Office of Food Additive Safety (HFS-200)

Center for Food Safety and Applied Nutrition

Food and Drug Administration

5001 Campus Dr.

College Park, MD 20740

Subject: Notice of a GRAS Exemption for Calcium Disodium EDTA

To Whom It May Concern,

170.225 Part 1 of a GRAS notice - Signed statements and certification:

(a)

Clinton Colley | Processing Manager
Tel: +61 3 5259 0005
366 The Esplanade, Indented Head, Victoria, 3223 Australia

ccolley@craigmostyn.com.au

CMG AUSTRALIA
JADE TIGER ABALONE

(b) No information is considered trade secret or confidentially commercial in this section in Part 1 of the GRAS Notice.

(c)

(1) I'm informing the Office of Food Additive Safety (HFS-200) that I'm submitting a GRAS notice in accordance with subpart E.

(2) The name of the organization is Jade Tiger Abalone Pty Ltd. The address of the organization is 366 The Esplanade, Indented Head, Victoria, 3223, Australia.

(3) The name of the notified substance is Calcium Disodium EDTA (INS 385).

(4) The indented conditions of use for Calcium Disodium EDTA is for canned abalone in brine. Calcium Disodium EDTA is added to the brine at a level not to exceed 250ppm in the end product. The purpose of the additive is to prevent the oxidation of the hemocyanin protein contained within the abalone. Oxidation of this copper containing protein causes the pigment to become blue.

Calcium Disodium EDTA prevents the protein from oxidizing through its sequestering capabilities. Therefore, Calcium Disodium EDTA's primary use is to promote color retention in canned abalone. Canned abalone in brine is traditionally consumed in Asian cuisine. It can be consumed at home or restaurants. Brine is generally discarded leaving the abalone meat to be consumed.

(5) The statutory basis for my conclusion of GRAS status for Calcium Disodium EDTA is that it is through scientific procedures in accordance with 21 CFR 170.30 (a) and (b).

(a) Scientific data and information that identifies the notified substance is as follows:

A joint report by the FAO and WHO on the toxicological evaluation of certain food additives indicated that the ADI for man of Calcium Disodium EDTA was estimated to be 0-2.5 mg /Kg body weight (FAO / Who 1974).

Section 172.120 of the US FDA Foods for Human Consumption lists a number of foods Calcium Disodium EDTA can be safely used in. The list contains 3 canned seafood products. These include canned crab (275ppm), canned clams (340ppm) and canned shrimp (250ppm). The use of Calcium Disodium EDTA in each of these products is to promote color retention. Note that clams and abalone come from the same phylum of molluscs and both require the additive for color retention in canned form.

It is listed as an approved food additive in the Codex Alimentarius International food Standards code. Codex Stan 192-1995 (FoodCatNo 09.4 - page 136) allows a maximum of 340ppm for Calcium Disodium EDTA in canned molluscs (abalone). Calcium Disodium EDTA in canned abalone is also approved for use in many other countries around the world. Some examples of these and their corresponding maximum levels are as follows:

Australia – 250ppm (FSANZ), New Zealand – 250ppm (FSANZ), Singapore – 250ppm (Singapore Food Agency), Hong Kong – 340ppm (Centre for Food Safety) and Japan – 250ppm (JETRO).

Calcium Disodium EDTA is essential for preventing the blue discoloration in canned abalone. This is referenced in well-known literature (Featherstone 2016). It was also documented in a scientific study that EDTA above concentrations of 200ppm significantly improved the colour of canned abalone (Chew 1973).

(c) Specifications of food grade material is as follows:

Solvitar™ meets the chemical test requirements of the European Pharmacopoeia (EP), United States Pharmacopoeia (USP), Food Chemical Codex (FCC), European Directive 380/2012/EC and JECFA.

Checkpoint	Specification	Units	Methods
Appearance	Free-flowing white micro-granules		Visual
Identification	Passes test		USP
Assay on anhydrous basis	98.0 – 102.0	%	USP
Water content	5.0 – 13.0	%	USP
Free EDTA as EDTA-Na_2	1.0 max	%	USP
Magnesium Chelating substance	Passes test		FCC
NTA-H_3	<0.10	%	USP
pH of 20% w/v aqueous solution	6.5 – 8.0		USP
pH of 1% w/v aqueous solution	6.5 – 7.5		FCC
Chloride	0.10 max	%	USP
Appearance of 5% solution	Colorless, clear		EP
Heavy metals as Pb	10 max	mg/kg	USP
Arsenic	3 max	mg/kg	SMA 885.06
Lead	2 max	mg/kg	FCC
Iron	80 max	mg/kg	EP
Mercury	1 max	mg/kg	SMA 968.07

(6) Calcium Disodium EDTA for use in canned abalone is not subject to the premarket approval of the Federal Food, Drug and Cosmetic act. Section 172.120 of the US FDA Foods for Human Consumption lists a number of foods Calcium Disodium EDTA can be safely used in already. Three of these are types of canned seafood (clams, crab and shrimp) that rely on the additive for color retention. As canned abalone relies on the additive for the same purpose, I strongly believe Calcium Disodium EDTA to be GRAS under the conditions of its intended use.

(7) I agree if the FDA asks to see the data and information that are the basis for my conclusion of GRAS status, either during or after the FDA evaluation of my choice, I will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon FDA request, I will allow them to review and copy the data and information during customary business hours at the address I specify for where these data and information will be available to them; and

(B) Upon FDA request, I will provide them with a complete copy of the data and information either in an electronic format that is accessible for their evaluation or on paper;

(8) None of the data and information in Parts 2 through 7 of my GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (*e.g.,* as trade secret or as commercial or financial information that is privileged or confidential).

(9) I certify that, to the best of my knowledge, my GRAS notice is a complete, representative, and balanced submission that includes unfavourable information, as well as favourable information, known to me and pertinent to the evaluation of the safety and GRAS status of the use of Calcium Disodium EDTA in canned abalone;

(10) The name and position of the person who signs the GRAS notice is as follows;

Clinton Colley – Processing Manager at Jade Tiger Abalone Pty Ltd

(11) When applicable, I state as required by §170.270 to:

(i) Authorize the FDA to send any trade secrets to the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture; or

(ii) Ask the FDA to exclude any trade secrets from the copy of the GRAS notice that they will send to FSIS.

170.230 Part 2 of GRAS notice – Identity, method of manufacture, specifications, and physical or technical effect:

(a) Scientific data and information that identifies the notified substance is as follows:

A joint report by the FAO and WHO on the toxicological evaluation of certain food additives indicated that the ADI for man of Calcium Disodium EDTA was estimated to be 0-2.5 mg /Kg body weight (FAO / WHO 1974).

Section 172.120 of the US FDA Foods for Human Consumption lists a number of foods Calcium Disodium EDTA can be safely used in. The list contains 3 canned seafood products. These include canned crab (275ppm), canned clams (340ppm) and canned shrimp (250ppm). The use of Calcium Disodium EDTA in each of these products is to promote color retention. Note that clams and abalone come from the same phylum of molluscs and both require the additive for color retention in canned form.

It is listed as an approved food additive in the Codex Alimentarius International food Standards code. Codex Stan 192-1995 (FoodCatNo 09.4 - page 136) allows a maximum of 340ppm for Calcium Disodium EDTA in canned molluscs (abalone). Calcium Disodium EDTA in canned abalone is also approved for use in many other countries around the world. Some examples of these and their corresponding maximum levels are as follows:

Australia – 250ppm (FSANZ), New Zealand – 250ppm (FSANZ), Singapore – 250ppm (Singapore Food Agency), Hong Kong – 340ppm (Centre for Food Safety) and Japan – 250ppm (JETRO).

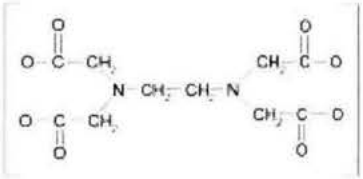
Calcium Disodium EDTA is essential for preventing the blue discoloration in canned abalone. This is referenced in well-known literature (Featherstone 2016). It was also documented in a scientific study that EDTA above concentrations of 200ppm significantly improved the colour of canned abalone (Chew 1973).

(1) Appropriate data and information on Calcium Disodium EDTA:

Chemical name - Ethylenediaminetetraacetic acid, calcium-disodium complex

Chemical formula - EDTA-CaNa2.2H2O

Structure:



Mol weight - 410.3 (dihydrate), 374.3 (anhydrous)

CAS number - 23411-34-9 (dihydrate), 62-33-9 (in some National Inventories registered as anhydrous)

Characteristic properties - Sequestering agent forming stable, water-soluble chelates with polyvalent metal ions in a wide pH range.

- Practically insoluble in alcohol.
- Calcium content 10 +/- 0.5%
- Solubility in water ~ 800 g/l water (20ºC)
- >1500 g/l water (80ºC)
- Bulk density untapped (poured) ~ 600- 800 kg/m3
- Bulk density tapped ~ 800-1000 kg/m3

(2) Calcium Disodium EDTA is not a biological material.

(b) Solvita is manufactured by Nouryon in The Netherlands before being shipped to IMCD Australia Limited who supply Jade Tiger. Solvitar is a food grade Calcium Disodium EDTA product that is made under stringent regulations in their factory in the Netherlands. Solvitar is manufactured under current good manufacturing practice (cGMP) to meet specifications of the Food Chemical Codex (FFC), European directive 231/2012/EC and the JECFA. Solvitar is also an approved food additive in the EU (E385) and US (FDA). The facility in the Netherlands that manufactures Solvitar is certified according to ISO 9001, ISO 14001 and FSSC22000 (Food Safety Scheme for food manufacturing in compliance with ISO 22000 and PAS220).

Based on the information provided by the supplier, Nouryon, Calcium Disodium EDTA is manufactured under cGMP via the following process.

- The following raw materials are batch mixed in stirred tank reactors (at atmospheric conditions) to produce an intermediate material:
  - Dissolvine Z (Ethyleendiamine tetra-azijnzuur, kristallijn H_4EDTA)
  - Sodium hydroxide, NaOH 50 wt%
  - Calcium hydroxide, $Ca(OH)_2$ 95 wt%
  - Water
- After filtering, this intermediate material is spray-dried to form Calcium Disodium EDTA by an evaporation process using hot air (natural gas fired).

(c) Specifications of food grade material is as follows:

Solvitar™ meets the chemical test requirements of the European Pharmacopoeia (EP), United States Pharmacopoeia (USP), Food Chemical Codex (FCC), European Directive 380/2012/EC and JECFA.

Checkpoint	Specification	Units	Methods
Appearance	Free-flowing white micro-granules		Visual
Identification	Passes test		USP
Assay on anhydrous basis	98.0 – 102.0	%	USP
Water content	5.0 – 13.0	%	USP
Free EDTA as EDTA-Na_2	1.0 max	%	USP
Magnesium Chelating substance	Passes test		FCC
NTA-H_3	<0.10	%	USP
pH of 20% w/v aqueous solution	6.5 – 8.0		USP
pH of 1% w/v aqueous solution	6.5 – 7.5		FCC
Chloride	0.10 max	%	USP
Appearance of 5% solution	Colorless, clear		EP
Heavy metals as Pb	10 max	mg/kg	USP
Arsenic	3 max	mg/kg	SMA 885.06
Lead	2 max	mg/kg	FCC
Iron	80 max	mg/kg	EP
Mercury	1 max	mg/kg	SMA 968.07

The test results of four non-consecutive batches of Calcium Disodium EDTA spanning the past 4 years have been included in Appendix A. All of these test results show full compliance to the above specification.

Jade Tiger is supplied by IMCD Australia Limited who purchase Calcium Disodium EDTA from its Dutch manufacturer, Nouryon. In the time spanning the four test results the company underwent a name change from AkzoNobel Specialty Chemicals to Nouryon, hence the different letterheads on the test results.

(d) The main technological effect Calcium Disodium EDTA is needed for is to provide colour retention in canned abalone. Codex Alimentarius standards for food additives allows a maximum of 340ppm for Calcium Disodium EDTA in canned abalone to achieve this effect safely. Calcium Disodium EDTA use in canned clams for the same technological effect has been approved by the FDA as safe at a level not to exceed 340ppm. Therefore it can be concluded that levels up to 340ppm of Calcium Disodium EDTA have been deemed safe to use in canned abalone and canned clams.

A study on the pigments of New Zealand and Australian abalone found that concentrations above 200ppm of Calcium Disodium EDTA significantly improved the colour of canned abalone (Chew 1973). In my past 15 years of experience canning abalone I have found Calcium Disodium EDTA is required at levels up to 250ppm to achieve colour retention. This coincides strongly with the study done by Chew on the pigments of New Zealand and Australian abalone.

Part 3 of GRAS notice - Dietary Exposure:

(a) A joint report by the FAO and WHO on the toxicological evaluation of certain food additives indicated that the ADI (Acceptable Daily Intake) for man of Calcium Disodium EDTA was estimated to be 0-2.5 mg/kg body weight (FAO / WHO 1974). Estimated daily intake of Calcium Disodium EDTA is 0.23 mg / Kg body weight (FDA 1998).

A study done on the risk assessment of sulphites in Australian Canned abalone noted the average serving size of canned abalone was 100 grams (Dobson 2011). Based on canned abalone in brine containing a maximum of 250ppm Calcium Disodium EDTA, dietary exposure can be calculated:

Acceptable ADI for Calcium Disodium EDTA = 2.5mg/kg of Body Weight (bw):

Theoretical Maximum Daily intake of Calcium Disodium EDTA in canned abalone in brine:

Maximum daily intake (mg/kg food)	Average Serving Size (g/day)	Calcium Disodium EDTA intake (mg/day)	Average body weight (kg bw)	Calcium Disodium EDTA intake (mg/kg bw/day)
250	100	25	60	0.42

Theoretical Maximum Daily intake of Calcium Disodium EDTA from other sources:

Based on information in GRAS Notification 573 for Calcium Disodium EDTA in beverages, the additional existing uses of calcium disodium EDTA and EDTA were identified.

- Sources of EDTA as regulated in the CFR (21 CFR 172.120 and 172.135).
- Sources of EDTA from further existing GRAS uses.
    - GRAS Notification 152, use of sodium iron EDTA as a source of dietary iron for food fortification purposes in powdered soft drinks provided in areas of the world with a high prevalence of iron deficiency, Kraft 2004.
    - GRAS Notification 178, use of sodium iron EDTA as a source of dietary iron for fortification of soy, fish, teriyaki, and sweet and sour sauces, Akzo Nobel 2005.
    - GRAS Notification 363, use of both calcium disodium EDTA and disodium EDTA for color, flavor, and/or texture retention agents in packaged cooked sweet corn products with or without sauce, Del Monte 2010.

The following data from the abovementioned sources is based on conservative estimates using the 90th percentile of data ranges for the portion of the US population showing the highest ADI's on a body weight basis for Calcium Disodium EDTA (children aged 2 – 12 years).

Intake from use of Calcium Disodium EDTA in Current GRAS Uses (mg/kg bw/day)	Intake from 21 CFR uses (mg/kg bw/day	Cumulative Calcium Disodium EDTA intake (mg/kg bw/day)
1.05	0.26	1.31

By combining the data from the above two tables it can be seen that the cumulative exposure to EDTA from the consumption of canned abalone and other sources is 0.42 + 1.31 = 1.73 mg/kg bw/day. This is well under the average daily intake of 2.5 mg/kg body weight stated by the FAO and WHO (FAO / WHO 1974).

(b) Not applicable.

(c) Not applicable.

(d) Sources for food consumption data used to estimate dietary exposure:

Estimated daily intake of Calcium Disodium EDTA was taken from the following study:

- FDA. 1998b. Food additive safety profiles of Tetrasodium EDTA, Disodium EDTA, Calcium Disodium EDTA, and Dipotassium EDTA. FDA database. Washington, DC.

Average serving size of canned abalone in brine was taken from the following study:

- Risk Assessment of sulphites in Australian canned abalone, Dr Susan Dobson November 2011.

Average adult body weight used was taken from the following guidelines:

- Codex Alimentarius Guidelines for the simple evaluation of dietary exposure to food additives.

ADI of Calcium Disodium EDTA for man was taken from the following study:

- Toxicological evaluation of certain food additives with a review of general principles and of specifications (FAO / WHO 1973).

(e) All assumptions made to estimate dietary consumption were based on one of the studies and/or guidelines listed in section (d).

Part 4 of GRAS notice – Self-limiting levels of use:

The amount of Calcium Disodium EDTA used in canned abalone is not limited due to unpalatable or technological applications. Solvitar used in our canning process does not impede food taste or quality in promoting colour retention (Solvitar 2013).

Part 5 of GRAS notice – Experience based on common use in food before 1958:

Not Applicable to the GRAS application.

Part 6 of GRAS notice – Narrative:

(a)(1) Explanation of why the data and information in this notice provide a basis that Calcium Disodium EDTA is safe under the conditions of its indented use in Canned Abalone:

Calcium Disodium EDTA under Section 172.120 of the US FDA Foods for Human Consumption currently lists a number of foods it can be used safely in already. The list contains 3 canned seafood products. These include canned crab (275ppm), canned clams (340ppm) and canned shrimp (250ppm). The use of Calcium Disodium EDTA in each of these products is to promote color retention in which canned abalone requires the use of the additive for the same technological purpose.

Calcium Disodium EDTA is currently permitted for use in canned abalone in many countries around the world. These include Australia, New Zealand, Singapore, Japan and Hong Kong. In addition, Codex Alimentarius standards for food additives allows a maximum of 340ppm for Calcium Disodium EDTA in canned abalone.

The maximum level of Calcium Disodium EDTA needed in canned abalone in brine to achieve color retention is 250ppm. At this level, the total daily intake of Calcium Disodium EDTA including consumption of canned abalone in brine and other existing sources in the diet is 1.73mg body weight). This is well under the acceptable limits of 2.5 mg/kg body weight set by the FAO and WHO (FAO / WHO 1974).

The following toxicological information is provided in the Solvitar Safety Data Sheet (Solvitar 2019):

Toxicology Assessment

Further information	:	No further data available.

Test result

Acute oral toxicity	:	LD50: > 5,000 mg/kg Species: Rat Literature data.
Acute inhalation toxicity	:	LC50 (Rat): > 1.13 mg/l Exposure time: 7 h
Skin irritation	:	Species: Rabbit Result: No skin irritation Method: OECD Test Guideline 404 Read-across (Analogy)
Eye irritation	:	Species: Rabbit Result: No eye irritation Method: OECD Test Guideline 405 Read-across (Analogy)
Sensitisation	:	Species: Mouse Result: Does not cause skin sensitisation. Method: OECD Test Guideline 429 Read-across (Analogy)
Germ cell mutagenicity Genotoxicity in vitro	:	reverse mutation assay Salmonella typhimurium Result: negative Method: OECD Test Guideline 471
Genotoxicity in vivo	:	Micronucleus test Species: Mouse Method: OECD Test Guideline 474 Result: negative Read-across (Analogy)
Carcinogenicity	:	Species: Rat Application Route: Oral NOAEC: > 250 mg/kg bw/day Result: negative Literature data.
Reproductive toxicity	:	Test Type: Three-generation study Species: Rat Application Route: Oral NOAEL: F1: > 250 mg/kg, F2: > 250 mg/kg, Literature data.

All of the above toxicology assessments in the Solvitar Safety Data Sheets were in favour of Calcium Disodium EDTA being safe under the indented conditions for use in canned abalone in brine. Acute oral toxicity in rats had an LD_{50} >5,000 mg/kg (Solvitar 2019). Canned abalone in brine will have a maximum limit of 250 mg/kg which is far below that value.

(2) All specific data and information used in this GRAS notice are generally available and references will be provided in Part 7 of this GRAS notice.

(b) The data and information I relied on to establish Calcium Disodium EDTA is safe under the conditions of its intended use were from sources held in high regard.

A number of Governmental Agencies were used to establish that Calcium Disodium EDTA is currently permitted for use in canned abalone. These included Food Standards Australia and New Zealand (FSANZ), Singapore Food Agency, Hong Kong Centre for Food Safety and the Japan External Trade Organization (JETRO). The proposed maximum level of 250ppm of Calcium Disodium EDTA for use in canned abalone in brine would be acceptable in all of these countries. In addition Codex Alimentarius standards for food additives allows up to 340ppm in canned abalone. Given that the use of Calcium Disodium EDTA in canned abalone by these governmental agencies is permitted, it can be concluded that a number of qualified experts have deemed the additive to be safe under its conditions of use.

Data and information used in the dietary exposure calculations were obtained from qualified experts and/or governmental agencies. Estimated daily intake of Calcium Disodium EDTA was taken from a study done by the FDA. The allowable adult daily intake of Calcium Disodium EDTA was taken from a report by the FAO /WHO. Serving Size of canned abalone was taken by a study done on the Risk Assessment of Sulphites in Australian canned abalone by Dr Susan Dobson. The codex Alimentarius guidelines for the simple evaluation of dietary exposure to food additives was used as the basis for calculating the acceptable ADI and Theoretical Maximum Daily Intake. Data from GRAS Notifications previously accepted by the FDA was used to calculate the dietary exposure for additional existing uses. All of these sources allowed for a highly accurate calculation of the total daily adult intake of Calcium Disodium EDTA which included the consumption of canned abalone in brine. The cumulative value of 1.73mg/kg body weight was significantly below the acceptable level of 2.5mg/kg body weight set by the FAO/WHO.

The use of Calcium Disodium EDTA in the USA is currently permitted for use in many foods already. Section 172.120 of the US FDA Foods for Human Consumption was used as a reference to show that the additive is considered safe for its intended conditions of use in three canned seafood products already. Levels permitted in these three canned products were as follows:

- Canned Clams – 340ppm
- Canned Crab – 275ppm
- Canned Shrimp – 250ppm

Given that canned abalone in brine requires a permitted level of 250ppm of the additive to achieve colour retention, this should fall under the same category as the other three canned seafood products.

"A complete course in canning and related processes" technical book stated that EDTA can be added to control discolouration in canned abalone (Featherstone, 2016). This book is now in its 14th edition and has been an integral reference for professionals in the canning industry for many years.

Solvitar is a food grade Calcium Disodium EDTA product that is made by Nouryon under stringent regulations in their factory in the Netherlands. Solvitar is manufactured to meet specifications of the Food Chemical Codex (FFC), European directive 231/2012/EC and the JECFA. The facility in the Netherlands that manufacture Solvitar is certified according to ISO 9001, ISO 14001 and FSSC22000 (Food Safety Scheme for food manufacturing in compliance with ISO 22000 and PAS220).

The information put forward in this section by many industry professionals and government bodies confirms that Calcium Disodium EDTA is safe to use in canned abalone under its intended use.

(c)(2) I have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with my conclusion of GRAS status.

Part 7 of GRAS notice – List of supporting data and information in my GRAS notice:

Chew D. Pigments of New Zealand Abalone (*Haliotis iris martyn*). University of New South Wales, School of Chemical Engineering, Department of Food Technology. 1973.

Code of Federal Regulations. Title 21, Part 172 – food additives permitted for direct addition to food for human consumption, subpart b – food preservatives, sec. 172.120 calcium disodium EDTA. US Government Printing Office; 2021. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.120.

Codex Alimentarius General Standard for Food Additives, Codex Stan 192-1995, 2019. FoodCatNo 09.4, page 138. Available from: http://www.fao.org/gsfaonline/docs/CXS_192e.pdf.

Codex Alimentarius Guidelines for the Simple Evaluation of Dietary Exposure to Food Additives, CAC/GL 3-1989, 2014. Available from: cxg_003e.pdf.

Dobson S. Risk Assessment of sulphites in Australian canned abalone. Australian Seafood Cooperative Research Centre. November 2011.

Exponent. GRN No. 573, for Calcium disodium EDTA in beverages. 2015. Submitted to FDA: March 12, 2015. Available from: http://wayback.archive-it.org/7993/20171031035327/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM456215.pdf

Featherstone S. A Complete Course in Canning and Related Processes, 14th Edition, Volume 3: Processing Procedures for Canned Food Products. 2016. Woodhead Publishing. page 249.

Food Standards Australia and New Zealand (FSANZ) Food Standards Code. Schedule 15 Substances that may be used as food additives. July 8, 2021. Available from: https://www.legislation.gov.au/Details/F2021C00607.

Hong Kong Centre for Food Safety. Preservatives in Food Regulation. Cap 132, sections 55 and 143. Schedule 1, No. 9.4.1. Available from: https://www.elegislation.gov.hk/hk/cap132BD.

Japan External Trade Organization (JETRO). Specifications and standards for foods, food additives etc. Under the Food Sanitation Act (Abstract) 2010, page 112. Available from: foodext2010e.pdf (jetro.go.jp).

Joint FAO/WHO Expert Committee on Food Additives. Toxicological Evaluation of Certain Food Additives with a Review of General Principles and of Specifications. Seventeenth report of the joint FAO/WHO expert committee on food additives, WHO Technical Report Series No. 539, 1973.

National Library of Medicine (National Centre for Biotechnology Information). Compound Summary. Calcium disodium ethylenediaminetetraacetate. Section 7.1 FDA Substances Added to Food. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/Calcium-disodium-ethylenediaminetetraacetate#section=Food-Additives-and-Ingredients.

Singapore Food Agency, Sale of Food Act 2005 (Chapter 283, Section 56(1)). Food Regulations. Cap 283, 26 (4). Available from: https://www.sfa.gov.sg/docs/default-source/legislation/sale-of-food-act/food_regulations.pdf.

Solvitar Application Leaflet, 2013.

Solvitar Product Data Leaflet, 2019.

Solvitar Safety Data Sheet, 2019.

U.S. Food and Drug Administration (FDA). 1998b. Food additive safety profiles of Tetrasodium EDTA, Disodium EDTA, Calcium Disodium EDTA, and Dipotassium EDTA. FDA database. Washington, DC: FDA.