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31.10.2012

Declaration of compliance for materials and articles intended to come into contact with food

We confirm that films from PVC

Pentaclear® PVC BX-M185/08-51/9500-100_0-ZZZ

are suitable for food contact.

No post consumer recyclates are utilised in the production of these films.

The films are in accordance with the European Regulation (EC) No 1935/2004 of October 27th 2004, the EU Regulation No 10/2011 of January 14th 2011 incl. all amendments as well as the German Consumer Articles Ordinance of October 11th 2010.

The monomers and additives used to manufacture these products are listed in the EU Regulation No 10/2011 incl. all amendments and European Regulation (EC) No 1935/2004, which is implemented into the National Legislations of the European Community member states. Therefore the use of these substances is allowed in the European Community member states.

Specific substances like catalysts, pigments, coatings, and silicones etc. acc. to the European Regulation (EC) No 1935/2004 comply with the following Recommendations of the Council of Europe:

AP (89) 1	Pigments
AP (92) 2	Polymerisation Aids
AP (2004) 1	Coatings
AP (2004) 5	Silicones

Additionally the products are in compliance with the European packaging directive 94/62/EC and its amendments 99/42/EC, 99/177/EC, 2004/12/EC and 2005/20/EC.

... / 2

Food Legislation - Revision 08
00 / 17.01.2012
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Specifications on the use of the material or article

Referred to article 22, paragraph 2 of the EU Regulation No 10/2011, the migration measurements, which are consulted for the declaration of compliance, are based on the previous rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC to 31.12.2012. According to paragraph 2 of this article the declaration of compliance can be accomplished on migration measurements starting from 01.01.2013 till the first of December 2015, either according to the methods of the Annex to Directive 82/711/EEC or according to the article 17 and 18 of the EU Regulation No 10/2011, so that still sufficient transition periods for the actualization of the tests exists and we refer further on the already existing migration measurements.

Overall migration (OM):

The overall migration limit of 10mg/dm² is met.

- Food simulants: 3% acetic acid (for foods that have a hydrophilic character),
10% ethanol (for foods that have a hydrophilic character),
vegetable oil or substitute fat tests for fatty food
- Test conditions: 10 days at 40°C

Specific migration (SM):

Where the European or National Legislation stipulates specific migration limits (SML) for the monomers used or alternatively highest permitted amounts in the products (QM), at least one of these two requirements is met under the above-mentioned test conditions.

In the case of vinyl chloride (VC) both are met. For the residual content of vinyl chloride monomer (VC), we guarantee a value of < 0.5 ppm (in accordance with the EC-directive 78/142/EEC, annex I: < 1.0 ppm).

This information is based on our current state of knowledge and on information from our raw material supplier.

Further information about storage conditions is available in the technical documentation or for special cases from the technicians of Klöckner Pentaplast.

Colorants:

The pigmented films are free of diaryl based pigments.

... / 3

Food Legislation - Revision 08
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Dual Use Additives:

Dual Use Additives acc. to the EU Regulation No 10/2011 are additives which are authorised for the manufacture of plastic materials and articles is at the same time authorised as food additive or flavouring substance. The film can contain dual use additives. Due to our knowledge – based on the information provided by raw material suppliers – adequate information about the substances can be provided upon request.

General:

For the permissible conditions of use (time, temperature, type of food), which follow from our test conditions, please refer to the Official Collection of Test Methods according to National Legislation like § 64 of the German Food and Feed Law of December the 9th 2010 or rather the EU Regulation No 10/2011 as well as the Directives 85/572/EEC and 82/711/EEC with their amendments.

The adherence to the requirements of the European Regulation (EC) No 1935/2004, particularly the suitability of the articles for the intended use, the effect to impairment of organoleptic characteristics such as smell and taste of the food as well as the compliance to all possible restrictions, must be guaranteed by the person, who brings the articles into the circulation.

By observing the above regulations, we have fulfilled our duty of care regarding the compliance of the products we supply with legislation governing food contact applications. It is the responsibility of the user to test the suitability of our products for the intended food application. We accept no liability for losses arising from the inadequate suitability of our products for the food medium being used by you.

This letter is intended for your company only and replaces previous letters of conformance resp. Declaration of compliance for EU member states. After a break in delivery lasting more than 12 months, this letter ceases to be valid for new deliveries of the relevant product.

You will be informed of any changes in the composition of our above mentioned products which are relevant to food contact legislation.

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