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

Supporting Document 1

APPLICATION A1047
SODIUM CARBOXYMETHYLCELLULOSE AS A FOOD ADDITIVE IN WINE
RISK AND TECHNICAL ASSESSMENT REPORT (Approval)

Executive Summary

Sodium carboxymethylcellulose (CMC) is an already permitted food additive in many foods but not in wine. The Application proposes its additional use in wine and sparkling wine as a stabiliser to inhibit tartrate crystal formation and subsequent precipitation during storage. Precipitation of tartrate crystals can cause cloudiness and sediment formation and thus may make the wine undesirable to drink.

Evidence assessed provided adequate assurance that the additive is technologically justified and has been demonstrated to be effective in achieving its stated purpose. As the additive is currently approved for other foods, no amendments to the specifications are necessary.

The hazard assessment considered the history of safe use of this additive. In the absence of any dietary hazard, CMC is considered to pose no public health and safety issues associated with the proposed use as a wine additive.

The overall conclusion of this risk and technical assessment is that the use of CMC as an additive in wine is technologically justified and raises no public health and safety issues.

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Introduction

1.1 Background

On 6 May 2010, Food Standards Australia New Zealand (FSANZ) received an Application from the Winemaker's Federation of Australia (WFA) seeking amendments to Schedule 1 of Standard 1.3.1 – Food additives and to Standard 4.5.1 – Wine Production Requirements (Australia only) of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of sodium carboxymethylcellulose (CMC) as an additive in wine.

CMC is a currently approved additive (INS number 466) in Standard 1.3.1, Schedule 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in Schedule 1) however use in wine is not currently permitted. In addition CMC is not currently specified in the list of additives approved for use in wine production requirements in Australia - Standard 4.5.1.

In wine and sparkling wine CMC is proposed for use to inhibit tartrate crystal formation and subsequent precipitation. Due to temperature changes during storage and transportation, tartrate which occurs naturally in wine can crystalline and then precipitate resulting in cloudy wine with sediment, which is undesirable to many consumers.

The Applicant is seeking the use of the additive as an additional method for tartrate crystal control rather than a replacement for existing methods.

The Applicant claims that use of the additive in wine for crystal stabilisation is highly effective and also has significant cost and environmental advantages over existing methods.

Currently as wine containing CMC is not approved in Australia or New Zealand this is a stricter standard than that in place in Europe.

The European Union has recently approved the use of the additive for wine produced in Europe (European Union 2009).

1.2 Risk assessment questions & scope

CMC is a new additive in wine but is already listed in the Code under Standard 1.3.1 as a permitted additive, usually at Good Manufacturing Practice (GMP) levels in many processed foods, including dairy products, confectionary soups, sauces. The following questions are addressed in this Risk and Technical Assessment Report:

- Is the proposed use of the additive technically justified in wine and sparkling wine?
- Is the use of the additive effective at the usage level described?
- Are wines and sparkling wines produced through the use of this additive safe for consumption?

This Risk and Technical Assessment Report is structured to address the above questions in order and comprises the following components:

1 CMC Characteristics, covering its chemistry, analysis, specification and production
2 Food Technology Assessment, which considers whether the use of the additive is technologically justified
3 Hazard Assessment, which evaluates the intrinsic toxicity of the additive and dietary exposure.

2. Additive characteristics

2.1 Chemistry of the additive

2.1.1 Chemical structure and identity

CMC is a cellulose based substance formed by the reaction between an alkali and chloroacetic acid on plant fibres.

C.A.S number: 9004-32-4

IUPAC name: acetic acid; 2,3,4,5,6 pentahydroxyhexanal

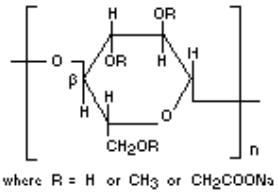
Chemical name: Cellulose, carboxymethyl ether, sodium salt

Other names: Carboxymethylcellulose, sodium salt
Sodium Carboxymethyl cellulose
CMC
Cellulose GUM

Chemical formula:

$[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$
where
n is the degree of polymerization
x = 1.50 to 2.80
y = 0.2 to 1.50
x + y = 3.00
(y= degree of substitution)

Structural formula:



where R = H or CH_3 or CH_2COONa

Formula weight: Structural unit with a degree of substitution of 0.20: 178.14
Structural unit with a degree of substitution of 1.50: 282.18
Macromolecules: greater than about 17,000 (n about 100)

2.1.2 Physical and chemical properties

Table 1: Physical and chemical properties (JECFA 2006)

Nature	White or slightly yellowish, almost odourless hygroscopic granules, powder or fine fibres
pH of a 1% solution	6-8.5
Purity	Not less than 99.5% of anhydrous substance
Major impurities	Lead ≤ 2 mg/kg Free glycolate ≤ 0.4% Sodium ≤12.4% of the anhydrous substance Sodium chloride ≤ 0.5% of the anhydrous substance
Degree of substitution	Not less than 0.20 and not more than 1.50
Solubility	Forms viscous colloidal solution with water. Insoluble in ethanol.

2.1.3 Methods of analysis

CMC may be analysed using foam and precipitation tests to distinguish it from other cellulose ethers, alginates, gums and gelatine. In addition a colour reaction test using a naphthol reagent and sulphuric acid can be used to determine it is CMC. Further details of these tests are available in JECFA 2006.

2.1.4 Specifications for identity and purity

JECFA has assessed CMC and has written a specification for it (JECFA 2006). The International Organisation of Vine and Wine (OIV) has also assessed and written a specification for CMC (OIV 2009). JECFA monographs are primary reference sources for specifications, as listed in clause 2 of Standard 1.3.4 - Identity and Purity, of the Code.

2.2 Production

CMC is obtained from plant fibres. Plant fibre pulp is reacted with sodium hydroxide and monochloro-acetic acid or its sodium salt. This reaction is then neutralized and the solvent recovered. The polysaccharide is then purified, dried, pulverized, sieved and packed. According to the OIV Monograph (OIV 2009) CMC for oenological use should be prepared exclusively from wood.

3. Food Technology Assessment

3.1 Technological justification

3.1.1 Use of the additive in wine and sparkling wine

The Application requests an extension of use of CMC to enable it to be used in wine and sparkling wine production as an additional tool for preventing clouding and sediment formation resulting from the precipitation of tartrate crystals during storage. Tartrate occurs naturally in wine and is mainly in the potassium form however calcium tartrate can also be present. As a result of change in storage temperature during transport tartrate can crystallise in wine resulting in cloudy wine with sediment which is undesirable to many consumers.

Current methods used in Australia to control tartrate crystallisation in wine can be divided into two categories: 1) encouraging and accelerating crystal growth followed by removing the crystals by filtering 2) inhibiting crystal precipitation.

The Application explains that the additive works by inhibiting crystal growth in wine. The additive acts as a protective colloid which prevents tartrate crystals seeding and subsequently precipitating. CMC is added to the wine towards the end of the production process unlike other existing tartrate crystal control methods chilling or filtration steps are not required.

Information provided by the applicant states that in contrast to metatartaric acid the effectiveness of this additive is temperature insensitive and thus crystal stability is obtained even with temperature fluctuations, such as those which occur during storage and transport. However other currently available methods for tartrate crystal control need to be retained as under certain circumstances e.g. for high quality wine, wine which is strongly saturated with tartrate or wines with high levels of calcium tartrate the existing methods may be more suitable.

A maximum use level of 100 mg/L is proposed in the application. Information provided with the application, namely results of tests to investigate the degree of tartrate crystal precipitation overtime is deemed sufficient by FSANZ to demonstrate that the use of CMC at this proposed level is effective.

3.1.2 Evidence of the effectiveness of the additive in wine

The Applicant stated that the additive has been trialled by several major companies, including in Australia, and has provided information to show increased stability of wines treated with CMC compared with untreated or metatartic acid treated wine.

Storage of additive treated wine at 17^0C for 10 months followed by storage at -4^0C for 8 days did not result in visual evidence of crystal precipitation. This test is an OIV accepted method to test the stability of tartrate crystals. In addition storage of additive treated wine at 17^0C for 10 months followed by checking the difference in conductivity by means of the minicontact process, showed the additive treated wine had a low difference in conductivity compared with untreated (Control) or metatartaric acid treated wine. The Applicant provided a paper which stated that low difference in conductivity means high stability with respect to tartrate. This information was provided by the Applicant to demonstrate stability of the wine treated with additive over time.

3.1.3 Cost and environmental advantages

As indicated in Section 3.1.1 above use of CMC for tartrate crystal control does not involve chilling or filtration step, both of which are energy dependent. The Applicant explains that the absence of these steps in wine production utilising CMC results in a more cost effective process with environmental advantages over other existing methods of control.

3.2 Conclusion

FSANZ considers that the need for and the effectiveness of the use of CMC in wine and sparkling wine at the proposed level of 100 mg/L, to inhibit the precipitation of tartrate crystals has been clearly demonstrated by the information provided in the application.

4. Hazard assessment

4.1 Hazard analysis

The additive has a long history of safe use as a food additive and has been considered by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in its evaluations of modified celluloses (of which CMC is one) at several meetings. Modified celluloses, including CMC, were most recently considered by JECFA at its 35th meeting (WHO 1990).

At this meeting JECFA established a group Acceptable Daily Intake (ADI) of 'not specified' for several modified celluloses including CMC. An ADI of 'not specified' is applicable to a substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other) and the total daily intake of the substance arising from its use or uses at the levels necessary to achieve the desired effect, does not represent a hazard to health. For this reason the establishment of an ADI expressed in numerical form is not deemed necessary.

The 35th JECFA meeting considered substantial additional human data which indicated that some individuals may experience laxative effects after consuming 5 g of modified celluloses per day. At higher doses, diarrhoea was reported in some individuals while in others constipation developed. JECFA noted that the amounts ingested in human studies did not exceed 30 g per person per day, which was at the time the recommended upper safe level of dietary fibre in general.

4.1.1 Allergenicity

Allergic responses, including anaphylaxis, have been reported with injectable medicinal products containing CMC. In addition, two cases of anaphylaxis have been associated with the use of a barium sulphate enema product that contains CMC. However, there are no reports of allergy to CMC in food (Dumond et al 2009).

4.2 Dietary exposure

FSANZ considers a dietary exposure assessment for CMC is not necessary because an ADI is not specified by JECFA and the additional contribution to dietary exposure in New Zealand and Australia arising from wine consumption will be negligible. Information provided by the Applicant indicates that CMC is added at a maximum level of 100 mg/L of wine. Thus, a 750 mL bottle of wine will only contain a small amount (75 mg) of CMC.

4.3 Risk assessment conclusion

The additive is a well characterised food additive with a long history of safe use. Consistent with its very low toxicity, an ADI of 'not specified' has been assigned by JECFA. Allergic reactions to the additive in food have not been observed. There are no public health and safety issues associated with the proposed use of CMC as a wine additive.

5. References

Dumond P, Franck P, Morisset M, Sainte Laudy J, Kanny G, Moneret-Vautrin DA (2009) Pre-lethal anaphylaxis to carboxymethylcellulose confirmed by identification of specific IgE--review of the literature. Eur Ann Allergy Clin Immunol, 41(6):171-176.

European Union (Commision Regulation (EC), No.606/2009) laying down certain detailed rules for implementing Council Regulation (EC) No.479/2008 as regards the categories of grapevine prodcuts, oenological practices and the applicable restrictions, viewed April 2011, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:193:0001:0059:EN:PDF

JECFA (Monograph 1, 2006) *Combined Compendium of Food Additive Specifications – Carboxymethyl cellulose*, viewed April 2011, http://www.fao.org/ag/agn/jecfa-additives/details.html?id=388.

OIV (2009) Monograph on Carboxymethylcellulose (cellulose gum) viewed April 2011 http://online.food chemicalscodex.org/online/pub/indix?fcc=7&s=1&oYr=2010&0Mo=11&oDa=28

WHO (1990) Evaluation of certain food additives and contaminants. Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization Technical Report Series; 789.