

# **Food Contact Status of Adhesives / Raw Materials**

- A voluntary agreement between the member companies of Industrieverband Klebstoffe e.V. (German Adhesives Association) -

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**Although there is no legal obligation for the declaration of compliance for adhesives/raw materials deriving from the European food contact legislation, the member companies of the German Adhesives Association (Industrieverband Klebstoffe e.V.) have voluntarily agreed upon an information format for products used in food contact and/or food-related applications.**

This agreement describes the legal food contact status of products along the value chain >> adhesive raw material manufacturers ↔ adhesive manufacturers ↔ down-stream users <<.

Furthermore this agreement emphasises the high degree of commitment and responsibility of IVK-members with respect to adequate consumer information throughout the food contact and/or food-related value chain.

This briefing note describes the legal background as well as the information format itself.

### Legal Basics

The EU-framework regulation 1935/2004 "Materials and Articles intended to come into Contact with Food" dated Oct. 27, 2004 is applicable for the European Market. This regulation defines the general conditions for the

suitability of materials and objects which - as packaging and/or convenience products - are intended to come in contact with food. Furthermore this framework regulation refers to specific regulations for individual food-contact relevant articles and/or materials such as plastics, ceramics, regenerated celluloses, etc. Annex I to this regulation announces *inter-alia* a specific directive/regulation for adhesives. This means that – at present – there is no adhesives/ raw material-specific regulation/directive on a European level.

Therefore there is no legal obligation for adhesives/raw material manufacturers to deliver declaration of compliance as described in article 16 of the European framework regulation 1935/2004!

However, article 6 of the European framework regulation 1935/2004 allows the application of national regulations, provided they are consistent with the contract agreements. The recommendations of the German Health Agency (Bundesamt für Risikobewertung = BfR - formerly BGVV and BGA) are legally recognised as applicable national regulations. Thus, a combination of these recommendations and other relevant EU-food contact regulations (e.g. the EU-Plastic-Directive 2002/72/EG) can be used to describe the legal food contact status of adhesives/raw materials.

The following options for the description of legal food contact status of adhesives/raw materials for food contact and/or food related applications have been derived from a combination of the BfR recommendations and the EU Plastics Directive:

#### **Option A Adhesive formulation meets the requirements of the EU Plastics Directive 2002/72/EG**

##### **Verification:**

1. It must be verified that the product composition corresponds with the requirements of the EU Plastics Directive 2002/72/EG, Annex II "Monomers and other Starting Substances" and Annex III "Additive-List".
2. It must be determined whether there are specific migration limits (SML) for substances used to formulate the product.

##### **Declaration:**

The product composition is in compliance with the requirements of the EU-Plastics-Directive 2002/72/EG, Annex II „Monomers and other Starting Substances“, as well as Annex III “Additive-List”.

If SMLs exist:

Please note the specific migration limit(s) for the following substance(s):

<b>Substance</b>	<b>Restriction/Limit</b>	<b>Concentration in Product x (mg/kg)</b>
e.g. Vinyl acetate	SML: 12 mg/kg	declaration optional

**Option B Adhesive formulation meets the requirements of a BfR recommendation and it contains components which are listed in the annexes of the EU Plastics Directive.**

**Verification:**

1. It must be verified that the product composition corresponds with the requirements of the relevant BfR recommendation (e.g. BfR XIV "Plastic-Dispersions").
2. It must be determined whether there are BfR recommendation restrictions, e.g. regarding concentration limits for certain substances.
3. It must be verified whether substances used to formulate the product are listed in Annex II „Monomers and other Starting Substances“ and/or Annex III „Additive-List“ of the EU-Plastics-Directive 2002/72/EG and whether there are specific migration limits (SML) for the substances used.

**Declaration:**

The product composition is in compliance with the requirements of the BfR recommendation "xyz" (e.g. BfR XIV "Plastic-Dispersions"). It contains components which are positively listed in the EU-Plastics-Directive 2002/72/EG, Annex II "Monomers and other Starting Substances" and/or Annex III "Additive-List".

If SMLs or other restrictions exist:

Please note the specific migration limit(s) and/or other specific restrictions for the following substance(s):

<b>Component</b>	<b>Restriction/Limit</b>	<b>Concentration in Product x (mg/kg)</b>
e.g. Vinyl sulfone acid	<i>amount: max. 8% (BfR XIV)</i>	<i>declaration optional</i>
e.g. Vinyl acetate	<i>SML: 12 mg/kg</i>	<i>declaration optional</i>
e.g. Emulsifier	<i>SML: xx mg/kg</i>	<i>declaration optional</i>

**Option C Adhesive formulation contains one or more components which are neither listed in a BfR recommendation nor in the EU Plastics Directive but for which other expedient rules are existing and applicable.**

**Verification:**

1. First it must be verified whether for these components other expedient applicable rules are existing.

**Declaration:**

The product composition is in compliance with the requirements of the BfR recommendation "xyz" (e.g. BfR XIV "Plastic-Dispersions") and/or with the EU-Plastics-Directive 2002/72/EG, Annex II "Monomers and other Starting Substances" and/or Annex III "Additive-List". The product contains (one or more) components, where the safe use/application is regulated by other guidelines.

If SMLs or other restrictions exist:

Please note the specific migration limit(s) and/or other specific restrictions for the following substance(s):

<b>Component</b>	<b>Restriction</b>	<b>Concentration in product x (mg/kg)</b>
e.g. Vinyl sulfone acid	<i>amount: max. 8% (BfR XIV)</i>	<i>declaration optional</i>
e.g. Vinyl acetate	<i>SML: 12 mg/kg</i>	<i>declaration optional</i>
e.g. Emulsifier	<i>SML: xx mg/kg</i>	<i>declaration optional</i>
e.g. Potassium sulfate	<i>amount: max. 0,5%</i>	<i>GRAS(21CFR 184.1643)</i>

**Option D**      **The formulation of a product contains one or more components which are neither listed in a BfR recommendation nor in the EU Plastics Directive, and for which there are no other expedient rules are existing.**

**Verification: / Declaration**

The safe use of the product must be verified by means of a suitable and appropriate testing.

### International Regulations

International companies often request declarations of compliance of products according to the regulations of the US-American FDA (Federal food, Drug & Cosmetic administration).

A fifth option (option E) for the description of the food contact status results from these requests, however, it is important to note that a declaration of compliance according to FDA have no legal significance in the European Market!

**Option E**      **Adhesive formulation and its use/application meets the requirements of a FDA-Regulation (e.g. 21 CFR175.105).**

**Verification:**

It must be ensured that the product formulation and its use/application meet the requirements of the respective FDA-paragraph. It should be considered that the FDA regulations describe specific uses/applications, paragraph by paragraph, and that the requirements vary depending on whether functional barriers are existing or not. Thus, not only the chemical composition of a product, but also the appropriate information on the down-stream use (end use/application) is relevant for the description of the food contact status according to FDA.

**Declaration:**

The product is suitable to be used for the manufacture of food-packaging according to paragraph xyz (e.g. 21 CFR 175.105 "Adhesives") Federal Food, Drug and Cosmetic Act.

### Migration Characteristics

Food packaging can be manufactured using different components/materials (paper, cardboard, foils, printing inks, plastic, etc) which could contain individual constituents with the ability to migrate.

In spite of the existing potential of migration of the different packaging components, there are other factors, such as the packaging design, coating

weight, time, material composition and finally the packed food itself which can determine the process of migration.

Being fully aware of this complexity, the legislator has assigned the responsibility for the approval/confirmation on the total amount of migration from a final food-packaging product to the food industry (packager).

## Template

### Confirmation of the Food Contact Status of Adhesives/Raw Materials

**Sender/Address Raw Material Supplier xy**

To  
Adhesive Manufacturer xy

**Subject.: Food Contact Status of our Product X**

**Dear Sirs,**

**We herewith would like to confirm the food contact status of our product X as follows:**

#### **Option A**

The product composition is in compliance with the requirements of the EU Plastics Directive 2002/72/EG, Annex II „Monomers and other Starting Substances“, as well as Annex III “Additive-List”.

Please note the specific migration limit(s) for the following substance(s):

<b>Substance</b>	<b>Restriction/Limit</b>	<b>Concentration in Product x (mg/kg)</b>
e.g. Vinyl acetate	<i>SML: 12 mg/kg</i>	<i>declaration optional</i>

#### **Option B**

The product composition is in compliance with the requirements of the BfR-Recommendation “xyz” (e.g. BfR XIV “Plastic-Dispersions”). It contains components which are positively listed in the EU Plastics Directive 2002/72/EG, Annex II “Monomers and other Starting Substances” and/or Annex III “Additive-List”.

Please note the specific migration limit(s) and/or other specific restrictions for the following substance(s):

<b>Component</b>	<b>Restriction/Limit</b>	<b>Concentration in Product x (mg/kg)</b>
e.g. Vinyl sulfone acid	<i>amount: max. 8% (BfR XIV)</i>	<i>declaration optional</i>
e.g. Vinyl acetate	<i>SML: 12 mg/kg</i>	<i>declaration optional</i>
e.g. Emulsifier	<i>SML: xx mg/kg</i>	<i>declaration optional</i>

#### **Option C**

The product composition is in compliance with the requirements of the BfR-Recommendation “xyz” (e.g. BfR XIV “Plastic-Dispersions”) and/or with the EU-Plastics-Directive 2002/72/EG, Annex II “Monomers and other Starting Substances” and/or Annex III “Additive-List”. The product contains (one or more) components, where the safe use/application is regulated by other guidelines.

Please note the specific migration limit(s) and/or other specific restrictions for the following substance(s):

<b>Component</b>	<b>Restriction</b>	<b>Concentration in product x (mg/kg)</b>
e.g. Vinyl sulfone acid	<i>amount: max. 8% (BfR XIV)</i>	<i>declaration optional</i>
e.g. Vinyl acetate	<i>SML: 12 mg/kg</i>	<i>declaration optional</i>
e.g. Emulsifier	<i>SML: xx mg/kg</i>	<i>declaration optional</i>
e.g. Potassium sulfate	<i>amount: max. 0,5%</i>	<i>GRAS(21CFR 184.1643)</i>

#### **Option D**

The safe use of the product has been verified and approved by means of a suitable and appropriate testing carried out by our department/external laboratory/institute.

Enclosed please find the respective test report.

Kind regards,