Propionates as Preservatives in Processed Meat

EXTENSION of USE APPLICATION

Food Standards Australia New Zealand

Applicant: KEMIN INDUSTRIES (Asia) PTE LTD
Submitted by: AXIOME PTY LTD

May 4, 2015

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Executive Summary:

This application, on behalf of Kemin Industries (Asia) PTE LTD,, requests approval for the extension of use of propionic acid, and its calcium, potassium and sodium salts, as anti-microbial preservatives in processed meat products.

According to FSANZ food recall data since 2005, microbial contamination is the principal cause for product recall, occurring most frequently in meat products, with contamination by *Listeria monocytogenes* reported as the most common causal organism. Whilst there are currently a range of preservatives approved for use in processed meat products, microbial contamination is still a major problem for manufacturers and a serious concern for consumers, particularly for at-risk groups. Standard 1.6.1 Microbial Limits in Food was amended in 2014 in recognition of this problem to include microbiological criteria for *Listeria monocytogenes* in 'Ready-To-Eat' foods.

The preservatives currently approved in the Food Standards Code for use in processed meat products include nitrites/nitrates, nisin, natamycin, sorbates and sulphites. Lactic acid, sodium diacetate, and other organic acids may also be used because of their 'schedule 2 additive' status. However, for control of contamination by *Listeria monocytogenes,* some of these preservatives are not effective and more specific for control of yeasts and mould or more suited for use in other foods. Nitrates and nitrites are primarily used as curing ingredients to achieve the characteristic flavour, colour and stability in processed meat products and provide protection against specific pathogenic bacteria such as *botulism*-producing organisms. However, these ingredients can be toxic to humans, and much controversy has surrounded the use of nitrite in recent years due to its potential carcinogenic risk. Despite the range of preservatives available to processors, *Listeria m.* contamination of processed meat products remains a serious and frequently occurring problem.

Propionates are particularly effective in inhibiting *Listeria monocytogenes* at the pH of meat products, and can be used at low dose rates without effect on product flavour. In combination with nitrite/nitrate they can provide control against a broader range of microorganisms and potentially result in reduced nitrite/nitrate use levels. Propionates are currently approved as preservatives in the Food Standards Code for use in Bread & Bakery Products and Flour Products, and sodium propionate in Oil Emulsions (< 80% oil).

The safety of Propionate is attested by the fact that they are a normal metabolic intermediate, a normal metabolite from carbohydrate fermentation in the large intestine, and naturally occur in foods such as butter, cheese and other dairy foods. As food preservatives they have been used widely for more than 50 years. The safety of propionates has been reviewed by JECFA, EFSA and US FDA and all of these agency reviews have confirmed or reconfirmed that there are no safety concerns in respect to the use of propionates as preservatives in the currently authorized uses and use levels.

CODEX permits propionic acid and its calcium, potassium and sodium salts in processed meat, poultry, and game products in whole pieces or cuts, and processed comminuted meat, poultry, and game products, under the conditions of GMP. In USA, sodium propionate and propionic acid are permitted in ready to eat meat and poultry, where antimicrobials are permitted, up to 0.5%.

Approval of this application would provide food manufacturers with a cost effective control against *Listeria monocytogenes* contamination in processed meat products.

1 General Information:

1.1 Applicant Details:

[redacted] – President, Food Technologies Asia Pacific & India
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[redacted]
website: www.kemin.com

Kemin Industries, Inc. manufactures specialty ingredients for the global food and feed industries, as well as health, nutrition, and beauty markets. It offers products for human use, including food technologies, nutraceuticals, pharmaceuticals, and personal care. The company also provides products for animals, such as swine, poultry, dairy, beef, pets, and feed. Kemin Industries, Inc. was founded in 1961 and is headquartered in Des Moines, Iowa USA with additional offices in Singapore; Tokyo, Japan; Sanzao, China; Herentals, Belgium; Lisbon, Portugal; Chennai, India; Des Moines, Iowa; and Sao Paulo, Brazil. The company has manufacturing facilities in Belgium, Brazil, China, India, Italy, Singapore, South Africa, and the United states. In Australia and New Zealand they are represented by Hawkins Watts Ltd.

Application Contact:

[redacted]
Axiome Pty Ltd
PO Box 1040
Bathurst NSW 2795

[redacted]

1.2 Purpose of the Application:

The purpose of this application is to request approval for the extension of use of the food preservative Propionic Acid, and its Calcium, Potassium and Sodium salts in the following products:

Standard 1.3.1 – Food Additives, Schedule 1 clauses:

8.2 Processed meat, poultry and game products in whole cuts or pieces

8.3 Processed comminuted meat, poultry and game products

1.3 **Justification for the Application:**

From FSANZ food recall statistics 2005 to 2014 included below, Table 1 and Figure 2 identify microbial contamination as the principal recall reason (33%) and this is typically the case for each year of data. For microbial contamination recalls, *Listeria monocytogenes* is reported as the most common causal organism (45%; Figure 3) with meat (including poultry) as the most common food category (49%; Figure 4) affected. Whilst there are a range of antimicrobial food preservatives approved for use in processed meat products, these statistics would suggest that they are not adequate to control contamination by *Listeria monocytogenes.*

Recall reason	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Total
Microbial contamination	18	22	21	15	28	14	13	25	12	26	194
Foreign matter	10	18	14	15	7	10	18	12	7	14	125
Labelling	1	3	4	2	1	1	1	2	2	0	17
Undeclared allergen	20	19	9	10	17	13	24	17	16	27	172
Chemical/contaminant	7	4	3	4	1	10	5	1	0	1	36
Biotoxin	2	0	0	2	1	2	4	1	2	3	17
Tampering	1	0	0	0	0	0	0	0	0	0	1
Other	5	1	0	3	0	3	2	2	3	5	24
Total	**64**	**67**	**51**	**51**	**55**	**53**	**67**	**60**	**42**	**76**	**586**

Table 1: Number of recalls coordinated by FSANZ by year and classification between 1 January 2005 and 31 December 2014

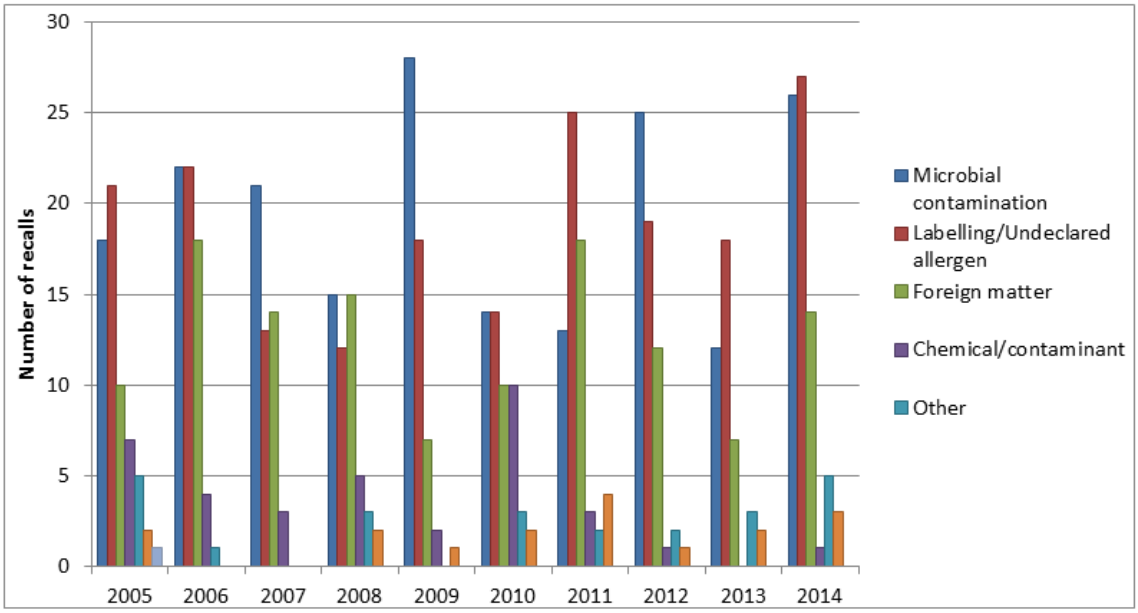


Figure 2: Number of food recalls coordinated by FSANZ each year shown by recall classification between 1 January 2005 and 31 December 2014

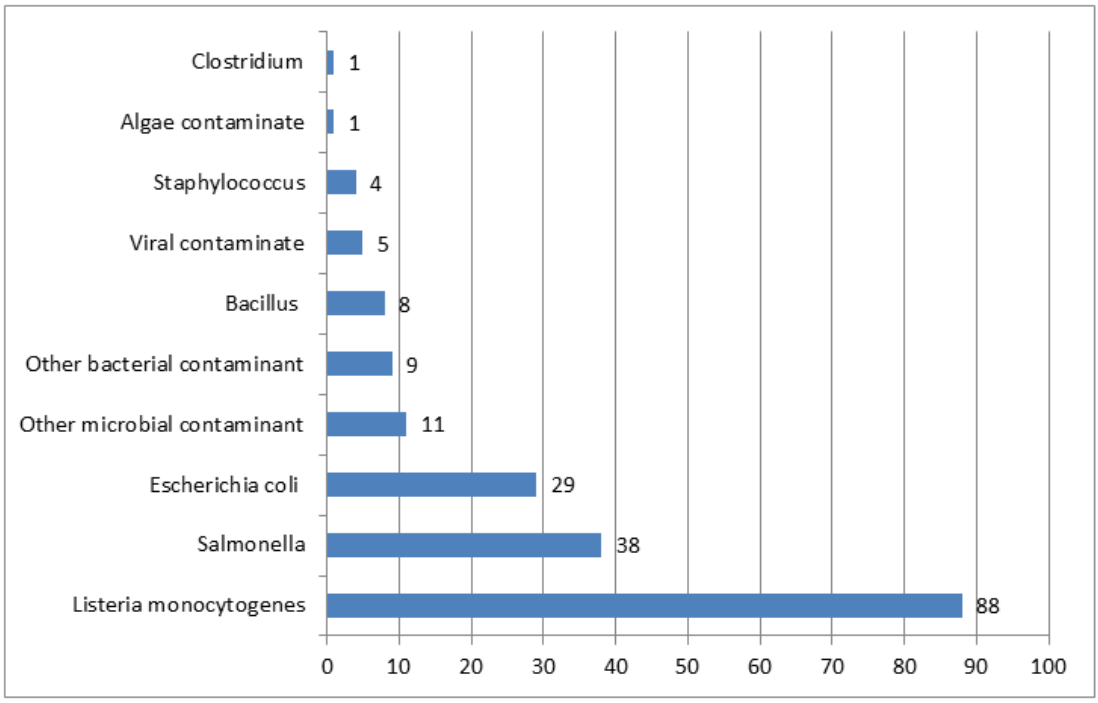


Figure 3: M croorgan sms assoc ated w th m crob a reca s from 1 January 2005 to 31 December 2014

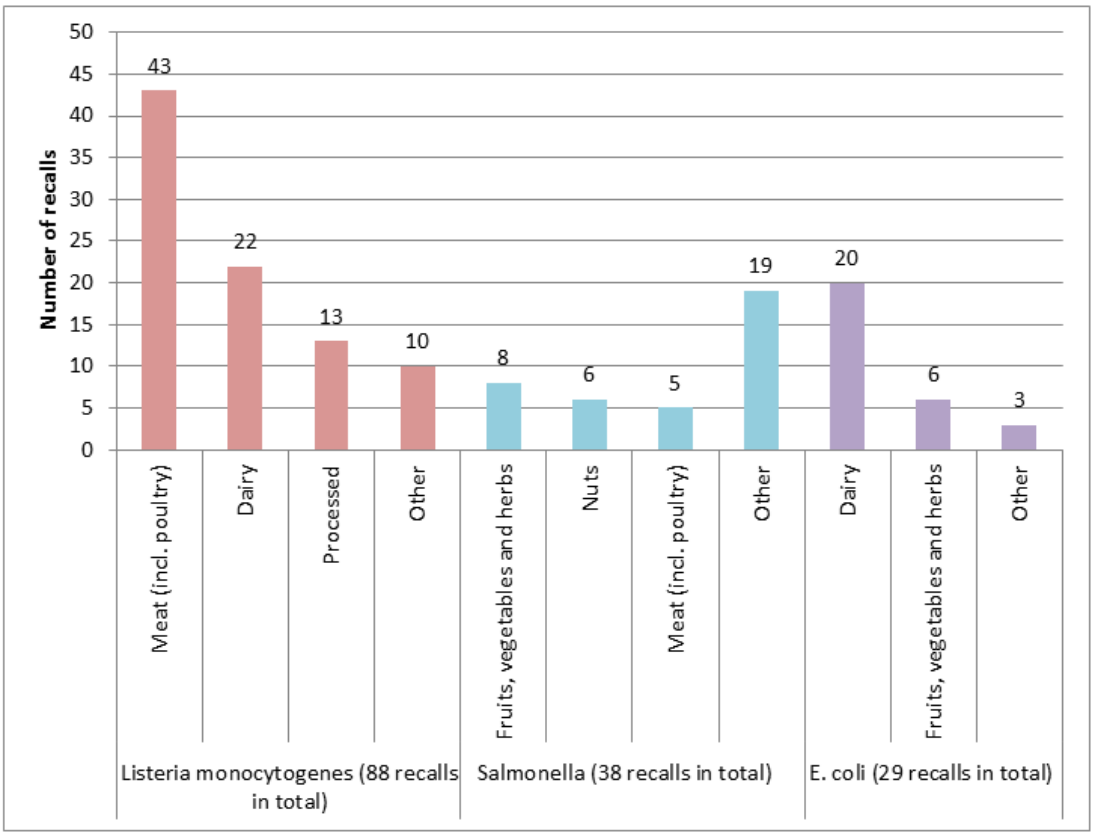


Figure 4: Type of food products recalled 1 January 2005 to 31 December 2014 due to microbiological contamination.

As discussed in Section 2.1 Propionates are very effective at inhibiting the growth *Listeria monocytogenes* in processed meat products, at low usage levels and without effect on product quality. The cost of using these additives and impact on finished

product cost, which is relatively small, is also discussed in Section 2.1. However any added cost would be far outweighed by the very significant cost to manufacturers for product recall, disposal of contaminated product, replacement in the supply chain and the adverse publicity and negative impact on the manufacturer and the product brand. It is therefore likely that a reduction in recalls from use of the additives would provide over time a reduction in product cost. No specific data is available at this stage to quantify cost benefit, however subsequent to approval and depending on extent of additive use by processed meat manufacturers, recall statistics would reflect any improvement.

While it is likely that consumers would over time receive a cost benefit, the most significant benefit would be related to health and safety via a reduction in the potential exposure to microbially contaminated (and specifically by *Listeria monocytogenes*) processed meat products.

No added costs to government are anticipated from the approval of this application. Instead there is possibly a cost benefit from a reduction in food recalls and therefore reduced administrative, reporting and other associated costs.

The application proposes regulatory changes that are consistent with the relevant Codex Alimentarius standards and therefore there would not be any negative impact in respect to international trade.

1.4 **Information to support the Application:**

Technical information, information on safety, and information on dietary exposure is provided in Sections 2, 3 and 4 in support of this application.

The application specifically relates to health and safety issues, that is the incidence of contamination of processed meat products with *Listeria monocytogenes* and the potential for reduced frequency of what is a serious and costly problem. Rather than adversely affect, benefits from the proposed regulatory change would result for the general population, and particularly for listeriosis at-risk population groups.

Consumer choice would not be affected by the proposed change. If used, the additives would need to listed in the product ingredient list thereby notifying consumers of their presence and thus providing the appropriate information if required for choice. No other issues have been identified concerning consumer choice for the proposed regulatory change.

At this stage, for commercial reasons the applicant has not undertaken any extensive marketing or promotion of their additives and therefore evidence of support from industry, which is provide in Appendix B, is limited. However, more extensive evidence of support from industry would be provided during the “Public Notification/Call for Submissions” step during assessment.

1.5 **Assessment Procedure:**

Based on guidance in the current 'Application Handbook', our determination is that the appropriate procedure for assessment of this application would be:

General Procedure Level 1

i.e. "extending the use of a food or food additive that is permitted under a standard" ('Application Handbook' page 16, 2.2.5 (a))

1.6 **Commercial Confidential Information (CCI):**

Certain (identified) technical information included in Appendix B is regarded by the applicant as **Confidential Commercial Information** and is provided in the application strictly on this basis. This information is the result of a significant research and development effort and investment by the applicant; it is not in the public domain and is considered as either proprietary or commercially sensitive. Some of this information is provided to clients, however this is strictly subject to a legally binding 'non disclosure agreement'. It would be disadvantageous to the applicant if this information were released into the public domain. Certain confidential, sensitive commercial and marketing information concerning Kemin Industries' BactoCEASE propionate product is also provided in Appendix B; it would be disadvantageous to the applicant if this information were released into the public domain.

1.7 **Exclusive Capturable Commercial Benefit (ECCB):**

The approval of this application would not confer an Exclusive Capturable Commercial Benefit.

Propionates have been used widely as preservatives in various processed food products for more than 60 years. Kemin Industries does not hold any patent, licence or any other instrument concerning these ingredients or the technological uses as covered by this application that provide any exclusive commercial benefit to them, their agents, customers or any other party.

1.8 **International and other National Standards:**

a) International Standards:

The Codex General Standard for Food Additives (37th Session Codex Alimentarius Commission 2014) permits the use of Propionic Acid (280), Calcium Propionate (282), Potassium Propionate (283) and Sodium Propionate (281) as preservatives under the conditions of GMP in the following food categories:

08.2 – Processed meat, poultry and game products or in whole pieces or cuts

08.3 – Processed comminuted meat, poultry and game products

b) Other National Standards and Regulations:

USA – Propionic Acid and Sodium Propionate are permitted in 'ready-to-eat' meat and poultry where antimicrobials are permitted up to 0.5%

1.9 **Statutory Declaration:**

STATUTORY DECLARATION

Statutory Declarations Act 1959

[redacted] (Regulator Affairs Consultant and Director – Axiome Pty Ltd), of [redacted] 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, an[redacted] declaration are true in every particular.

Signature[redacted]

Declared at Bathurst Council on 4th of May 2015

Before me,

Signature:[redacted]

Justice of the Peace - 148820

[redacted]

1.10 Checklist

General requirements (3.1)

☑ 3.1.1 Form of application
- ☑ *Application, abstracts and other key documents in English*
- ☑ *Executive Summary (separated from main application electronically and in hard copy)*
- ☑ *Relevant sections of Part 3 clearly identified*
- ☑ *Pages sequentially numbered*
- ☑ *Electronic copy (searchable)*
- ☑ *1 hard copy*
- ☑ *Electronic and hard copy identical*
- ☑ *Hard copy capable of being laid flat*
- ☑ *All references provided (in electronic and hard copy)*

☑ 3.1.2 Applicant details

☑ 3.1.3 Purpose of the application

☑ 3.1.4 Justification for the application
- ☑ *Regulatory impact information*
- ☑ *Impact on international trade*

☑ 3.1.5 Information to support the application
- ☑ *Data requirements*

☑ 3.1.6 Assessment procedure
- ☑ *General*
- ☐ *Major*
- ☐ *Minor*
- ☐ *High level health claim variation*

☑ 3.1.7 Confidential Commercial Information
- ☑ *Confidential material separated in both electronic and hard copy*
- ☑ *Formal request including reasons*
- ☑ *Non-confidential summary provided*

☑ 3.1.8 Exclusive Capturable Commercial Benefit
- ☐ *Justification provided*

☑ 3.1.9 International and other national standards
- ☑ *International standards*
- ☑ *Other national standards*

☑ 3.1.10 Statutory Declaration

☑ 3.1.11 Checklist/s provided with application
- ☑ *3.1 Checklist*
- ☐ *Any other relevant checklists for Parts 3.2-3.7*

Food Additives (3.3.1)			
☑	A.1 Nature and technological function information	☑	B.1 Toxicokinetics and metabolism information
☑	A.2 Identification information	☑	B.2 Toxicity information
☑	A.3 Chemical and physical properties	☑	B.3 Safety assessments from international agencies
☑	A.4 Impurity profile	☑	C.1 List of foods likely to contain the food additive
☑	A.5 Manufacturing process	☑	C.2 Proposed levels in foods
☑	A.6 Specifications	☑	C.3 Likely level of consumption
☑	A.7 Food labelling	☑	C.4 Percentage of food group to contain the food additive
☑	A.8 Analytical detection method	☑	C.5 Use in other countries (if applicable)
☑	A.9 Additional functions	☐	C.6 Where consumption has changed, information on likely consumption

2 Technical Information:

2.1 Nature and Technological Function:

The technological function that propionic acid, and calcium, potassium and sodium propionates will fulfill in the food categories requested, is "anti-microbial preservative". This application is specifically focused on the control of *Listeria monocytogenes* contamination in:

08.2 – Processed meat, poultry and game products or in whole pieces or cuts

08.3 – Processed comminuted meat, poultry and game products

The reasons and justification why these ingredients are needed to fulfill this function are discussed in Section 1.3.

Propionates have been demonstrated to be particularly effective for inhibiting growth of *Listeria monocytogenes* in processed meat products[1], either singly or in combination with other preservatives[2,3,4] for synergistic effect.

The mechanism for antimicrobial activity, as with other lipophilic organic acids, is thought to be that they inhibit or kill microorganisms by interfering with the permeability of the microbial cell membrane, thus disrupting important metabolic processes. The undissociated form of the lipophilic acid is required for antimicrobial activity. Thus inhibitory potency, together with other factors, is linked to pKa value (propionate has a pKa value of 4.87). Compared to other organic acids such as lactic acid[5] (pKa 3.83), the higher pKa value of propionic acid means that far lower levels can be used to achieve the same antimicrobial potency (refer table below).

	pH	
un-dissociated acid (%)	**Propionic**	**Lactic**
99	2.87	1.83
95	3.59	2.55
90	3.92	2.88
80	4.27	3.23
70	4.50	3.46
60	4.69	3.65
50	**4.87**	**3.83**
40	5.05	4.01
30	5.24	4.20
20	5.47	4.43
10	5.82	4.78
1	6.87	5.83
0.5	7.17	6.13

Kemin Industries have undertaken a series of efficacy studies for their BactoCEASE□ propionate product is a range of processed meat products. The reports for these studies, which demonstrate how effective propionate is in controlling *Listeria monocytogenes*, are included in Appendix B. Results for a trial conducted by a meat

processor in the Aust./NZ market are also included similarly demonstrating the effectiveness of propionates. Information on the cost of treatment with Kemin Industries' BactoCEASE propionate product is provided in Appendix B.

2.2 Identity:

Propionic Acid

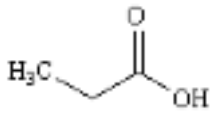
CAS: Propanoic Acid 79-09-4

IUPAC: Propanoic Acid

INS No. 280

Synonyms: Propanoic acid, carboxyethane, ethanecarboxylic, acid ethylformic acid, methylacetic acid

Structural formula:



Description: an oily liquid with a slightly pungent odour; miscible with water and ethanol

Calcium Propionate

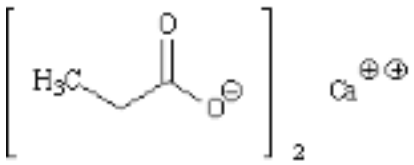
CAS: Calcium Propionate 4075-81-4

IUPAC: Calcium Propanoate

INS No. 282

Synonyms: Calcium propanoate

Structural formula:



Description: white crystals, powder or granules with not more than a faint odour of propionic acid; freely soluble in water, soluble in ethanol

Potassium Propionate

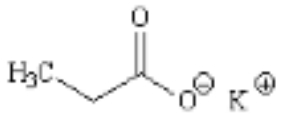
CAS: Potassium Propionate 327-62-8

IUPAC: Potassium Propanoate

INS No. 283

Synonyms: Potassium propanoate

Structural formula:



Description: white or colourless crystals; freely soluble in water, soluble in ethanol

Sodium Propionate

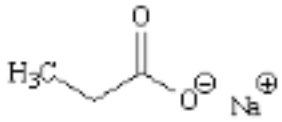
CAS: Sodium Propionate 137-40-6

IUPAC: Sodium Propanoate

INS No. 281

Synonyms: Sodium propanoate

Structural formula:



Description: White or colourless, hygroscopic crystals with not more than a faint characteristic odour; Freely soluble in water, soluble in ethanol

2.3 Chemical and physical properties:

Analytical information is provided in Appendix B demonstrating the stability of propionic acid in processed meat products.

2.4 Impurity profile:

Propionic acid, and its calcium, potassium and sodium salts are approved as preservatives for use in certain foods in the Food Standards Code. Their purity for use and hence the level and type of impurities is controlled by the requirements of Standard 1.3.4 Identity and Purity, which references JECFA Food Additive Specifications as one of the primary specification sources. Copies of the JECFA specifications are included in Appendix A; impurities and limits for these are detailed in these specifications.

2.5 Manufacturing process:

Although numerous fermentation processes have been identified and evaluated, the industrial production of propionic acid is almost entirely by chemical synthesis (petrochemical route). The main processes include the Reppe process where ethylene is reacted with carbon monoxide and steam (synthesis gas) in the presence of a nickel catalyst, to produce propionaldehyde, which is then oxidised to propionic acid, and the Larson process from ethanol and carbon monoxide using boron trifluoride as a catalyst. It is also obtained by oxidation of propionaldehyde, as a by-product in the Fischer-Tropsch process for the synthesis of fuel and in wood distillation as a by-product of the pyrolysis. Very pure propionic acid can be obtained from propionitrile.

Calcium, potassium and sodium propionates are produced by the reaction of propionic acid with the respective hydroxides or carbonates.

Note that Kemin Industries is not a manufacturer of propionic acid. Their proprietary product, BactoCEASE→ is formulated from propionic acid and the specification formulation details and are provided in Appendices A and B respectively.

2.6 Specification for identity and purity:

Copies of the current JECFA FAO Food Additive Specifications for Propionic Acid, Calcium Propionate, Sodium Propionate and Potassium Propionate are provided in Appendix A.

2.7 Food labelling:

Referring to Standards 1.3.1, the functional class for these additives is 'Preservative' and the INS code numbers are:

Propionic Acid	280
Sodium Propionate	281
Calcium Propionate	282
Potassium Propionate	283

2.8 Analytical method:

The analytical method developed by Kemin Industries for determination of propionic acid in processed meat products is included in Appendix B.

2.9 Potential additional functions:

There are no additional technological functions provided by these additives at the use levels indicated in this application. Metabolism of propionates is discussed in **Section 3 - Safety**.

3 Safety:

The safety of Propionates for use in foods is demonstrated by the following:

- Propionic acid is found naturally in humans as a normal intermediary metabolite
- Propionic acid, with other short chain fatty acids, is a major metabolic by-product of carbohydrate fermentation in the large intestine. SCFA's have important gastrointestinal functions and beneficial health effects
- Propionic acid is naturally present in foods such as cheese, butter and other dairy foods. It also occurs as a product of bacterial fermentation.
- Propionates have been used widely as preservatives in food products for more than 60 years without the advent of any safety concerns
- The safety of propionates for use as preservatives in food has been evaluated by JECFA, EFSA, US SCOGS and all of these assessments have concluded that there are no safety concerns for current use levels and authorisations.

3.1 Toxicokinetics and metabolism:

Absorption, distribution, metabolism and excretion is discussed in detail in the EFSA "Scientific Opinion on the re-evaluation of propionic acid, sodium propionate, calcium propionate, and potassium propionate as food additives" 2014. (Refer section 3.1)

3.2 Toxicity:

Toxicity is discussed in detail in the EFSA "Scientific Opinion on the re-evaluation of propionic acid, sodium propionate, calcium propionate, and potassium propionate as food additives" 2014. (Refer section 3.2)

3.3 Safety assessment reports:

The safety of Propionic acid and its calcium, potassium, and sodium salts for use in foods have been assessed by JECFA (1961, 1965, 1973, 1997), the US Select Committee on GRAS Substances (1979) and the European Food Safety Authority (2014). In all of these assessments, the relevant agencies concluded that there were no safety concerns for the current use levels and authorisations. The most recent reports by these agencies are included in Appendix B.

4 Dietary Exposure:

4.1 Foods proposed for use in/changes to currently permitted foods:

The foods proposed for use of the additives in are:

08.2 – Processed meat, poultry and game products or in whole pieces or cuts

08.3 – Processed comminuted meat, poultry and game products

4.2 Maximum use levels:

Typical use levels range from 0.1 – 0.25% as propionic acid on food product weight.

a) Estimated Dietary Exposure – Australia:

At the upper use level (0.25%), and applying this to food intake data reported in the 2011-2013 Australian Health Survey: Nutrition First Results – Food and Nutrients (Table 6.3 Median Amount of Foods Consumed), if used in all processed meat products the estimated daily intake of propionic acid would be:

85mg (Processed meat: 34 grams/day 'Persons')

185.7mg (Processed delicatessen meat, mammalian: 75 grams/day'Persons') (NB. this processed meat sub-category reported highest amount consumed)

b) Estimated Dietary Exposure – New Zealand:

The 2008/2009 Adult Nutrition Survey and 2002 Children's Nutrition Survey only report nutrient intake and frequency of consumprton of some foods. Since data for amount of food consumed is not available, we are not able to provide estimated daily intake of propionic acid from use in processed meat products in New Zealand.

Note: JECFA has assigned an ADI "Not Limited" for Propionic acid, and calcium, potassium, and sodium propionates. In the Codex General Standard for Food Additives, propionic acid and calcium, potassium and sodium propionates are included in the list of "Additives Permitted for Use in Food in General" and can be used in accordance with GMP. They are permitted on this basis in the corresponding Codex food categories as requested in this application.

4.3 Market usage estimates:

refer Appendix B ('Confidential Commercial Information')

4.4 Use in other countries:

refer Appendix B ('Confidential Commercial Information')

5 References:

1) Kathleen A. Glass, Lindsey M. McDonnell, Roxanne Vontayson, Brandon Wanless, and Mani Badvela. 2013. Inhibition of Listeria monocytogenes by Propionic Acid–Based Ingredients in Cured Deli-Style Turkey. *Journal of Food Protection, Vol. 76, No. 12, 2013, Pages 2074–2078*

2) "Intervention Strategies: Control of Listeria monocytogenes in Processed Meat and Poultry by Combinations of Antimicrobials". 2005. *United States Department of Agriculture.*

3) Glass and Claus, AMIF Final Report, June 2006. "Controlling *L. monocytogenes* in RTE Meats Using Benzoate, Propionate and Sorbate". *University of Wisconsin-Madison*

4) Kathleen A. Glass,* Lindsey M. McDonnell, Rob C. Rassel, and Kristine L. Zierke. 2007. Controlling *Listeria monocytogenes* on Sliced Ham and Turkey Products Using Benzoate, Propionate, and Sorbate. *Journal of Food Protection, Vol. 70, No. 10, 2007, Pages 2306–2312*

5) L. A. Mellefont* and T. Ross. 2007. Effect of Potassium Lactate and a Potassium Lactate-Sodium Diacetate Blend on *Listeria monocytogenes* Growth in Modified Atmosphere Packaged Sliced Ham. *Journal of Food Protection, Vol. 70, No. 10, 2007, Pages 2297-2305*