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

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Supporting document 1

Risk and technical assessment – Application A1332

Cross-linked polyester resins as an adsorbent processing aid in wine

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Executive summary

amaea Limited applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit molecularly-imprinted adsorbent resins (molecularly-imprinted polymers or MIPs), which are a type of cross-linked polyester resin, as a processing aid in wine. The applicant's resin can be used during wine production as an adsorbent agent, removing molecules associated with smoke taint due to exposure of grapes to bushfires.

The available evidence provides adequate assurance that the proposed use of the applicant's molecularly-imprinted adsorbent resin as an adsorbent agent processing aid is technologically justified. It performs its primary technological function during wine production and does not perform a technological purpose in the final, treated wine. As such, it meets the definition of a processing aid for the purposes of the Code.

The applicant's adsorbent resin meets the identity and purity specifications for 'polyester resins, cross-linked' in the Code of Federal Regulations, which is a secondary reference listed in subsection S3—3(h) of Schedule 3 – Identity and purity, in the Code.

FSANZ did not identify any safety concerns associated with the use of the applicant's adsorbent resin, under the proposed use conditions. The applicant's resin is approved for use in wine production in New Zealand, Canada, Japan and the USA.

Cross-linked polyester resins meeting the same specifications are also already approved for use in food in Australia and New Zealand, as well as overseas. Taken together, this provides a history of safe use of cross-linked polyester resins, including the applicant's resin.

Likelihood of exposure of consumers to cross-linked polyester resins, including the applicant's, from use in wine production is considered to be negligible and, on this basis, a dietary exposure assessment was not conducted. No reports of adverse effects of oral exposure to cross-linked polyester resins were located by a literature search, and no case reports of allergic reactions due to oral exposure to wines or other food made with the use of cross-linked polyester resins were found.

Overall, FSANZ concludes there are no safety concerns from the use of cross-linked polyester resins, including the applicant's molecularly-imprinted adsorbent resin, in the

quantity and form required to perform its typical function in wine production, which must be consistent with Good Manufacturing Practice.

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1 Introduction

amaea Limited applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit molecularly-imprinted adsorbent resins (molecularly-imprinted polymers or MIPs), which are a type of cross-linked polyester resin, as a processing aid in wine.

In a bushfire event smoke-derived volatile phenols can be taken up by grapes where they accumulate in the skins and pulp. During fermentation of the wine, such volatile phenols can cause the wine to develop unpleasant smoky characteristics, compromising wine quality and therefore saleability (Huo et al. 2024).

The applicant's molecularly-imprinted adsorbent resin has been developed to carry out precise and selective adsorption of these undesirable phenolic compounds associated with smoke taint. The applicant has indicated the processing aid would be used in accordance with Good Manufacturing Practice (GMP).[1]

1.1 Objectives of the assessment

The objectives of this risk and technical assessment were to:

- determine whether the applicant's molecularly-imprinted adsorbent resin achieves its technical purpose as a processing aid in the quantity and form proposed to be used
- evaluate potential public health and safety concerns that may arise from use of cross-linked polyester resins as an adsorbent agent in wine.

2 Food technology assessment

2.1 Identity of the processing aid

Cross-linked polyester resins are synthesised through condensation reactions between acids and alcohols or epoxides, forming a polyester backbone. Unsaturated groups within this backbone are then copolymerised with a cross-linking agent, resulting in a rigid, three-dimensional thermoset structure.

Molecularly-imprinted adsorbent resins (or MIPs), are a type of cross-linked polyester resin engineered using a molecular imprinting technique to create template-shaped cavities in the polyester matrix. The result is a synthetic polymer capable of capturing template or target molecules in its binding sites with high specificity and affinity.

There is no common chemical name for cross-linked polyester resins or MIPs as they can be produced from a range of acids, alcohols or epoxides and cross-linking agents. Likewise, the final structure will be dependent on the specific chemicals used to produce it. Section 2.1.1 of this report details the compositional requirements for cross-linked polyester resins in

[1]GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*

(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and

(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:

*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*

(ii) is not intended to accomplish any physical or other technical effect in the food itself;

(c) preparing and handling the substance in the same way as a food ingredient.

accordance with established specifications.

2.1.1 Specifications for identity and purity

There are relevant identity and purity specifications in the Code with which all cross-linked polyester resins must comply whenever added to food in accordance with the Code or sold for use in food.

The relevant specification is listed at subsection 177.2420 of Title 21 (21 CFR §177.2420) of the 2022 compilation of the Code of Federal Regulations. This is a secondary reference listed in subsection S3—3(h) of Schedule 3 of the Code. Specifically, 21 CFR §177.2420 sets out the specific acids, alcohols, epoxides and cross-linking agents permitted for use in the production of cross-linked polyester resins and limits for extractives. In addition, paragraph §177.2420(d) of Title 21 of that Code requires that, in accordance with GMP, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

The application includes evidence to show the applicant's adsorbent resin complies with the specification listed in 21 CFR §177.2420. This information is deemed confidential commercial information (CCI) under section 114 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) and can only be disclosed under certain circumstances in accordance with that Act. It has been evaluated by FSANZ but cannot be disclosed in this report. Based on the information provided, the applicant's resin meets the relevant specifications.

In addition, 21 CFR §177.2420 stipulates that cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the above prescribed conditions.

Schedule 3 of the Code includes specifications for arsenic and heavy metals (section S3—4) in cases they are not already detailed within specifications in sections S3—2 or S3—3. These specifications are of limited applicability to cross-linked polyester resins given their composition and that they are highly insoluble. As such, compositional analysis targets organic extractives rather than metals.

2.2 Chemical and physical properties of the processing aid

The applicant's molecularly-imprinted adsorbent resin is a non-ionic, non-acidic and non-alkaline highly cross-linked resin in the form of semi-spherical beads. As described in section 2.1 of this report, the resin has been synthesised by the polymerisation of a selection of monomers in the presence of a template molecule to selectively capture unwanted molecules in wine, specifically, phenolic compounds responsible for smoke flavour and aroma.

The applicant's adsorbent resin is chemically inert in the matrix for which it has been designed for use, in this case, wine. The cross-linking agent serves to preserve the morphology of the polymer matrix, stabilise the imprinted binding sites, and provide high mechanical strength and stability over a wide pH and temperature range. In addition, the resin has been synthesised to have high porosity and high surface area, which contribute to its ability to act as an adsorbent agent. The application states the surface area-to-mass ratio of the polymer particles has been experimentally calculated to be 307.2 m^2/g.

As a result of the resin's chemical and physical properties, it is more durable to harsh chemical media, heat and pressure than biological receptors (Loc 2009), as evidenced by its operating temperature and pH ranges (Table 1).

The applicant has conducted extended stability tests on its adsorbent resin, involving storage at pH 2.8 (representing the more acidic end of the pH range of wine) for a two-year period. Testing results were provided at Attachment F of the application. Results indicated there were no changes to the resin's physical form. Adsorption efficiency was maintained.

Table 1: Chemical and physical properties of applicant's adsorbent resin

Chemical and physical properties of molecularly-imprinted adsorbent resin	
Commercial name	amaea VPx
Function	Selective adsorption of phenolic compounds responsible for smoke flavour and aroma
Synonym	Acryl based monomer derivative
Appearance	Non-uniform beads/granules, 0.3 – 3 mm
Colour	White/off white
Operating temperature range	0°C – 50°C
Operating pH range	2 – 8
Stability	Stable at pH 2.8 for 2 years
Maximum cycles before replacement	400
Eluent	Eluent 85-99% ethanol at room temperature

2.3 Manufacturing process

2.3.1 Production of the processing aid

The manufacturing process described by the applicant for their molecularly-imprinted adsorbent resin involves conducting the polymerisation reaction in the presence of functional monomers and template or target compounds that are analogous to the target that is intended to be separated and retained by the resin.

After polymerisation, the template is extracted from the manufactured resin, leaving a three-dimensional network polymer with specific binding sites that correspond to the target molecules (Huo et al. 2025, Huo et al. 2024). The ability for selective capture is due to the specific properties of the target molecule including its shape, size, chemical structure and functional groups (Carballido et al. 2022; Li et al. 2021) (Figure 1).

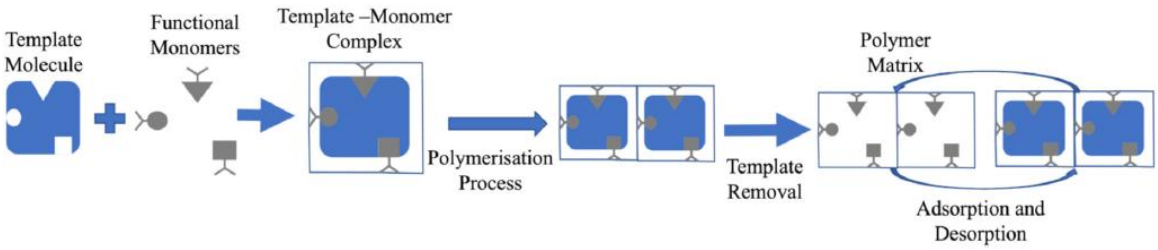

Figure 1: Schematic of molecular imprinting technology (source: Huo et al. 2025)

As described in section 2.1.1 of this report, the applicant has provided evidence to show its

molecularly-imprinted adsorbent resin is produced in compliance with 21 CFR §177.2420. In addition, in line with 21 CFR §177.2420(d), the resin is thoroughly cleansed prior to its first use in contact with food. The production process does not involve or result in the carry-over of any allergens.

2.4 Technological purpose and justification

2.4.1 Technological purpose

The technological purpose of the processing aid, as stated by the applicant, is as an adsorbent agent, selectively binding phenolic compounds such as syringol, guaiacol and cresol that are associated with smoke flavours and aromas in wine due to exposure of grapes to bushfires.

In practice, the resin beads are packed into a stainless steel column into which the affected wine is pumped. The recommended dose rate is up to 40 grams of resin per litre of wine, with a flow rate of 5–150 column volumes per hour. As the wine passes through the column, the smoke marker compounds are captured and removed. The applicant's technical data sheet (Attachment G of the application) indicates that a single pass through the column is effective in significantly reducing the target compounds, including from low target levels (<100 ppb).

The adsorbent resin continues to capture target molecules in the wine until saturation is reached. At that point the resin is regenerated by passing a food grade solvent (e.g. 85-99% ethanol at room temperature) through the column which, due to a change in polarity, will release the captured compounds. The applicant states the resin can be used repeatedly without a loss in adsorption efficacy or mechanical strength. The technical data sheet states the maximum cycles before replacement is 400.

The treatment process is illustrated in Figure 2 below.

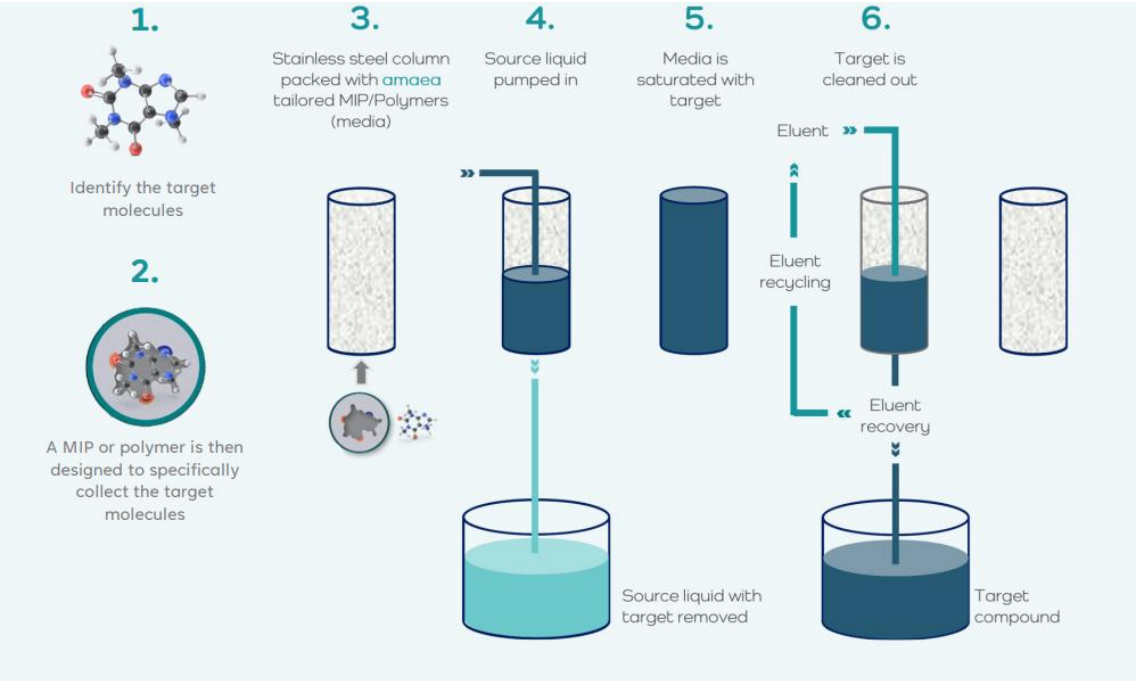

Figure 2: Molecularly-imprinted polymers treatment process (source: www.amaea.com)

2.4.2 Technological justification

Smoke exposure due to wild/bushfires has a significant impact on the wine industry that is challenging for winemakers to manage. Information obtained from the applicant's website indicates that, in 2020, wildfires cost the US wine industry an estimated $3.7 billion in total losses.

The applicant's molecularly-imprinted adsorbent resin has been the subject of numerous smoke remediation trials, including several published studies provided at Attachments A and B of the application (Huo et al. 2024; Huo et al. 2025). In general, the trials demonstrated a good capacity for the resin to remove volatile phenols from white or red fermentations or wine, ameliorating the sensory perception of smoke taint without unduly affecting the wine's positive flavour/aroma profile and quality. For example, Huo et al. (2024) noted up to a 57% removal of volatile compounds from a smoke-affected Pinot Noir wine.

From the application, over one million litres of smoke impacted wine were treated with the resin in the first six months of its commercial use in North America. Its use in the United States and Canada has been met with high rates of success in returning smoke impacted wines to their intended price category, therefore maximising value recovery from damaged wine.

Other advantages of using the resin as an adsorbent agent, as stated by the applicant, include:

- high degree of accuracy and selectivity in the adsorption of target molecules, when compared with currently permitted resins in Standard 4.5.1, such as ion exchange resins
- ability to process high volumes of wine over their useful life
- ability for repeat use, displacing single use additives, minimising waste generation and reducing labour requirements
- minimal impact on the fruit character and body of treated wines.

The applicant has demonstrated that their adsorbent resin performs its primary technological function during the processing of the wine i.e. whilst the wine is being pumped through the stainless steel column containing the resin. Losses of the resin into the treated wine are prevented using standard filtration techniques and, as such, the processing aid is unlikely to be present or exert any function in the final food. Therefore, the adsorbent resin meets the definition of a processing aid. In accordance with section 4.5.1—5(8), use of the processing aid must be consistent with conditions of GMP.

2.5 Analytical method

Although filtration techniques are employed to prevent the movement of the resin particles into the treated wine, the application provided details of the methods that could be used to detect traces of the resin or its components extracting into wine during commercial use (CCI). FSANZ's assessment is that these methods are suitable for detecting and quantifying traces of the processing aid or its components extracting into wine during commercial use.

2.6 Food technology conclusion

The use of the applicant's molecularly-imprinted adsorbent resin in wine is consistent with its functions as a processing aid. Its stated benefits include the ability to selectively bind undesirable phenolic compounds responsible for smoke taint in wine, returning smoke impacted wines to acceptable quality. The evidence presented provides adequate assurance

that the use of this processing aid, in the proposed quantity and form (which must be consistent with GMP), is technologically justified.

The adsorbent resin performs its technological function during wine production and does not perform a technological purpose in the final treated wine. This is because standard filtration techniques during wine processing prevent it from remaining in the wine following treatment. It therefore functions as a processing aid for the purposes of the Code.

There are relevant identity and purity specifications for cross-linked polyester resins in the Code. These are listed in the US CFR, which is a secondary reference listed in subsection S3—3(h) of Schedule 3 of the Code. The applicant has provided evidence that their resin meets these specifications.

3 Safety assessment

This safety assessment aims to evaluate potential public health and safety concerns that may arise from using cross-linked polyester resins, including the applicant's molecularly-imprinted adsorbent resin, as a processing aid in wine production.

3.1 History of safe use

Cross-linked polyester resins meeting the same specification as the applicant's molecularly-imprinted adsorbent resin are already approved in the Code for use in wine production in New Zealand. Cross-linked polyester resins meeting this specification are also approved for use as a processing aid in foods in Australia and New Zealand.

Cross-linked polyester resins may be used in other countries for production of wines which are permitted for sale in Australia. Besides New Zealand, the applicant's resin is also approved for wine production in the USA, Canada, and Japan.

3.2 Toxicological data

Exposure and kinetics

The applicant has provided confidential information to specify the identity of the chemicals used to synthesise their molecularly-imprinted adsorbent resin, and data to demonstrate that those chemicals are not detectable by residuals analysis.

Cross-linked polyester resins, in general, are unlikely to be present in wine when sold. Exposure of wine to a cross-linked polyester resin is conducted within a column as described in section 2.4.1 of this report. Subsequently the wine is filtered to remove any particles of resin that may have been removed from the column.

Filtration for the removal of particles is a normal part of wine production in Australia. A range of filtration techniques is described by the Australian Wine Research Institute[2]. Many of the described techniques would also remove particles of polyester resin. The applicant employs several methods to prevent the movement of the resin into the treated wine. Particle sizes of the molecularly-imprinted absorbent resin are manufactured to be greater than 0.3 mm and filtration techniques employ 1 µm (0.001 mm) filters at the column's outlet. Similarly, other cross-linked polyester resins would be removed from treated wine by filtration.

The applicant has provided information to confirm that their molecularly-imprinted resin is

[2] Filtration – physical removal of microorganisms - The Australian Wine Research Institute

stable during prolonged storage and use.

Likelihood of exposure of consumers to the resin from its use in wine production is therefore considered to be negligible. Should oral exposure occur, the molecularly-imprinted absorbent resin is macroscopic (≥ 0.3 mm) and insoluble, and therefore systemic absorption from the gastrointestinal tract is unlikely.

No case reports of adverse effects of oral exposure to cross-linked polyester resins were located by literature search (EBSCO, PubMed).

3.3 Potential for allergenicity

A small number of case reports of contact allergy resulting from occupational exposure to polyester resin systems were found in the scientific literature (PubMed, EBSCO). There are also rare case reports of asthma being triggered in workplaces in which polyester resins are manufactured. No case reports of allergic reactions due to oral exposure to wines or other food made with the use of cross-linked polyester resins were found. There is no risk to consumers of allergy arising from the use of cross-linked polyester resins during wine production.

3.4 Approvals by other regulatory agencies

Canada

Under the Canadian Food and Drugs Act and its associated regulations, processing aids may be marketed without prior approval from the Canadian Health Products and Food Branch (HPFB) based on a company making a safety determination pursuant to Section 4(1) of the Food and Drugs Act, meaning a determination that use of the processing aid does not render the food injurious to health. The applicant has obtained independent advice that the proposed uses of its molecularly-imprinted adsorbent resin is in full compliance with the Canadian Food and Drugs Act and the Food and Drugs Regulations.

Japan

In Japan, there is a positive list for permitted plastic base polymers in the Food Sanitation Act, which includes a listing for “cross-linking polyester” for use in food production, including, specifically, alcoholic beverage production. The listing specifies the permitted acids, alcohols and/or epoxides, and cross-linking agents that may be used to manufacture a cross-linking polyester copolymer.

USA

Under 21 CFR §177.2420, regulated by the FDA, cross-linked polyester resins may be used repeatedly for applications in food in accordance with three basic requirements: (1) the resin meets certain compositional requirements; (2) finished food-contact articles derived from the cross-linked polyester meet certain limits for extractables; and (3) finished food-contact articles are cleansed prior to first use. The FDA’s Center for Food Safety and Applied Nutrition has formally notified the applicant in writing (dated January 2023) that it has no objection to the use of its molecularly-imprinted adsorbent resin in the treatment of wine, based on compliance with 21 CFR §177.2420.

The applicant also obtained a preliminary conclusion from the Alcohol and Tobacco Tax and Trade Bureau (TTB) in 2024, permitting the use of such polymers generally as a wine and juice treating material and process. The TTB holds the authority to approve such processes under 27 CFR §24.250 (Title 27 – Alcohol, Tobacco and Other Excise Taxes, Part 24 –

Wine, Section 250 – Application for use of new treating material or process).

4 Dietary exposure assessment

A dietary exposure assessment was not conducted because residual levels of the applicant's cross-linked polyester resin, and the chemicals used to synthesise it, are expected to be negligible in the wine (see section 3.2 of this report for details). This is consistent with the assessment of processing aids in wine in Application A1127 in 2017 (FSANZ 2017).

5 Discussion

The use of the applicant's molecularly-imprinted adsorbent resin as a processing aid in wine is consistent with its known functions. It will be used during wine-making where it will carry out precise and selective adsorption of undesirable molecules, including phenolic compounds, associated with smoke taint due to exposure of grapes to bushfires.

The resin functions as a processing aid for the purposes of the Code and does not perform a technological purpose in the food for sale. The evidence presented provides adequate assurance that the use of this resin, in the proposed quantity and form (which must be consistent with GMP), is technologically justified.

The applicant's cross-linked polyester resin meets the identity and purity specifications for 'polyester resins, cross-linked' in the US CFR, which is a secondary reference listed in subsection S3—3(h) of Schedule 3 – Identity and purity, in the Code. Cross-linked polyester resins meeting this specification are already approved for use in food in Australia and New Zealand, as well as overseas.

FSANZ did not identify any safety concerns associated with the use of the applicant's adsorbent resin, under the proposed use conditions. The applicant's resin is approved for use in wine production in New Zealand, Canada, Japan and the USA.

Cross-linked polyester resins meeting the same specifications are also already approved for use in food in Australia and New Zealand, as well as overseas. Taken together, this provides a history of safe use of cross-linked polyester resins, including the applicant's resin.

Likelihood of exposure of consumers to cross-linked polyester resins from use in wine production is considered to be negligible due to its macroscopic nature and the use of standard filtration techniques in wine making. Chemicals used to synthesise the resin have been found to be indetectable by residuals analysis. On this basis, a dietary exposure assessment was not conducted.

No reports of adverse effects of oral exposure to cross-linked polyester resins were located by literature search. No case reports of allergic reactions due to oral exposure to wines or other food made with the use of cross-linked polyester resins were found.

Overall, FSANZ concludes there are no safety concerns from the use of cross-linked polyester resins, including the applicant's molecularly-imprinted adsorbent resin, in the quantity and form required to perform its typical function in wine production, which must be consistent with GMP.

6 References

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