

Food Legislation Status of Adhesives used in the Manufacture of Materials and Articles intended to come into Contact with Food

Version: March 2016

Legal provisions can change at short notice. This technical briefing note will therefore only be published online.

Compiled and revised by the Technical Committee Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe e.V. (German Adhesives Association), Düsseldorf, Germany.

General information concerning the series of TKPV Technical Briefing Notes “Conformity work relating to adhesives used in the manufacturing of materials and articles intended to come into contact with food”

A number of special legal requirements and industry standards apply to adhesives used in the manufacturing of materials and articles intended to come into contact with food - e.g. food packaging. This serves consumer protection. By compiling this series of technical briefing notes the Technical Committee Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe e.V. wants to make these legal requirements and industry standards more transparent. In this series, specific requirements regarding adhesives, their production as well as the selection procedures for appropriate adhesive raw materials will be described. Furthermore, they contain recommendations on the implementation of the Regulation concerning “good manufacturing practice” and hygienic standards during production.

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| TKPV 1 | Guideline – Food legislation status of adhesives used in the manufacturing of materials and articles intended to come into contact with food |
| TKPV 2 | Guideline – Food legislation status of adhesive raw materials for adhesives used in the manufacturing of materials and articles intended to come into contact with food |
| TKPV 3 | Guideline – “Good manufacturing practice” for adhesives used in the manufacturing of materials and articles intended to come into contact with food |
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1 Introduction

Materials and articles intended to come into contact with food must conform to special requirements and regulations concerning their safety in terms of food legislation and suitability for purpose. Adhesives play a major role in the production of food contact materials. Even during the development of products for such applications, the adhesive manufacturing industry already takes into account not only the technical requirements, but also food legislation aspects. The Technical Committee Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe has compiled this guideline in order to explain the complex food legislation issues by using food packaging as an example.

According to Article 3 of Regulation (EC) No 1935/2004, it is not only the distributor who is responsible for the composition of food packaging, but also the packer and packaging manufacturer. All of them are obliged to examine and determine whether incoming or outgoing goods comply with quality and suitability standards. This includes the evaluation of possible substance transfers to food (migration).

Downstream suppliers and adhesive manufacturers, among others, are usually notified by the packaging manufacturer of his requirements. He pays particular attention to the professional processing of the adhesive (good manufacturing practice) and ensures the suitability of his packaging through specific audits. Extensive and manifold requirements for food packaging necessitate – for their conception and creation – the cooperation of experts throughout all

of the production stages. Only when the adhesive manufacturer is as familiar with all of the conditions as the packaging manufacturer, will he be able to offer an adhesive tailored to those needs.

Ultimately, only the distributor or the filler/packer, can make the overall decision regarding whether a material and/or an article intended to come into contact with food is safe within the meaning of Article 3 of Regulation (EC) No 1935/2004. He is responsible for obtaining from his suppliers all data that offers information about possible interactions of materials and articles intended to come into contact with food and with the food itself. Based on this data he must also make an evaluation within the context of above mentioned Regulation or have this carried out by an authorized institute.

2 Legal Basis

2.1 European Regulation (EC) No 1935/2004

Decisive for an evaluation of materials and articles intended to come into contact with food is Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

Article 1 defines the purpose, subject matter and scope of this Regulation.

General requirements are described in Article 3:

Article 3 – General Requirements

1. *Materials and articles, [...], shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:*

- (a) *endanger human health;*
or
- (b) *bring about an unacceptable change in the composition of the food;*
or
- (c) *bring about a deterioration in the organoleptic characteristics thereof.*

...

Article 5 of the Regulation refers to Annex I, in which materials and articles are listed for which specific measures may be adopted. Article 5 further describes the scope of such possible measures. Annex I also lists adhesives for which no specific measures currently exist.

Article 6 permits Member States to adopt and maintain additional specific national provisions.

Article 16 stipulates that the specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration of conformity. A specific measure as defined in Article 5 does not yet exist for adhesives. Therefore, no legal basis currently exists for issuing declarations of compliance for adhesives. However, in order to provide necessary information in the supply chain, the member companies of the Industrieverband Klebstoffe have voluntarily agreed upon an information format for food contact materials which describes the food legislation status of adhesives (see page 7/8, IVK Information Format). Such an information format can also be used where specific national provisions should apply to the food contact material.

Beyond this, members of the Industrieverband Klebstoffe have agreed upon an information format describing the food legislation status of adhesive raw materials. This format will be described in greater detail in the TKPV-Technical Briefing Note 2 "Guideline - Food legislation status of adhesive raw materials for adhesives used in the manufacturing of material and articles intended to come into contact with food."

Article 17 regulates the traceability of materials and articles covered by the Regulation.

This Regulation shall be binding in its entirety and directly applicable in all EEA States (EU Member States, plus Norway, Iceland and Liechtenstein).

2.2 Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) [German Foods, Consumer Goods and Feedstuffs Code]

The requirements of Article 3 of Regulation (EC) No 1935/2004 can be found in §§ 30 and 31 of the LFGB:

§ 30: "It is prohibited

1. *To manufacture or treat articles in such a manner that through their intended purpose or foreseeable use, their material composition renders them, especially through toxicological composite substances or contamination, a health hazard."*

§ 31 (1): *"It is prohibited to circulate or utilize materials and articles intended to come into contact with food, in the meaning of § 2 (6) sentence 1 point 1, that do not comply with the requirements laid down for their manufacture in Article 3 (1) of the Regulation (EC) No 1935/2004."*

2.3 Specific Regulations

The requirements for the materials listed in Annex I and for articles intended to come into contact with food are set forth in greater detail in the specific EU measures (according to Article 5). Of the 17 groups of materials and articles for which specific measures can be adopted mentioned in Annex I to Regulation (EC) No 1935/2004 only a few are actually subject to specific regulations.

2.3.1 Plastic Materials Regulation (EU) No 10/2011

Materials and articles, for example made of plastic and intended to come into contact with food, have been regulated specifically in Regulation (EU) No 10/2011 of 14.01.2011. This Regulation and its supplements (see section 6) replace Directive 2002/72/EC on plastic materials.

Article 12 establishes the overall migration limit of substances released from materials and articles into food, covered by the definition in Article 2 of the Regulation. According to Article 12, Sentence 1, the total of constituents released shall not exceed an overall migration limit of 10 mg/dm² of surface area. Article 12, Sentence 2 stipulates that the overall migration limit of constituents released into food intended for infants and young children shall not exceed 60 mg/kg of food. Additionally, Article 11 defines specific migration limits (SMLs) for certain substances contained in materials and articles – regulated by Regulation (EU) No. 10/2011 – intended to come into contact with food.

For the manufacture of materials and articles made of plastic, plastic composites and plastic layers in multi-layered composite materials and articles intended to come into contact with food, the following applies: Since the Regulation is based upon the positive lists principle, only substances can be used that have been authorized explicitly in accordance with Articles 5 and 6.

In accordance with Article 6, Sentence 4, non-intentionally added substances (NIAS) may also be present which, for instance, can originate from approved substances in the form of contaminants.

Article 13 contains information about substances that may not be used. These are primarily those substances not contained in the Union list and classified as 'mutagenic', 'carcinogenic', or toxic to reproduction, together with substances having nanostructures, unless they are not shown in the Union list under "Specifications".

In accordance with the definition of the EU Commission, a nanomaterial is: *"a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one*

or more external dimensions is in the size range 1 nm - 100 nm."

Most dispersions used in the adhesive sector comprise larger sized particles and, when used properly, the adhesives form films with dimensions that far exceed 100 nm. Provided that the adhesive manufacturer does not indicate otherwise for a particular product, one may assume that polymer dispersions do not fall under the provisions of the European Commission's Recommendation 2011/696/EU (see EPDLA Position Papier, section 6).

2.3.2 Union Guidance on Regulation (EU) No. 10/2011

This published Union Guidance is intended to provide assistance in the interpretation and implementation of issues relating to the declarations of conformity, the conformity assessment and the communication of this information throughout the "food contact materials" supply chain.

Adhesives for the manufacture of food contact materials made of plastics/plastic composites are referred to in this Union Guidance as "non-plastic intermediate materials".

Paragraph 4.3.2 lists all of the relevant points that a manufacturer of "non-plastic intermediate materials" must communicate within the supply chain. The information format used by member companies of the IVK (see annex) takes all of the elements required by the Union Guidance into consideration.

2.3.3 Adhesives

Adhesives do not necessarily consist of the same substances as plastics. Regulation (EC) No 1935/2004 already provides for the issuance of a specific measure for adhesives. Because of this, different substances are permitted in the adhesive layers of materials and articles made of plastic than in those for plastics that are allowed in the EU. The composition of these adhesive layers can be regulated by other EU Regulations or national laws.

The composition of adhesives used in the manufacture of materials and articles intended to come into contact with food, must be such, that the finished goods in which they were used must fulfil the requirements of Article 3 of Regulation (EC) No 1935/2004. In the absence of an adhesive-specific regulation, information for the risk assessment can be taken from specific EU regulations such as the above-mentioned Regulation (EU) No 10/2011 (plastic materials regulation). This applies particularly to specific limits (e.g. SMLs) relating to the substances used in the adhesives.

2.4 International Regulations

In particular companies with global operations frequently request a declaration that the products are approved in terms of food legislation in accordance with the requirements of the US FDA (Federal Food, Drug & Cosmetic Administration).

A further option for describing the status of the product in terms of food legislation results from this. It must, however, be stated that declarations pursuant to FDA regulations have no legal basis whatsoever for the European market.

For this purpose it must be ensured that the food contact material fulfils the requirements of the FDA paragraphs (e.g. 21 CFR § 175.105). It should be noted here that these FDA regulations describe specific applications, paragraph-by-paragraph, and therefore differentiate between whether or not functional barriers exist when the adhesive is used. FDA testing therefore not only demands a review of the chemical composition of a product, but it is also necessary to provide information about the end application.

3 Implementing and Managing Legal Requirements when using Adhesives in Food Packaging

Since there is to-date no EU specific measure relating to adhesives, legally binding declarations of conformity in accordance with Article 16 or Article 5 of Regulation (EC) No 1935/2004 cannot be issued. Therefore, the evaluations of the European authorities (EFSA) should be preferably consulted in order to gain information concerning the food legislation status of an adhesive used in the manufacture of materials and articles intended to come into contact with food.

3.1 Specific National Measures

Until a related EU specific measure for adhesives has been published, national regulations of EU Member States can also be consulted when assessing all raw materials necessary for the manufacturing of adhesives, e.g. the pertinent German BfR-recommendations.

3.2 Olfactory and Gustatory Safety (Organoleptic Influence)

Olfactory and gustatory safety is difficult to define objectively. It can only be assessed through sensory analysis, i.e. using systematic taste and smell tests carried out by appropriate test technicians (DIN 10955). Packaging can influence the taste and smell of food. The following parameters play a role:

- The type and structure of packaging
- The processing, filling and/or storage conditions and/or
- The properties of packaging and auxiliary materials

The latter includes adhesives. Since food has different sensitivities, sensorial tests can only be performed appropriately with the corresponding food or an appropriate food simulant and the intended packaging.

By working closely together with the respective packer, adhesive manufacturers take into account the aforementioned aspects. Already during the formulation of adhesives for the manufacture of materials and articles intended to come into contact with food, they purposefully select corresponding raw materials. It can be assumed that inadmissible sensorial influences of food will not occur when adhesives are used professionally and for their intended purpose.

3.3 Description of the Food Legislation Status of Adhesive Raw Materials

In the absence of an EU specific measure for adhesives, the declaration of conformity requested in Article 16 of Regulation (EC) No 1935/2004 does not apply to adhesives. Nevertheless, it is necessary to exchange an adequate level of information throughout the supply chain in order to ensure a high safety standard of materials and articles intended to come into contact with food. For this reason, the members of the Industrieverband Klebstoffe have agreed on a format for the communication of all relevant information (see IVK Information Format).

This identifies several options for communicating the necessary information. The common denominator in all of this is that all substances capable of migrating are subject to the limitations (e.g. specific migration limits or ADI values) and are listed with information on the limitations, unless it can be ensured through other means that these limitations can be safely adhered to.

4 Packaging Suitability

4.1 Filling Material Resistance and Conditions of Use

Food packaging must be resistant to the filling material. In principle, this means that it has to be suitable for packaging the respective filling material. This applies to both the intended as well as the unintended (reasonably be expected) brief food contact of its individual constituents during practical use. It must therefore be guaranteed that, in any event, any interaction between materials and articles intended to come into contact with

food and the filling material – that could lead to the filling material negatively affecting health, odour or taste – is excluded. Under the influence of the respective filling material (that can be e.g. dry, granulated, hard, soft, pasty, sticky, fluid, watery, hygroscopic, sour, fat, oily) the adhesive should not lose its adhesive strength on the packaging material or change the shape of the packaging. The adhesive may not e.g. discolour, become soft or show any other types of alteration. Therefore, depending on the type of packaging, the processing, transport and storage conditions, and the filling material itself, specifically suitable and often very different adhesives are used.

4.2 Migration from other Packaging Components

Food packaging generally consists of several components. Apart from paper, cardboard and/or plastics, printing inks, varnishes, waxes and a wide range of other adjuvants are also used when manufacturing materials and articles intended to come into contact with food. The above-mentioned EU Regulations approach this issue holistically: Substances can migrate into the food from any single packaging component, whereby the sum of all specific migration limits of a substance may not be exceeded. Which substances in particular migrate to food – and in which concentrations – depends upon several factors. These include the composition of the packaging material and/or on the adjuvants applied, the storage conditions and duration, and – decisively – also on the type of filling material.

5 Summary

During the manufacture of food packaging, the members of the Industrieverband Klebstoffe work closely together with the packaging manufacturer and the packer. They select the adhesives for the manufacture of materials and articles intended to come into contact with food in such a manner that they can comply with all legally binding requirements. Possible migrations from these adhesives are evaluated according to existing EU or national regulations of the EU Member States (e.g. BfR recommendations). Generally one has to consider that the adhesive manufacturer only delivers a subcomponent of the finished food packaging. He can neither influence the proper processing of his product nor the other components. The legislator has therefore determined that the distributor of materials and articles intended to come into contact with food, and/or the packaged foods, is fully accountable for ensuring that the finished products fulfil the legal requirements.

6. Relevant Legal Regulations and Position Papers

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Amended by:

Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009

Commission Regulation (EU) No 10/2011 of 14 January 2011

on plastic materials and articles intended to come into contact with food

Last amended by:

Commission Regulation (EU) No 202/2014 of 5 February 2015

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) [German Food, Contact Materials and Animal Feed Code] of 3 June 2013

Redrafted through announcement of 3.6.2013 I 1426

Last amended by: Article 2 par. 33 and Article 4 par. 20 G of 7.8.2013 I 3154

Commission recommendation of 18 October 2011 on the definition of nanomaterials (2011/696/EU)

EPDLA's position paper on polymer dispersions and nano-technology

European Polymer Dispersion and Latex Association (EPDLA)

Avenue E. van Nieuwenhuysse 4 (box 2)

B - 1160 Brussels

Union Guidance on Regulation (EU) No. 10/2011 on materials and articles intended to come into contact with food, in relation to the communication of information throughout the supply chain

Commission Regulation (EU) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

Industrieverband Klebstoffe - Information Format Describing the food legislation status of adhesives used in the manufacturing of materials and articles intended to come into contact with food

Sender/Address Adhesive Manufacturer xyz

To
Adhesive Manufacturer xyz

Date: Date of document creation

Subject: Food Legislation Status of our Adhesive X

Dear Sir or Madam,

We herewith confirm the food legislation status of our adhesive X as follows:

The adhesive meets the relevant requirements of framework Regulation EU No. 1935/2004 and allows food contact materials to be manufactured such that these also comply with the requirements of framework Regulation 1935/2004. The prerequisite for this is the observance of good manufacturing practice and of the information set forth below.

Option A

The adhesive is produced exclusively with adhesive raw materials, whose starting substances are listed in the Union list of the Regulation (EU) No 10/2011.

The following limitations apply:

| Starting substances | CAS No./EINECS FCM No./REF.No./E No./FL No. | Regulation/limitation | Conc. in adhesive x (mg/kg) |
|---|--|---|--------------------------------|
| e.g. vinyl acetate | CAS 108-05-4 | SML: ((EU) No.10/2011)/12 mg/kg | Indic. recommended (max. val.) |
| e.g. waxes, paraffinic, refined, low viscosity | REF No. 95858 | SML: (EU) No. 10/2011)/0.05 mg/kg *see below for further limitations | Indic. recommended (max. val.) |
| Other substances | | | |
| e.g. acetaldehyde | CAS 75-07-0 | SML(T): ((EU) No.10/2011)6 mg/kg | Indic. recommended (max. val.) |

* Not for use with articles that come into contact with greasy foodstuffs for which food simulant D is defined. Average molecular weight: at least 350 Da. Viscosity at 100°C: at least 2.5 cSt (2.5×10^{-6} m²/s). Content of hydrocarbons with carbon number less than 25: not more than 40% w/w

Information about reaction products that can occur during further processing of the adhesive will not be considered here, e.g. through pyrolysis.

Option B

During the manufacture of the adhesive (beyond Option A) substances are used that are not listed in the Union list of Regulation (EU) No 10/2011. However, these non-listed substances fulfil the requirements of national regulations (of the EU Member States), e.g. a BfR recommendation.

The following limitations apply:

| Starting substances | CAS No./EINECS FCM No./REF.No./E No./FL No. | Regulation/limitation | Conc. in adhesive x (mg/kg) |
|-------------------------|--|-----------------------------------|--------------------------------|
| e.g. vinylsulfonic acid | CAS 1184-84-5 | BfR XIV/< 8% | Indic. recommended (max. val.) |
| e.g. vinyl acetate | CAS 108-05-4 | SML: ((EU) No. 10/2011)/12 mg/kg | Indic. recommended (max. val.) |
| e.g. emulsifier | FCM 799 | SML: ((EU) No. 10/2011)/1.8 mg/kg | Indic. recommended (max. val.) |
| Other substances | | | |
| e.g. acetaldehyde | CAS 75-07-0 | SML(T): ((EU) No.10/2011)/6 mg/kg | Indic. recommended (max. val.) |

Information about reaction products that can occur during further processing of the adhesive will not be considered here, e.g. through pyrolysis.

Option C

The adhesive contains substances that are listed in the Union list of Regulation (EU) No 10/2011 or comply with requirements of national regulations (of the EU Member States) e.g. a BfR recommendation. Furthermore, the adhesive contains substances (one or more) whose safe use is regulated by other ordinances (e.g. as food additives or flavouring substances pursuant to Regulations (EC) No. 1333/2008 and No. 1334/2008 (dual use substances).

The following limitations apply:

| Starting substances | CAS No./EINECS FCM No./REF.No./E No./FL No. | Regulation/limitation | Conc. in adhesive x (mg/kg) |
|----------------------------|--|--|--------------------------------|
| e.g. vinylsulfonic acid | CAS 1184-84-5 | BfR XIV/< 8% | Indic. recommended (max. val.) |
| e.g. vinyl acetate | CAS 108-05-4 | SML: ((EU) No. 10/2011)/12 mg/kg | Indic. recommended (max. val.) |
| e.g. emulsifier | FCM 799 | SML: ((EU) No. 10/2011)/1.8 mg/kg | Indic. recommended (max. val.) |
| e.g. potassium sulphate | CAS 7778-80-5 | GRAS (21 CFR 184.1643)/ Amount: max. 0.5% | Indic. recommended (max. val.) |
| Other substances | | | |
| e.g. acetaldehyde | CAS 75-07-0 | SML(T): ((EU) No.10/2011)/6 mg/kg | Indic. recommended (max. val.) |
| e.g. benzoic acid | E 210 | ADI: 5 mg/kg bodyweight and day | Indic. recommended (max. val.) |
| e.g. quinine hydrochloride | FL14.011 | In categories 14.1. and 14.2 (drinks) maximum 100 mg/kg | Indic. recommended (max. val.) |

Information about reaction products that can occur during further processing of the adhesive will not be considered here, e.g. through pyrolysis.

Option D

The adhesive also contains substances (beyond Option C) for which no regulations exist. A risk assessment of these substances has to ensue. This assessment can be implemented by the adhesive raw material manufacturer, the adhesive manufacturer or other parties in the supply chain. Prerequisite for this is the designation of these non-regulated substances.

The following limitations apply:

| Starting substances | CAS No./EINECS FCM No./REF.No./E No./FL No. | Regulation/limitation | Conc. in adhesive x (mg/kg) |
|----------------------------|--|--|--------------------------------|
| e.g. vinylsulfonic acid | CAS 1184-84-5 | BfR XIV/< 8% | Indic. recommended (max. val.) |
| e.g. vinyl acetate | CAS 108-05-4 | SML: ((EU) No. 10/2011)/12 mg/kg | Indic. recommended (max. val.) |
| e.g. emulsifier | FCM 799 | SML: ((EU) No. 10/2011)/1.8 mg/kg | Indic. recommended (max. val.) |
| e.g. potassium sulphate | CAS 7778-80-5 | GRAS (21 CFR 184.1643)/ Amount: max. 0.5% | Indic. recommended (max. val.) |
| Other substances | | | |
| e.g. acetaldehyde | CAS 75-07-0 | SML(T): ((EU) No.10/2011)/ 6 mg/kg | Indic. recommended (max. val.) |
| e.g. benzoic acid | E 210 | ADI: 5 mg/kg bodyweight and day | Indic. recommended (max. val.) |
| e.g. quinine hydrochloride | FL14.011 | In categories 14.1. and 14.2 (drinks) maximum 100 mg/kg | Indic. recommended (max. val.) |
| e.g. Methanol | CAS 67-56-1 | No evaluation | Indic. recommended (max. val.) |

Information about reaction products that can occur during further processing of the adhesive will not be considered here, e.g. through pyrolysis.

Option E

The safety in terms of food legislation of the adhesive for the intended purpose has been proven through appropriate testing performed by a specialist department/an external laboratory/institute. Please find attached a copy of the test report. Any limitations listed in this report must be observed.

Option F

The adhesive meets the requirements of FDA paragraphs xyz (e.g. 21 CFR 175.105 "Adhesives"), which are not valid in Europe, and may be used for the manufacture of adhesives/food packaging in accordance with the provisions of the Federal Food, Drug and Cosmetic Act.

In accordance with the relevant provisions, however, an overall assessment of the food contact material in terms of its end use is required and this can only be carried out by the supplier. This also encompasses a sensory assessment of the organoleptic properties

With kind regards,

The recommendations and data given in this technical briefing note are to the best of our knowledge in keeping with the present state-of-the-art. They are intended purely for information and as non-committal guidelines. Therefore, no warranty claims can be derived from them.

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