FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Application A603 Supporting Document 3

FOOD TECHNOLOGY REPORT

Summary

The Applicant, Golding Handcrafts, claims that there is a technical need to extend the use of the red food colouring erythrosine in Australia and New Zealand from preserved cherries to food colouring preparations used to colour icing and other cake decorations for the technological purpose of achieving colour enhancement.

This has been substantiated with claims that food colourings preparations containing erythrosine possess superior colouring characteristics to alternative red food colourings including colour strength, longevity, lack of bleeding and quality of the finished product. Consequently this allow for a greater range of colouring effects to be achieved including wider ranges of pinks, lavenders, violets, royal blue and true black. The Applicant notes that commercial products are currently available for this purpose in the United States of America (USA) and seeks to import and sell these colourings preparations for cake icing and related products for use in Australia and New Zealand.

The merit of using erythrosine is strongly supported by some companies, in particular, Americolor™ Corporation and CK Products, two of the largest companies who use erythrosine in products for cake decorating purposes. They have advised the Applicant that the purpose of adding erythrosine to food is to achieve a precise visual effect and unique shades which are unattainable by using any other food colours. The colour hue and intensity is directly affected by the amounts of erythrosine added and the proposed amounts are consistent in achieving the intended result – to colour the food. Colour combinations are individually weighed and added to the mix for each single recipe so that a consistent final effect is obtained. Addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

Erythrosine is an effective red food colouring thereby fulfilling a technological function in foods.

1 Introduction

An Application was received from Golding Handcrafts on 20 March 2007 seeking to amend Standard 1.3.1. Erythrosine is a cherry-reddish-pink synthetic food colouring with its use in Australia and New Zealand being currently restricted to preserved cherries (known as maraschino cherries, cocktail cherries or glace cherries), up to a maximum level of 200 mg/kg. The Applicant is seeking to extend the use of erythrosine from preserved cherries to food additive preparations used to colour icing and other cake decorations. The applicant has stated that the concentration of erythrosine used in the final icing produced would not exceed a proposed maximum use level of 2 mg per kg of icing, allowing for potential wastage by the end consumer, with a recommended maximum of 0.5 mg/kg of icing for the required colouring effect to be achieved.

Food colourings are used in food products for the maintenance and restoration of natural colourings lost during processing and for a general improved visual appearance, to produce aesthetically and psychologically pleasing foods. The proposed extension for the use of erythrosine in food colouring preparations would be to improve the visual appearance of iced cakes and other baked goods.

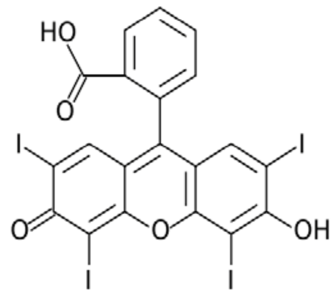
Erythrosine is a synthetically produced food colouring agent classed as a xanthene colour (Emerton, 2008) and is composed of mainly the disodium salt of 2',4',5',7'-tetraiodofluorescein (Mai *et al*., 2006).

The erythrosine form applied for by this Applicant is the water soluble salt and does not include the insoluble aluminium lakes of erythrosine[1]. Alternative artificial red food colourings currently permitted for use in Australia and New Zealand are allura red AC, ponceau 4R, azorubine / carmoisine and amaranth. Natural red food colourings are also available and these include cochineal and carmines, and beet red.

The scope of this Food Technology Report will include the technical information provided by the Applicant, published studies in scientific literature and other available technical data.

2. Characterisation of erythrosine

Red 3 erythrosine or 'tetraiodofluorescein' is a reddish-pink synthetic fluorone food dye. Its detection wavelength is between 520 nm – 530 nm (Yoshioka and Ichihashi, 2008).

IUPAC name:	2 - (6-hydroxy - 2,4,5,7 - tetraiodo-3-oxo-xanthen-9-yl) benzoic acid
Molecular formula:	$C_{20}H_6I_4Na_2O_5$
Molar mass:	879.86 g/mol
Chemical name: (as provided by the Applicant)	disodium salt of 9(o-carbozy-phenyl)-6-hydroxy-2, 4, 5, 7-tetraiodo- 3H-xanthen-3-one
Chemical structure:	

[1] The use of erythrosine lakes in the United States ceased in 1990, and lakes are no longer permitted for use in foods; stated to be due to toxicological concerns (von Elbe and Schwartz, 1996; Downham and Collins, 2000).

The structure of erythrosine suggests that it is insoluble in acid, stable to alkali conditions and exhibits strong fluorescence (von Elbe and Schwartz, 1996). The erythrosine structure contains high levels of bound iodine, however its bioavailability in the body is extremely limited (Parkinson and Brown, 1981; Wenlock *et al.*, 1982; Katamine *et al*., 1987; Lee *et al*., 1994; Prestwich and Gerrard, 2005).

Table 1: Synonyms of erythrosine

Erythrosine synonyms
FD&C Red No. 3
E number E127 (C.I Food Red 14)
Colour Index (1975) no. 45430 (C.I. Acid Red 51)
INS No. 127
Erythrosine BS
Erythrosine B
Red 3
CAS No. 16423-68-0

3. Production of erythrosine

The production process for commercial erythrosine available in Australia and the United States is covered by Hazard Analysis and Critical Control Process (HACCP) and a HACCP manual has been provided within the Application for the production of erythrosine. In summary this process involves the input of raw materials into a reaction followed by neutralisation, distillation, isolation, drying and grinding to obtain the finished product.

Erythrosine colouring preparations are generally available to food processors in a fine powered form. However, this may prove problematic in terms of a retail consumer product due to dusting and clumping issues, and consequently the final colouring products are available in granules, gels and other pre-made forms (e.g. cake icing, pens/paints, colouring sands), as has been suggested in this Application.

3.1 Chemical synthesis of erythrosine

The chemical synthesis specifically involves condensing phthalic anhydride and resorcinol, followed by purifying and iodinating the fluorescein obtained, followed by hydrolysing with sodium hydroxide and iodine (Mai *et al*., 2006), to obtain the primary component of erythrosine, the disodium salt of 2',4',5',7'- tetraiodofluorescein, via the intermediary , 2-(2',4'-dihydroxybenzoyl) benzoic acid (Wada *et al*., 2004).

3.2 Specifications

During the synthesis of erythrosine various intermediaries, side reaction impurities and other contaminates, such as partially iodinated compounds, may be present (Wada *et al*., 2004; Ryvolova *et al.*, 2007). However processes are in place to minimise these and ensure compliance with chemical specifications and Good Manufacturing Practices (GMP).

Physical and Microbiological specifications are not applicable to this product. The Erythrosine of this Application complies with a relevant monograph published in the FAO Combined Compendium of Food Additive Specifications (Monograph 1) (JECFA, 1993). This is a primary source listed in clause 2 of Standard 1.3.4 – Identity and Purity of the Code.

Table 2: Specifications stated by the Applicant for erythrosine food colouring

Dye Content	
Volatile matter	13% max
Water Insoluble Matter	0.2% max
Unhalogenated Intermediates	0.1% max
Sodium Iodine	0.4% max
Triiodoresorcinol	0.2% max
2(2',4'-Dihydroxy-3', 5'- diiodobenzoyl) Benzoic Acid	02% max
Monoiodofluoresceins	1.0% max
Other Lower Iodinated Fluoresceins	9.0% max
Lead (as Pb)	10 ppm max
Arsenic (as As)	3 ppm max

Table 3: Comparison of international specifications for Erythrosine (Supplied by Applicant)

NAME	U.S FD&C	Canada	E.C	F.A.O / W.H.O	Sensient Australia
Dye Content	87% min	85% min	87% min	87% min	88% min
Moisture & Salt	13% max			13% max	
Water Insolubles	0.2% max	0.2% max	0.2% max	0.2% max	0.2% max
Intermediates (combined total)		0.5% max	0.5% max		
Sodium Iodide	0.4% max		0.1% max	0.1% max	0.4% max
Unhalogenated	0.1% max				0.1% max
Triiodoresorcinol	0.2% max		0.2% max	0.2% max	0.2% max
DHDIBBA	0.2% max		0.2% max	0.2% max	0.2% max
Fluorescein			20 ppm max	20 ppm max	
Subsidiary Dyes (combined total)		5.0% max	4.0% max	4.0% max	
Mono Iodo	1.0% max				1.0% max
Other Lower Iodo	9.0% max				9.0% max
Heavy Metals		40 ppm max	40 ppm max	40 ppm max	
Mercury			1 ppm max		
Lead	10 ppm max	10 ppm max	10 ppm max	10 ppm max	10 ppm max
Cadmium			1 ppm max		
Arsenic	3 ppm max	3 ppm max	3 ppm max	3 ppm max	3 ppm max
Zinc				50 ppm max	
X-Band	1% max				
Group	7% max				
Total Primary Amines			0.01% max		
Ether Extracts		0.2% max	0.2% max	0.2% max	No GMO allergens

4. Determination methods for erythrosine

The identification of erythrosine may be conducted utilising spectrophotometric, colorimetric or visual methods. The standard method of assay for use in foods is spectroscopy, with the colour contrast determined by measuring the absorbance of an aqueous solution (buffered at a neutral pH) at 526 nm. The dye content is determined using an $E_{1\%1cm}$ of 1100 as pure dye strength (Emerton, 2008; Codex Alimentarius, 2008).

In the case of a mixture of food colourings, the determination of individual colours based solely on absorbance measurements at corresponding wavelengths can be problematic as there may be overlaps on the absorption spectra, especially between red and yellow dyes (Ryvolova *et al.*, 2007). In this case multicomponent analysis of food colourings can be completed via derivative spectrophotometric methods, allowing for the simultaneous determinations of two or more food colourings in the same sample without the need for separation (Ozgur *et al.*, 2002). Derivative spectrophotometric methods may utilise both ultraviolet and visible absorption and allows for qualification of unresolved spectra bands, thereby eliminating the effects of baselines shifts and tilts (Bosch Ojeda and Sanchez Rojas, 2004).

Other determination methods may require prior chemical separation before absorption detection is completed utilising methods such as High Performance Liquid Chromatographic (HPLC) (Berzas-Nevado *et al*., 1999; Minioti *et al*., 2007; Zhang *et al*., 2007), capillary electrophoresis (Evans, III, 2003), micellar electrokinetic chromatography and isotachophoresis (Ryvolova *et al.*, 2007).

5. Packaging and Stability

Pure erythrosine is generally sold in polythene inner bags (25 kg) inside fibre drums. Erythrosine preparations should be stable for an indefinite period if kept in a closed container which is held at ambient temperature and humidity. After a period of 3 years physical changes may start to occur due to agglomeration which in turn may affect colour strength. The colouring preparations proposed in this Application are colouring gels and other pre-made products including cake icing, pens/paints and colouring sands.

The Applicant has stated that the colouring preparations are sold in bottles that limit usage by the end consumer with the use of droppers, thereby controlling the final amount dispensed. The proposed maximum level to be used in icing preparations is 2 mg/kg of icing, which is stated to be a conservative level allowing for wastage by the end user. The recommended usage amount for the required colouring effect to be achieved is estimated at 0.5 mg/kg of icing.

6. Technological function of erythrosine

Food colourings are used in food products for the maintenance and restoration of natural colours during processing and for improved visual appearance to produce aesthetically and psychologically pleasing foods (Sawaya *et al*., 2008). In this case, the Applicant wishes to sell products to both consumers and cake decorating professionals for use as colouring agents to aesthetically improve the colouring of cake icing and the decorations used for cakes.

Whilst natural colours are often preferred by consumers, synthetic food colours are found to be more stable than natural food colourings and are also cheaper to produce (Yoshioka and Ichihashi, 2008).

The Applicant claims that erythrosine has significant advantages over alternative red food colourings (i.e. Red 40 Allura Red and Carmine) as it possesses superior colouring characteristics such as strength, longevity, lack of bleeding, the quality of the final colour, and subsequently the visual quality of the food. For example, the Applicant states that use of colour preparations containing Red 40 - Allura Red results in foods with an orange/red colour. To achieve bright pinkish/red colours, colour preparations specifically containing erythrosine are needed. These claims however have been substantiated with anecdotal submissions provided by the Applicant. Overall, the Applicant argues that the use of food colouring preparations containing erythrosine allows for a wider range of colours in decorating cakes (including ranges of pinks, lavenders, violets, royal blue and black), with less total colouring required to be added, due to the inherent stability provided by erythrosine.

The merit of using erythrosine is strongly supported by some companies, in particular, Americolor™ Corporation and CK Products two of the largest companies who use erythrosine in products for cake decorating purposes. They have advised the Applicant that the purpose of adding erythrosine to food is to achieve a precise visual effect and unique shades which are unattainable by using any other food colours. The colour hue and intensity is directly affected by the amounts of erythrosine added and the proposed amounts are consistent in achieving the intended result – to colour the food. Colour combinations are individually weighed and added to the mix for each single recipe so that a consistent final effect is obtained. Addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

Within the United States of America (USA), erythrosine (FD&C Red No. 3) is permitted for colouring food generally (including dietary supplements) in amounts consistent with GMP (US FDA, 2008). All batches of erythrosine used in the USA need to be certified according to US FDA regulations. Commercial food colouring preparations imported from the USA would also comply with these regulations.

Foods which may include erythrosine in the USA as a colouring additive are processed meat products, canned fruit salads, pie filling, maraschino cherries, gelatin dessert products, ice creams, sherbets, candy and confectionery products, beverages, sauces, jams, bakery products, cereals, and puddings. Erythrosine is also used as a red food colouring in Japan for a wide variety of foods (Yoshioka and Ichihashi, 2008; Emerton, 2008).

7. Alternatives to Erythrosine

Synthetic red colourings

Current available red colouring alternatives to using erythrosine in icing / cake decorating colouring preparations include Allura red, Ponceau 4R, Azorubine / Carmoisine and Amaranth, all of which are classified as ‘monoazo’ colours. See Table 4 below for further information and comparisons. These alternative synthetic red food colourings, like erythrosine, would also be considered Kosher by the Jewish community.

Allura Red AC (in the US referred to as FD&C40) has a bright yellowish red shade and is described by the Applicant as having an orange/red coloured shade. Allura Red AC possesses good heat and light stability however it is not stable to retort conditions. Due to its yellow undertones, Allura Red AC cannot produce bright pinks or purples colours when blended with other colouring agents. Allura Red AC is permitted for use in the EU and the USA as well as widely used in other countries including Japan. There are currently no Codex provisions for Allura Red AC (Emerton, 2008).

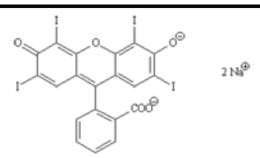
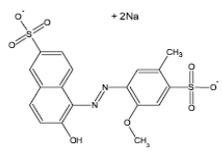
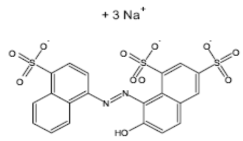
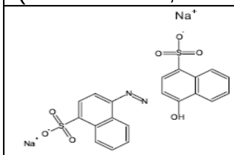
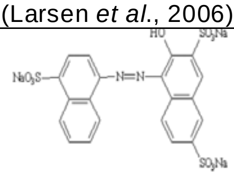
Ponceau 4R has not been considered by the Applicant in their dossier. This is a bright red colouring. Ponceau 4R possesses good heat and light stability, with poor stability to alkaline conditions and fruit and benzoic acids.

Ponceau 4R is permitted for use in foodstuffs to a maximum level in the EU but is not permitted for use in the USA. There are a number of Codex provisions for Ponceau 4R in a wide range of food products (Emerton, 2008).

Azorubine / Carmoisine (E122) has also not been considered by the Applicant in their dossier. This colouring has a bluish-red colour and is normally supplied as a water-soluble sodium salt (Emerton, 2008). Azorubine / Carmoisine however is prohibited for use in the USA, Japan and Canada. There are currently no Codex provisions for Azorubine/Carmoisine (Emerton, 2008).

Amaranth has also not been considered by the Applicant in their dossier. This colouring has a bluish-red shade with good heat and light stability. Amaranth is restricted to use in certain food products in the EU, however, Amaranth, like erythrosine, may not be sold to consumers as a component of a food additive preparation. Amaranth is not permitted for use in the USA due to toxicological concerns (Emerton, 2008).

Table 4: Alternative artificial red food colouring

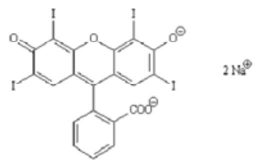
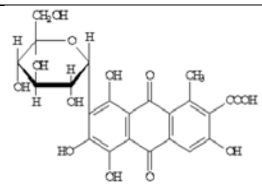
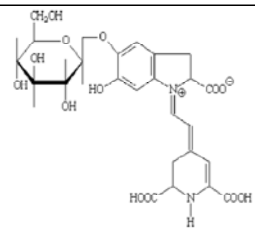
Food colouring	**INS number**	**Description**	**ADI**	**Permissions in the Code**	**Structural formula**
Erythrosine (for comparison)	*127*	*Bright bluish-red colour*	*0 - 0.1 mg/kg*	In preserved cherries known as maraschino cherries, cocktail cherries or glace cherries to a maximum of 200 mg/kg (Schedule 1)	 (JECFA, 1993)
Allura red AC	129	Bright red shade	0 - 7 mg/kg	Colours permitted to a maximum level of 290 mg/kg in processed foods and to a maximum level of 70 mg/L in beverages not specified in Schedule 1 (Schedule 4)	 (Larsen *et al.*, 2006)
Ponceau 4R	124	Bright red shade	0 - 4 mg/kg JECFA in 1983		 (Larsen *et al.*, 2006)
Azorubine / Carmoisine	(E122)	Bright bluish-red colour	0 - 4 mg/kg JECFA 1993		 (Larsen *et al.*, 2006)
Amaranth	123	Bluish-red shade	0 - 0.5 mg/kg	In confectionary to a maximum of 300 mg/kg (Schedule 1)	 (JECFA, 1984)

8.1 Natural red colourings

Carmine is the calcium aluminium lake of cochineal extract (made from carminic acid derived from cochineal insects). Carmine is a red colour used in a wide variety of food and drinks, with superior stability characteristics, a greater pH range and is an effective red colouring at levels lower than other natural red colours (Hendy and Houghron, 1996). It has been claimed that Carmine is not a suitable alternative to erythrosine as it is not considered kosher. The Jewish community does not accept foods coloured with carmine as kosher due to the product being extracted from beetles. Additionally the cost of carmine is high when compared to other red colours. The demand for and use of carmine has increased, especially since the reduction in permissions for usage of erythrosine in various countries and products, and consequently the costs have increased.

Beet red or betanin is extracted from the red beetroot vegetable (*Beta vulgaris*) and comprised of different water soluble red pigments. Available commercial extracts however may possess the characteristic odour and potentially the taste of the beetroot. Beet red has only limited stability to heat and light and is also prone to oxidation. Its colouring is a blue – pink/ deep red colour (Emerton, 2008).

Table 5: Alternative natural red food colouring

Food colouring	INS number	Description	ADI	Permissions in the Code	Structural formula
Erythrosine (for comparison)	*127*	*Bright bluish-red colour*	*0 – 0.1 mg/kg*	In preserved cherries known as maraschino cherries, cocktail cherries or glace cherries to a maximum of 200 mg/kg (Schedule 1)	 (JECFA 1993)
Cochineal and carmines	120	The naturally occurring pigment from cochineal is orange, with the calcium aluminium lake being red	0 – 5 mg/kg	Colours permitted in accordance with GMP in processed foods specified in Schedule 1 of the Code	 (JECFA, 2000)
Beet Red	(E162)	Blue – pink colour (highly heat labile)	ADI not specified	Colours permitted in accordance with GMP in processed foods specified in Schedule 1 of the Code	 (JECFA, 1987)

9. Bleeding properties

The main technological disadvantage of dyes other than erythrosine for use in red cherries (the current only permitted use of erythrosine in Australia/New Zealand) is that when fruit salad mix is cooked in the can, the alternative dye migrates (bleeds) into the other fruits, and the pears and peaches turn a pink shade. This involves high heat (high time/temperatures of retort processing) under an acidic environment. Due to processed cherries requiring an extended shelf life (seasonal production) it is essential to have a colouring of greater stability over the shelf life of the product (estimated at approximately 15 months). The Applicant has stated that erythrosine has a higher quality red colouring than its alternatives, with superior colouring characteristics including a lack of bleeding.

10 Heat stability

Erythrosine has superior heat stability to other red food colouring alternatives. Consequently this is the reason it is able to be used successfully in canned preserved cherries where as alternative red food colourings are unsuccessful in this usage.

Canned products undergo retort processing with high time/ high temperature combinations leading to colour bleed and ultimate loss from the target product (i.e. preserved cherries). Unlike erythrosine use in preserved cherries, heat stability is not an issue in colouring cake icings and cake decorating as the red colouring is added after the baking process and it is possible to use alternative, less heat-stable red food colourings for use in cake icings.

11. Allergenicity

The erythrosine preparation is not considered to be allergenic and no allergenic materials (as listed in the code on Table to clause 4, Standard 1.2.3) are likely to be present in the manufacture of this colouring.

12. Conclusion

Currently in both Australia and New Zealand, red colouring preparations containing erythrosine are not permitted for use in iced cakes and cake decorating, alternative red colourings used include combinations of synthetic red food colouring such as allura red, ponceau 4R, azorubine / carmoisine, with natural red food colouring alternatives also including carmine and beet red.

The Applicant claims that there is a technical need to extend the use of the red food colouring erythrosine in Australia and New Zealand from preserved cherries to food colouring preparations used to colour icing and other cake decorations to achieve colour enhancement.

This has been substantiated with claims that food colourings preparations containing erythrosine possess superior colouring characteristics including its colour strength, longevity, lack of bleeding and quality of the finished product and allow for a greater range of colouring effects to be achieved including ranges of pinks, lavenders, violets, royal blue and black.

Erythrosine is known to be an effective red food colouring fulfilling a technological function in foods.

13. References

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