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PRODUCTS**
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APPLICATION

OCTOBER 2016

TO:

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:

APPLICATION FOR APPROVAL OF USE OF POLYSORBATE
20 AS A FOOD ADDITIVE

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ADMINISTRATIVE INFORMATION

Applicant Details

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

Organisation: Earlee Products Pty Ltd (hereafter Earlee)

Nature of Business

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

Earlee Products is one of the most advanced manufacturers of ingredients and food premixes in the southern hemisphere offering a complete range of innovative products incorporating imaginative ingredient blends and manufacturing methodology essential in creating a real point of difference that will exceed customers' expectations.

Details of Other Parties Associated with the Application

(As per section 3.1.1 B of the Application Handbook as at 1 March 2016)

APPLICATION INFORMATION

Status of Similar Applications

(As per Section 3.1.1 D of the Application Handbook as at 1 March 2016)

The Applicant is not aware of any similar applications.

Assessment Procedure

(As per section 3.1.1 F of the Application Handbook as at 1 March 2016)

Earlee seeks to proceed with an **unpaid** application for consideration as a General Procedure, Level 1 (maximum of 350 hours).

Confidential commercial information

(As per section 3.1.1 G of the Application Handbook as at 1 March 2016)

This application **does contain** information that is confidential commercial information (CCI).

Earlee has provided information to support this application which it considers to be CCI. This information is provided separately and clearly labelled as CCI.

The CCI information is not publicly available and disclosure of the information would cause Earlee to suffer a detriment.

Exclusive capturable commercial benefit

(As per section 3.1.1 I of the Application Handbook as at 1 March 2016)

This application will **not** confer an exclusive capturable commercial benefit for Earlee or any other individual company.

1 PURPOSE OF THE APPLICATION

(As per section 3.1.1 C of the Application Handbook as at 1 March 2016)

The purpose of this application is to request an amendment to Schedule 16 – Types of substances that may be used as food additives of the *Australia New Zealand Food Standards Code* (hereafter the Code) to permit the use of Polyoxyethylene (20) Sorbitan Monolaurate or Polysorbate 20 (Additive 432) (hereafter referred to as Polysorbate 20) as a food additive (emulsifier) at GMP.

The Applicant notes that FSANZ prefers that the proposed amendment is kept general and suggested drafting is not provided in this Application.

2 JUSTIFICATION FOR THE APPLICATION

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

2.1 Need for the Proposed Change

(As per section 3.1.1 D(a) of the Application Handbook as at 1 March 2016)

2.1.1 Purpose of using the Food Additive

The Applicant is seeking approval for the use of Polysorbate 20 as an emulsifier at levels of less than 0.05% in the final food product as a functional component in a surface spray or dipping solution for cooked processed meats/small goods and processed fish and fish products.

The Polysorbate 20 is part of a water-based liquid delivery system containing antimicrobial ingredients to be applied to raw and cooked meat surfaces to prevent the growth of bacteria, yeasts and mould.

To be effective, the active ingredients must completely 'wet' the surface so that direct contact is made with the microbes. The 'actives' are blends of natural, anti-bacterial food ingredients, including infusions of plant extracts from fruits, herbs and spices. Natural, weak organic food acids are added to stabilize the preparation. To disperse these infusions requires an edible, pH tolerant, surfactant with good surface wetting properties.

Through extensive product development trials, the Applicant has determined that Polysorbate 20 is the only emulsifier that satisfied all their necessary criteria:

- It is a liquid at room/refrigerated temperatures;
- Is stable in a low pH environment; and
- It is 'water-soluble' and 'film-forming' in aqueous solution and has a sufficiently high enough hydrophilic lipophilic balance (HLB) value (16.7) to form 'oil in water' emulsions, allowing stable dispersion of herb and spice (essential) oils.

Distilled monoglycerides are not water-soluble and therefore unsuitable. Polysorbate 40 and 80 are not 'film forming', while Polysorbate 60 is insoluble at refrigerated temperatures. Sorbitans are also unsuitable as they are only 'oil soluble' as exhibited by their low hydrophilic lipophilic balance (HLB) (see table below).

Table 1: Comparison of Polysorbate 20 and alternatives

Attribute	Polysorbate 20	Polysorbate 40	Polysorbate 60	Polysorbate 80	Sorbitan 20	Sorbitan 40	Sorbitan 60	Sorbitan 80
Additive No.	432	431	435	433	493	495	491	494
Approved in ANZ	N	Y	Y	Y	N	N	Y	N
HLB [1]	16.7	15.6	14.9	15	8.6	6.7	4.7	4.3
Solubility	Water	Water	Water 40°C	Water	Oil	Oil	Oil	Oil
Liquid at room/refrig temp	Y	Y	Y	Y	Y	N	N	Y

[1] hydrophilic lipophilic balance – the larger the number the better

Note: the ‘actives’ and other ingredients are not the subject of this application which is solely for the approval of Polysorbate 20. The Applicant will ensure that all other ingredients to be used in the water-based liquid delivery system are compliant with the Code prior to making the product available for sale.

2.2 Advantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 March 2016)

The Applicant proposes that approval of Polysorbate 20 has the following advantages:

- opportunity for applicant to disperse water based antimicrobial products for application onto raw and cooked meats that can extend the shelf life by inhibiting the growth of food spoilage and food poisoning microorganisms including *L. monocytogenes*, *S. aureus*, *C. jejuni*, *E coli*, yeasts and moulds;
- extended shelf life over untreated products; and
- provides an alternative to current lactate/acetate systems available without sodium addition at a significant cost reduction whilst maintaining shelf life extension.

The benefit of extended shelf life is discussed further under Section 2.7.1.

2.3 Disadvantages of the Proposed Change

(As per section 3.1.1 D(b) of the Application Handbook as at 1 March 2016)

The Applicant has not identified any disadvantages for the proposed change.

Products containing Polysorbate 20 as a food additive will be required to be labelled to indicate the presence of the food additive as emulsifier (432).

2.4 Public Health and Safety Issues

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

This is addressed under Section 5 of this application.

2.5 Consumer Choice

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

This application does not present any consumer choice issues – food products will be labelled and consumers can choose if they wish to purchase a product containing Polysorbate 20.

2.6 Support for the Proposed Change

(As per section 3.1.1 D of the Application Handbook as at 1 March 2016)

The Applicant does not have letters of support.

2.7 Regulatory Impact Information

(As per section 3.1.1 D.1 of the Application Handbook as at 1 March 2016)

2.7.1 Costs and Benefits of the Application

(As per section 3.1.1 D.1.1 of the Application Handbook as at 1 March 2016)

Costs and Benefits – Consumer

The proposed amendment places no additional economic cost on consumers – Polysorbate 20 will be labelled and consumers can choose if they wish to purchase a product containing this food additive.

The water-based liquid delivery system which contains the Polysorbate 20 has been demonstrated by the Applicant to increase product shelf life resulting in reduced wastage due to spoilage.

The potential benefit to the consumer is food safety. The water-based liquid containing Polysorbate 20 not only enhances the shelf life by inhibiting the growth of background standard bacteria (spoilage) but also pathogenic bacteria such as *Staphylococcus aureus*, *E. coli*, and *L. monocytogenes*.

The following graphs (Figures 1 and 2) show both shelf life achieved and antimicrobial efficacy. For the SPC graph, a standard comminuted ham product with the dip solution added at 0.5% uptake was used. The dip solution ingredient declaration is:

Water, vinegar, spice, herb and fruit extracts (processing aids food acid (lactic acid), emulsifier (432))

The function of the Polysorbate 20 (emulsifier 432) is to solubilise the extracts and ensure full surface wetting of the meat/fish product to ensure efficient dispersal of the active ingredients. Different products will require different amounts of extracts therefore a range of use levels of Polysorbate 20 will be needed for the solubilisation but will never exceed X% (amount is CCI – refer to Appendix 8) in the finished product and typically (in >95% of products) XX% - XX% (amount is CCI – refer to Appendix 8).

The zone of inhibition test (Figure 2) is a procedure performed on an agar disk. All microbiological work including SPC's were carried out at Niche Food Microbiology.

Figure 1:

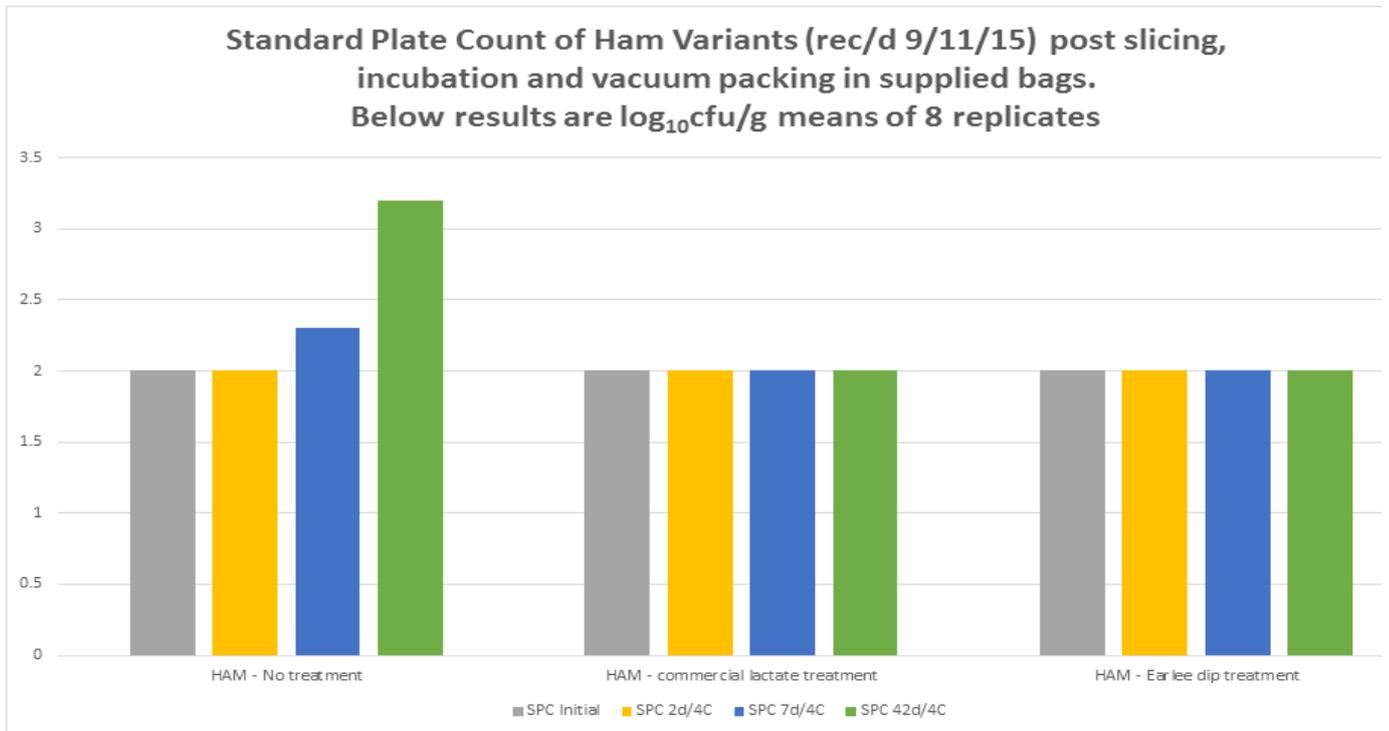
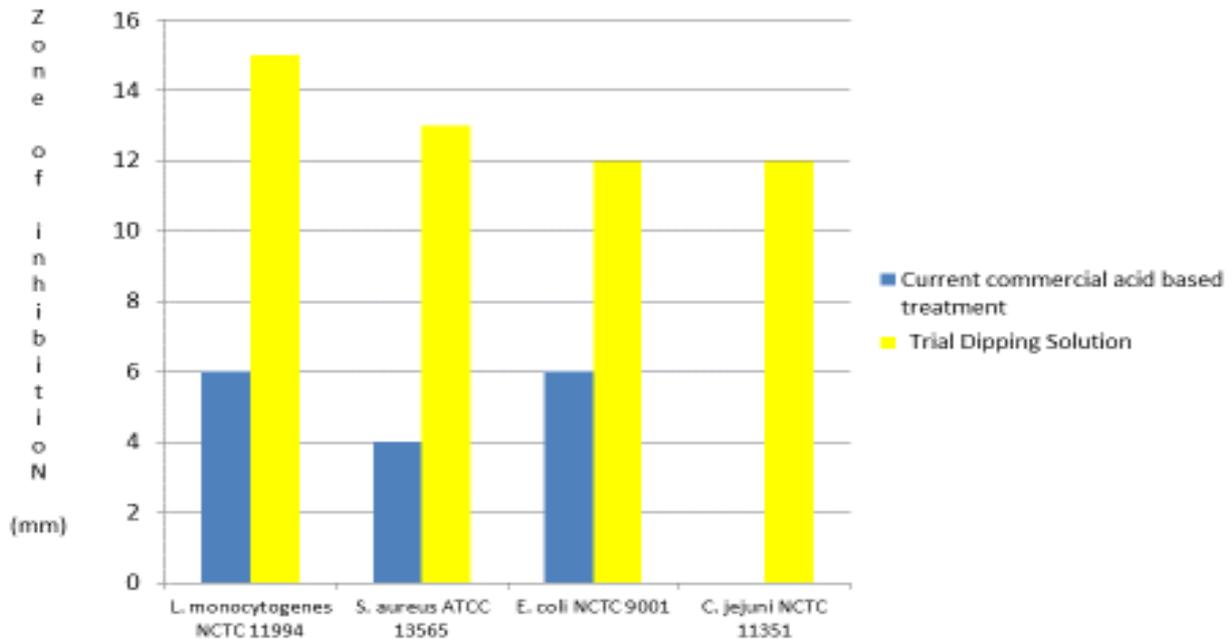


Figure 2:

Graphic portrayal of the antimicrobial efficacy of the current commercial acid based treatment versus Trial Dipping Solution against four foodborne microbes (*Listeria monocytogenes*, *Staphylococcus aureus*, *Escherichia coli* and *Campylobacter jejuni*)



Costs and Benefits - Industry and Business

Use of Polysorbate 20 will be at the discretion of business, therefore there are no direct costs imposed on industry.

Where a business chooses to use Polysorbate 20, there will be the cost involved in:

- purchase of the additive or a blend containing the additive;
- labelling the product to indicate the presence of Polysorbate 20; and
- analysis to ensure compliance with specified level of usage.

The potential benefits to industry are:

- reduction of overall costs by using a dipping solution (containing Polysorbate 20) as the dispersal agent for the applicants blend of natural antimicrobial ingredients replacing the current additives (sodium acetate/sodium lactate blend) at 20% of their usage;
- no sodium contribution to the finished product; and
- no impact on taste or colour.

Costs and Benefits – Government

The proposed amendment places no additional regulatory costs on Government beyond the initial regulatory cost of approving the use of Polysorbate 20 as a food additive.

2.7.2 Impact on International Trade

(As per section 3.1.1 D.1.2 of the Application Handbook as at 1 March 2016)

The Applicant notes that, in developing food standards, FSANZ must have regard to its WTO obligations; the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass consideration of international standards and trade issues.

If this application is approved, businesses in Australia and New Zealand will have access to Polysorbate 20 to enable them to develop and manufacture improved products and products containing Polysorbate 20 manufactured overseas will be permitted to be sold in Australia and New Zealand.

3 INFORMATION TO SUPPORT THE APPLICATION

(As per section 3.1.1 E of the Application Handbook as at 1 March 2016)

3.1 FSANZ Act Objectives

Information is provided in this application to enable the objectives specified in Section 18 of the FSANZ Act to be addressed as follows:

High Order Policy Principles	Section of Application
(a) The protection of public health and safety.	5.0
(b) The provision of adequate information relating to food to enable consumers to make informed choices.	2.5
(c) the prevention of misleading or deceptive conduct.	2.5

4 INTERNATIONAL AND OTHER NATIONAL STANDARDS

(As per section 3.1.1 J of the Application Handbook as at 1 March 2016)

The status of Polysorbate 20 with respect to other national standards or regulations is presented under this section of the Application.

4.1 International Standards

(As per section 3.1.1 J.1 of the Application Handbook as at 1 March 2016)

Codex

Food Chemicals Codex (FCC) has published a monograph on Polysorbate 20. This is provided as **Appendix 1**.

Polysorbate 20 is a Codex listed food additive in Codex CAC/GL 36-1989, with INS 432. (**Appendix 1**)

Polysorbate 20 is permitted in the Codex General Standard for Food Additives (GSFA, Codex STAN 192-1995) which sets forth the conditions under which permitted food additives may be used in all foods, whether or not they have previously been standardized by Codex. A list of permissions for the family of polysorbates, including Polysorbate 20 is provided in **Appendix 1**.

JECFA (Joint FAO/WHO Expert Committee on Food Additives)

JEFCA has published a monograph on Polysorbate 20. This is provided as **Appendix 2**.

4.2 Other National Standards or Regulations

(As per section 3.1.1 J.2 of the Application Handbook as at 1 March 2016)

4.2.1 Australia/New Zealand

Current Permissions for Polysorbates

Polysorbates are currently permitted to be added to food in Australia and New Zealand under the following Standards of the Australian New Zealand Food Standards Code (the Code).

Table 2: Current permissions for Polysorbates in the Australia New Zealand Food Standards Code

Additive	Standard	Permitted Products	Level permitted
431 Polysorbate 40 - Polyoxyethylene (40) stearate	Schedule 15	Dried milk, milk powder, cream powder (1.5); and Wine, sparkling wine and fortified wine (14.2.2)	GMP GMP
433 Polysorbate 80 - Polyoxyethylene (20) Sorbitan Monooleate	Schedule 16	Additive permitted at GMP	GMP
435 Polysorbate 60 - Polyoxyethylene (20) Sorbitan Monostearate	Schedule 16	Additive permitted at GMP	GMP
436 Polysorbate 65 - Polyoxyethylene (20) Sorbitan Tristearate	Schedule 16	Additive permitted at GMP	GMP

4.2.2 Other Countries

The following table provides a summary of permissions for Polysorbate 20 in other countries.

Table 3: Polysorbate 20 approvals in other countries

Country/Jurisdiction	Regulation	Link
United States of America	FDA 21 CFR (172.515) Synthetic flavouring substances and adjuvants	Link 1 (below)
United States of America	FDA 21 CFR (178.3400) Emulsifiers and/or surface-active agents	Link 2 (below)
Europe	Annex II of Regulation (EC) No 1333/2008 – Community list of food additives approved for use in foods and conditions of use	Appendix 3
Japan	Approved as a Designated food additive. Designated additives are those designated by the Minister of Health, Labour and Welfare as substances that are unlikely to harm human health based on Article 10 of the Food Sanitation Act.	Appendix 4
Singapore	Approved and listed under the Sixth Schedule – Permitted Emulsifiers and Permitted Stabilisers (Regulation 21(2)) – Food Regulations – Agri- Food & Veterinary Authority of Singapore for use at GMP levels.	http://tinyurl.com/zmyvlf

US FDA Link 1:

http://www.ecfr.gov/cgi-bin/text-idx?SID=9436b5fe022a04302437b70635bf53a0&mc=true&node=se21.3.172_1515&rqn=div8

US FDA Link 2:

http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=9436b5fe022a04302437b70635bf53a0&mc=true&n=sp21.3.178.d&r=SUBPART&ty=HTML#se21.3.178_13400

5 SUBSTANCES ADDED TO FOOD - FOOD ADDITIVE

(As per section 3.3.1 [Food Additives] of the Application Handbook as at 1 March 2016)

5.1 Technical Information on the food additive

(As per section 3.3.1 A of the Application Handbook as at 1 March 2016)

Policy Guidelines

Information is provided in this section to address the Policy Guideline - Addition to Food of Substances other than Vitamins and Minerals¹.

Specific Order Policy Principles – Technological Function

The addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where:

Specific Order Policy Principles – Technological Function	Section of Application
a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose'); and	1 & 2
b) the addition of the substance to food is safe for human consumption; and	5.2
c) the amounts added are consistent with achieving the technological function; and	5.1.1
d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and	5.1.1
e) no nutrition, health or related claims are to be made in regard to the substance	N/A

The following information on the substance, Polysorbate 20, is representative of the commercial product for which approval is sought.

¹<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf>

5.1.1 Nature and technical function of the additive

(As per section 3.3.1 A.1 of the Application Handbook as at 1 March 2016)

This section includes information related to the technological function of the food additive and includes the following specific information.

- a) For the purpose of this application, Polysorbate 20 will perform the technological function listed in Schedule 14 - Technological purposes performed by substances used as food additives:

Emulsifier – facilitates the formation or maintenance of an emulsion between two or more immiscible phases. Polysorbate 20 is used in an oil in water emulsion.

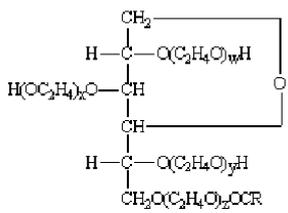
- b) Polysorbate 20 is required to fulfil the function of a dispersal agent for the natural antimicrobial agents present in the Applicant's dips and sprays used in processed raw and whole, comminuted meat, poultry, seafood and game products to enhance the shelf life by inhibiting the growth of background standard bacteria (spoilage) but also pathogenic bacteria such as *Staphylococcus aureus*, *E. coli*, and *L. monocytogenes*. (Refer to Figures 1 and 2)
- c) Evidence that the amounts proposed to be added is consistent with achieving the technological function is provided under Section 2.7.1.

The product is applied to the surface of the food which is then allowed to drain, placed in a plastic bag or thermoformed tray and vacuum packed. Therefore, during normal shelf life (42 days) most of the solution diffuses into the surface with the remainder held by capillary action on the surface but nothing is lost as this is a closed system.

5.1.2 Information to enable identification of the additive

(As per section 3.3.1 A.2 of the Application Handbook as at 1 March 2016)

Table 4: Polysorbate 20 - identification information

Property	Description
Chemical name	Polyoxyethylene (20) Sorbitan Monolaurate
Structural formula	 <p>where $w + x + y + z = \text{approx. } 20$ and RCO- is the fatty acid moiety</p>
Molecular Formula	$C_{26}H_{50}O_{10}$
Common or usual name [and synonyms]	Polysorbate 20; Tween 20
CAS Register Number	9005-64-5
EC Number	500-018-3
Molecular weight	522.6692 g/mol
IUPAC Name	2-[2-[3,4-bis(2-hydroxyethoxy)oxolan-2-yl]-2-(2-hydroxyethoxy)ethoxy]ethyl dodecanoate

Source: National Center for Biotechnology Information. PubChem Compound Database; CID=443314
https://pubchem.ncbi.nlm.nih.gov/compound/Tween_20#section=Information-Sources

5.1.3 Information on the chemical and physical properties of the additive

(As per section 3.3.1 A.3 of the Application Handbook as at 1 March 2016)

Polysorbate 20 has a monograph of identity published in:

- (a) Food Chemicals Codex (FCC) has published a monograph on Polysorbate 20. This is provided as **Appendix 1**.
- (b) JEFCA has published a monograph on Polysorbate 20. This is provided as **Appendix 2**.

5.1.4 Information on the impurity profile for a typical preparation

(As per section 3.3.1 A.4 of the Application Handbook as at 1 March 2016)

Table 5: Polysorbate 20 - impurities and by products present

Impurity	Acceptance Criteria
Water (Vol. 4)	Not more than 3% (Karl Fischer Method)
Sulfated ash (Vol. 4)	Not more than 0.25% Test 5 g of the sample
Acid value (Vol. 4)	Not more than 2
Saponification value (Vol 4)	Not less than 40 and not more than 50
Hydroxyl value (Vol. 4)	Not less than 96 and not more than 108
Lead (Vol. 4)	Not more than 2 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4.

5.1.5 Manufacturing process

(As per section 3.3.1 A.5 of the Application Handbook as at 1 March 2016)

Polysorbates are prepared from sorbitol in a three step process:

1. Water is removed from the sorbitol to form a sorbitan (a cyclic sorbitol anhydride);
2. The sorbitan is partially esterified with a fatty acid such as oleic or stearic acid to yield a hexitan ester; and
3. Ethylene oxide is chemically added in the presence of a catalyst to yield the Polysorbate (Rowe et al 2009).

5.1.6 Specification for identity and purity

(As per section 3.3.1 A.6 of the Application Handbook as at 1 March 2016)

Polysorbate 20 has a monograph of identity published in:

- (a)** Food Chemicals Codex (FCC) has published a monograph on Polysorbate 20. This is provided as **Appendix 1**.
- (b)** JEFCA has published a monograph on Polysorbate 20. This is provided as **Appendix 2**.

5.1.7 Information for food labelling

(As per section 3.3.1 A.7 of the Application Handbook as at 1 March 2016)

Class and number

Polysorbate 20 has the additive number 432.

Products containing Polysorbate 20 will be labelled to meet the requirements of Standard 1.2.4 and Schedule 7 (Food additive class names):

- Emulsifier (Polysorbate 20); or
- Emulsifier (polyoxyethylene (20) sorbitan monolaurate); or
- Emulsifier (432).

5.1.8 Analytical method for detection

(As per section 3.3.1 A.8 of the Application Handbook as at 1 March 2016)

Research in relation to a method of analysis for polysorbates in food has identified that chromatography is one of the widely used analytical techniques that can be used to determine the levels of emulsifiers, including polysorbates, in foods and pharmaceutical products.

Rohman et al (2013) note that:

“Chromatography is one of the powerful analytical techniques used in the analysis of food components due to its capability for the separation and quantitative analyses of emulsifiers.”

In their review of chromatographic techniques for detection and quantification of emulsifiers in food, Rohman et al (2013) described the following:

- Gas chromatography (GC);
- High performance liquid chromatography (HPLC);
- Supercritical fluid chromatography (SFC); and
- Planar chromatography (Paper and thin layer chromatography).

Rohan et al (2013) concluded that chromatography is the method of choice for analysis of emulsifiers in food samples due to its capability for separation and quantification. Paper and thin layer chromatographies have been widely used which attributed to their simplicity and relatively low costs.

Plante et al (2011) note that:

“The characterization of Polysorbate is extremely challenging as polysorbates are complex, containing polydispersed heterogeneous mixtures of large non-UV active molecules.”

Plante et al described several approaches for analysis of Tween (Polysorbate) formulations:

- A full gradient high performance liquid chromatography (HPLC);
- A partial gradient HPLC;
- A rapid separation liquid chromatography (RSLC); and
- An on-line dilution method to measure APTs at low concentration while quantifying Tween products.

Plante et al (2011) concluded that:

“These analytical approaches solve some of the important challenges encountered with the characterization and quantitation of polysorbates and other nonionic surfactants which are beneficial to processes in the food and pharmaceutical industries.”

Fekete et al (2010) have reported on a method for the specific determination of Polysorbate 80 in liquid formulations in the presence of proteins and excipients. The method involved the use of fast liquid chromatographic (HPLC) separation and charged aerosol detection (CAD). The rapid LC-CAD method is suitable for quantifying Polysorbate 80 in the range of 10-60 g/ml in protein solutions within good manufacturing practices (GMPs) of the pharmaceutical industry. The authors note that the most widely used technique for analysis of Polysorbate 80 is conventional HPLC techniques.

5.1.9 Potential additional functions of the food additive when added to food

(As per section 3.3.1 A.9 of the Application Handbook as at 1 March 2016)

Polysorbate 20 has no additional functions in the products it is intended to be used in.

5.2 Information related to the safety of the food additive

(As per section 3.3.1 B of the Application Handbook as at 1 March 2016)

The current ADI of 25mg/kg bodyweight/day is a group ADI that applies to all five polysorbates (20, 40, 60, 65 and 80). It was established by JECFA, 17th meeting, in 1974. The evaluation concluded that:

Level causing no toxicological effect:

Rat: 50 000 ppm (5%) in the diet equivalent to 2500 mg/kg bw.

Estimate of acceptable daily intake for man

0-25 mg/kg bw

In 2015, EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated the polysorbates (**Appendix 5**) and also established a **group** ADI of 25 mg/kg bw/day for polysorbates 20, 40, 60, 65 and 80.

Due to the currency of this evaluation it is highly relevant to the current application. Consequently, an additional overview of the data has not been prepared by the applicant. The sections below will be addressed with reference to the EFSA evaluation.

5.2.1 Information on the toxicokinetics and metabolism of the food additive and, if necessary, its degradation products and/or major metabolites

(As per section 3.3.1 B.1 of the Application Handbook as at 1 March 2016)

The EFSA 2015 reevaluation of polysorbates did not identify any new studies relevant to toxicokinetics and metabolism that were not already reported/included in the evaluation of JECFA undertaken in 1973 (**Appendix 6**). EFSA concluded that data on absorption and metabolic fate suggested hydrolysis of the ester bond between polyoxyethylene and the fatty acid of polysorbates in the gastro-intestinal tract after oral application. Fatty acids are absorbed, metabolised and excreted in the same way as dietary fatty acids. Cleavage of the polyoxyethylene and sorbitan bond does not occur and only small amounts of polyoxyethylene sorbitans are absorbed.

5.2.2 Information on the toxicity of the food additive and, if necessary, its degradation products and major metabolites

(As per section 3.3.1 B.2 of the Application Handbook as at 1 March 2016)

The EFSA 2015 reevaluation of polysorbates reports that a literature search using Toxline, Medline and SciFinder identified a number of studies not considered previously by JECFA in 1973. The following studies assessed by EFSA and that are directly applicable to Polysorbate 20 are provided as references.

Table 6: Studies on Polysorbate 20 assessed by EFSA

Study Area	Reference
Acute oral toxicity	Bartsch et al. (1976)
Short-term and sub chronic toxicity	Li et al. (2011) Kimura and Yoshida (1982) Nakata and Kimura (1994) Harris et al. (1951a) Eagle and Poling (1956) Poling et al. (1956) Harris et al. (1951b)
Chronic toxicity and carcinogenicity	Eagle and Poling (1956) Poling C, Eagle E and Rice E (1956)
Developmental toxicity studies	NTP (1992); Price et al (1994)

The EFSA reevaluation concluded that:

- The acute oral toxicity of all polysorbates was low.
- Taking into account the overall information on structure–activity relationships, polysorbates do not give rise to concerns for genotoxicity.
- Available long-term oral studies did not fulfil the requirements of current standards but long-term studies in rats indicated a NOAEL of 5 % in the diet (approximately 2,500 mg/kg bw/day) based on an oral carcinogenicity study with Polysorbate 80 (NTP, 1992).
- Applying an uncertainty factor of 100, EFSA established a group ADI of 25 mg/kg bw/day for polysorbates 20, 80, 40, 60 and 65 (E 432, E 433, E 434, E 435 and E 436, respectively). This is consistent with the ADI established previously by JECFA (1974).

5.2.3 Safety assessment reports prepared by international agencies or other national government agencies, if available.

(As per section 3.3.1 B.3 of the Application Handbook as at 1 March 2016)

Table 7: Safety Assessments on Polysorbate 20 prepared by international agencies or governments

Agency	Safety Assessment	
JECFA	Monograph of Identity	Appendix 2 and 6
EFSA	Panel on Food Additives and Nutrient Sources Added to Food. Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives.	Appendix 5
Japan	Food Safety Commission. Evaluation Report of Food Additives Polysorbates (Polysorbates 20, 60, 65 and 80), June 2007.	Appendix 7

5.3 Information related to the dietary exposure to the food additive

The use of Polysorbate 20 in foods at the levels proposed by the Applicant is not expected to lead to any adverse health effects when consumed at the intended levels in the foods described within the application.

(As per section 3.3.1 C of the Application Handbook as at 1 March 2016)

5.3.1 A list of the food groups or foods proposed to contain the food additive, or changes to currently permitted foods

(As per section 3.3.1 C.1 of the Application Handbook as at 1 March 2016)

The individual proposed food-uses of Polysorbate 20 by the Applicant are set out in **Appendix 8**, following the categories set out in Schedule 15.

5.3.2 The maximum proposed level and/or the concentration range of the food additive for each food group or food, or the proposed changes to the currently permitted levels

(As per section 3.3.1 C.2 of the Application Handbook as at 1 March 2016)

The individual proposed food-uses of Polysorbate 20 by the Applicant are set out in Appendix 8, following the categories set out in Schedule 15.

5.3.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

(As per section 3.3.1 C.3 of the Application Handbook as at 1 March 2016)

As advised, the purpose of this application is to request an amendment to the *Australia New Zealand Food Standards Code* (hereafter the Code) to permit the use of Polyoxyethylene (20) Sorbitan Monolaurate or Polysorbate 20 (Additive 432) (hereafter referred to as Polysorbate 20) as a food additive (emulsifier) at GMP.

The Applicant is proposing to use Polysorbate 20 in processed raw and whole, comminuted meat, poultry and game products (including but not exclusively goat, kangaroo, buffalo, emu, crocodile, wild boar, pheasant) and processed fish and fish products which are listed in the most recent Australian and New Zealand National Nutrition surveys.

5.3.4 The percentage of the food group in which the food additive is proposed to be used or the percentage of the market likely to use the food additive

(As per section 3.3.1 C.4 of the Application Handbook as at 1 March 2016)

This information is set out in **Appendix 8**.

5.3.5 Information relating to the use of the food additive in other countries, if applicable

(As per section 3.3.1 C.5 of the Application Handbook as at 1 March 2016)

This information has been addressed under Section 4.1.

5.3.6 For foods where consumption has changed in recent years, information on likely current food consumption

(As per section 3.3.1 C.6 of the Application Handbook as at 1 March 2016)

Existing survey data are sufficient to enable estimates of likely intake of Polysorbate 20.

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