



Certificate

Food safety assessment of a printed cellulose casing and a printed laminate casing

Client: Resino Trykfarver AS
2750 Ballerup, Denmark

Order: PA/4222/09

Samples: cellulose casing, (sample 2: 09/1003_02)
PA/PE/PA laminate casing (sample 3: 09/1003_03)
both printed with the printing ink system "Revalux 168-13"

The cellulose casing and the laminate casing were printed with Resino's water based printing ink system "Revalux 168-13". The printing ink formulation was disclosed to Fraunhofer IVV by the manufacturer on the basis of confidentiality.

Printing ink components used for materials in contact with foodstuff are not specifically regulated on national and EU level. The conformity with the general requirements for food contact materials as stated in Article 3 of the EU Framework Regulation (EC) No 1935/2004 needs to be assessed for the printing ink components.

Migration and screening studies of the casings were performed in order to assess the food safety of the printed ink layer (Fraunhofer IVV test report PA/4222/09 dated 23.11.2009). The migration potential of high volatile components originating from the printing was analysed using headspace gas GC-FID/MS. In addition, the dichloromethane extracts and the ethanolic migration solutions of the printed casings were analysed by GC-FID/MS for medium volatile components and by HPLC-MS for low volatile components related to the printing.

In the printed casings several residual solvents like ethanol, acetone and ethylene glycol monobutyl ether as well as the aldehyde 2-ethylacrylaldehyde were identified and (semi-)quantified. There are no specific requirements for residual levels of solvents established e.g. in the EU Plastics Directive 2002/72/EC for plastics in contact with food. However, according to Article 3 of the EU Framework Regulation materials and articles in contact with food must be manufactured so that they do not transfer their constituents to food in quantities which could bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof. It must be pointed out that solvents and aldehydes may already have a strong odour at low concentrations and therefore can bring about a change or deterioration, respectively, of the organoleptic characteristics of the packed food.

On EU level, an assessment of the use of ethylene glycol monobutyl ether in food contact materials was published in the "Synoptic document" (dated June 2005). The former Scientific Committee for Food (SCF) of the EU Commission has allocated a temporary group-TDI (tolerable daily intake) of 0,05 mg/kg body weight / day to ethylene glycol monobutyl ether and to eight other related substances. This TDI value corresponds to a specific migration limit of 3 mg/kg food. Based on the results of the headspace analysis this specific migration limit can not be exceeded for the printed casing samples.

In the ethanolic migration solutions of the printed casings glycerine and dibutyl sebacate were identified by screening analyses (Fraunhofer IVV test report PA/4222/09 dated 23.11.2009). Glycerine and dibutyl sebacate are authorized by the EU Plastics Directive 2002/72/EC (lastly amended by Regulation (EC) No 975/2009) without specific restrictions.

In addition, styrene and acrylic acid are approved as monomers for plastic materials for food contact application according to the EU Plastics Directive 2002/72/EC (lastly amended by Regulation (EC) No 975/2009). The migration of acrylic acid and styrene were not detectable in ethanolic migration solutions at a detection limit of 0,002 mg/dm² (acrylic acid) and 0,02 mg/dm² (styrene), respectively.

Furthermore, the specific migration of a substance used as crosslinker into the food simulant 95 % ethanol was investigated (Fraunhofer IVV test report PA/4222/09 dated 23.11.2009). The crosslinker was not detectable in the ethanolic migration solutions at a detection limit of 0,001 mg/dm² (area related migration) and 0,008 mg/kg (filling related migration), respectively. Therefore, the migration of the crosslinker complies with the limit of 0,01 mg/kg food(simulant) for non-evaluated printing ink components.

The limit of 0,01 mg/kg food(simulant) for non-evaluated printing ink components is derived from the "functional barrier" principle according to Article 7a of the EU Plastics Directive 2002/72/EC as well as from the recommendation of the Council of Europe¹ and the EuPIA guidelines² on the use of printing inks for food packaging materials and articles.

Based on the performed screening and specific migration analyses, the cellulose casing and the laminate casing comply with the safety requirements of Article 3 of the EU Framework Regulation (EC) No. 1935/2004 with respect to the used printing ink system and therefore can be used for the intended applications conditions cooking for up to 4 hours / 100 °C followed by long term storage.

¹ Council of Europe's policy statement concerning packaging inks applied to the non-food surface of food packaging; 2. version dated 10.10.2007

² EuPIA (European Printing Ink Association) "Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles" (dated April 2008)

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Freising, 21st May 2010



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