

02 March 2017

General statement of Compliance for Water-based Varnishes

Hi-Tech Coatings International (hereafter referred to as "Hi-Tech") certifies that the water based varnishes they produce comply with the following regulations and industrial standards:

1. The product is manufactured in compliance with general and detailed rules on good manufacturing practice as defined by European Printing Ink Association (EuPIA) resulting from the Commission Regulation (EC) No 2023/2006. Hi-Tech holds ISO 9001 and ISO 14001 certificates.
2. The product complies with the EuPIA exclusion list of commodities for print colours and related products as well as the following regulations:
 - a. The amount of lead, chromium, cadmium and mercury falls according to the information we received from the raw material manufacturers below the total maximum threshold of 100 ppm given by Directive 94/62/EC (packing and wastage). Hence a conformity relating to the requirements on toys by German Standards Institute (DIN) EN-71-3 and CONEG Model Toxics Legislation is given.
 - b. Restriction of Hazardous Substances Directive II (RoHS-II) Directive 2011/65/EU
 - c. Regulation (EC) No 1895/2005 concerning the restriction of use of certain epoxy derivatives.
 - d. Council directive 78/142/EEC, relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.

3. According to the information of our raw material manufactures we can state that in the properly dried form the polymers used in the formulation of this product will comply with FDA Guideline 21CFR176.180 (Components of paper and paperboard in contact with dry food).

According to the information of our raw material manufactures we can state that the polymers used by us and our raw material suppliers find compliance, in the properly dried coating form, to FDA Guideline 21CFR176.170 (Components of paper and paperboard in contact with aqueous and fatty food) with the following limitations:

For use only in contact with foods of types IV-A, V and VII in table 1 of paragraph (C) 21CFR176.170, under use conditions E through G in table 2 of paragraph (C) 21CFR176.170, and with foods of types VIII and IX without use temperature restriction.

4. According to the information of our raw material manufactures we can state that all our used raw materials are not derived from the Jatropha Plant.
5. According to the information of our raw material manufactures we can state that all our used raw materials do not contain animal derived content.
6. According to the information provided by Hi-Tech's raw material suppliers the product does not contain the following substances:
 - Substances fulfilling one or more of the criteria defined in Article 57 of the EU REACH Regulation can be identified as "substances of very high concern" (SVHC) and put on the "candidate List for authorization" which is also called "REACH SVHC list". (including last ECHA update 12-01-2017 Halogenated Hydrocarbons
 - Mineral Oil Saturated Hydrocarbons (MOSH)
 - Mineral Oil Aromatic Hydrocarbons (MOAH)
 - Phthalate Plasticisers
 - Naphthalene Plasticisers
 - N-Methylpyrrolidone
 - PVC
 - PAK's (polycyclic aromatic hydrocarbon)
 - Formaldehyde
 - o-Nonylphenol, o-Phenylphenol
 - Organotin compounds
 - Boric acid and its derivatives
 - PFOA (Perfluorooctanoic acid)
 - PFOS (Perfluorooctanesulfonic acid)
 - FTOH (Fluorotelomer alcohols)
 - PFC (Perfluorocarbonic acid)
 - ITX (Isopropylthioxantone)
 - Benzophenone

- 4-Methyl Benzophenone
- Hydroxy Benzophenone
- Bisphenol A, F and S
- Nano – Materials

However any or all of the above may be present at background trace levels as they would naturally be found to occur in the environment.

Regulation (EC) No 1935/2004 requires that materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs or which are brought into contact with foodstuffs, must not transfer any components to the packed foodstuff in quantities which could endanger human health, or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

This means that the manufacturer of the finished article and the filler have the legal responsibility that it is fit for its intended purpose.

The selection of raw material follows substantially the recommendations of the Federal Institute for Risk Assessment (BfR), the Federal Office of Consumer Protection and Food Safety (BVL) and the U.S. Food and Drug Administration (FDA). Therefore, it may be assumed, that a print product manufactured by using the product meets the requirements of Regulation (EC) No 1935/2004, if the product has been used according to the technical data sheet or comparable technical information and by applying a state of the art production technique and a design of the food package that ensures that the print (ink and varnish) does not come into contact with the food.

Food packaging are made from several components (in addition to substrates like paper, board or plastics; printing inks, coatings, adhesive and other additives are used). Substances of all these components may interact with each other as well as with the food. The possibility of a migration and deterioration of characteristics of food does not only depend on the composition of the product, but of the additionally used components and printing conditions (such as printing speed and temperatures) as well. The components and printing conditions are determined by the manufacturer of the final packaging and are not subject to the control of Hi-Tech.

It is in the responsibility of the manufacturer of the final packaging and of the manufacturer of the final article to ensure that no substances from the packaging are transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. The verification of compliance with legal provisions may only be proven at the final product, the printed and/or coated food packaging. The manufacturer of the final article bears the responsibility for that final article is suitable for its intended use as food packaging.

The preceding information shall support the manufacturing of safe food. The information is given to the best knowledge on basis of the current state of knowledge and depends to some extent on statements and analysis of third parties (e.g. laboratories, providers of commodities); Hi-Tech does not assume any liability for the correctness of the statements and analysis of third parties. The certificate of compliance does not discharge customers and the manufacturer of the packaging from observing all applicable laws, provisions and instructions concerning health and safety, especially not from performing a risk assessment of the particular place of work and a safety assessment regarding food contact as well as the maintenance of a risk management system.

Hi-Tech Coatings International



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