BALL CORPORATION
Beverage Packaging Europe

Declaration of compliance for food contact legislation of beverage cans coated with Valspar 4020W01D inside liner

I, the undersigned, **Charlotte Bedford**, on behalf of **Ball Corporation, European Technical Centre, Delaware Drive, Milton Keynes, MK15 8HG, UK**, acting in my position of **Regulatory Affairs Manager**, declare that **aluminium cans** produced using Epoxy based food contact protection coating and characterised as hereafter:

Family of material: **Aluminium cans**

Characteristic components, from the inside outwards:

- Coating: **Valspar 4020W01D** epoxy based material with minimum thickness 2.7g/m2
- Aluminium: **AA3104 alloy H19 temper** minimum thickness 90µm

[The external basecoat, inks and over-print varnish do not need to comply with food contact regulations as they are separated from the food by the functional barrier of a continuous aluminium layer of at least 6 microns thickness]

complies with the requirements of the following regulations

EUROPE

- **EU Framework Resolution ResAP (2004)1** on coatings intended to come into contact with foodstuffs
- **EU Regulation 1895/2005** Restricting use of certain epoxy derivatives in materials intended to come into contact with food
- **EU Regulation 1935/2004** Food contact framework Legislation
- **EU Regulation 2023/2006** on good manufacturing practice
- **EU Directive 94/62/EC (Article 11)** placing restriction on use of certain heavy metals
- **CEPE: Code of Practice for coated articles where the food contact layer is a coating**. Annex X: GMP Food Contact materials
- **EU Regulation 2018/213** on the use of bisphenol A in varnishes and coatings intended to come into contact with food

FRANCE

The food contact materials used in these articles contain epoxy resins based on BPA or BPX (a generic description for a series of substances based on bisphenol). Therefore the aforementioned articles do not comply with the French regulations in force concerning materials and articles in contact with food products namely, The Law No. 2012-1442 dated 24 December 2012 to the suspension of the import and the placing on the market of any conditioning food vocation containing bisphenol A.

USA

- **USA Food and Drug Regulations 21 CFR 175.300** on resinous and polymeric coatings
- **USA CONEG (Coalition of Northeastern Governors) Regulation** restricting the use of certain heavy metals

Ball Beverage Packaging Europe has defined and documented a Quality Management System that meets the requirements identified in ISO 9001, ISO14000 and OHSAS18001. In order to ensure the highest levels of hygiene, food and personal safety are maintained, individual facilities have specific programmes in place to manage these risks and adhere to both customer and legal/regulatory

requirements (such as those operated by the International Standards Organisation, OHSAS and the British Retail Consortium/Institute of Packaging) thus confirming compliance with GMP requirements.

INFORMATION ON USED SUBSTANCES

All constituents of the food contact coating referenced above comply with Council of Europe Resolution ResAP((2004)1, which stipulates the restriction of starting substances for coatings intended to come in to the contact with foodstuff. Compliance is confirmed by specific migration testing for restricted substances.

Where specific migration limits need to be applied for corresponding substances, testing for compliance is carried out by approved external laboratories. For required analysis, all applied simulants, durations and temperatures are in accordance to EU Regulation 10/2011EC. The migration testing procedures described in Regulation EU 10/2011 are designed for compliance testing of plastic food contact materials. Nevertheless, the procedures are applied accordingly for migration testing of coated cans.

To demonstrate compliance with the specific and overall migration limits, food simulant A (Ethanol 10%), food simulant B (Acetic acid 3%) and food simulant D1 (Ethanol 50%) were applied to a specimen representative of the material with surface to volume ratio of 6 dm^2 to 1 Kg of simulant.

Additionally, to demonstrate compliance with the overall migration limit for all food types, testing with distilled water was applied.

The test conditions for all foods for long term storage are defined in Regulation EC 10/2011 annex V chapter 3 (3.1) and shown in table 3 of the “Standardised testing conditions”. Test condition OM5, 1 hour at 121°C, is intended for high temperature applications up to 121°C and test condition OM2, 10 days at 40°C, is intended “any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes”. Both of these test conditions are applied successively to the samples.

The specific migration is analysed using an analytical method in accordance with the requirements of Article 11 of Regulation EC 882/2004 and these migration tests are certified by Institute Nehring report STGM19-091 (LULU03-095 dated 10 September 2015).

SPECIFICATIONS

When our cans are used in accordance to our technical data sheets, the food contact coating referenced above, under normal and foreseeable conditions for use is suitable for the storage of **aqueous, acidic and alcoholic products (maximum 20% alcoholic content) to be pasteurised or milk and dairy products to be processed up to 121°C**

It is the customer’s responsibility to ensure appropriate handling and application of the can and end. In the event of a change in the packaged product, its composition or its intended use, as well as in the event of a change in the conditions for using the material or the object, the persons for whom this declaration is intended must ensure the compatibility of the content/contents for which he/she then accepts responsibility.

According to the requirements set in **Swiss Ordinance 817.023.21**, we can confirm that all inks (and over-print varnish) used on the can are not in food contact and aluminium can be seen as an impermeable barrier for any potential migrate from the outside surfaces.

Bisphenol A was detected in the migrates at acceptable levels with 3% acetic acid, 20% ethanol, 50% ethanol and sunflower oil. This complies with EU Regulation 2018/213.

The outside decoration and coating are applied to the formed can so there is no risk of set-off as the inside, food contact surface is physically separated from the outside surface.

Based on statements from our suppliers, we can confirm that none of the substances contained in their preparations are stated on present candidate list of Substances of Very High Concern (SVHC) maintained in the Registration, Evaluation and Authorisation of Chemicals (REACH) system.

No dual-use additives are contained in the internal or external coatings on our cans.

There is no intentional use of phthalates as additives or components of the food contact coatings or external materials.

We can confirm that none of the 14 major allergens listed in Annex II of **EU Regulation 1169/2011** are used in our products for any direct food contact or indirect food contact materials nor are they introduced after manufacture. Based on our knowledge of our raw materials and manufacturing process, we can state that none of the aforementioned allergens are present in the products supplied.

According to the legal definition adopted by the EU Commission, we can confirm there are no specifically engineered novel nanomaterials which are currently in commercial use in our can and end production

Furthermore, we certify that the food contact coating referenced above is composed entirely of synthetic chemical materials and does not contain any animal products or animal by-products, therefore it would be considered acceptable for the packaging of halal products and comply with the general guidelines for use of the term “halal” as defined in **Codex CAC/GL 24-1997**. Similarly, they are, therefore, suitable for packaging vegan and Kosher foods.

This declaration of compliance has been drawn up on the basis of declaration by our suppliers of raw materials and analysis of overall and specific migrations.

This declaration is valid for a period of five years. It will be renewed in all cases where the previous conformity is no longer ensured and in case of changes to the relevant regulations.

Charlotte Bedford
Regulatory Affairs Manager
Ball Corporation Technical Centre Tongwell UK

Signed

15th August 2018

TEST CERTIFICATE

Internal Protection Lacquer Valspar 4020W01D of Beverage Cans

Your ref. July 25, 2015/A. Woollaston
Our ref./document LULU03-095

2015-09-10

Update of our test report STGM19-091 of August 08, 2011

INFORMATION ON SAMPLE AND CLIENT

Client details	:	Rexam Beverage Can Europe Ltd. Delaware drive Tongwell MK15 8HG UK
Requested analysis	:	Examination with respect to compliance with current requirements of the EU and the German food laws as well as US FDA Regulations
Start of assessment	:	2011-05-04
End of assessment	:	2011-08-31
Sample description	:	Beverage cans with internal lacquer Valspar 4020W01D, external decoration "Lift" and "Fanta", closed
Lab sample code	:	6819900
Sample received	:	April 18, 2011

1. PRESENTLY GOVERNING EU AND EU MEMBER STATES NATIONAL LEGISLATIVE CONTEXT

- Regulation (EC) No 178/2002
- Regulation (EC) No 1935/2004
- Regulation (EC) No 1895/2005
- Council of Europe Resolution AP (2004) 1
- CEPE Code of Practice for coated articles where the food contact layer is a coating, Edition 4,
- 21 CFR 175.300 US FDA Regulations

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2. EXAMINATION / TESTING PROCEDURE

2.1 Compositional evaluation of sample

The composition of lacquer **Valspar 4020W01D** was disclosed to the testing laboratory. The composition has been checked with regard to possible restrictions for the use of the applied starting substances for food contact applications. The evaluation of the compositional data covered all starting substances for which the chemical identity was disclosed to the testing laboratory. For each substance it was checked whether the substance is evaluated for food contact applications according to the requirements of the European Food Safety Authority (EFSA). The evaluations are mentioned for instance in the Food Contact Materials Database of the EU Commission, DG Sanco, Annexes to Regulation (EC) No. 10/2011, Council of Europe Resolution AP (2004) 1 or the CEPE Code of Practice.

In order to certify the compliance of the internal protection lacquer overall migration tests, selected specific migration tests and a sensory evaluation were carried out.

According to the results of our assessment all starting substances, with the exception of two catalysts*, used for manufacturing the protection lacquer **Valspar 4020W01D**, are evaluated according to EFSA requirements. All starting substances are permitted for the use in coatings according to CEPE Code of Practice and CoE Resolution AP (2004) 1 as well as CoE Resolution AP 92 (2).

All of the starting substances are permitted according to 21 CFR 175.300 of the US FDA Regulations.

According to the result of our assessment the following starting substances for which restrictions have been expressed are used.

Starting substance	PM-Ref. No.	SCF-List	Restriction	Remarks
Formaldehyde	17260	3	SML(T) = 15 mg/kg	
Bisphenol A	13607	2	SML = 0.6 mg/kg	
BADGE, BADGE.H_2O, BADGE.$2H_2O$	13510	2	SML = 9 mg/kg	
BADGE.HCl.H_2O, BADGE.HCl, BADGE.2HCl	-	3	SML = 1 mg/kg	
N.N-dimethylaminoethanol	16150	2	SML = 18 mg/kg	
Epichlorohydrin	16750	4A	QM = 1 mg/kg	
Methacrylic acid	20020	2	SML(T) = 6 mg/kg	
Catalyst A*	-	-	SML = 0.05 mg/kg	Res. AP 92 (2)
Catalyst B*	-	-	SML = 1 mg/kg	Res. AP 92 (2)

*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

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2.2 Migration / extraction conditions

The coated cans were filled with aqueous and non-aqueous solvents under test conditions which are suitable to simulate the influence of foodstuff.

The conditions for testing were applied in accordance to Regulation (EU) No 10/2011 which is since from May 1, 2011. The migration testing procedures described in Regulation (EU) No 10/2011 are designed and required for compliance testing of plastic food contact materials. Nevertheless the procedures were applied accordingly for migration testing of coated cans.

In applying 21 CFR 21 CFR 175.300 of the US FDA Regulations, the extraction into 8 % ethanol and n-heptane was determined.

a. Overall migration tests

The overall migration was determined as dry residue of the migrates. The organic components of the dry residue were determined as their chloroform soluble parts according to the requirements of 21 CFR 175.300.

b. Specific migration tests

The migrates were analysed for formaldehyde and bisphenol A.

The examination for formaldehyde was carried out using a photometric method.

The migration of BADGE as well as its chlorohydrin and water adducts and bisphenol A was examined in 3 % acetic acid, 20 % ethanol, 50 % ethanol and sun flower oil after sterilisation for 1 h at 121 °C and subsequent storage for 63 d 40 °C. The analysis of the aqueous migration solutions was carried out after extraction with ethanol and directly by RP-HPLC/ fluorescence detection. Sunflower oil was extracted with n-hexane/acetonitrile and tested by RP-HPLC/ fluorescence detection.

c. Residual starting substance tests

After extraction with methanol the lacquer film has been analysed for residual N.N-dimethylaminoethanol by gaschromatography with mass specific detection.

d. Organoleptic tests

The cans were filled with the flavour sensitive test solution tap water. The contact was carried out under various time/temperature conditions and surface/volume ratio of 1 can : 330 ml. The sensory evaluation was carried out as triangle tests by a taste panel with particular experience. As blank we used tap water which had not been in contact with the coating material. The evaluation was carried out in accordance with DIN 10 955 (German Institute for Standardisation).

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3. RESULTS

3.1 Compositional evaluation of sample

The protection lacquer **Valspar 4020W01D** contains 8 starting substances for which restrictions have to be regarded when the lacquer is used in contact with foodstuffs. Except Catalyst A* and B* all starting substances are evaluated according to EFSA requirements for food contact applications. According to our best knowledge Catalyst A* and B* are not categorised as CMR substances. According to current interpretation of the EU food law such substances may be used in food contact applications if their migration into foodstuffs does not exceed a concentration of 10 µg/kg (ref. CEPE Code of Practice Art. 4 , EuPIA Guideline). According to Council of Europe Resolution AP 92 (2) a specific migration limit of 0,05 mg/kg resp. 1 mg/kg for both catalysts* must not be exceeded.

Test results are corrected by results for the applied lid.

3.2 Migration

a. Overall migration tests

Simulants	t/T conditions	Dry residue of migrates mg/dm²	Chloroform soluble parts of dry residue mg/dm²
3 % acetic acid	1 h 121 °C + 10 d 40 °C	2.6	-
20 % ethanol	1 h 121 °C + 10 d 40 °C	1.9	-
50 % ethanol	1 h 121 °C + 10 d 40 °C	3.7	-
Isooctane	2 h 60 ° + 2 d 20 °C	1.3	-

Simulants	t/T conditions	Dry residue of migrates mg/in²	Chloroform soluble parts of dry residue mg/in²
8 % ethanol	2 h 65 °C	0.013	0.006
n-heptane	2 h 65 °C	< 0.006	< 0.006

*The identity of the components is known to the testing laboratory. It is kept under confidentiality by the raw material supplier.

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b. Specific migration tests

	Simulants	t/T condition	Results
Formaldehyde	3 % acetic acid 20 % ethanol	1 h 121 °C + 63 d 40 °C 1 h 121 °C + 63 d 40 °C	0.23 mg/dm² 0.20 mg/dm²
Bisphenol A	3 % acetic acid 20 % ethanol 50 % ethanol sunflower oil	1 h 121 °C + 63 d 40 °C 1 h 121 °C + 63 d 40 °C 1 h 121 °C + 63 d 40 °C 1 h 121 °C + 63 d 40 °C	0.003 mg/dm² 0.008 mg/dm² 0.002 mg/dm² n.d. (< 0.001 mg/dm²)

n.d. = not detectable

BADGE reaction products

3 % acetic acid 1 h 121 °C + 63 d 40 °C

	Results
BADGE	n.d. (< 0.001 mg/dm²)
BADGE.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.2H_2O	0.02 mg/dm²
BADGE.HCl.H_2O	0.001 mg/dm²
BADGE.HCl	n.d. (< 0.001 mg/dm²)
BADGE.2HCl	n.d. (< 0.001 mg/dm²)

n.d. = not detectable

20 % ethanol 1 h 121 °C + 63 d 40 °C

	Results
BADGE	n.d. (< 0.001 mg/dm²)
BADGE.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.2H_2O	0.02 mg/dm²
BADGE.HCl.H_2O	0.001 mg/dm²
BADGE.HCl	n.d. (< 0.001 mg/dm²)
BADGE.2HCl	n.d. (< 0.001 mg/dm²)

n.d. = not detectable

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50 % ethanol 1 h 121 °C + 63 d 40 °C

	Results
BADGE	n.d. (< 0.001 mg/dm²)
BADGE.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.2H_2O	0.03 mg/dm²
BADGE.HCl.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.HCl	n.d. (< 0.001 mg/dm²)
BADGE.2HCl	n.d. (< 0.001 mg/dm²)

n.d. = not detectable

Sunflower oil 1 h 121 °C + 63 d 40 °C

	Results
BADGE	n.d. (< 0.001 mg/dm²)
BADGE.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.2H_2O	n.d. (< 0.001 mg/dm²)
BADGE.HCl.H_2O	n.d. (< 0.001 mg/dm²)
BADGE.HCl	n.d. (< 0.001 mg/dm²)
BADGE.2HCl	n.d. (< 0.001 mg/dm²)

n.d. = not detectable

c. *Residual starting substance tests*

Methanol extraction, GC-MS

	Result
N.N-dimethylaminoethanol	n.d. (< 0.006 mg/dm²)

n.d. = not detectable

d. *Organoleptic tests*

Simulant t/T conditions	Surface/volume ratio	Appearance	Odour	Flavour
Tap water 1 h 121 °C + 10 d 40 °C	1 can : 330 ml	0.8	1.0	1.5

0 = no deviation detectable
1 = deviation slightly detectable
2 = slight deviation
3 = considerable deviation
4 = strong deviation

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4. EVALUATION OF RESULTS

Based on a surface area to volume ratio of 6 dm²/1 kg, the following statement can be made:

a. *Overall migration tests*

The dry residues of the migrates are below the limit mentioned in Resolution AP (2004) 1 of the Council of Europe. They are also lower than the limits mentioned in 21 CFR 175.300 of the US FDA Regulations concerning resinous coatings.

b. *Specific migration tests*

The analysis of the migrates showed no specific migration of formaldehyde and bisphenol A which could give reason for concerns.

Low concentrations of BADGE.$2H_2O$ and BADGE.H_2O.HCl were detectable in the aqueous migrates. The material is in compliance with Regulation (EC) No. 1895/2005.

c. *Residual starting substance tests*

The lacquer film does not contain detectable residues of N.N-dimethylaminoethanol

d. *Organoleptic tests*

The sensory evaluation showed no deviation which could give reason for doubts concerning creation of off-odours or off-flavours in food. Also there was no diffusion of colours and/or turbidity detectable.

5. CONCLUSION

According to the results of our evaluation the beverage cans internally coated with protection lacquer **Valspar 4020W01D** comply with regard to the composition and the migration properties with requirements of §§ 30 and 31 (1) of the Lebensmittel- und Futtermittelgesetzbuch (LFGB) (German Law Book on Foodstuff and Feeds) and Art 3 of Regulation (EC) No 1935/2004 as well as Regulation (EC) No 1895/2005.

The beverage cans internally coated with protection lacquer **Valspar 4020W01D** comply with requirements of 21 CFR 175.300 of the US FDA Regulations.

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Under conditions of appropriate application and under circumstances of destined and expected use it does not add any particles and/or components to food which are harmful to human health, which alter odour or flavour of food.

Braunschweig, 2015-09-10

INSTITUT NEHRING GmbH

Dr. Ulrich Nehring
General Manager

Dr. Ulrich P. Nehring
Von der Industrie- u. Handelskammer Braunschweig öffentl. best. u. vereid. Handels- u. Lebensmittelchemiker
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