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

Supporting Document

RISK AND TECHNICAL ASSESSMENT REPORT (AT APPROVAL)

Executive Summary

Co-extruded polystyrene and polyvinyl polypyrrolidone (PVPP) (the resin) is a new filtration and absorbent agent proposed for use to remove particulates and haze material from beverages such as beer. Various cross-linked polystyrene- and styrene-based resins and PVPP are already permitted food processing aids in Australia and New Zealand.

Evidence presented in support of the Application provided adequate assurance that the resin is technologically justified and has been demonstrated to be effective in achieving its stated purpose. As the resin is not a novel polymer, and specifications for the individual constituents (polystyrene and PVPP) already exist, no amendment to the specifications is considered necessary.

The hazard assessment considered the chemistry and impurity profile of the resin, unpublished data on the acute toxicity and genotoxicity of the resin, and the migration of residual monomers into beverage. Results indicate that there is likely to be no migration of monomers from the resin and negligible carry-over of the resin in treated beverages. The history of safe use of polystyrene and PVPP was also taken into consideration. In the absence of any dietary hazard posed by the resin and the very limited potential for its migration into beverages, the resin is considered to pose a negligible risk to public health and safety.

The overall conclusion of this risk and technical assessment is that the use of co-extruded polystyrene and PVPP as a processing aid is technologically justified and raises no public health and safety issues.

Table of Contents

1. Introduction

1.1 Background

On 3 June 2010, Food Standards Australia New Zealand (FSANZ) received an Application from BASF Australia Pty Ltd seeking an amendment to the Table to Clause 6 of Standard 1.3.3 – Processing Aids of the Australia New Zealand Food Standards Code (the Code) to permit the use of co-extruded polystyrene and polyvinyl polypyrrolidone (PVPP) (the resin) as a processing aid.

The resin (trade name Crosspure®) is produced by co-extrusion of polystyrene and polyvinyl polypyrrolidone (PVPP), and is proposed for use to remove suspended particles, such as some microorganisms and haze-forming compounds (e.g. polyphenols) from beverages. The Applicant stated that the use of the resin replaces two processing steps in the production of beer, namely filtration (commonly through diatomaceous earth) and adsorption of haze-forming material (commonly through the use of cross-linked PVPP). The use of the resin therefore eliminates the need to use diatomaceous earth, which is a finite resource and has a limited life-of-use.

While the Application and its supporting data are specifically focussed on the use of the resin in the processing of beer (which is anticipated to be its main use), the Applicant is seeking a consideration of a broader permission to include other beverages and liquid foods.

1.2 Risk Assessment Questions & Scope

The resin is a new food processing aid but is comprised of polymers that are already listed in the Code as permitted processing aids. The following questions are addressed in this Risk and Technical Assessment Report:

- Is the use of the resin technologically justified?
- Are beverages produced through the use of the resin safe for consumption?

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

(1) Food Technology Assessment, which considered whether the use of the resin is technologically justified and described the chemical properties of the compound.

(2) Hazard Assessment, which evaluated the intrinsic toxicity of the resin and the potential migration of the resin, its constituents or impurities into simulated beverage.

2. Resin Characteristics

2.1 Chemistry of the resin

2.1.1 Chemical structure and identity

The resin is an extrudate from polystyrene (70%) and polyvinyl polypyrrolidone (PVPP) (30%). The marketing name used for the resin is Crosspure®.

Polystyrene:

C.A.S number: 9003-53-6

PVPP

C.A.S number: 9003-39-8

INS No: 1202

Other names: Cross-linked polyvinylpyrrolidone, crospovidone (FCC), insoluble polyvinyl pyrrolidone

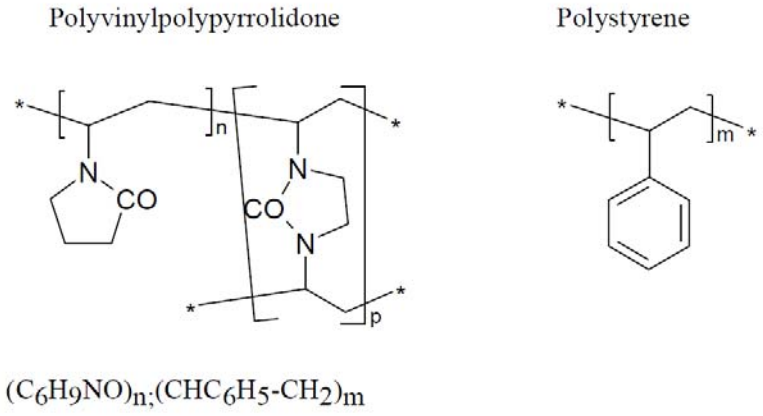

Figure 1: Chemical structure of PVPP and polystyrene

2.1.2 Physical and chemical properties of the resin

Table 1: Physical and chemical properties of the resin

Nature	White to slightly beige powder
Weight average molecular mass of individual components	**Polystyrene** weight average molecular weight, M_w = 275,000 g/mol; polydispersity M_w/M_n = 2.65, (M_n = number average molecular weight) maxiumum content of 1% oligomeric species **PVPP** is insoluble in water, alcohol and all common solvents and its molecular weight distribution therefore cannot be measured.
Density	1.0945 g/mL
Purity	Approximately 100%
Major impurities	None

Melting point and decomposition temperature	Decomposition – approx. 200°C No decomposition/transformation is expected in the expected use temperature of under 20°C. Temperatures during cleaning and regeneration of the resin will vary up to 80°C.
Solubility	The resin is insoluble in water and ethanol
Octanol/water partition (log $P_{O/W}$)	Insoluble
Reactivity	Inert, non-reactive
Stability	Stable at pH range 2-14
Hydrolysis	No
Interaction with food substances	Physical interaction with food substances only, no chemical interaction

Two grades of the resin, of differing average particle diameter, are produced. Typically both grades are used in a mixture in the filtration process. A description of the particle sizes in each grade is provided in Table 2.

Table 2: Description of particle sizes of the two grades of the resin

Diameter at the:	Finer Grade (Crosspure® XF)	Coarser Grade (Crosspure F)
10th percentile	14 µm	20 µm
50th percentile	30 µm	57 µm
90th percentile	52 µm	107 µm

2.1.3 Methods of analysis

Styrene may be analysed using gas chromatography (GC), while the other monomers may be analysed using mass spectrometry (MS) and high pressure liquid chromatography (HPLC).

2.1.4 Specifications for identity and purity

The coextruded resin itself has not been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, JECFA has assessed PVPP and has written a specification for it (Monograph 1 2006)[1]. Food Chemicals Codex (FCC) has also assessed and written a specification for PVPP[2]. These monographs are primary reference sources for specifications, as listed in clause 2 of Standard 1.3.4 - Identity and Purity, of the Code. Specifications for polystyrene are included in the Code of Federal Regulations of the United States of America (§177.1640)[3], which is a secondary reference source in clause 3 of Standard 1.3.4. As the co-extrusion process does not create a new polymer, i.e. there is no chemical cross-linking of PVPP and polystyrene, each individual polymer must comply with the relevant specifications for that polymer, and a separate specification for the resin is not necessary. The Applicant stated that the PVPP used complies with the relevant JECFA specifications and that the polystyrene used complies with the relevant Code of Federal Regulations specifications.

[1] JECFA (Monograph 1, 2006) *Combined Compendium of Food Additive Specifications – Insoluble Polyvinylpyrrolidone*, viewed August 2010. http://www.fao.org/ag/agn/jecfa-additives/details.html?id=229 .
[2] FCC (2010) *FCC Monographs: Crospovidone*, viewed August 2010. http://online.foodchemicalscodex.org/online/pub/index?fcc=7&s=1&oYr=2010&oMo=11&oDa=28.
[3] US Government, *Code of Federal Regulations,* viewed August 2010. http://frwebgate2.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=e47b2D/2/2/0&WAISaction=retrieve.

2.2 Production

The resin is manufactured by extrusion of a mixture of polystyrene (70%) with PVPP (30%). The granules thereby produced are then further processed to obtain two grades of the resin, each of different average particle diameters. Finally the products are sieved.

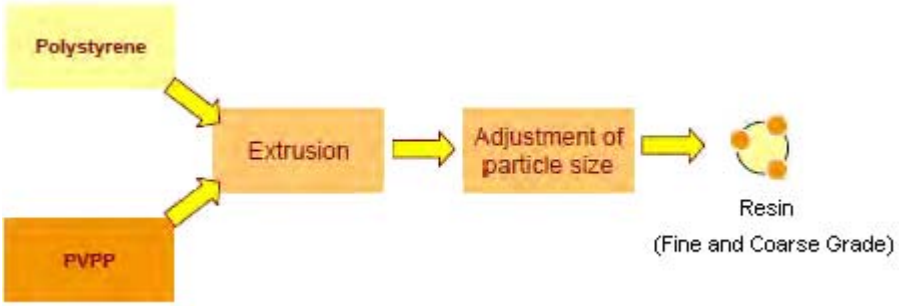

Figure 2: Production process for the resin

3. Food Technology Assessment

3.1 Technological Justification

3.1.1 Use of the resin in beer processing

The resin is intended to be used primarily in beer manufacture to replace both the filtration step, usually performed by diatomaceous earth, as well as the stabilisation step, usually performed by permitted processing aids such as PVPP. The resin physically filters particulates including some microorganisms (yeasts and bacteria) comparable to the filtration performed by diatomaceous earth. The resin also stabilises the treated beverage by adsorbing precursor substances (polyphenols and polyphenol-protein complexes), that are known to form haze and particulates in the aged beverage. The resin is therefore able to be used as a single-step alternative to these two steps. Although the primary use for the resin is envisaged to be in beer manufacture, it is expected that it would also function to remove particulates and haze material from other beverages.

The Applicant explains that the resin is used in filtration systems similarly to the way in which diatomaceous earth is currently used. The resin is suspended in water and continuously fed into the beverage stream using a metering pump. The temperature of the beverages is typically between -1°C and 20°C at this time. The resin is then subsequently removed from the beverages through filtration, and the resin filter cake is then regenerated through intensive washing for repeated use. There is negligible carry-over of the resin into the final treated beverage (see section 4.5.1). Sodium hydroxide (2-5%) and water are used to clean the filter cake, with the temperature at this time not expected to exceed 80°C. Use levels are likely to be in the range of 50-150g of resin per 100 litres of beverage, depending on the beverage's characteristics. The food contact time will depend on the filter type used and will vary between 5 and 10 minutes. Figure 3 shows the use of the resin in the overall context of beer production.

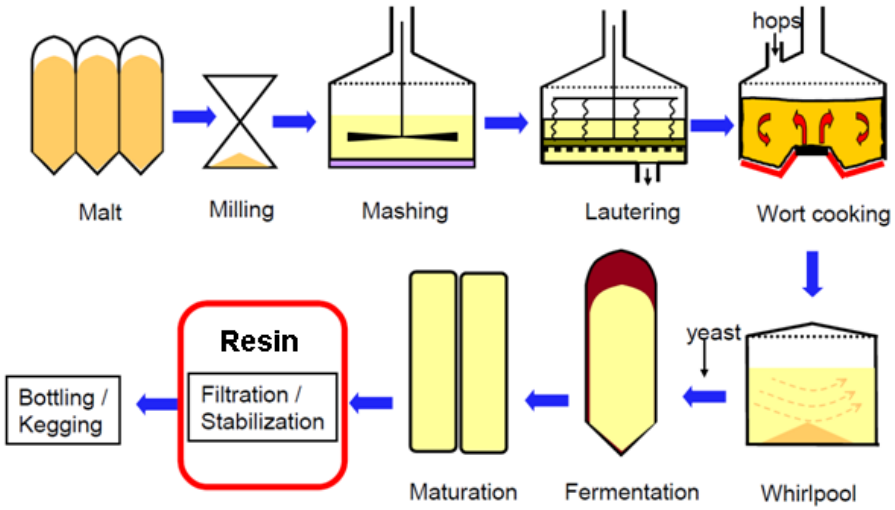

Figure 3: Schematic of brewery process, showing positioning of resin in overall process

3.1.2 Evidence for the effectiveness of the resin

The Applicant stated that a commercial form of this resin has been trialled extensively in breweries in Germany, Eastern Europe, China, North America and South America, with favourable results in comparison with the traditional process. The Applicant has provided information to show signs of reductions in haze and in total polyphenols in beer treated with the resin.

Taste panels assessed the aroma, taste quality, body, liveliness and quality of bitterness on a hedonic scale of 1 (very bad) to 5 (very good) of beer treated with the commercial resin product and beer treated with the traditional processes. The taste panel results for the fresh beer were similar for both treatments, suggesting that the resin does not alter the quality of the beer. However, the Applicant stated that after forced ageing there was an improvement in the organoleptic properties of the resin-processed beer over the traditionally-processed beer.

3.2 Stability

The regeneration of the resin after 17 uses results in a resin with a spread of particle sizes which is virtually identical to that of a fresh batch of resin. This information has been provided by the Applicant to demonstrate the stability of the resin after repeated uses.

3.3 Conclusion

The stated purpose for this resin, namely for removal of particulates including some microorganisms, and haze material (polyphenols and polyphenol-protein complexes), is clearly articulated in the Application and the evidence presented in support of the Application provides adequate assurance that the resin is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

4. Hazard Assessment

4.1 Introduction

This hazard assessment was undertaken to characterise the toxicity potential of the resin. The assessment was based on unpublished data submitted by the Applicant on the chemistry and impurity profile of the resin, toxicity studies conducted on the resin and an analysis of the migration of residual monomers into simulated beverage. The history of safe use of polystyrene and PVPP was also taken into consideration.

4.1.1 Physicochemical Properties

The physicochemical properties of the resin are described in the Food Technology Assessment (Section 2.1.1). Analysis of two different grades of the resin, Crosspure® F and Crosspure® XF, by laser diffraction determined that the particle size distribution was approximately 5-181 µm and 3-91 µm, respectively. As the minimum particle size is greater than the technical cut-off for nanoparticles (i.e. 100 nm or 0.1 µm), the resin is not classifiable as a nanomaterial.

4.1.2 Impurity Profile

There are no major impurities in the resin. Low concentrations of residual polystyrene or PVPP monomers may be present in the resin (Table 3).

Table 3: Residual polystyrene and PVPP monomers in Crosspure®

Monomer	CAS No.	Proposed Max Specification (mg/kg)	Mean analytical values (mg/kg)[1]
2-pyrrolidone	616-45-5	150	118
N-vinyl-2-pyrrolidone	88-12-0	5	3
1,3'-divinylimidazolidin-2-one	13811-50-2	2	<2
Styrene	100-42-5	8	4

1 = Determined from six batches of the resin

The equilibration, use and regeneration of the resin following use involve extensive washing, including with 2-5% sodium hydroxide. This process would ensure that potential impurities would be removed from the resin and would therefore be unlikely to migrate in to the beverage. The contact time with the resin is 5-10 minutes, which also minimises the potential for any impurities to enter the beverage.

4.2 History of Use

The resin has a relatively short history of use in other parts of the world and has been trialled in Europe, China and America. However, polystyrene and PVPP are widely used as processing aids and are approved for food contact in many countries.

Of relevance to Australian and New Zealand consumers, various cross-linked polystyrene- and styrene-based resins and PVPP are already permitted food processing aids. Various types of styrene and cross-linked styrene derived resins, copolymers and terpolymers of styrene are listed in the Tables to Clause 6, 8 and 11 in Standard 1.3.3 of the Code at levels commensurate with Good Manufacturing Practice (GMP). PVPP is listed in the Table to Clause 6 as a permitted decolourant, clarifying, filtration and adsorbent agent, with a maximum residual level of 100 mg/kg allowed in the final food. Standard 4.5.1 – Wine Production Requirements, also permits the use of PVPP as a processing aid in the

production of wine, sparkling wine and fortified wine; no more than 100 mg/L is permitted in the final beverage. The monomer of PVPP, polyvinyl pyrrolidone (PVP), is a permitted food additive in table-top sweeteners at GMP (11.4 in Schedule 1 of Standard 1.3.1). However, while various cross-linked polystyrene- and styrene-based resins are currently permitted processing aids, polystyrene itself is not permitted as a processing aid.

4.3 Overseas approvals

The resin is approved for use in France, Russia and the US. Specific regulatory approval is not required in the European Union, China, India, the Philippines or South Africa and therefore the resin may be used in these jurisdictions.

4.4 Evaluation of Submitted Toxicity Studies

The submitted toxicity studies were conducted on Crosspure® F but are also considered valid for Crosspure® XF because both substances are chemically identical; they are derived by mechanical processing (i.e. sieving) of the same starting material.

4.4.1 Acute Oral Toxicity Study

Gamer AO & Hoffman HD (2001) Crosspure F – Acute oral toxicity study in Wistar rats. Report/Project No. 10A0467/011063. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany. **GLP**: Germany. **QA statement**: Yes. **Guidelines**: OECD (Test Guideline 423), EEC (Directive 96/54/EC) & US EPA (OPPTS Guideline 870.1100)

Crosspure® F (99% purity; Batch No. ZK 1681/85; sourced from the Sponsor) in 0.5% carboxymethyl cellulose (CMC) was administered to three fasted female Han Wistar (CrlGlxBrlHan:WI) rats as a single gavage dose of 2000 mg/kg bw. The study authors stated that the dose selection was based on the physicochemical properties of the resin as pronounced acute toxicity was not expected. In the absence of any overt signs of toxicity, the test was repeated with three male Wistar rats. Rats were sourced from Charles River Deutschland GmbH (Sulzfeld, Germany). Females were 14-18 weeks old and had an average weight of 204 g, while males were 8-12 weeks old and had an average weight of 219 g before administration. Following dosing, food and water were available *ad libitum*. Observations for mortalities and clinical signs were made at least daily. Bodyweight was recorded prior to dosing and weekly thereafter. Survivors were sacrificed 14 days after dosing and necropsied. There were no mortalities. Bodyweight gains were unremarkable and there were no macroscopic abnormalities detected at necropsy. The median lethal dose was >2000 mg/kg bw.

4.4.2 Genotoxicity studies

Engelhardt G & Hoffmann HD (2002) *Salmonella typhimurium/Escherichia coli* reverse mutation assay (standard plate test and preincubation test) with Crosspure F. Report/Project No. 40M0467/014109. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. **GLP**: OECD & Germany. **QA statement**: Yes. **Guidelines**: OECD (Test Guideline 471) & EEC (Directive 2000/32, B.13/B.14; 19 May 2000)

Engelhardt G & Leibold E (2002a) *In vitro* chromosomal aberration assay with Crosspure F in V79 cells. Report/Project No. 32M0467/014114. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. **GLP**: OECD & Germany. **QA statement**: Yes. **Guidelines**: OECD (Test Guideline 473) & EEC (Directive 2000/32, B.10; 19 May 2000)

Engelhardt G (2002a) Amendment No. 1 to the report: *In vitro* chromosomal aberration assay with Crosspure F in V79 cells. Report/Project No. 32M0467/014114. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. **GLP**: OECD & Germany. **QA statement**: Yes.

Engelhardt G & Leibold E (2002b) Cytogenetic study *in vivo* with Crosspure F in the mouse micronucleus test after two intraperitoneal administrations. Report/Project No. 26M0467/014107. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. **GLP**: OECD & Germany. **QA statement**: Yes. **Guidelines**: OECD (Test Guideline 474) & EEC (Directive 2000/32, B.12; 19 May 2000)

Engelhardt G (2002b) Amendment No. 1 to the report: Cytogenetic study in vivo with Crosspure F in the mouse micronucleus test after two intraperitoneal administrations. Report/Project No. 26M0467/014107. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany.

Two *in vitro* studies and one *in vivo* genotoxicity study were submitted as part of the current Application. These studies were GLP compliant and conducted according to appropriate test guidelines. However, in the study of Engelhardt and Hoffman (2002), the stability of the test substance in the vehicle or in water was not determined; this is not considered by FSANZ to affect the validity or interpretation of either study. Signed QA statements were contained in the respective study reports. The two *in vitro* studies were conducted in the presence and absence of an exogenous source of metabolic activation (S9 liver preparations from Aroclor 1254-induced rats). Positive and negative (vehicle) controls were tested in each study and gave expected results.

The resin showed no evidence of mutagenic or clastogenic activity in these assays (Table 4).

Table 4: Summary of genotoxicity studies

Test	Test system	Test article	Concentration or dose range	Result	Reference
Bacterial reverse mutation (Ames test)	*S. typhimurium* strains TA98, TA100, TA1535 & TA1537. *E. coli* WP2 uvrA ±S9	Crosspure F 99% purity; Batch No. ZK 1681/85 Acetone vehicle	4-2500 µg/plate (preincubation test) 23-5750 µg/plate (standard plate test)	Negative No cytotoxicity Precipitation ≥575 µg/plate	Engelhardt & Hoffman (2002)

Test	Test system	Test article	Concentration or dose range	Result	Reference
Chromosomal aberration	V79 cells (Chinese hamster) 4 h exposure & 18 h harvest time (±S9) 18 h exposure & 18 or 28 h harvest time (-S9) 4 h exposure & 28 h harvest time (-S9)	Crosspure F (suspension) 99% purity; Batch No. ZK 1681/85 DMSO vehicle	312.5-2500 µg/mL	Negative No cytotoxicity Precipitation at every concentration	Engelhardt & Leibold (2002a) Engelhardt (2002a)
Mouse micronucleus	NMRI ♂ mice (5/group) 2 x IP doses separated by 24 h Bone marrow sampled after 24 h	Crosspure F (suspension) 99% purity; Batch No. ZK 1681/85 0.5% CMC vehicle	500, 1000 & 2000 mg/kg bw (20 mL/ kg bw dose volume)	Negative Toxicity[1]	Engelhardt & Leibold (2002b) Engelhardt (2002b)

DMSO = dimethyl sulfoxide; IP – intraperitoneal; 1 = squatting posture observed from 1 h after dosing lasting to 4 h after the 1st injection (all doses) to 28 h (500 mg/kg bw) or 2 d (1000 and 2000 mg/kg bw) after the second injection.

4.5 Evaluation of Submitted Migration Studies

Migration studies were conducted using simulated beverages containing either 10% ethanol or 3% acetic acid. These 'simulants' are prescribed in European legislation[4] as appropriate surrogates for the assessment of the migration of constituents of plastic materials intended to come into contact with foodstuffs. A solution of 10% ethanol is specified for the assessment of all alcoholic and aqueous foods (with the ethanol concentration adjusted if the actual alcohol concentration is >10%), while a solution of 3% acetic acid is specified for all aqueous and acidic foods.

4.5.1 Migration of the resin into simulated beverages

Störmer A & Berghammer A (2005) Test Report Part 1. Determination of overall migration from Crosspure® into food stimulants. Report No. PA/4255/05. Lab: Franhofer Institute for Process Engineering and packaging. Sponsor: BASF Aktiengesellschaft, Fine Chemicals Division, Ljumburgerhof, Germany.

This study analysed the migration of Crosspure® F and Crosspure® XF (Batch No. unspecified; sourced from the Sponsor) into an aqueous simulant of 3% acetic acid or 10% ethanol at 20°C. It was stated that the test materials were suspended in simulant, stirred and filtered; no further methodological details were given except that the test method was in accordance with European Standard EN 1186-3. Results are given in Table 5 and indicate that the mean migration into simulant was well below the German and European standards,

[4] Council Directive 82/711/EEC, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1982L0711:19970901:EN:PDF

which is that migration should be <60 mg/kg food simulant.

These results indicate that the amount of the resin in the final treated beverage is minimal.

Table 5: Migration of the resin into a simulated beverage

Overall migration	Crosspure® F	Crosspure® XF
Into 3% acetic acid	18 (4, 19, 30)	22 (26, 24, 17)
Into 10% ethanol	14 (14, 7, 22)	24 (26, 24, 22)

Results expressed as the mean migration (in mg/kg simulant) of 3 measurements, with the individual measurements given in parentheses. The analytical tolerance was ±12 mg/kg.

4.5.2 Migration of residual monomers into simulated beverages

Störmer A & Ungewib J (2005) Test Report Part 2. Determination of 2-pyrrolidin-2-one, 1-vinyl-pyrrolidin-2-one, 1,3-divinylimidazolidin-2-one and styrene. Report No. PA/4255/05. Lab: Franhofer Institute for Process Engineering and packaging. Sponsor: BASF Aktiengesellschaft, Fine Chemicals Division, Ljumburgerhof, Germany.

The concentrations of 2-pyrrolidione, 1-vinyl-2-pyrrolidone, 1,3-divinylimidazolidin-2-one and styrene were analysed following the use of Crosspure® F or Crosspure® XF (Batch Nos. unspecified; sourced from the Sponsor) under conditions similar to those of intended use (summarised in Table 6). Styrene was analysed using gas chromatography (GC), while the other monomers were analysed using mass spectrometry (MS) and high pressure liquid chromatography (HPLC). With the exception of 1,3-divinylimidazolidin-2-one, the stability of each monomer at room temperature was assessed. The limit of detection (LOD) for each analyte was as follows: 2-pyrrolidione = 10 µg/L in 10% ethanol and 12 µg/L in 3% acetic acid; 1-vinyl-2-pyrrolidone and 1,3-divinylimidazolidin-2-one = 10 µg/L in 10% ethanol; degraded 1,3-divinylimidazolidin-2-one = 15 µg/L in 3% acetic acid; styrene = 45 µg/L.

Table 6: Details of migration tests on resin monomers

Test	Description
1. Migration into water following conditioning of Crosspure® F or Crosspure® XF	Crosspure® was suspended in 2% NaOH, filtered & washed with 11 x 50 mL water – the last 50 mL of water was analysed for monomers.
2. Migration into simulant[1] using conditioned Crosspure® F or Crosspure® XF	Simulant was stirred for 30 min with Crosspure® at room temperature then filtered. The filtrate was analysed for monomers.
3. Migration into water following regeneration of Crosspure® F or Crosspure® XF	Crosspure® was mixed with 2% NaOH & incubated at 80°C for 20 min. The suspension was filtered & washed with water to reach a neutral pH - the last wash was analysed for monomers.
4. Migration into a simulant[1] using regenerated Crosspure® F or Crosspure® XF	Simulant was stirred for 30 min with Crosspure® at room temperature then filtered. The filtrate was analysed for monomers.

1 = aqueous simulated beverage containing 10% ethanol or 3% acetic acid

2-pyrrolidone was stable in 10% ethanol or 3% acetic acid. 1-vinyl-2-pyrrolidone was almost completely (~99%) degraded (to 2-pyrrolidone) in 3% acetic acid within 4 h but was stable in 10% ethanol. A similar pattern of stability was observed for 1,3-divinylimidazolidin-2-one; unstable in 3% acetic acid and stable in 10% ethanol.

For both Crosspure® F and Crosspure® XF, 1-vinyl-2-pyrrolidone, 1,3-divinylimidazolidin-2-one and 1,3-divinylimidazolidin-2-one were undetectable in all washing water and simulant samples. 2-pyrrolidone was only detectable in the washing water used to condition Crosspure® F and Crosspure® XF (22 and 142 µg/L, respectively). Styrene was

undetectable in all washing water and simulant samples coming into contact with Crosspure® F or Crosspure® XF.

On the basis of these findings, it is unlikely that any of the residual monomers would be detectable in beverages prepared using either Crosspure® F or Crosspure® XF, under normal production conditions.

4.6 Discussion

Data and information submitted in support of this Application were adequate to assess the hazard of the resin. No public health and safety issues were identified based on the following considerations:

- Various cross-linked polystyrene- and styrene-based resins and PVPP are already permitted food processing aids in Australia and New Zealand. The resin is produced by extrusion of polystyrene and PVPP, which does not involve any chemical modification of either compound.

- Regulatory approval of the resin has been granted in France, Russia and the US. Additionally, it is permitted for use in many other countries.

- The resin was not acutely toxic to male or female rats at a dose of 2000 mg/kg bw.

- The resin was not mutagenic, and not clastogenic *in vitro* or *in vivo*.

- Factors that limit the potential for migration of monomers or other impurities into the final food include the short food contact time (5-10 minutes) and that the resin is extensively washed prior to and after use.

- The use of the resin under conditions of intended use resulted in migration (into simulated beverages containing 10% ethanol or 3% acetic acid) lower than current European and German standards. These results are considered to be an appropriate surrogate for aqueous, alcoholic (where the alcohol content is $\leq$10%) and acidic foods.

- The use of the resin under conditions of intended use resulted in undetectable levels of monomers in simulated beverages containing 10% ethanol or 3% acetic acid. These results are considered to be an appropriate surrogate for aqueous, alcoholic (where the alcohol content is $\leq$10%) and acidic beverages and liquid foods.

- In view of the current permissions for the use of styrene resins and PVPP resins as food processing aids, and based on the above considerations, there would be no public health and safety issues associated with the use of the resin to process a variety of beverages.

5. Overall Conclusion

The use of co-extruded polystyrene and PVPP as a processing aid is technologically justified and raises no public health and safety issues.

6. References

Engelhardt G (2002a) Amendment No. 1 to the report: *In vitro* chromosomal aberration assay with Crosspure F in V79 cells. Report/Project No. 32M0467/014114. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. *Unpublished*.

Engelhardt G (2002b) Amendment No. 1 to the report: Cytogenetic study *in vivo* with Crosspure F in the mouse micronucleus test after two intraperitoneal administrations. Report/Project No. 26M0467/014107. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany. *Unpublished*.

Engelhardt G & Hoffmann HD (2002) *Salmonella typhimurium/Escherichia coli* reverse mutation assay (standard plate test and preincubation test) with Crosspure F. Report No. 40M0467/014109. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. *Unpublished*.

Engelhardt G & Leibold E (2002a) *In vitro* chromosomal aberration assay with Crosspure F in V79 cells. Report/Project No. 32M0467/014114. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany*. Unpublished.*

Engelhardt G & Leibold E (2002b) Cytogenetic study *in vivo* with Crosspure F in the mouse micronucleus test after two intraperitoneal administrations. Report/Project No. 26M0467/014107. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen, Germany. *Unpublished*.

Gamer AO & Hoffman HD (2001) Crosspure F – Acute oral toxicity study in Wistar rats. Report No. 10A0467/011063. Lab & Sponsor: Experimental Toxicology & Ecology, BASF Aktiengesellschaft, Ludwigshafen/Rhein, Germany. *Unpublished*.

Störmer A & Berghammer A (2005) Test Report Part 1. Determination of overall migration from Crosspure® into food stimulants. Report No. PA/4255/05. Lab: Franhofer Institute for Process Engineering and packaging. Sponsor: BASF Aktiengesellschaft, Fine Chemicals Division, Ljumburgerhof, Germany. *Unpublished*.

Störmer A & Ungewib J (2005) Test Report Part 2. Determination of 2-pyrrolidin-2-one, 1-vinyl-pyrrolidin-2-one, 1,3-divinylimidazolidin-2-one and styrene. Report No. PA/4255/05. Lab: Franhofer Institute for Process Engineering and packaging. Sponsor: BASF Aktiengesellschaft, Fine Chemicals Division, Ljumburgerhof, Germany. *Unpublished*.