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| S. Dubail/Dr. Peter Mayr April 4, 2017 | STWC48-117 (1716-030/1717-337) | 0531-23899-0 |

Examination of J3092 H401F056 6074010056 Protection Lacquer

We were appointed with the examination of **J3092 H401F056 6074010056 Protection Lacquer** with respect to current food legislation.

According to your information the material is intended to be used as internal protection lacquer for aluminium tubes in contact with all kind of foodstuff to be pasteurised and stored for more than six months.

This product is a slightly modified version of a tested protection lacquer (our test report STWC40-117 of December 6, 2017). Therefore the test results have been adopted from this test report.

In order to carry out the examinations we received a wet sample of the above mentioned lacquer and coated aluminium panels. We applied the wet sample onto suitable inert substrates by doctor application. The lacquer film was cured during 3 minutes at 260 °C resp. 6 minutes at 220 °C (PMT). The dry coating layer thickness was 7 – 11 µm.

The coated substrates were brought into contact 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 with Regulation (EU) No 10/2011 which is valid for plastic food contact materials and articles.

In applying 21 CFR 175.300 of the USA FDA Regulations, the extraction into n-heptane was determined.

Die Prüfergebnisse beziehen sich ausschließlich auf die Prüfgegenstände. Prüfberichte und Gutachten dürfen ohne Genehmigung des Prüfinstitutes weder vollständig noch auszugsweise vervielfältigt werden.

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D-PL-19570-02-00



PROCEDURE OF THE EXAMINATIONS

1. Evaluation of the lacquer composition

The composition of **J3092 H401F056 6074010056 Protection Lacquer** 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 Santé, Council of Europe Resolution AP (2004) 1, CEPE Code of Practice and 21 CFR 175.300 of the US FDA Regulations. Based on the results of the composition evaluation the required tests for specific migration and residual monomer contents in the lacquer have been selected. In addition the specific migration of BFDGE as well as its chlorohydrin and water adducts was examined.

2. Overall migration

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.

3. Analysis of the migrates

Each substance was analysed with the simulant which is regarded as the strictest migration solution due to chemical and/or physical properties of the resp. substance.

The migrates were analysed for formaldehyde, aluminium, bisphenol A and bisphenol F.

The specific migration of formaldehyde was carried out using a photometric method.

The concentration of aluminium was determined by ICP-MS.

The migration of BADGE and BFDGE as well as their chlorohydrin and water adducts, bisphenol A and bisphenol F was examined in 3 % acetic acid, 50 % ethanol and sunflower oil after pasteurisation for 1 h at 100 °C and 10 d at 60 °C. The analysis of the migration solutions was carried out after extraction with ethanol resp. directly by RP-HPLC/fluorescence detection.

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

4. Extraction of the lacquer film

The coating film has been examined by headspace GC-MS for residual Monomer A*.

After extraction with diethylether of the lacquer film the extract has been tested by gaschromatography with mass specific detection for residual epichlorohydrin.

After extraction with toluene the coating film has been analysed for residual polycyclic aromatic hydrocarbons (PAH) by gaschromatography with mass specific detection (GC-MS).

5. Sensory evaluation

The enamelled substrates were brought into contact with the flavour sensitive test solution tap water. The contact was carried out at defined time/temperature conditions and a surface/volume ratio of 1 cm² : 2 ml. The sensory evaluation was carried out as pairwise comparative test by a taste panel with particular experience. As blanks 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).

RESULTS OF THE EXAMINATIONS

1. Evaluation of the lacquer composition

According to the results of our assessment all starting substances used for manufacturing **J3092 H401F056 6074010056 Protection Lacquer** are evaluated according to EFSA requirements and 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.

Solvents of the "solvent naphtha" type may contain polycyclic aromatic hydrocarbons (PAH) as impurities. When solvent naphtha is used for the manufacture of lacquers PAH may be present in the cured coating film.

In order to estimate the toxicological relevance of a possible PAH contamination in food contact coatings naphthalene and benzo(a)pyrene can be taken as representative components because naphthalene usually occurs in rather high concentration in solvent naphtha and benzo(a)pyrene can be regarded as the most toxic component of PAH.

*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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For naphthalene EPA has established a Reference Dose for Chronical Oral Exposure (RFD) of 0.02 mg/kg b.w. /day (IRIS 1998, No 436). For benzo(a)pyrene, which is classified as carcinogenic, a Risk Level of 0.110 µg/kg food/day was established.

Taking a daily consumption of 0.5 kg food by a consumer with a body weight of 80 kg into account throughout a lifetime of 78 years a tolerance level, the so called "Level of Concern", for naphthalene of 1.6 mg/kg food can be estimated. For benzo(a)pyrene the "Level of Concern" is similar with the Risk Level of 0.110 µg/kg food.

According to the result of our composition check the following starting substances for which restrictions have been expressed are used:

| Starting substance | PM Ref. no | Restriction | Remarks |
|--|------------|------------------|-----------------------|
| Formaldehyde | 17260 | SML = 15 mg/kg | - |
| Aluminium | - | SRL = 5 mg/kg | CoE CM / Res (2013) 9 |
| BADGE, BADGE.2H ₂ O, BADGE.H ₂ O | - | SML = 9 mg/kg | - |
| BADGE.H ₂ O.HCl, BADGE.HCl, BADGE.2HCl | - | SML = 1 mg/kg | - |
| Bisphenol A | 13480 | SML = 0.6 mg/kg | - |
| Monomer A* | - | SML = 0.05 mg/kg | - |
| Epichlorohydrin | 16750 | QM = 1 mg/kg FP | - |
| Polydimethylsiloxane, gamma-hydroxypropylated | 76730 | SML = 6 mg/kg | - |
| Additive A* | - | SML = 3 mg/kg | - |
| Additive B* | - | SML = 2.4 mg/kg | - |

Taking the concentration in the lacquer system into account even under conditions of total migration polydimethylsiloxane, gamma-hydroxypropylated, Additive A* and Additive B* will not exceed their specific migration limits (SML) in the simulant or food.

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According to the results of our composition check two additives* which are permitted as food additives according to EU legislation have been identified as starting substances (dual use additives). These additives do not migrate, or because of their low concentration in the material they do not migrate according to our opinion in amounts, which could have technological effects in the food.

2. Overall migration

| Simulants | t/T conditions | Dry residue of migrates mg/dm ² | Cloroform soluble parts of dry residue mg/in ² |
|-----------------|----------------------------|---|---|
| 3 % acetic acid | 1 h 100 °C + 10 d 40 °C | 1.2 | - |
| 10 % ethanol | 1 h 100 °C + 10 d 40 °C | 1.6 | - |
| 50 % ethanol | 1 h 100 °C + 10 d 40 °C | 3.0 | - |
| Sunflower oil | 1 h 100 °C + 10 d 40 °C | 2.7 | - |
| n-heptane | 2 h 65 °C | < 1.0 | < 0.01 |

3. Analysis of the migrates

| | Simulants | t/T conditions | Results |
|--------------|-----------------|-------------------------|------------------------------------|
| Formaldehyde | 3 % acetic acid | 1 h 100 °C + 10 d 60 °C | 0.02 mg/dm ² |
| | 50 % ethanol | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.02 mg/dm ²) |
| Aluminium | 3 % acetic acid | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |
| Bisphenol A | 3 % acetic acid | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |
| | 50 % ethanol | 1 h 100 °C + 10 d 60 °C | 0.003 mg/dm ² |
| | sunflower oil | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |
| Bisphenol F | 3 % acetic acid | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |
| | 50 % ethanol | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |
| | sunflower oil | 1 h 100 °C + 10 d 60 °C | n.d. (< 0.001 mg/dm ²) |

n.d. = not detectable

*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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BADGE and BFDGE reaction products

3 % acetic acid, 1 h 100 °C + 10 d 60 °C

| | Results |
|----------------------------|------------------------------------|
| BADGE | n.d. (< 0.001 mg/dm ²) |
| BADGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.2H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.HCl.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.HCl | n.d. (< 0.001 mg/dm ²) |
| BADGE.2HCl | n.d. (< 0.001 mg/dm ²) |
| BFDGE | n.d. (< 0.001 mg/dm ²) |
| BFDGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.HCl.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2HCl | n.d. (< 0.001 mg/dm ²) |

n.d. = not detectable

50 % ethanol, 1 h 100 °C + 10 d 60 °C

| | Results |
|----------------------------|------------------------------------|
| BADGE | n.d. (< 0.001 mg/dm ²) |
| BADGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.2H ₂ O | 0.04 mg/dm ² |
| BADGE.HCl.H ₂ O | 0.006 mg/dm ² |
| BADGE.HCl | d.n.p. |
| BADGE.2HCl | n.d. (< 0.001 mg/dm ²) |
| BFDGE | n.d. (< 0.001 mg/dm ²) |
| BFDGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.HCl.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2HCl | n.d. (< 0.001 mg/dm ²) |

n.d. = not detectable

d.n.p. = determination not possible due to matrix interferences

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Sunflower oil, 1 h 100 °C + 10 d 60 °C

| | Results |
|----------------------------|------------------------------------|
| BADGE | n.d. (< 0.001 mg/dm ²) |
| BADGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.2H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.HCl.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BADGE.HCl | n.d. (< 0.001 mg/dm ²) |
| BADGE.2HCl | n.d. (< 0.001 mg/dm ²) |
| BFDGE | n.d. (< 0.001 mg/dm ²) |
| BFDGE.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.HCl.H ₂ O | n.d. (< 0.001 mg/dm ²) |
| BFDGE.2HCl | n.d. (< 0.001 mg/dm ²) |

n.d. = not detectable

4. Extraction test of the lacquer film

Headspace GC-MS, 0.5 h 150 °C

| | Result |
|------------|------------------------------------|
| Monomer A* | n.d. (< 0,001 mg/dm ²) |

n.d. = not detectable

Diethylether extraction, GC-MS

| | Result |
|-----------------|------------------------------------|
| Epichlorohydrin | n.d. (< 0.001 mg/dm ²) |

n.d. = not detectable

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Toluene extraction, GC-MS

| | Results** |
|-------------------------|------------------------------------|
| Naphthalene | 0.01 µg/dm ² |
| Acenaphthalene | n.d. (< 0.003 µg/dm ²) |
| Acenaphthene | n.d. (< 0.003 µg/dm ²) |
| Fluorene | n.d. (< 0.003 µg/dm ²) |
| Phenanthrene | 0.003 µg/dm ² |
| Anthracene | n.d. (< 0.003 µg/dm ²) |
| Fluoranthene | 0.003 µg/dm ² |
| Pyrene | 0.008 µg/dm ² |
| Benzo(a)anthracene | n.d. (< 0.003 µg/dm ²) |
| Chrysene | n.d. (< 0.003 µg/dm ²) |
| Benzo(b)fluoranthene | n.d. (< 0.003 µg/dm ²) |
| Benzo(k)fluoranthene | n.d. (< 0.003 µg/dm ²) |
| Benzo(a)pyrene | n.d. (< 0.003 µg/dm ²) |
| Indeno(1,2,3-c,d)pyrene | n.d. (< 0.003 µg/dm ²) |
| Dibenzo(a,h)anthracene | n.d. (< 0.003 µg/dm ²) |
| Benzo(g,h,i)perylene | n.d. (< 0.003 µg/dm ²) |

n.d. = not detectable

**Determination carried out by subcontractor

5. Sensory evaluation

| Simulants t/T conditions | Surface/volume ratio | Appearance | Odour | Flavour |
|--------------------------------------|--------------------------|------------|-------|---------|
| tap water 1 h 100 °C + 10 d 40 °C | 1 cm ² : 2 ml | 1.0 | 1.0 | 1.0 |

0 = no deviation detectable

1 = deviation slightly detectable

2 = slight deviation

3 = considerable deviation

4 = strong deviation

EVALUATION

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

1. Evaluation of the composition

J3092 H401F056 6074010056 Protection Lacquer contains nine starting substances for which restrictions have to be regarded when the lacquer is used in contact with foodstuffs. All starting substances are evaluated according to EFSA requirements for food contact applications.

2. Overall migration

The dry residues of the migrates are low and well below the limit mentioned in Resolution AP (2004) 1 of the Council of Europe. This applies to the overall migrates as well as to their chloroform soluble parts. They are also lower than the limits mentioned in 21 CFR 175.300 of the US FDA Regulations concerning resinous coatings.

3. Analysis of the migrates

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

Low concentrations of BADGE and its chlorohydrin and water adducts were detectable in the migrate with 50 % ethanol. The material is in compliance with Regulation (EC) No. 1895/2005.

4. Extraction test of the lacquer film

The coating film **does not** contain detectable residues of Monomer A* and epichlorohydrin.

Under applied test conditions no PAH were detectable in the lacquer film. The sum of extractable PAH was well below 0.03 µg/dm² (resp. 0.18 µg/kg for a surface/mass ratio of 6 dm²/1 kg).

When a total migration of the PAH is assumed and a Consumption Factor (CF) of 0.17 for coated metal as well as a daily consumption of 3 kg food is taken into account an Estimated Daily Intake (EDI) of 0.09 µg PAH or 0.03 µg/kg food can be calculated. This amount is significantly below the estimated "Level of Concern" for naphthalene of 1.6 mg/kg food and for benzo(a)pyrene of 0.110 µg/kg.

5. Sensory evaluation


The sensory evaluation showed no deviation which could give reason for doubts concerning creation of off-odours or off-flavours in food.

According to the results of our evaluation the **J3092 H401F056 6074010056 Protection Lacquer** complies with regard to its 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.

The lacquer complies with requirements of 21 CFR 175.300 of the US FDA Regulations provided that the polycyclic aromatic hydrocarbon content from the solvents is limited to a technologically unavoidable amount.

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.

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