25: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
26. Confidential Appendix 26: The data contained in this appendix were obtained in cooperation with a potential named customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
27. Confidential Appendix 27: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
28. Confidential Appendix 28: The data contained in this appendix were obtained in cooperation with a potential named customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
29. Confidential Appendix 29: The data contained in this appendix were obtained in cooperation with a potential customer who has requested the information not be made available to competitors who have not invested in helping develop the product until that customer has had an opportunity to derive benefit from their investment in collaborating in the development of the product. Disclosure of the information could adversely affect ongoing/long-term relations with the named co-operator.
30. Confidential Appendix 30: The appendix lists certain potential customers in Australia and provides their comments in relation to products currently used in their interest in lauric arginate. Identifying these customers and their comments could adversely affect their relationship with current suppliers and potentially adversely affect the relationship between the companies and the Australian distributor for lauric arginate.
31. Confidential Appendix 31: This appendix contains detailed information on the manufacturing of lauric arginate. Release of this information could enable competitors to produce the product without the need to invest in developing the manufacturing methods, testing methods, etc that has been necessary for the pioneer.

As can be seen from the above, the information provided in the Confidential Appendices is information that has a commercial value that could be destroyed or diminished if the information was disclosed. Furthermore, with respect to the

To: FSANZ  
Re: Lauric Arginate (Laboratorios Miret, S.A.)  
22 August 2008

---

Page 6 of 6

manufacturing details, the information contains trade secrets, the value of which would be diminished if not negated if the information was disclosed.

I look forward to receiving advice as to the fee payable for this application. Upon receipt of the confirmation of the fee payable, I will arrange payment directly to FSANZ.

Yours faithfully,



Consultant to Laboratorios Miret, S.A.

## STATUTORY DECLARATION

*Statutory Declarations Act 1959*

I, Michael Tichon of 8 Coomalie Avenue, Castle Hill, New South Wales, Consultant to Laboratorios Miret, S.A.

make the following declaration under the *Statutory Declarations Act 1959*:

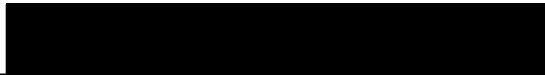
1. the applicant is Laboratorios Miret, S.A.,
2. the applicant is expected to derive a financial gain from the amendment to the Standard,
3. all other unrelated persons or bodies, including unrelated commercial entities would require the agreement of the applicant in order to benefit financially from the approval of the application.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.



Declared at Parramatta on 21<sup>st</sup> day of August, 2008

Before me,



No 111298

[Signature of person before whom the declaration is made]\*

Full Name: Warren McHattay

Qualification: Justice of the Peace

Address: 38-40 George St,  
PARRAMATTA

## STATUTORY DECLARATION

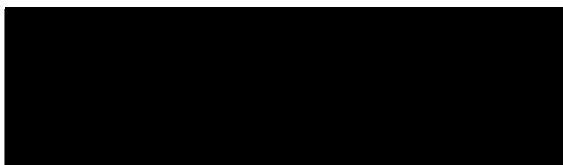
*Statutory Declarations Act 1959*

I, Michael Tichon of 8 Coomalie Avenue, Castle Hill, New South Wales, Consultant to Laboratories Miret, S.A.

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.



Declared at Parramatta on 21<sup>st</sup> day of August, 2008

Before me,



[Signature of person before whom the declaration is made]\*

Warren McHattan

Full Name:

111298

Qualification:

Justice of the Peace

Address:

Unit 2 Level 2  
38-40 George St  
Parramatta



## **CHECKLIST FOR STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD**

### **General Requirements (3.1)**

<input checked="" type="checkbox"/>	Form of application	<input checked="" type="checkbox"/>	Assessment procedure
<input checked="" type="checkbox"/>	Applicant details	<input checked="" type="checkbox"/>	Confidential Commercial Information
<input checked="" type="checkbox"/>	Purpose of the application	<input checked="" type="checkbox"/>	Exclusive Capturable Commercial Benefit
<input checked="" type="checkbox"/>	Justification for the application	<input checked="" type="checkbox"/>	International standards
<input checked="" type="checkbox"/>	Information to support the application	<input checked="" type="checkbox"/>	Statutory Declaration

### **Food Additives (3.3.1)**

<input checked="" type="checkbox"/>	Support for the application	<input checked="" type="checkbox"/>	Analytical detection method
<input checked="" type="checkbox"/>	Nature and technological function information	<input checked="" type="checkbox"/>	Toxicokinetics and metabolism information
<input checked="" type="checkbox"/>	Identification information	<input checked="" type="checkbox"/>	Toxicity information
<input checked="" type="checkbox"/>	Chemical and physical properties	<input checked="" type="checkbox"/>	Safety assessments from international agencies
<input checked="" type="checkbox"/>	Impurity profile	<input checked="" type="checkbox"/>	List of foods likely to contain the food additive
<input checked="" type="checkbox"/>	Manufacturing process	<input checked="" type="checkbox"/>	Proposed levels in foods
<input checked="" type="checkbox"/>	Specifications	<input checked="" type="checkbox"/>	Percentage of food group to contain the food additive
<input checked="" type="checkbox"/>	Food labelling	<input checked="" type="checkbox"/>	Use in other countries (if applicable)

			with changed consumption patterns
<input type="checkbox"/>	Manufacturing process information	<input type="checkbox"/>	Nutritional purpose
<input type="checkbox"/>	Specification information	<input type="checkbox"/>	Analytical detection method
<input type="checkbox"/>	Need for nutritive substance in food	<input type="checkbox"/>	Proposed food label
<input type="checkbox"/>	Demonstrated potential deficit or health benefit	<input type="checkbox"/>	Toxicokinetics and metabolism information
<input type="checkbox"/>	Consumer awareness and understanding	<input type="checkbox"/>	Animal or human toxicity studies
<input type="checkbox"/>	Actual or potential behaviour of consumers	<input type="checkbox"/>	Safety assessments from international agencies
<input type="checkbox"/>	Demonstration of no adverse affects to any population groups	<input type="checkbox"/>	List of food groups or foods likely to contain the nutritive substance
<input type="checkbox"/>	Impact on food industry	<input type="checkbox"/>	Proposed maximum levels in food groups or foods
<input type="checkbox"/>	Impact on trade		