Apeel Sciences

Application to Amend the Australia and New Zealand Food Standards Code

Expansion of Use of the Food Additive Mono- and Diglycerides of Fatty Acids (INS 471) in Schedule 15

September 1, 2019

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Abbreviations Used in This Document

ACS	American Chemical Society
ADI	Acceptable Daily Intake
bw	Body weight
CCFA	Codex Committee on Food Additives
COFEPRIS	Mexico Federal Commission for the Protection Against Sanitary Risk
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization
FCC	Food Chemicals Codex
g	Gram
GMP	Good Manufacturing Practice
GSFA	General Standard for Food Additives
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	Kilogram
mg	Milligram
MPL	Maximum permitted level
NHFPC	China National Health and Family Planning Commission
NLT	Not less than
NMT	Not more than
US	United States
USP	United States Pharmacopeia
WHO	World Health Organization
Wt. %	Weight percent

1.0 General Information

1.1. Applicant Details

Company Name

Apeel Technology, Inc. (Doing business as Apeel Sciences)

Company Contact

[redacted]

Mailing Address

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USA

Nature of Applicant's Business

Apeel Sciences develops and manufactures solutions to extend the shelf life and postharvest quality of fresh produce.

Details of Other Individuals, Companies, or Organizations Associated with the Application

The following Apeel Sciences representatives are involved in the preparation, submission, and stewardship of this application:

[redacted]

[redacted]

1.2. Purpose of the Application

Apeel Sciences is applying to FSANZ to amend Schedule 15 of the Australia New Zealand Food Standards Code ("Code"), Substances that may be used as food additives, to add mono- and diglycerides of fatty acids (INS 471) as a permitted food additive with the technical function of glazing agent at a maximum permitted level (MPL) of "Good Manufacturing Practice" ("GMP") in the Food Category (FC) 4.1.2 (Surface treated fruits and vegetables).

1.3. Justification for the Application

Fresh fruits and vegetables undergo many physical and physiological changes during postharvest storage and handling, including loss of moisture, tissue softening (due to ripening), decrease in organic acid levels, production and losses of volatile flavor compounds, and breakdown of cell materials due to respiration.

For nearly a century, edible films and coatings, such as wax on various fruits, have been used by commercial growers to prevent loss of moisture and to create a shiny fruit surface for aesthetic purposes.[1] These practices were accepted long before their associated chemistries were understood and are still utilized in the present day on a diverse array of both fruits and vegetables. There are several different types of edible packaging, and a variety of edible barrier compositions on the market. Among the different types of hydrophobic film-forming barrier materials are fatty acids and alcohols, and acetylated glycerides. Edible barriers based on hydrophobic substances such as lipids were developed specifically for limiting moisture migration within foods. The different lipid-based film-forming or barrier compounds include lecithins, mono- and diglycerides, and mono- and diglyceride esters, among other compounds. These substances are used as glazing agents, emulsifiers, and surface-active agents.

However, not all fruits and vegetables are capable of withstanding the harsh process by which traditional waxes or resins are applied, which often involves movement across a rough brush-bed surface and a

[1]Dhall, 2013.

considerable amount of heat applied to the produce to dry or "set" the wax or resin. As such, several fruits and vegetables, such as berries, are too delicate for the application of these waxes or resins. Additionally, not only might the waxing process be harsh for delicate fruits such as berries, but the data presented in Figure 2 suggest that robust produce such as lemons may also have reduced shelf life when treated with a traditional wax, even when compared against untreated (unwaxed) produce. In contrast, INS 471 coatings can be applied to a wider array of produce categories using a variety of different application methods tailored to the needs of the corresponding crop category while providing superior performance in comparison to other edible coatings currently available on the commercial market.

Edible coatings formulated with INS 471 have been demonstrated to increase the shelf life of more than 30 categories of fruits and vegetables, including climacteric and non-climacteric categories and those with edible and non-edible peels. Given the beneficial properties of mono- and diglycerides, **Apeel Sciences intends to use INS 471 as a completely edible coating (or as a component of an edible coating) formulated to serve as a glazing agent that covers the surface of fresh fruit and vegetables to act as a physical diffusion barrier that reduces moisture loss and oxidation.**

Apeel Sciences' edible coating, INS 471, is currently used commercially as a glazing agent on a variety of fresh produce categories in the US and Peru. Preparations are also currently underway to commercially launch in Mexico and the European Union (EU) in 2019. A summary of existing regulatory clearances for the use of INS 471 edible coatings on fresh fruits and vegetables (which extend beyond the US, Peru, Mexico, and the EU) is provided in Sections 1.9 and 1.10 below.

Schedule 15 of the Code currently allows for mono- and diglycerides of fatty acids in several food categories, as discussed in Section 3.0, Safety. Further, mono- and diglycerides of fatty acids are listed in Schedule 16 of the Code, Types of substances that may be used as food additives, as additives permitted at a maximum permitted level (MPL) of "GMP."

The benefits to Australia and New Zealand industry and consumers are discussed in the sections below.

a. Industry Support for the Proposed Change

Apeel Sciences has received interest for the use of INS 471 fruit and vegetable coating from growers, packers, and retailers located in Australia and New Zealand, as well as exporters that export produce from New Zealand. The extension of shelf life provided by INS 471 coatings enables: reduction of food waste along the entire fresh produce supply chain; access to new markets for growers, packers, and distributors; improved maintenance of produce quality levels along the produce supply chain; reduced reliance on refrigeration throughout the supply chain; and reduced environmental impact by switching to a less-carbon intensive means of transport. Retailers can offer consumers fruits and vegetables that stay ripe for longer, as well as produce sourced from local, new, and diverse regions that may not have been accessible previously due to the short shelf life of unique varietals or long shipping times.

1.4. Regulatory Impact Information

a. Cost and Benefits to the Consumer

The use of INS 471 as a glazing agent extends the postharvest shelf life of fruits and vegetables, enabling a variety of important benefits for the consumer. Increased shelf life allows produce to travel longer distances from farm to table, providing improved access for consumers to fresh fruits and vegetables (where these fresh products are important elements of a healthy diet, and the improved access contributes to

improved food security). Increased shelf life also means that INS 471-protected produce better maintains its quality as it moves through the supply chain from farm to consumer. Additionally, by enabling the extension of fresh produce shelf life, consumers can be introduced to native crop varietals with short shelf life and exotic fruits and vegetables that are not commonly grown in their local market, which promotes and maintains diversity in the global food system, preserves cultural norms, supports healthy diets, and extends the benefits of diverse food choices to consumers around the world. Moreover, consumers will have more time to consume their produce after purchase, reducing food waste in consumers' homes.

The INS 471 coating does not disguise the freshness or quality of produce, nor does it hide a problem with the produce; rather, the INS 471 coating prolongs the shelf life and maintains the nutritional and organoleptic qualities of fresh fruits and vegetables. The INS 471 coating does not enhance the color or flavor of spoiled food. It only preserves the moisture content and quality of the produce, which is established at the time of harvest.

A third-party taste study was conducted to compare the taste of untreated and INS 471-treated avocado flesh. No discernable difference in taste between the untreated and INS 471-treated avocados was reported by taste testers when the untreated and INS 471-treated avocados were observed at the same level of ripeness.[2]

An additional taste study compared untreated and INS 471-treated strawberries, harvested ripe, treated, and tasted on the same day. Again, the study indicated there was no perceivable difference in taste between the two strawberry groups.[3]

The proposed amendment to the Code places no additional economic cost on the consumer. Retailers are, in fact, looking for ways to be more competitive on the market and they have indicated that they see an opportunity to try to lower the costs of fresh produce in response to the savings gained by reducing their in-store and upstream losses.

b. Cost and Benefits to Industry

Conventional edible coatings for fresh fruits and vegetables have typically been formulated to impart shine, but may not necessarily enable increased postharvest shelf-life. In contrast, the shelf life extension offered by appropriately formulated INS 471 coatings can provide notable benefits.

The benefits to industry include:

- more time to connect growers, packers, and shippers of all kinds of different crop categories (i.e., local or native varieties, as well as exotics) and of all scales (i.e., larger industrial as well as smallholder players) to retailers and consumers;
- reduced reliance on disposable packaging (e.g., plastic wrap on cucumbers or modified atmosphere bags for bell peppers);
- reduced food waste at each stage of the fresh produce supply chain (e.g., reduced losses upon pack-out at grower / packer facilities and reduced shrink in retail environments);
- ability to shift from expensive and carbon-intensive modes of transportation to more cost effective and environmentally friendly ones (e.g., shifting from air freight to sea freight); and

[2] Apeel Sciences, 2018*a*.
[3] Apeel Sciences, 2018*b*.

- reduced reliance on cold chain infrastructure (which is particularly important for emerging markets where the cold chain infrastructure may be entirely lacking, discontinuous, or unreliable).

For a company that chooses to use INS 471 edible coatings, there will be economic costs associated with the purchase of the INS 471 edible coating or the services to apply the coating to fresh produce, which will be offset by the savings gained by reducing losses within their operations.

c. Cost and Benefits to Government

Related to the benefits listed above, the use of INS 471 as a glazing agent on produce in Australia and New Zealand will allow trade of INS 471-coated produce between key import and export markets, such as China, Japan, and the United States, where INS 471 is already allowed as a glazing agent for fresh fruits and vegetables in these countries. Additionally, the use of INS 471 as a glazing agent on fruits and vegetables can create opportunities for produce import to and export from Australia and New Zealand to markets that have been too far or too costly to access, or where the distances have created challenges for maintaining quality.

The proposed amendment places no additional regulatory costs on FSANZ beyond the initial cost of the evaluation of this application and any resulting amendments that are made to the Code.

d. Impact on International Trade

The approval of mono- and diglycerides as a glazing agent for surface treated fruits and vegetables would bring the Code into alignment with other countries where the food additive is currently allowed for this purpose, including key trading partners such as China, Japan, and the United States, and thus reduce barriers to trade with these markets. INS 471 is allowed for use as a glazing agent on all surface treated fruits and vegetables in Canada, Chile, China, Colombia, Japan, Mexico, Peru, and the United States, and is allowed on certain fruits in the European Union. Additionally, the Codex Alimentarius Commission adopted a recommendation from the Codex Committee on Food Additives (CCFA) at their 42nd session in July 2019 for the expansion of use of INS 471 as a glazing agent on surface-treated fresh fruits and vegetables. This adoption of INS 471 provisions opens trade opportunities with additional markets who recognize the General Standard for Food Additives (GSFA) as their national standard.

1.5. Information to Support the Application

Information is provided in this application to enable the objectives specified in Section 18 of the FSANZ Act to be addressed, as summarized below.

Data Requirements

The information presented in this application is a summary of the available literature on mono- and diglycerides. The literature referenced within this application is publicly available, with the exception of the following sources:

- Apeel Sciences. 2018*a*, 'Avocado Treatment.'
- Apeel Sciences. 2018*b*, 'Strawberry Treatment.'
- China National Health and Family Planning Commission (NHFPC). 2018, 'Notice on Approving a New Food Enzyme of Fructosyl Transferase (Also Named β-Fructose Transferase) and Expanding the Application Scope of Seven Food Additives including Mono-and Diglycerides of Fatty Acids (NHFPC Notice 2018#2).' Personal communication, February 26, 2018.

Protection of Public Health and Safety

Please refer to the following sections for information related to public health and safety:

- Section 2.3.a, Metabolic Fate
- Section 3.0, Safety
- Section 4.0, Dietary Exposure

Protection of Consumer Choice

Edible coatings are commonly used to protect the appearance and preserve the shelf life of produce. In Australia and New Zealand, many citrus varieties commonly have an edible coating applied. Schedule 15 of the FSANZ Food Standards Code allows the following food additives to be applied to surface treated fruits and vegetables: ammonium phosphates; sucrose esters of fatty acids; beeswax, white and yellow; carnauba wax; and shellac. Therefore, it is reasonable to assume that consumers are aware of their presence on fruits and vegetables.

1.6. Assessment Procedure

Apeel Sciences anticipates that this application will be assessed using General Procedure, Level 1, in accordance with the Food Standards Australia New Zealand Application Handbook as of 1 March 2016.

1.7. Confidential Commercial Information (CCI) or Other Confidential Information

This application contains information that Apeel Sciences considers to be Other Confidential Information. As such, a non-confidential, redacted version of this application is provided separately.

1.8. Exclusive Capturable Commercial Benefit (ECCB)

The approval of this application will not confer to Apeel Sciences an Exclusive Capturable Commercial Benefit as defined in Section 8 of the Food Standards Australia New Zealand Act of 1991.

1.9. International Standards

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

INS 471 has long been recognized as safe. JECFA has reviewed mixtures of mono- and diglyceryl esters of long-chain saturated and unsaturated fatty acids (JECFA No. 471) that occur in food fats and determined in its 17th report that "mono- and diglycerides differed little from food so that their use need not be limited."[4,5] Further, a World Health Organization (WHO) toxicological evaluation of certain food additives

[4] An acceptable daily intake (ADI) without an explicit indication of the upper limit of intake (i.e., "not limited") may be assigned to substances of very low toxicity, especially those that are food constituents or that may be considered as foods or normal metabolites in man. An additive having a "not limited" ADI must meet the criteria of good manufacturing practice—for example, it should have proven technological efficacy and be used at the minimum level of efficacy. Furthermore, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance.

[5] WHO Technical Report Series, 1974.

noted that mono- and diglycerides are consumed every day in a normal mixed diet and are also formed from triglycerides during digestion and absorption of every meal that contains fat. The evaluation concludes that the acceptable daily intake of mono- and diglycerides for man should be "not limited" when used as an emulsifier and stabilizer.[6]

b. Codex Alimentarius General Standard for Food Additives (GSFA)

The substantial history of safe use of INS 471 has resulted in GSFA approval for use in 27 food categories, including but not limited to: infant formulae; follow-up formulae; formulae for special medical purposes of infants; fresh pastas and noodles and like products; and coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa.[7,8] In addition, as a GSFA Table 3 additive, INS 471 is approved for use at GMP in 61 food categories.[9] A complete list of allowances for INS 471 under the Codex GSFA is provided in Appendix 1.

Additionally, in July 2019, the Codex Alimentarius Commission, at its 42nd session, adopted a recommendation from the Codex Committee on Food Additives for the expansion of use of INS 471 as a glazing agent on surface-treated fresh fruits and vegetables. This adoption is reflected in the current GSFA (Appendix 1).

1.10. Other Standards and Regulations

This section includes allowances for INS 471 as a glazing agent (or equivalent technical function) in countries and regions that have comparable regulatory processes to FSANZ; these allowances are food additive specific rather than product specific.

a. Chile

Chile allows the use of mono- and diglycerides of fatty acids for all technological functions and all food categories at levels of GMP.[10]

b. China

China allows the use of mono- and diglycerides of fatty acids (INS 471) as a coating agent on surface-treated fresh fruit and surface-treated fresh vegetables at levels of GMP.[11]

c. European Union (EU)

The EU has authorized the use of mono- and diglycerides of fatty acids (E 471) for the surface treatment of citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, and pomegranates at levels of GMP.[12]

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[6] WHO Food Additives Series, 1974.
[7] Codex Alimentarius Commission, 2019.
[8] Note: Of the 27 GSFA-approved food categories, only the 4 categories for infants and children have a prescribed maximum use level; the remaining 23 are all at GMP.
[9] Codex Alimentarius Commission, 2019.
[10] Chile Ministry of Health, 1997*a* & 1997*b*.
[11] China National Health and Family Planning Commission (NHFPC), 2018.
[12] European Commission, 2019.

d. Japan

Glycerol esters of fatty acids (INS 471) are allowed for use in Japan for all functional classes and food categories.[13, 14]

e. Mexico

Mexico's Federal Commission for the Protection Against Sanitary Risk (COFEPRIS) permits mono- and diglycerides of fatty acids (INS 471) as a glazing agent for use in several food categories, including fruits and vegetables, at levels of GMP, in accordance with Annex II of the Additives Agreement.[15]

f. Peru

Peru's General Directorate of Environmental Health and Food Safety (DIGESA) permits the use of food additives that are included in the list of additives allowed by the Codex Alimentarius.[16] Therefore, because mono- and diglycerides of fatty acids is included in the GSFA, INS 471 is permitted for use as a glazing agent in Peru.

g. United States (US)

Mono- and diglycerides that consist of a mixture of glyceryl mono- and diesters and minor amounts of triesters are affirmed as Generally Recognized as Safe (GRAS) for direct addition to food in the US, under Title 21 of the US Code of Federal Regulations (CFR), Section 184.1505. These substances are prepared from fats or oils or fat-forming acids and are derived from edible sources. Mono- and diglycerides are traditionally manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The products are further purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90 wt. % glycerides. The ingredients are used in food with no limitation other than current Good Manufacturing Practice and can be used in food for multiple purposes, for example, as: a dough strengthener; an emulsifier and emulsifier salt; a flavoring agent and adjuvant; a formulation aid; a lubricant and release agent; a solvent and vehicle; a stabilizer and thickener; a surface-active agent; a surface-finishing agent; and a texturizer.[17]

Mono- and diglycerides applied as a glazing agent / surface-finishing agent on the surfaces of fresh fruits and vegetables is also allowed for use in the United States in accordance with a self-determination of US Food and Drug Administration (FDA) GRAS status.[18] Further, mono- and diglycerides applied as a glazing agent to fresh produce is the subject of a voluntary GRAS Notification (GRN 648) to the FDA, to which the FDA responded with "No Questions" regarding the safety under the proposed conditions of use.[19]

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[13] Japan Ministry of Health, Labour and Welfare, 2018.
[14] Note that on page 1367 of Japan's Specifications and Standards for Food Additives, the Standards for Use permit all food additives in all foods, where standards applying to specific individual food additives are listed on pages 1368–1390. There is no specific standard that applies to INS 471.
[15] Mexico COFEPRIS, 2018.
[16] DIGESA, 1998.
[17] US Title 21 CFR §184.1505, 1992.
[18] Under US Title 21 CFR §170.205, submission of a GRAS notice to the FDA is voluntary. Alternatively, an ingredient may be self-affirmed / self-determined as GRAS through a complete review and assessment of the safety of the ingredient and requires a consensus of safety among a panel of experts who are qualified by training and expertise to evaluate the safety of food.
[19] US FDA GRAS Notice No. GRN 000648, 2016.

1.11. Statutory Declaration

The Statutory Declaration is provided in Appendix 2.

1.12. Checklist

The completed FSANZ application checklists for General Requirements and Food Additives are provided in Appendix 3.

2.0 Technical Information

2.1. Nature and Technological Purpose

Mono- and diglycerides (INS 471) applied to the surface of fresh fruits and vegetables serves the technical function of "glazing agent," as defined in Schedule 14 of the Code:

- Glazing agent: *"imparts a coating to the external surface of a food."*

Fresh fruits and vegetables undergo many physical and physiological changes during postharvest storage and handling, including loss of moisture, tissue softening (due to ripening), decrease in organic acid levels, production and losses of volatile flavor compounds, and breakdown of cell materials due to respiration.

Commercial growers and producers began glazing / coating fruits and vegetables approximately 100 years ago in the 1930s as a way to extend shelf life, preserve quality, and improve the appearance of produce, among others.[20] Among the reasons to apply INS 471 as a glazing agent or coating to fruits and vegetables are:

- To reduce shrinkage due to water loss;
- To provide a barrier to free gas exchange;
- To maintain the quality and nutritional value of produce; and
- To reduce postharvest food waste.

The shelf life extension resulting from the use of INS 471 on fresh fruits and vegetables benefits all stages of the supply chain, from growers to the end consumer.

As previously mentioned, not all fruits and vegetables are capable of withstanding the harsh process by which traditional waxes or resins are applied, which often involves movement across a rough brush-bed surface and a considerable amount of heat applied to the produce to dry or "set" the wax or resin. As such, several fruits and vegetables, such as berries, are too delicate for the application of these waxes or resins. In contrast, INS 471 coatings can be applied to a wider array of produce categories using a variety of different application methods tailored to the needs of the corresponding crop category while providing superior performance in comparison to other edible coatings currently available on the commercial market.

[20] Dhall, 2013.

The efficacy of INS 471 as a glazing agent has been demonstrated by Apeel Sciences on more than 30 categories of fruits and vegetables.[21] A few examples have been directly added to this submission to demonstrate the versatility and efficacy of INS 471 edible coatings on fruits and vegetables, including climacteric categories and non-climacteric categories, and those with edible and non-edible peels.

A time-lapse study conducted under ambient conditions shows the shelf life extension of asparagus treated with INS 471 compared to untreated asparagus over the course of 12 days (Figure 1). The untreated asparagus showed significant signs of dehydration by Day 7 (e.g., dehydrated stem ends, which would cause the asparagus to be considered of unmarketable quality), while the INS 471 treated asparagus remained of acceptable quality for sale and consumption at Day 12.

Figure 1: Time-lapse images of INS 471 treated asparagus compared against untreated asparagus.

[21] Visit "Apeel Time-Lapse Studies" (www.apeel.com/time) for time-lapse images of fruit and vegetable categories.

Another time-lapse study conducted under ambient conditions shows the shelf life extension of lemons treated with INS 471 compared to untreated lemons and lemons treated with conventional food wax over the course of 60 days (Figure 2). The untreated lemons showed signs of spoilage before 31 days, waxed lemons showed signs of spoilage by Day 31, and the lemons treated with INS 471 showed no signs of spoilage. Finally, after 60 days, the lemons treated with INS 471 were of acceptable quality while the untreated and waxed lemons showed significant signs of dehydration and discoloration—making them unfit for sale or consumption.

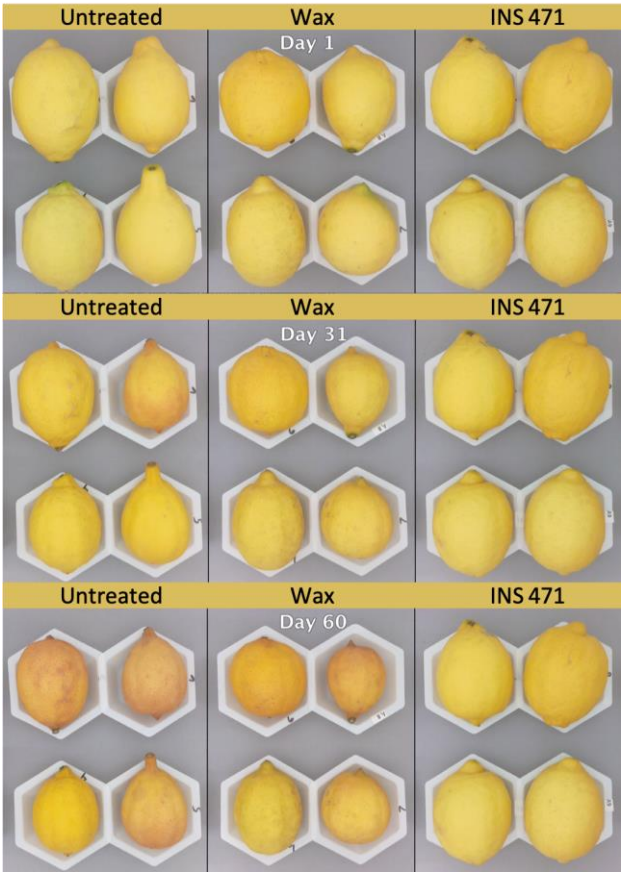

Figure 2: Time-lapse images of INS 471 treated lemons compared against untreated lemons and lemons treated with conventional wax.

Footage from an avocado time-lapse study conducted under ambient conditions shows the shelf life extension of avocados treated with INS 471 compared to untreated avocados over the course of 30 days (Figure 3). The untreated avocados in the images became ripe by Day 10 while the treated avocados were still unripe. In the end, after 30 days, the avocados treated with INS 471 were of acceptable quality while the untreated avocados showed significant signs of spoilage—making them unfit for sale or consumption.

Figure 3: Time-lapse images of INS 471 treated avocados compared against untreated avocados.

INS 471 may be used as a coating on any fruit or vegetable. When used as directed, INS 471 is applied to the surface of fruits and vegetables. The proposed amount of addition of INS 471 to the surface of fresh fruits and vegetables is GMP, as the quantity required to achieve the technical function is inherently self-limiting given the unique characteristics of each fruit and vegetable. The quantity of INS 471 required to achieve the intended technological effect varies with the specific application. Some factors that affect the quantity of INS 471 are: the type of fruit or vegetable; seasonality; region of origin of the produce; climate in location of coating application; and desired shelf life extension. A limit of GMP is consistent with the Codex Alimentarius Commission adoption of INS 471 as a glazing agent on surface-treated fresh fruits and vegetables in the GSFA.[22]

[22] Codex Alimentarius Commission, 2019.

2.2. Identification

Chemical Name

INS 471 includes a wide range of chain lengths and isomers of mono- and diglycerides. The Chemical Abstracts Service (CAS) numbers and International Union of Pure and Applied Chemistry (IUPAC) names for the general families of mono- and diglycerides are provided in Table 1 below.

Table 1: CAS Numbers for General Families of Mono- and Diglycerides and Example IUPAC Names That May be Included as Components of an INS 471 Glazing Agent

CAS Number	Description of Chemical Family	IUPAC Name
67701-33-1	C14–18, mono- and diglycerides, saturated	Example: 1,3-dihydroxypropan-2-yl myristate
68990-53-4	C14–22, monoglycerides, saturated	Example: 1,2-dihydroxypropan-3-yl palmitate
85251-77-0	C16–18, mono- and diglycerides, saturated	Example: 1,3-dihydroxypropan-3-yl stearate

Chemical Structure

The generalized chemical structures of INS 471 are provided in Figure 4.

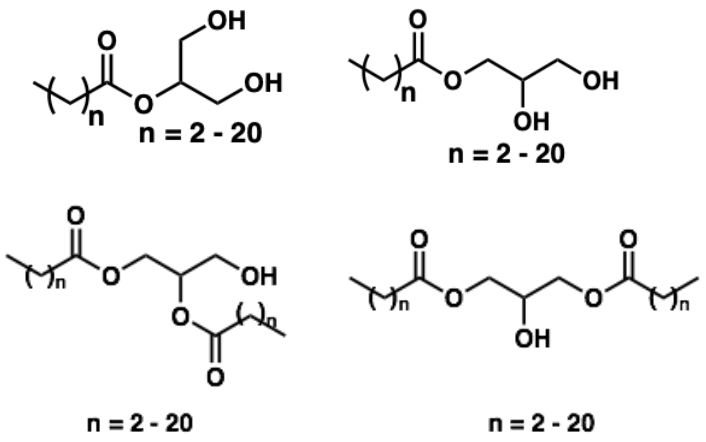

Figure 4: General chemical structures of monoglycerides and diglycerides of fatty acids.

Common Name and Synonyms

Mono- and diglycerides of fatty acids; glycerolipids; glycerol esters of fatty acids; glyceryl monostearate, glyceryl monopalmitate, glyceryl monooleate; etc.; monostearin, monopalmitin, monoolein, etc.; INS 471.

Manufacturers' Code

Not applicable.

Marketing Name

Mono- and diglycerides; glycerolipids.

2.3. Chemical and Physical Properties

INS 471 has a monograph of identity published by the following sources:

- JECFA. 2006, 'Online Edition: "*Combined Compendium of Food Additive Specifications*".' Additive: Mono- and Diglycerides (Appendix 4).
- USP. 2019, '*Food Chemicals Codex* (FCC).' Mono- and Diglycerides (Appendix 5).

To use INS 471 as a glazing agent on fresh fruits and vegetables, INS 471 is dispersed in water prior to its application to the surface of the produce. When deposited onto the food surface, it forms a thin film. INS 471 does not react with the food surface. To confirm this inert behavior, INS 471 was deposited onto the surfaces of as-received, untreated avocados and the avocados were stored under ambient light at room temperature (~ 20℃). The INS 471 layer and the naturally occurring avocado surface waxes were then extracted after deposition and the extracts were analyzed for evidence of changes to the deposited INS 471. Specifically, INS 471 was extracted from the surface of avocados stored at room temperature on Days 0, 1, 2, 6, 8, and 10. The data demonstrate that the INS 471 that was applied was recovered.[23]

Nanotechnology[24] is not used to make INS 471 coatings; INS 471 is not intentionally manufactured to generate particles that are less than 100 nanometers in length in any of the particles' dimensions.

a. Metabolic Fate

The mono- and diglycerides used as a glazing agent on the surface of fresh produce are the same as those found naturally as well as those produced during the hydrolysis of triglycerides in the gastrointestinal tract. There is no evidence to indicate that mono- and diglycerides from this food additive are metabolized differently than mono- and diglycerides found in nature or resulting from the digestion of triglycerides.

In extreme cases, such as the cooking or frying of foods treated with INS 471, the chemistry of saturated mono- and diacylglycerides suggest that the coating may partially undergo hydrolysis to free fatty acids and glycerol, which will not pose any safety hazard to the end consumer (particularly at the relatively low doses of INS 471 that a consumer may potentially consume (*vide infra*)).

More information on the safety of INS 471 is provided in Section 3.0, Safety.

2.4. Impurity Profile

The INS 471 used as an edible coating (or as a component of an edible coating) may be comprised entirely of mono- and diglycerides manufactured by Apeel Sciences, entirely of mono- and diglycerides that are

[23] To measure the stability of INS 471 on the surface of fruits and vegetables, INS 471 was applied to a group of 10 avocados held at ambient temperature. A group of 10 untreated avocados were held under the same conditions to serve as the control. The INS 471 coating was then extracted from the surface of groups of 10 avocados on each of Days 0, 1, 2, 6, 8, and 10. To extract the INS 471 coating from the surface, each avocado was repeatedly rinsed 10 times each with a total of 10 mL of dichloromethane (DCM). The 10 mL of DCM was re-collected after each rinse and reused for the subsequent rinse on the same avocado. A rinse of the next avocado within a given group was then conducted using 10 mL of fresh DCM. The resulting DCM solution collected from each individual avocado was then analyzed by UPLC-ELSD by dilution of the DCM solution into methanol.

[24] FSANZ, 2018*a*.

commercially sourced, or a combination of Apeel-manufactured and commercially sourced mono- and diglycerides. All mono- and diglycerides manufactured or sourced by Apeel Sciences come from plant feedstocks. Possible impurities of INS 471 are residues of solvents used in the manufacturing processes, any inorganic impurities and heavy metals, and any pesticide residues from the raw plant feedstocks. The specified purity of the final product ensures that impurities remain low. Additionally, heavy metals specifications (i.e., arsenic, lead) have been set and are provided in Table 2.

To ensure that pesticide residues are within regulated limits when raw plant material is used as a feedstock, the extracted oil or the final INS 471 product is tested in accordance with Schedules 20 (Maximum Residue Limits) and Schedule 21 (Extraneous Residue Limits) of the Code for Australia and the published Maximum Residue Levels for Agricultural Compounds Food Notice by the New Zealand Ministry for Primary Industries for New Zealand.[25] The final product is also tested for the allergens listed in Schedule 1.2.3 of the Code (Information Requirements – Warning Statements, Advisory Statements and Declarations) to ensure that regulated allergens are not present.

2.5. Manufacturing Process

Mono- and diglycerides of fatty acids are produced from heating oils or fats with excess glycerol, or by direct esterification of glycerol with fatty acids.[26]

Mono- and diglycerides are manufactured according to current Good Manufacturing Practices (GMP) for food. Where solvents are required in the process, only food grade solvents are used. Where a definition of "food grade" has been established by the Food Chemicals Codex (FCC) or JECFA, only reactants or solvents complying with the monograph are used. Where no monograph has been published, American Chemical Society (ACS) or United States Pharmacopeia (USP) reagent grade standards are used to establish food grade specifications.

The final INS 471 coating formulations may be comprised entirely of mono- and diglycerides manufactured by Apeel Sciences, a combination of Apeel Sciences-manufactured and commercially sourced mono- and diglycerides, or solely of commercially sourced mono- and diglycerides. Regardless of whether the mono- and diglycerides are manufactured by Apeel Sciences or commercially sourced, all final formulations will have a total glyceride content of not less than 90 wt. % and will meet the FCC specifications for mono- and diglycerides as well as the JECFA specifications for INS 471, presented in Table 2.

2.6. Specification for Identity and Purity

Proposed specifications are provided in the FCC and JECFA monographs for mono- and diglycerides (INS 471), as summarized in Table 2. A copy of the JECFA and FCC monographs are provided in Appendix 4 and Appendix 5, respectively. Apeel Sciences' mono- and diglycerides meet both FCC and JECFA specifications.

Further, the total glyceride content will be not less than 90 wt. %. The results of three (3) non-consecutive batches of INS 471 are provided in Appendix 6.

[25] New Zealand Ministry for Primary Industries for New Zealand, 2018.
[26] European Food Emulsifiers Manufacturers Association (EFEMA), 2015.

Table 2: FCC[27] and JECFA[28] Specifications for INS 471 (Mono- and Diglycerides)

Parameter	FCC Specifications	JECFA Specifications
Total monoglycerides	Not specified[29]	
Alpha-monoglycerides	Not specified	NLT 30%
Free glycerol	NMT 7%	NMT 7%
Hydroxyl value	Not specified	
Soap (as sodium oleate)		NMT 6%
Acid value	NMT 6	NMT 6
Iodine value	Not specified	
Water content		NMT 2% (Karl Fischer Method)
Residue on ignition (sulfated ash)	NMT 0.5%	
Arsenic	NMT 3 mg/kg	
Lead	NMT 2 mg/kg	NMT 2 mg/kg

2.7. Information for Food Labelling

In most cases, fruits and vegetables that are surface-treated with INS 471 are not required to bear a label that discloses INS 471 as an ingredient in Australia and New Zealand. Section 1.2.1–6 of the Code states that a food is required to bear a label with a list of ingredients unless it is whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) in a package that does not obscure the nature or quality of the food.[30]

Additionally, food additives are not required to be labelled in unpackaged foods (such as fruits and vegetables displayed for retail in bulk or lose bins) and food contained in small packages (i.e., a package with a surface area of less than 100 cm^2), in accordance with Section 1.2.42(3)(c) of the Code.[31]

Surface treatment of produce is not a new concept, and most consumers have consumed produce that has been treated with various edible coatings. In Australia and New Zealand in particular, many citrus varieties are coated with postharvest waxes. In other markets, several fruits and vegetables (e.g., apples, cucumbers, lemons) are often coated with waxes or resins for aesthetic purposes.

[27] USP, 2019.
[28] JECFA, 2006.
[29] Although total monoglyceride content is not specified by FCC or JECFA, Apeel Sciences' specification for total glyceride content in not less than 90 wt. %.
[30] FSANZ, 2018*b*.
[31] FSANZ, 2019.

The INS 471 coating does not disguise the freshness or quality of produce, nor does it hide a problem with the produce; rather, the INS 471 coating prolongs the shelf life and maintains the nutritional and organoleptic qualities of fresh fruits and vegetables. The INS 471 coating does not enhance the color or flavor of spoiled food. It only preserves the moisture content and quality of the produce, which is established at the time of harvest.

2.8. Analytical Method for Detection

There are widely available methods of analysis for detecting and quantifying mono- and diglycerides and the specifications in Table 2. The test methods used to measure each parameter in the specifications is provided in Appendix 7.

2.9. Potential Additional Purposes of the Food Additive When Added to Food

Mono- and diglycerides have no additional functions in the food products it is intended to be used in (i.e., fresh fruits and vegetables).

3.0 Safety

Mono- and diglycerides are currently allowed by the Code for use in a variety of food categories. Schedule 15 of the Code permits INS 471 in the following foods in Australia and New Zealand:

- Liquid milk to which phytosterols, phytostanols or their esters have been added (FC 1.1.1.1) at 2,000 mg/kg;
- Precooked rice under Cereals (whole and broken grains) (FC 6.1) at GMP;
- Infant formula products (FC 13.1) at 4,000 mg/L;
- Infant formula products for specific dietary use based on a protein substitute (FC 13.1.3) at 5,000 mg/L; and
- Food for infants (FC 13.2) at 5,000 mg/kg.

Further, Schedule 16 of the Code permits INS 471 for use at levels of GMP in several food categories, including Food Category 4.1.3, fruits and vegetables that are peeled, cut, or both peeled and cut.

Additionally, an acceptable daily intake (ADI) of "not limited" was established for mono- and diglycerides by JECFA in its 17th report.[32, 33]

[32] An ADI without an explicit indication of the upper limit of intake (i.e., "not limited") may be assigned to substances of very low toxicity, especially those that are food constituents or that may be considered as foods or normal metabolites in man. An additive having a "not limited" ADI must meet the criteria of good manufacturing practice—for example, it should have proven technological efficacy and be used at the minimum level of efficacy. Furthermore, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance.
[33] WHO Technical Report Series, 1974.

3.1. Toxicokinetics, Metabolism, and Degradation Products

The digestion and absorption of *long-chain triglycerides*, the major form of dietary lipids, is a highly efficient process involving several distinct steps such as emulsification, hydrolysis by lipases into fatty acids and monoacylglycerols, dispersion of these products in to an aqueous environment, and uptake by enterocytes. Following ingestion, long-chain triglycerides are broken down by buccal, gastric, pancreatic, and intestinal lipases to form two free long-chain fatty acids and sn2-monoacylglycerol. The middle fatty acid remains attached to the glycerol backbone.[34] The long chain fatty acid and sn2-monoacylglycerols are packaged into micelles for transport through the blood. The micelles contain bile salts, phospholipids, and other emulsifiers that help in binding to enterocytes. After incorporation into micelles, absorption into the intestinal mucosa can occur throughout the small intestine.

Metabolism studies indicate that—based on chain length—medium and long chain triglycerides are readily broken down into medium- and long-chain fatty acids and absorbed via the portal or lymphatic route. Medium-chain fatty acids are directly absorbed into the portal vein, preferentially oxidized in the liver, and ultimately metabolized to carbon dioxide, acetate, and ketones. Long chain fatty acids and sn2 long-chain monoacylglycerols are packaged into micelles, which are then absorbed across the intestinal mucosa. The sn2-monoacylglycerols and long-chain fatty acids are reformed into triacylglycerols, and secreted into the lymphatic system as chylomicrons, for eventual uptake into the adipose tissues for storage and later release as an energy source. It is well known that the intestine is capable of assimilating dietary fat via phosphatidic acid and monoacylglycerol pathways of acylglycerol synthesis, which under normal conditions contribute about 20% and 80%, respectively, to the total chylomicron triacylglycerol formation.[35]

In a study to understand the mechanism of absorption of diglycerides, the hydrolysis of the diglyceride 1,3-diolein wax examined and shown to be nearly completely hydrolyzed to free fatty acids with low levels of monoglycerides present. The 2017 European Food Safety Authority (EFSA) Panel concluded from this study that it is very likely that hydrolysis of mono- and diglycerides by lipases in the gastrointestinal tract would occur, resulting in the release of glycerol and fatty acids. [36]

The available studies indicate that, regardless of their constituent fatty acid, monoacylglycerols are typically well absorbed.[37] However, the free fatty acid absorption depends on their structure, with mono- and polyunsaturated fatty acids and saturated fatty acids with chain lengths of 12 carbons or less being better absorbed than long-chain saturated fatty acids.[38] In the small intestine, triacylglycerols esterified with palmitic acid at the sn2 position are converted to free fatty acids and 2-monopalmitin (the 2-monoacylglycerol), which is readily absorbed.[39]

As the subject of the present application covers mono- and diglycerides, the above discussion is applicable to the metabolism of these constituents. The above discussion also suggests that, similar to triacylglycerides, both of these constituents are readily digested, absorbed and metabolized. The available information also indicate that different fatty acid chains or positioning are unlikely to affect the overall oral toxicity, as the fatty acid portions of molecules are largely cleaved prior to absorption by mucosal cells.

[34] Hoy and Xu, 2001.
[35] Yang and Kuksis, 1991.
[36] EFSA Panel on Food Additives and Nutrient Sources Added to Food, 2017*a*.
[37] Lien et al., 1997.
[38] *Ibid*.
[39] *Ibid*.

3.2. Toxicity, Degradation Products, and Major Metabolites

Please refer to the information provided in Section 3.3.

3.3. Safety Assessment Reports

In addition to the numerous safety assessments conducted by other regulatory bodies and international organizations, in 2017, EFSA conducted a re-evaluation of the safety of mono- and diglycerides of fatty acids when used as a food additive.[40] The EFSA Panel concluded that there was no need for a numerical ADI and that there was no safety concern for the reported uses and use levels for INS 471. In the re-evaluation, the Panel states that it is highly likely that hydrolysis of mono- and diglycerides by lipases in the gastrointestinal tract will occur, resulting in the release of glycerol and fatty acids. These two substances, glycerol and fatty acids, were also re-evaluated by the Panel in 2017, and the Panel concluded that there was no safety concern regarding their use as food additives.[41, 42]

The 2017 EFSA re-evaluation of mono- and diglycerides also states that no adverse effects were reported in short-term and subchronic studies in rats and hamsters, even at the highest dose tested of 2,500 mg diacylglycerol/kg body weight (bw) per day in rats and 7,500 mg glycerol stearate/kg bw per day in hamsters. Further, the available studies did not raise any concern with regard to genotoxicity.

The Panel's re-evaluation also states that there is no indication for a genotoxic, carcinogenic or reprotoxic potential from the available data.

4.0 Dietary Exposure

4.1. Food Groups Proposed to Contain the Food Additive

The proposed food uses and maximum permitted levels for mono- and diglycerides (INS 471) are presented in Table 3. While INS 471 is permitted in a variety of foods in Australia and New Zealand, INS 471 is not currently permitted in the proposed food category presented in Table 3.

4.2. Maximum Proposed Use Levels

Please refer to Table 3 for the proposed food uses and maximum permitted levels for mono- and diglycerides (INS 471).

Table 3: Proposed Food Uses and Maximum Permitted Levels for INS 471

Food Category No.	Description	Proposed MPL	Included Foods
4.1.2	Surface treated fruits and vegetables	GMP	All fruits and vegetables

[40] EFSA Panel on Food Additives and Nutrient Sources Added to Food, 2017*a*.
[41] EFSA Panel on Food Additives and Nutrient Sources added to Food, 2017*b*.
[42] EFSA Panel on Food Additives and Nutrient Sources added to Food, 2017*c*.

4.3. Likely Level of Consumption

The food group for which the new use of INS 471 is proposed, surface treated fruits and vegetables, is included within the data for "fruit products and dishes" and "vegetable products and dishes" in the 2011–12 Australia Health Survey. "Fruit products and dishes" includes fresh, dried, and preserved fruit as well as mixed dishes where fruit is the major component. "Vegetable products and dishes" includes vegetables and dishes where vegetable is the major component. All food items, both unprocessed and processed, listed under "fruit products and dishes" and "vegetable products and dishes" have been conservatively included in the dietary exposure calculations in this section.

The relevant 2011–12 Australia Health Survey data is as follows:

- The reported mean "fruit products and dishes" consumption was 145.8 grams per day, where consumption varied with age group. Children aged 4 to 8 years consumed 187.7 grams per day (mean value), the most of any age group. Young people aged 14 to 18 years consumed 106.0 grams per day and people aged 51 to 70 years consumed 152.2 grams per day (mean values).[43]
- The reported mean vegetable consumption was 156.2 grams per day, where consumption varied with age group. Children aged 4 to 8 years consumed 93.5 grams per day (mean value), young people aged 14 to 18 years consumed 119.3 grams per day (mean value), and people aged 51 to 70 years consumed 187.1 grams per day (mean value), the most of any age group.[44]

INS 471 may be used as a glazing agent on any fruit or vegetable. The quantity applied varies with the specific application. Some factors that affect the quantity of INS 471 are: the type of fruit or vegetable; seasonality; region of origin of the produce; climate in location of coating application; and desired shelf life extension. A limit of GMP is consistent with the Codex Alimentarius Commission adoption of INS 471 as a glazing agent on surface-treated fresh fruits and vegetables in the GSFA.[45]

The most conservative estimate of the maximum quantity of INS 471 that will be applied to the surface of fresh fruits and vegetables is 152 g per 100 kg of produce. Using this value of 152 g of INS 471 per 100 kg of produce, the quantities of INS 471 consumed per day by age group for fruits and vegetables are presented in Table 4.

[43] Australian Bureau of Statistics, 2014*a*.
[44] *Ibid.*
[45] Codex Alimentarius Commission, 2019.

Table 4: Mean Consumption (g/day) and Corresponding Consumption Levels of INS 471 (mg/day) for Fruits and Vegetables

Age Group (Years)	Fruit products and dishes		Vegetable products and dishes		FC 4.1.2 (Surface treated fruits and vegetables)*	
	Fruit Consumed (g/day)	**INS 471 Consumed on Fruit** (mg/day)	**Vegetables Consumed** (g/day)	**INS 471 Consumed** (mg/day)	**FC 4.1.2 Consumed** (g/day)	**INS 471 Consumed on FC 4.1.2** (mg/day)
Mean Consumption (all age groups)	145.8	221.6	156.2	237.4	302	459.0
2-3	185.5	282.0	67.9	103.2	253.4	385.2
4-8	187.7	285.3	93.5	142.1	281.2	427.4
9-13	167.4	254.4	116.4	176.9	283.8	431.4
14-18	106	161.1	119.3	181.3	225.3	342.5
19-30	106.3	161.6	160.3	243.7	266.6	405.2
31-50	142.6	216.8	177.3	269.5	319.9	486.2
51-70	152.2	231.3	187.1	284.4	339.3	515.7
71 and over	181.2	275.4	174	264.5	355.2	539.9

*– The quantity of FC 4.1.2 (surface treated fruits and vegetables) consumed is the sum of the mean consumption of the categories "fruit products and dishes" and "vegetable products and dishes" from Table 5.1 and Table 5.3 of the 2011–2012 Australian Health Survey: Nutrition First Results – Foods and Nutrients, Australia.[46]

4.4. Likely Level of Consumption for Foods Not Currently Listed in the most Recent Australian or New Zealand National Nutrition Surveys (NNSs)

The food groups for which the new use of INS 471 is proposed, surface treated fruits and vegetables (FC 4.1.2), is included in the 2011–12 Australia Health Survey within the categories "fruit products and dishes" and "vegetable products and dishes." Therefore, this section is not applicable.

4.5. 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

100% of the proposed use of mono- and diglycerides as a glazing agent is intended for Food Category 4.1.2, Surface treated fruits and vegetables, where up to 100% of the fruits and vegetables included in this Food Category may be surface treated with mono- and diglycerides. Additionally, the use of INS 471 as a glazing agent on fresh fruits and vegetables may be utilized by the entire fresh produce market.

[46] Australian Bureau of Statistics, 2014*b*.

4.6. Use of the Food Additive in Other Countries

INS 471 is used commercially as a glazing agent (or equivalent technical function, such as "coating agent") for fresh fruits and vegetables in the following countries or regions:

- EU allows use at GMP on citrus fruit, melons, pineapples, bananas, papayas, mangoes, avocados, and pomegranates;
- Mexico allows use at GMP on all fresh fruits and vegetables;
- Peru allows use at GMP on all fresh fruits and vegetables; and
- United States allows use at GMP on all fresh fruits and vegetables.

4.7. For Foods Where Consumption Has Changed in Recent Years, Information on Likely Current Food Consumption

Apeel Sciences is not aware of any recent changes in fruit or vegetable consumption since the 2011–12 Australia Health Survey. Therefore, the 2011–12 Australia Health Survey contains the most up-to-date data on fruit and vegetable consumption in Australia and New Zealand.

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6.0 List of Appendices

Appendix 1. Codex GSFA (2019) Allowances for INS 471

Appendix 2. Statutory Declaration

Appendix 3. FSANZ Application Checklist

Appendix 4. JECFA Monograph for INS 471

Appendix 5. FCC Monograph for Mono- and Diglycerides

Appendix 6. INS 471 Batch Analysis

Appendix 7. Analytical Methods for Detection

Appendix 1. Codex GSFA (2019) Allowances for INS 471

Appendix Table 1: Excerpt from Table 1 (Additives Permitted for Use Under Specified Conditions in Certain Food Categories or Individual Food Items) of the GSFA (Rev. 2019) for Mono- and Di-Glycerides of Fatty Acids

MONO- AND DI-GLYCERIDES OF FATTY ACIDS

INS 471 Mono- and di-glycerides of fatty acids Functional Class: Antifoaming agent, Emulsifier, Glazing agent, Stabilizer

FoodCatNo	FoodCategory	MaxLevel	Notes	Year Adopted
01.1.2	Other fluid milk (plain)	GMP	410	2018
01.2.1.1	Fermented milks (plain), not heat-treated after fermentation	GMP	234 & 235	2015
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	GMP	234	2015
01.2.2	Renneted milk (plain)	GMP		2015
01.4.1	Pasteurized cream (plain)	GMP	236	2013
01.4.2	Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)	GMP		2013
02.1.3	Lard, tallow, fish oil, and other animal fats	GMP	408, XS211	2018
04.1.1.2	Surface-treated fresh fruit	GMP	453	2019
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	GMP	455	2019
06.4.1	Fresh pastas and noodles and like products	GMP		2014
06.4.2	Dried pastas and noodles and like products	GMP	256	2014
08.1.1	Fresh meat, poultry, and game, whole pieces or cuts	GMP	16 & 326	2015
08.1.2	Fresh meat, poultry, and game, comminuted	GMP	281	2014
09.2.2	Frozen battered fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms	GMP	41	2015
09.2.3	Frozen minced and creamed fish products, including mollusks, crustaceans, and echinoderms	GMP		2015
09.2.4.1	Cooked fish and fish products	GMP	241	2015
09.2.4.3	Fried fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	41	2015
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	GMP	300, XS167, XS189, XS222, XS236, XS244 & XS311	2018
10.2.1	Liquid egg products	GMP		2015
10.2.2	Frozen egg products	GMP		2014
11.4	Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings)	GMP	258	2014
12.1.2	Salt Substitutes	GMP		2014
13.1.1	Infant formulae	4000 mg/kg	72	2014
13.1.2	Follow-up formulae	4000 mg/kg	72	2014
13.1.3	Formulae for special medical purposes for infants	4000 mg/kg	72	2014
13.2	Complementary foods for infants and young children	5000 mg/kg	268 & 275	2014
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	GMP	160	2014

Appendix Table 2: Excerpt from Table 3 of the GSFA (Rev. 2019),
Additives Permitted for Use in Food in General, Unless Otherwise Specified, In Accordance with GMP

INS No	Additive	Functional Class	Year Adopted	Acceptable, including foods conforming to the following commodity standards
471	Mono- and di-glycerides of fatty acids	Antifoaming agent, Emulsifier, Glazing agent, Stabilizer	1999	CS 117-1981, CS 105-1981, CS 87-1981, CS 141-1983, CS 309R-2011, CS 249-2006

Appendix 2. Statutory Declaration

(See next page.)

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, [redacted] at Apeel Sciences, located at 71 South Los Carneros Road, Goleta, California, USA, 93117 make the following declaration under the *Statutory Declarations Act 1959* for the application to amend the Australia and New Zealand Food Standards Code for the expansion of use of the food additive mono- and diglycerides of fatty acids (INS 471) in Schedule 15:

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; and
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.

[redacted]

Declared at Goleta, California on 30 of August, 2019.

Before me,

[redacted]

Please see attached for jurat and stamp.

CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA
COUNTY OF SANTA BARBARA

Subscribed and sworn to (or affirmed) before me

on this 30 day of AUGUST, 2019

by [redacted]

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

[redacted]

[redacted]

[SEAL]

Description of Attached Document (Optional)	Method of Signer Identification
The preceding Californnia Jurat is attached to a document titled/for the purpose of: _____	Proved to me on the basis of satisfactory evidence:
Containing _____ pages, and dated 8/30/2019	☒ Form(s) of Identification
The signer(s) capacity or authority is/are as:	☐ Credible Witness(es)
☒ Individual(s)	**Notarial Event is detailed in notary journal on:**
☐ Attorney-in-Fact	Page # 109 Entry # 7
☐ Corporate Officer(s): _____	Notarized by:
☐ Guardian/Conservator	[redacted]
☐ Partner - Limited/General	
☐ Trustee(s)	
Representing: _____	
_____	

Appendix 3. FSANZ Application Checklist

Checklist for General requirements

General requirements (3.1.1)		
Check	**Page No.**	**Mandatory requirements**
☒	N/A	A Form of application ☒ *Application in English* ☒ *Executive Summary (separated from main application electronically)* ☒ *Relevant sections of Part 3 clearly identified* ☒ *Pages sequentially numbered* ☒ *Electronic copy (searchable)* ☒ *All references provided*
☒	4	B Applicant details
☒	5	C Purpose of the application
☒	5	D Justification for the application ☒ *Regulatory impact information* ☒ *Impact on international trade*
☒	8	E Information to support the application ☒ *Data requirements*
☒	9	F Assessment procedure ☒ *General* ☐ *Major* ☐ *Minor* ☐ *High level health claim variation*
☒	9 (N/A)	G Confidential commercial information ☐ *CCI material separated from other application material* ☐ *Formal request including reasons* ☐ *Non-confidential summary provided*
☒	9	H Other confidential information ☒ *Confidential material separated from other application material* ☒ *Formal request including reasons*
☒	9 (N/A)	I Exclusive Capturable Commercial Benefit ☐ *Justification provided*
☒	9	J International and other national standards ☒ *International standards* ☒ *Other national standards*

☒	12	K Statutory Declaration
☒	12	L Checklist/s provided with application ☒ *3.1.1 Checklist* ☒ *All page number references from application included* ☒ *Any other relevant checklists for Chapters 3.2–3.7*

Checklist for applications for substances added to food

Food additives (3.3.1)		
Check	**Page No.**	**Mandatory requirements**
☒	12	A.1 Nature and technological purpose information
☒	16	A.2 Identification information
☒	17	A.3 Chemical and physical properties
☒	17	A.4 Impurity profile
☒	18	A.5 Manufacturing process
☒	18	A.6 Specifications
☒	19	A.7 Food labelling
☒	20	A.8 Analytical detection method
☒	20	A.9 Additional functions
☒	17, 21, 22	B.1 Toxicokinetics and metabolism information
☒	22	B.2 Toxicity information
☒	22	B.3 Safety assessments from international agencies
☒	22	C.1 List of foods likely to contain the food additive
☒	22	C.2 Proposed levels in foods
☒	24	C.3 Likely level of consumption
☒	24	C.4 Percentage of food group to contain the food additive
☒	25	C.5 Use in other countries (if applicable)
☒	25	C.6 Where consumption has changed, information on likely consumption

Appendix 4. JECFA Monograph for INS 471

(See next page.)

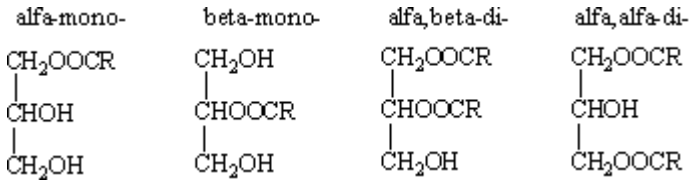
MONO- AND DIGLYCERIDES

Prepared at the 17th JECFA (1973), published in FNP 4 (1978) and in FNP 52 (1992). Metals and arsenic specifications revised at the 55th JECFA (2000). An ADI not limited' was established at the 17th JECFA (1973)

SYNONYMS Glyceryl monostearate, glyceryl monopalmitate, glyceryl monooleate, etc; monostearin, monopalmitin, monoolein, etc.; GMS (for glyceryl monostearate); INS No. 471

DEFINITION A mixture of mono- and diglyceryl esters of long chain, saturated and unsaturated fatty acids that occur in food fats; contain not less than 30% of alpha-monoglycerides and may also contain other isomeric monoglycerides, as well as di- and triglycerides, free glycerol, free fatty acids, soap and moisture; usually manufactured by the glycerolysis of edible fats and oils, but may also be prepared by esterification of fatty acids with glycerol, with or without molecular distillation of the product.

Structural formula



where -OCR represents the fatty acid moiety

Formula weight

Glyceryl monostearate: 358.6
Glyceryl distearate: 625.0
These are two major components of commercial products

DESCRIPTION White or cream coloured hard fats of waxy appearance, plastic products or viscous liquids

FUNCTIONAL USES Emulsifier

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4) Insoluble in water; soluble in ethanol, chloroform and benzene

Infrared absorption The infrared spectrum of the sample is characteristic of a partial fatty acid ester of a polyol

Tests for fatty acids (Vol. 4) Passes tests

Test for glycerol (Vol. 4) Passes tests

PURITY

Water (Vol. 4) Not more than 2.0% (Karl Fischer Method)

Acid value (Vol. 4)	Not more than 6
Free glycerol (Vol. 4)	Not more than 7%
Soap	Not more than 6%, calculated as a sodium oleate Add 10.00 g of the sample to a mixture of 60 ml of acetone and 0.15 ml of bromophenol blue solution (0.5%), previously neutralized with 0.1 N hydrochloric acid or 0.1 N sodium hydroxide. Warm gently on a water bath until solution is complete, and titrate with 0.1 N hydrochloric acid until the blue colour is discharged. Allow to stand for 20 min, warm until any solidified matter has re-dissolved and, if the blue colour reappears, continue the titration. Each ml of 0.1 N hydrochloric acid is equivalent to 0.0304 g of $C_{18}H_{33}O_2Na$.
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, “Instrumental Methods.”
METHODS OF ASSAY	Determine as described under *alpha-Monoglyceride and Free Glycerol Contents* in Volume 4

Appendix 5. FCC Monograph for Mono- and Diglycerides

(See next page.)

Mono- and Diglycerides

Mono- and Diglycerides

Published in: FCC 11 2S
First Published: Prior to FCC 6
Last Revised: FCC 11, Second Supplement

Add the following:
▲**INS:** 471▲2S (FCC 11)

DESCRIPTION

Mono- and Diglycerides occur as a substance that varies in consistency from yellow liquids through white- to pale yellow-colored plastics to hard, ivory-colored solids. They consist of mixtures of glycerol mono- and diesters, with minor amounts of triesters, and of edible fats or oils or edible fat-forming fatty acids. They are insoluble in water, but are soluble in alcohol, in ethyl acetate, and in chloroform and other chlorinated hydrocarbons.

Function: Emulsifier; stabilizer

Packaging and Storage: Store in well-closed containers.

IMPURITIES

Inorganic Impurities

- **Arsenic,** ***Arsenic Limit Test, Appendix IIIB***
  Sample solution: Prepare as directed for organic compounds.
  Acceptance criteria: NMT 3 mg/kg
- **Lead,** ***Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB***
  Sample: 10 g
  Acceptance criteria: NMT 2 mg/kg

SPECIFIC TESTS

- **Acid Value (Fats and Related Substances),** ***Method II, Appendix VII***
  Acceptance criteria: NMT 6
- **Free Glycerin,** ***Free Glycerin or Propylene Glycol, Appendix VII***
  Acceptance criteria: NMT 7.0%
- **Hydroxyl Value,** ***Method II, Appendix VII***
  Acceptance criteria: Results should conform to the representations of the vendor.
- **Iodine Value,** ***Appendix VII***
  Acceptance criteria: Results should conform to the representations of the vendor.
- **1-Monoglyceride Content,** ***1-Monoglycerides, Appendix VII***
  Acceptance criteria: Results should conform to the representations of the vendor.
- **Residue on Ignition (Sulfated Ash),** ***Appendix IIC***
  Sample: 5 g
  Acceptance criteria: NMT 0.5%
- **Saponification Value,** ***Appendix VII***
  Sample: 4 g
  Acceptance criteria: Results should conform to the representations of the vendor.
- **Total Monoglycerides,** ***Appendix VII***
  Acceptance criteria: Results should conform to the representations of the vendor.

Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
MONO- AND DIGLYCERIDES	Gina Clapper Senior Scientific Liaison +1 (301) 692-3626	FI2015 Food Ingredients 2015

Page Information

- FCC 11 2S - page 1797
- FCC 11 - page 818
- FCC 10 - page 885

Appendix 6. INS 471 Batch Analysis

Appendix Table 3: Batch Analysis for Three Non-Consecutive Lots of Mono- and Diglycerides (INS 471)

Parameter	FCC Specifications	JECFA Specifications	Lot #3067	Lot #3079	Lot #3106
Total glycerides *(Apeel Sciences specification: NLT 90 wt. %)*			100 wt. %	100 wt. %	100 wt. %
Total monoglycerides	Not specified		(Not measured)	(Not measured)	(Not measured)
Alpha-monoglycerides	Not specified	NLT 30%	57.6 wt. %	56.1 wt. %	58.8 wt. %
Free glycerol	NMT 7%	NMT 7%	< 5 wt. %	< 5 wt. %	< 5 wt. %
Hydroxyl value	Not specified		(Not measured)	(Not measured)	(Not measured)
Soap (as sodium oleate)		NMT 6%	< 0.156 wt. %	< 0.156 wt. %	< 0.156 wt. %
Acid value	NMT 6	NMT 6	4.6	2.8	2.2
Iodine value	Not specified		1.7	0.27	0.23
Water content		NMT 2% (Karl Fischer Method)	0.30%	< 0.20%	< 0.36%
Residue on ignition (sulfated ash)	NMT 0.5%		< 0.1%	< 0.1%	< 0.1%
Arsenic	NMT 3 mg/kg		< 0.0965 ppm	< 0.0923 ppm	< 0.187 ppm
Lead	NMT 2 mg/kg	NMT 2 mg/kg	< 0.0965 ppm	< 0.0923 ppm	< 0.0931 ppm

* – Soap reported as sodium stearate. Multiplying reported value by 0.99 provides the soap value as sodium oleate.
NLT – "Not less than"
NMT – "Not more than"

Appendix 7. Analytical Methods for Detection

Appendix Table 4: Analytical Methods for Mono- and Diglycerides

Parameter	**Test Method***
Total glycerides	Apeel TM-0014 (UHPLC-ELSD)
α-Monoglyceride content	
Free glycerol	Apeel TM-0008 (UHPLC-ELSD)
Soap	Apeel TM-0016 (Titration) **OR** Food Chemicals Codex, 11th Ed. *Soap,* Appendix VII
Acid value	Apeel TM-0019 (Titration) **OR** Eurofins Method: FFA2_S Official Methods and Recommended Practices of the AOCS, Fifth Ed., Method Ca 5a-40, American Oil Chemists' Society, Champaign, Illinois (1997) (modified). United States Pharmacopeia, Thirty-Fifth Revision, <401 Fats & Fixed Oils>, USP Convention, Inc., Rockville, MD (2012). For extraction: Official Methods of Analysis of the AOAC International, 18th Ed, (2005), AOAC International, Gaithersburg, MD. Official Method 983.23 (modified).
Iodine value	Calculated in accordance with FCC monograph for Fully Hydrogenated Oils and Fats (FCC 10)
Water content	Apeel TM-0012 (Karl Fischer) **OR** <USP 921> Eurofins Method: KFMO_S The United States Pharmacopeia, Thirty Seventh Revision, <921>, Method 1a, The United States Pharmacopeial Convention, Rockville, MD (2014) (modified).
Residue on ignition	<USP 281> Eurofins Method: ROI_S United States Pharmacopeia, Twenty-ninth Revision, <281>, United States Pharmacopeial Convention, Inc.: Rockville, Maryland (2005). United States Pharmacopeia, 41st Revision - National Formulary 36th Edition. USP Convention. Rockville, MD (2017) (modified).

Parameter	Test Method*
Arsenic	Apeel TM-0021 (ICP-OES) **OR** Inductively Coupled Plasma – Mass Spectrometry (ICP-MS)
Lead	