10. Adhesives for Food Packaging Applications

Commissioned by the ILSI Europe Packaging Materials Task Force
About ILSI Europe

Founded in 1986, the European branch of the International Life Sciences Institute (ILSI Europe) fosters collaboration among the best scientists from industry, academia and the public sector to provide evidence-based scientific consensus in the areas of nutrition, food safety, consumer behaviour and sustainability. ILSI Europe aims to build multi-stakeholder science-based solutions for a sustainable and healthier world. To deliver science of the highest quality and integrity, scientists collaborate and share their unique expertise in expert groups, workshops, symposia and resulting publications.

All ILSI Europe activities are conducted under the supervision of the Scientific Advisory Committee. ILSI Europe bylaws mandate that the Scientific Advisory Committee must be composed of a maximum of 20 experts with more than 50% coming from the public sector. The Scientific Advisory Committee plays an important role in reviewing all activities with respect to their scientific quality, validity and coherence with ILSI Europe’s programme. The Scientific Advisory Committee also provides scientific advice to the Board of Directors, which must be composed of at least 50% public sector scientists, the remaining directors representing ILSI Europe’s member companies.

This publication is made possible by support of the ILSI Europe Packaging Materials Task Force. Industry members of this task force, as well as the composition of the Board of Directors and the Scientific Advisory Committee are listed on the ILSI Europe website at http://www.ilsi.eu.

The opinions expressed herein and the conclusions of this publication are those of the authors and do not necessarily represent the views of ILSI Europe nor those of its member companies.
PACKAGING MATERIALS
10. ADHESIVES FOR FOOD PACKAGING APPLICATIONS

By Monika Toenniessen
CONTENTS

INTRODUCTION 4
1. Definitions 4
  1.1 Adhesive 4
  1.2 Adhesion 4
  1.3 Cohesion 5
  1.4 Surface tension 5
  1.5 Wetting 5
  1.6 Migration 6

2. ADHESIVE TECHNOLOGIES 6
  2.1 Chemically reacting systems 6
    2.1.1 Reactive polyurethane adhesives 6
  2.2 Physically setting systems 8
    2.2.1 Adhesives based on natural polymers 8
    2.2.2 Dispersion / emulsion-based adhesives 12
    2.2.3 Hotmelt adhesives 14
  2.3 Precoated systems 17
    2.3.1 Coldseals 17
    2.3.2 Heatseals 18

3. TYPICAL APPLICATIONS OF ADHESIVES 20
  3.1 Typical applications of reactive polyurethane adhesives in food packaging 20
  3.2 Typical applications of adhesives based on natural polymers in food packaging 21
  3.3 Typical applications of adhesives based on dispersions / emulsions 21
  3.4 Typical applications of hotmelt adhesives 22
  3.5 Typical applications of coldseals in food packaging 22
  3.6 Typical applications of heatseals in food packaging 23

4. LEGAL BACKGROUND SURROUNDING ADHESIVES INTENDED TO BE USED FOR FOOD CONTACT APPLICATIONS 23
  4.3 Regulation (EU) No. 10/2011 as amended – Plastics Regulation 24
  4.4 EU Member States’ legislation 25
  4.5 Others: recommendations, resolutions, etc. 26

5. EVALUATION OF ADHESIVE INTENDED TO BE USED IN FOOD CONTACT APPLICATIONS 27
  5.1 Migration 27
  5.2 Estimating migration 27
  5.3 Migration testing 27
  5.4 NIAS (Non-intentionally added substances) 28
  5.5 Substance-specific risk assessment 28

SOURCES 30
ANNEX I – Technology / application matrix 31
ANNEX II – Abbreviations: 32

Authors: Dr Monika Toenniessen, Henkel (DE)
Scientific Reviewers: Prof. Cristina Nerin, University of Zaragoza (ES) and Dr Hermann Onusseit, Onusseit Consulting (DE)
Coordinators: Dr Lucie Geurts, ILSI Europe (BE)
INTRODUCTION

In most cases today, food comes in packaging. The packaging protects the contents against chemical and biological contamination and deterioration, and avoids mechanical damage during transport. Adhesives are indispensable in the production of food packaging. More than 80% of food packaging contains adhesives, although often only to a small extent. Depending on the food in question, there are very different requirements on its packaging. To meet all requirements, the adhesives industry offers products based on a varied range of technologies for use in food packaging.

The present Black & White Report was prepared by members of the Association of the European Adhesive and Sealant Industry (FEICA). It is directed to food packers and adhesive users, as well as to other members of the supply chain and related scientific staff. It aims to provide an overview of the variety of adhesives that can be used in food packaging. In addition, the Black & White Report describes the typical ingredients of the various types of adhesives and their different behaviours. Furthermore, it describes typical applications of the various adhesives, thus giving the reader assistance in choosing the right adhesive for his or her individual application.

Finally, the Black & White Report provides an overview of the food contact legislation relevant for food packaging adhesives, together with guidance on the evaluation of adhesives intended for food contact applications. The report informs potential users about the successful use of adhesives in the various fields of food packaging. It provides a basic understanding of different types of adhesives, taking into account the complexity of the wide variety of possible applications. For detailed questions on the use and processing of a product, the user should contact his or her respective adhesive supplier.

1. DEFINITIONS

1.1 Adhesive

According to the definition of EN 923: “Adhesives. Terms and definitions”, adhesives are non-metallic substances capable of joining materials by surface bonding (adhesion), with a bond possessing adequate internal strength (cohesion). The adhesive forms the connecting element between the two joined parts, which would not stick together without it. Adhesives can be grouped by chemistry, by application, or by the reaction mechanism.

1.2 Adhesion

According to IUPAC, adhesion is the “process of attachment of a substance to the surface of another substance”.

According to the Union Guidelines on Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, adhesion “is the force of attraction between molecules in different layers”.

There are different types of adhesion: adhesion by covalent bonding (in this case both layers are chemically modified) and adhesion by physical bonding (no chemical modification of either layer). A basic requirement for good mechanical adhesion is good wetting of the substrate by the adhesive.

1 https://www.beuth.de/de/norm/din-en-923/246519375
1.3 Cohesion

Cohesion is the internal strength of a material and describes the force of attraction between molecules within the same layer.

Gases have no cohesion, liquids show low cohesion, while the cohesion in solids is extremely high. During the drying process of a water-based or a solvent-based adhesive, as well as during the setting process of a hotmelt product, the cohesion strength increases.

Figure 1: Effect of adhesion and cohesion

1.4 Surface tension

Surface tension is a phenomenon that liquids exhibit in order to reach the energetically most favourable form of the liquid surface with respect to a given volume (e.g. sphere). This surface tension is caused by the fact that at the liquid–air interface, the liquid molecules have a greater attraction to each other (due to cohesion) than to the molecules in the air (due to adhesion). Due to the inward-directed force, the surface of a liquid contracts and tends to be as small as possible (e.g. drops).

Surface tension has the dimension of force per unit length, or of energy per unit area. The two are equivalent, but when referring to energy per unit of area, it is common to use the term surface energy, and you may often see this term used in reference to solids. However, the term surface tension is often used interchangeably, and we will use surface tension in this publication. Polyethylene and polypropylene have a low surface tension for a solid, making them difficult to bond. Glass has a high surface tension, which enables easy bonding.

1.5 Wetting

Depending on the difference between the surface tensions, a liquid tends to spread more or less over the whole surface of the substrate (see left drawing in figure 2). This effect is called wetting. In order to develop adhesion, the liquid must wet the solid substrate sufficiently, otherwise bonding will be impossible. The efficiency of wetting can be characterised by the contact angle θ (see figure below). To develop sufficient bonding strength, the surface tension of the adhesive should be lower than that of the substrate, otherwise the bonding will not be adequate due to insufficient wetting of the substrate (see right drawing in figure 2).
1.6 Migration

Migration is the transfer of substances from one layer into another by diffusion. This interaction occurs during the whole time the foodstuff is packed. Diffusion always goes into two directions, from the packaging into the foodstuff and vice versa. Migration refers in general to the transfer of substances from the packaging material into the food or food simulant.

In general, the lower the molecular weight of a substance, the higher the tendency for migration. According to the EFSA note for Guidance for Petitioners\(^2\) (30.7.2008) “components with a molecular mass above 1,000 dalton (Da) are very unlikely to be absorbed by the gastrointestinal tract and thus are not considered to present a toxicological risk”. It is therefore the collective understanding that in regards to migration, only those molecules which are toxicologically relevant are taken into consideration. The migration potential depends on the composition and properties of the packaging material and the packed food, and is also heavily influenced by time and temperature.

2. ADHESIVE TECHNOLOGIES

2.1 Chemically reacting systems

2.1.1 Reactive polyurethane adhesives

General description

Polyurethane adhesives are reactive adhesives. This means that these products are applied on substrates as mixtures of low molecular weight entities (monomers and oligomers) and use a chemical curing reaction to create a polymer, often cross-linked (e.g. trimeric HMDI, see chapter 2.1.1., figure 4). Polyurethanes are formed by polyaddition polymerisation. Among the reactive adhesives, polyurethanes are by far the most diverse group: they can be water-based, solvent-based or solvent-free products; purely moisture-curing or two-component adhesives.

The polyurethane structure is built by the reaction of multifunctional isocyanates with multifunctional alcohols as follows:

---

\(^2\) https://www.efsa.europa.eu/de/efsajournal/pub/21r
Figure 3: Curing mechanism of polyurethane adhesives

<table>
<thead>
<tr>
<th>R N=C=O + R'-OH</th>
<th>R-NH-CO-O-R'</th>
</tr>
</thead>
<tbody>
<tr>
<td>isocyanate</td>
<td>urethane</td>
</tr>
<tr>
<td>alcohol</td>
<td></td>
</tr>
</tbody>
</table>

One-component polyurethane adhesives are based on NCO terminated urethane prepolymers. These products are moisture-curing according to the following reaction:

\[
\text{R-N=C=O} + \text{H}_2\text{O} \rightarrow \text{R-NH-CO-OH}
\]

isocyanate terminated water carbamic acid terminated PU prepolymer

\[
\text{R-NH-CO-OH} \rightarrow \text{R-NH}_2 + \text{CO}_2
\]

amine terminated PU prepolymer

\[
\text{R-NH}_2 + \text{R-N=C=O} \rightarrow \text{R-NH-CO-NH-R}
\]

PU / polyurea polymer

Reactive polyurethane hotmelts contain polyurethane prepolymers with blocked NCO end groups. These prepolymers are solid at room temperature.

Polyurethane adhesives show very good adhesion to various substrates, high mechanical strength, as well as good flexibility and chemical resistance. Due to these properties, polyurethane adhesives are used in a wide range of applications.

Ingredients / Composition

For the production of urethane adhesives, either aromatic or aliphatic diisocyanates are used, most commonly the following types:

Figure 4: Diisocyanates typically used for polyurethane adhesives
The use of aromatic isocyanates might promote the formation of primary aromatic amines (PAA) if the reactive adhesive is not fully cured. As these amines are considered to be carcinogenic, the substances have to be monitored. Aromatic isocyanates are more reactive than aliphatic types, while aliphatic isocyanates possess better UV stability and heat stability. The most commonly used diisocyanate is 4,4’-MDI, which can contain varying amounts of 2,4'-MDI depending on the grade. The technical quality of TDI mostly is a mixture of 2,4-TDI and 2,6-TDI (80:20), but pure 2,4-TDI is also commercially available. Due to steric reasons the reactivity of 2,4-TDI is 10 times higher than that of 2,6-TDI.

IPDI and HMDI are aliphatic diisocyanates with less reactivity than MDI or TDI. They are mainly used in water-based urethane systems and high performance adhesives, either solvent-based or solvent-free.

Monomeric isocyanates are hazardous to human health and can be sensitising. Therefore, NCO terminated prepolymer are generally used, which reduces the content of free isocyanate monomers and accelerates the curing process.

Next to diisocyanates, the second main ingredient in polyurethane adhesives are the diols or polyol components. Typical diols are for example ethylene glycol, diethylene glycol and propylene glycol. In addition to these glycols, OH-terminated oligomers based on polyethers or polysteres are also used for polyurethane adhesives. Among the polyether polyols, ethoxylated or propoxylated oligomers are mainly used. For polyester polyols dicarboxylic acids like adipic acid, ortho-phthalic acid or isophthalic acid react with polyols in excess so that OH-terminated polyesters are formed. Castor oil is a polyol on natural base, which can also be used as an OH component in polyurethane adhesives.

In addition to the basic components diisocyanate and diol, formulations of polyurethane adhesives sometimes contain additives such as catalysts to improve the reactivity and selectivity of the polyaddition as well as the adhesion. Further possible additives are antioxidants or silanes.

Manufacturing process of the adhesive
Isocyanates are extremely sensitive to moisture and react spontaneously with water. Therefore, the production and filling of polyurethane adhesives must be carried out under protective nitrogen gas to avoid premature curing during the manufacturing process. Additionally, the water content of each raw material must be controlled before starting to mix the ingredients of the formulation.

Usually polyurethane adhesives are produced by simply mixing the ingredients in a predefined order. In the case of preparing prepolymer, the mixture is slightly heated to 50-80 °C to speed up the formation of the prepolymer.

2.2 Physically setting systems
2.2.1 Adhesives based on natural polymers

General description
Adhesives based on natural polymers have been known for many centuries. They are either based on animal sources or on vegetable polymers. In the case of animal sources, the polymeric substances are proteins; in the case of vegetable sources, they are generally carbohydrates. In addition, mixed glues are used containing animal or vegetable based polymers combined with synthetic polymers.

The natural polymers are mainly hydrophilic and are dissolved in water as a so-called colloidal solution. A colloid is a system of finely dispersed particles; clusters of up to 50,000 atoms, with a
size of 1 to 1,000 nm in a continuous medium; in this case water. These particles cannot be easily filtered out of the medium. Colloidal solutions consist of two phases, one dispersed phase - the dispersed particles, and one continuous phase - the medium. Real solutions in contrast consist of only one phase. In some formulations, especially if the adhesive is activated by heating, starch is used in the form of suspensions insoluble in cold water (5 – 40 µm particle size), stabilised by other hydrocolloids.

Adhesives based on natural polymers have poor ageing resistance, especially in humid environments. They are easily biodegradable, which is an important aspect for the application of these products with regard to environmental impacts, for example waste water treatment and waste paper recycling. The ageing resistance can be improved by crosslinking of the biopolymer with wet-strength agents.

Adhesives based on vegetable polymers contain plant polymers such as starch or modified cellulose. These polymers are so-called polysaccharides; their basic repeating unit is glucose. Native starch and cellulose are not water soluble due to their superstructures. So, very often the degradation products of starch, the dextrins (short chain polysaccharides formed by thermal degradation or acidic hydrolysis), or chemically modified starches, such as carboxymethyl starch, are used to prepare a colloidal solution. In addition, cellulose is often modified by etherification to improve its solubility. The best water solubility is achieved with methoxyl content of 25 to 35 %.

Adhesives based on animal polymers contain proteins such as collagen or casein. Their basic repeating units are amino acids. Collagen is prepared from different parts of animal bodies such as skins or bones. Collagen glues are based on the decomposition products of proteins, which are dissolved colloidal in water. Collagen glues swell in cold water, forming a gel which melts at temperatures above 40 °C into a sol. The reversible gel-sol conversion by water absorption is an important property for the application of these adhesives.

Casein is a very important animal polymer for adhesives. It is obtained from cow's milk by acid precipitation using lactic acid or hydrochloric acid, which can result in different properties due to different molecular structures. The primary structure of this protein can be chemically modified to achieve different rheological behaviours.

Ingredients / Composition

Due to their superstructures, natural polymers such as starches and casein are not water soluble but can be converted into a soluble form either by increased temperature or by an alkali treatment.

• Starch

*Figure 5: Molecular structure of starch*

The main component of a starch-based adhesive is native or modified starch obtained from maize, wheat or potato. To bring these materials into solution, alkalis such as sodium hydroxide, potassium hydroxide or ammonia are used in the formulation. Even with a low solid content, starch glues can exhibit a very high viscosity. By adding melamine formaldehyde or urea formaldehyde resins, the
water resistance of starch glues can be improved. Starch glues contain a certain amount of urea to adapt the setting time to the required specific application. As with all water-based adhesives, a preservative and a defoamer are crucial to the composition.

- **Dextrin**

  Figure 6: Molecular structure of dextrin

  ![Molecular structure of dextrin](image)

  Dextrin glues contain dextrins together with water, preservatives and defoamers. To increase the adhesion, alkali or borax can be added to the formulation. Due to the low molecular weight of the dextrins, these glues can contain 60 to 70% solid content.

- **Cellulose**

  Figure 7: Molecular structure of cellulose

  ![Molecular structure of cellulose](image)

  Methylcellulose is soluble in cold water, but not in hot water. Carboxymethylcellulose is not soluble at all in water. To bring carboxymethylcellulose into a colloidal solution the adhesive formulation needs alkali. Very often methylcellulose and carboxymethylcellulose are mixed in a formulation to achieve the desired behaviour in the application in question. To avoid the formation of lumps during the dissolution of the modified cellulose, these materials are often treated with glyoxal at the surface of the powder. Only 1 to 2% of cellulose ethers are necessary to achieve a sufficient viscosity. To increase the solid content of the adhesive solution, polyethylene glycol is sometimes added. In addition, the formulation contains a preservative and a defoamer.
• Casein

Figure 8: Molecular structure of casein

Casein is not soluble in pure water and has to be solubilised, for example in an alkaline medium. Most often, sodium hydroxide or ammonia, or sometimes borax, are used. Formulations of casein glues mostly contain a certain amount of starch. To improve the tack (adhesion strength) or the water resistance of the adhesive a crosslinker for casein might be added. Typically, crosslinkers for proteins are metal salts containing bi- or trivalent metals, for example calcium or aluminium. To influence the setting time, casein glues contain urea. All formulations need a preservative and a defoamer.

Manufacturing process of the adhesive

• Starch

Colloidal solutions of starches are obtained by heating them above their specific gelatinisation temperature. For maize starch this is 62 – 63 °C, potato starch 55 - 58 °C and for wheat starch 58 - 60 °C. During this process, the starch granules swell, absorb water and create a pasty solution. Full gelatinisation is obtained at around 95 °C and 20 minutes holding time under these conditions. After the cooking process of the starch, the solution possesses a high viscosity. By defining the cooking conditions (concentration of starch, temperature profile, cooking time) it is possible to influence important adhesive properties, such as waterholding capacity and drying time. The gelatinisation temperature can be decreased by adding alkali such as sodium hydroxide. Native starches are often solubilised in alkali of high concentration and afterwards neutralised with nitric acid. Modified starches are mostly easily soluble in water and do not need alkali.

• Dextrin

Depending on the length of the molecule chains, dextrins are either soluble in cold water or need to be dissolved at elevated temperatures under stirring at high speed to achieve high shearing of the material. Dextrin glues of long-chain dextrins with high solid content and high viscosity often need to be heated up to 90 °C to dissolve the dextrins. After this treatment, the dextrin is matured on storage at low temperature. This maturation can take 1 to 2 months. During this process the viscosity of the dextrin solution increases by one order of magnitude up to 300.0 mPas. After the maturation, the dextrin glue is stirred again to homogenise the solution and to improve the rheological properties of the product.
• Cellulose
Cellulose adhesives based on cellulose ether, mostly methyl cellulose, are easy to prepare. These materials can be dissolved in water at room temperature together with the other ingredients of the formulation such as polyethylene glycol.

• Casein
Casein glues are prepared by dissolving casein powder in alkaline medium. Because of the protein structure, this material is very sensitive to elevated temperatures. Therefore, the temperature and length of time for which the casein is broken down during the manufacturing process is extremely important because this treatment causes denaturation of the protein, which changes the rheological properties and storage stability.

2.2.2 Dispersion / emulsion-based adhesives

General description
Polymer dispersions are colloidal systems with polymer particles dispersed in water. The particle size in polymer dispersions can vary between several nanometres up to a few microns. The particles need to be stabilised by surfactants or colloidal systems such as polyvinyl alcohol.

Polymer dispersions have the advantage of combining the high molecular weight of the polymer with low viscosity (good workability). Since the high molecular weight of the polymer does not affect the viscosity of the dispersion, it is possible to design adhesives with high cohesive strength and toughness and yet have viscosities that allow easy application by for example roller, nozzle or spraying. The viscosity and rheology of the polymer dispersions is mainly controlled by the stabilising system.

Film formation is absolutely critical for the bonding of a dispersion adhesive. It is a physical process running over several stages (see figure 9). It starts with the evaporation of the water in the adhesive. With the decreasing water content of the adhesive, the polymer particles come more and more into contact with each other, resulting in the fusion of the particles to form a film.

Figure 9: Film formation in a bonded joint for a polyacrylate dispersion (source: IVK)
Polymer dispersions are widely used as the polymeric base for a variety of applications such as adhesives, paints, carpet backing, paper coating and many others. The specific requirements in the different application determine the type of polymer and the type of the stabilising system used for the application.

Composition/Ingredients
The main components of polymer dispersions are the polymer particles, water and the stabilising system.

Important polymer dispersions are based on for example acrylates (polymers of acrylic esters), styrene-acrylates, styrene-butadiene dispersions or polyvinyl acetate (PVAc) homo- or copolymers.

The polymer composition determines the properties of the final adhesive: stiffness, softness, superficial tack, adhesion and cohesion. An important characteristic of the polymer is the glass transition temperature, which controls (and indicates) mainly the stiffness, softness and tack of the dried polymer film. Sometimes small amounts of special comonomers, for example crosslinking comonomers, are added to enhance specific properties such as water resistance or heat resistance.

As water-based dispersions are susceptible to attack from bacteria or fungi, they need appropriate protection against microorganisms through the addition of suitable biocides.

Defoamers are necessary for good processability of the final adhesive.

Thickening agents increase the viscosity of the adhesives and are used to optimise the required rheology for the application of the adhesives. Typical thickening agents are starches, casein, dextrins, cellulose derivatives, polyvinyl alcohols, polyacrylic acids or polyacrylamides.

Wetting agents are added to improve the wetting, especially of low surface tension films. This is important when coating with the adhesive at high speed.

Sometimes further additives such as ingredients to regulate the pH are used.

• PVAc - Homopolymer dispersions

Polyvinyl acetate based polymers adhere particularly well to cellulose-based surfaces such as wood and paper. For this reason, PVAc-based homo- and copolymer dispersions are the most commonly used dispersions in the paper packaging industry.

Usually the polymer dispersions used for paper packaging adhesives are stabilised with polyvinyl alcohol as a protective colloid or co-stabilised with additional surfactant.

After drying, PVAc homopolymers form hard and brittle films and thus need formulation with plasticisers to enhance the flexibility of the film. Plasticisers based on benzoates, acetates or phthalates are usually no longer used in packaging adhesives.

Beside the plasticisers, typical formulations of paper packaging adhesives based on PVAc homopolymers include filler and additional water, sometimes additional PVOH or starch and other additives such as tackifiers, foam control agents, etc.

• PVAc - Copolymer dispersions

The stiffness (or glass transition temperature) of a polymer can not only be reduced by addition of plasticisers, but also by copolymerisation with suitable (softer) comonomers. Typical comonomers for vinyl acetate are for example other vinyl esters, maleinates and ethylene.

One of the most important PVAc copolymers is vinyl acetate/ethylene (VAE). VAE dispersions are produced via emulsion polymerisation under ethylene pressure. The ethylene content of these
Vinyl acetate/ethylene (VAE) copolymers can typically vary up to ~25% relative to the polymer (in contrast to EVA hot melts, where ethylene is the main monomer).

VAE copolymers show - in addition to high adhesion to cellulose - very good adhesion to a variety of more difficult to bond surfaces such as PVC, lacquered or coated papers, and metal or plastic foils, which are frequently laminated or combined with straight wood or paper.

This property enables the formulator to develop high performing adhesives without the necessity to use plasticisers or tackifiers. They are therefore especially suited as base polymers for adhesives intended to be used in food contact materials.

Typically, adhesives based on VAE dispersions are only slightly formulated. Most important is the adjustment of the viscosity to match the requirements of the application machine. Other modifications include addition of extra PVOH to adjust the open time and other ingredients such as foam control agents, rheological additives, etc.

If not intended to be used for food contact materials, VAEs can also be formulated with tackifiers and plasticisers.

- **Adhesives based on acrylic polymers and copolymers, including styrene acrylate terpolymers and reactive systems**

  Acrylic polymer dispersions are used in a broad variety of industrial processes. The dispersions contain small polyacrylic particles dispersed in water. As the viscosity of the polymer itself has little influence on the overall viscosity, dispersions offer the possibility to apply high molecular weight polymers in a low-viscosity medium. After evaporation of water, the small particles form a homogenous functional polymer film.

  Due to the wide range of available acrylic monomers, polyacrylate dispersions can be specifically adapted to the required properties of adhesives.

  Tackifying resins are often added to pressure sensitive adhesives to improve the tack.

  Typical tackifiers for polyacrylates are modified natural resins, such as esterified abietic acids, and dimerised or hydrogenated gum rosins.

**Manufacturing**

Synthetic polymer dispersions can be produced by suspension polymerisation or micro-emulsion polymerisation (where the polymerisation occurs in the monomer particles) or via emulsion polymerisation (where the particles are formed upon polymerisation in the aqueous phase).

Such production processes typically include a reaction stage (where the dispersion is made starting from monomers, initiator, production auxiliaries and water), followed by a purification stage to remove the remaining volatile impurities, filtration to remove coagulum and a final adjustment stage.

**2.2.3 Hotmelt adhesives**

**General description**

Non-reactive hotmelt adhesives belong to the group of physically setting adhesives, where the setting takes place without any chemical change to the polymer. Solvent-free hotmelt adhesive is solid at room temperature. The adhesive is heated and starts to melt at temperatures above 65 °C. The hotmelt adhesive in its liquid state has very good wetting properties. The physical setting
Packaging Materials: Adhesives for Food Packaging Applications

The characteristic of a hotmelt used for packaging is that it is very fast setting as a consequence of the temperature difference between the cold substrates to be bonded and the hotmelt. This results in either an immediate increase of viscosity or the recrystallisation of the hotmelt and leads, in comparison to other adhesive technologies, to a very short open time. Hotmelts are often used where quick processing and short bonding phases are required.

Depending on the final properties desired, various polymers or copolymers can be used. They influence the adhesion, the cohesion and the temperature behaviour. Essential features for hotmelts are the softening point, the temperature where the polymer deforms, and the melting temperature, generally seen as a temperature range where the adhesive melts. Other parameters important for the application are processing temperature and melt viscosity. The processing temperature depends on the molecular weight of the polymers and is normally expected to be in the range of 100 - 240 °C; higher temperatures are the exception. The melt viscosity is also viscosity resulting from waxes or paraffins, but also resins and oils, assures good wetting of the substrate. The melt viscosity particularly determines the application method (roller or die application for packaging hotmelts). For pressure sensitive (PSA) hotmelts the methods include slot die coating, rotating bar nozzle and off-roll or on-roll application.

Hotmelts vary also in their thermal stability. With increasing heating time, most hotmelts tend to discolour, become brownish and drop in viscosity. The addition of stabilisers and antioxidants avoids these effects. The solidification rate of a hotmelt is crucial in determining the time required to achieve the final mechanical strength. It should be mentioned that there are two different solidification processes possible. In the case of amorphous polymers, solidification starts with the rise in viscosity and ends when the glass transition temperature (Tg) is reached. For crystalline polymers the solidification starts with the recrystallisation process.

The temperature difference between substrates and crystalline hotmelts determines the solidification speed. The higher the melting temperature, the higher the ∆T and the quicker the solidification process. Unfortunately, this advantage is often connected with a volume contraction (shrinking), which could also lead to poorer adhesion.

**Ingredients / Composition**

- **Polymers**

  Hotmelts consist of various polymers or copolymers. The choice of the polymer affects the adhesion, the bonding strength and the temperature behaviour.

  The most common polymers for packaging adhesives are copolymers of ethylene vinyl acetate, due to their very good price-performance ratio. The parameters to set the properties of the polymer are the molecular weight and the ratio of vinyl acetate to ethylene. The copolymer is quite stable against oxidation and thermal degradation. The higher the concentration of vinyl acetate the greater its plasticising properties. However, this is linked with a decrease in thermal stability.

  Polyolefins produced with the help of metallocene catalyst technology are increasingly used as polymers for hotmelt adhesives. With the advantage of more uniform polyolefins and a narrow molecular weight distribution they are also characterised by a low level of low molecular weight components, which results in better thermal stability.

  Hotmelts based on synthetic rubbers are characterised by the block formation of co-monomers,
which are also called “block copolymers”. The most common block copolymers are styrene-butadiene-styrene (SBS) and styrene-isoprene-styrene (SIS), which are often used together with resins and/or oils to allow a certain elasticity of the hotmelt. Due to their stickiness, these hotmelts are mainly used for tapes, self-adhesive labels, bottle labelling and pallet stabilisation.

Amorphous poly-a-olefins (APAO) are not commonly used for hotmelt adhesives intended for packaging applications. Due to their special setting behaviour, they are often used for pallet stabilisation for items such as sacks or cartons. They are more likely to be found in the manufacture of tissue and towel products or diapers.

* **Resins**

Resins are polymer mixtures of compounds of non-unified character. Resins are often used to increase the tackifying properties of a hotmelt. They also influence the wetting properties and the viscosity in the molten state, and finally they also affect the processing temperature. Resins are difficult to define, as they cover a big group of different chemistries. They all have in common a melting or softening range, combined with brittleness in the solid state.

The most common tackifiers for packaging adhesives are petroleum-based resins. These are derived from the polymerisation of low unsaturated hydrocarbons (ethylene, propylene, butylene, iso-butylene); so-called C5-resins. Polymerisation of unsaturated hydrocarbons with 9 carbon atoms (e.g. indene, methylindene, derivatives of styrene) leads to C9-Resins. Mixtures of both are often used to modify an adhesive’s properties.

One of the natural resins used is colophony. It is a mixture of different resin and rosin acids, which are derived from the distillation of conifer or pine resins. Due to their skin sensitising properties, resins belonging to this group are often fully hydrated or chemically modified (e.g. rosin ester).

* **Waxes**

Waxes can be of plant or animal origin (e.g. beeswax), but can be also of synthetic nature. They are used to adjust the setting time of a hotmelt adhesive. They consist of hydrocarbons, higher alcohols, acids and esters or polyolefins. The classification of a wax is based on its properties, such as solubility, melting point and crystalline properties. Waxes may improve the adhesion of a hotmelt to a substrate, stabilise the structure and reduce the melting viscosity. They are characterised by a melting point which can start from 40 °C. Waxes have a characteristic narrow melting range, except for the polyolefin-based waxes. Paraffins and waxes also exhibit a very low degradation tendency at high temperatures.

The various waxes are characterised through their origin, their melting point or their molecular weight. Paraffin waxes have a melting point between 45 and 70 °C, the molecular weight remains in general below 500 dalton. Microcrystalline waxes have a melting point between 60 and 95 °C, where linear hydrocarbon chains are accompanied by branched and cyclic molecules. The Fischer-Tropsch waxes are very stable synthetic waxes with melting points of 100 - 115 °C. Polyethylene waxes can have a molecular weight between 500-3,500 dalton, which also determines the melting range of 85 - 140 °C.

* **Oils**

Purified naphthenic or paraffinic oils are not common in classic packaging hotmelt adhesives, but they are often used for pressure sensitive hotmelt adhesives in order to plasticise the block copolymers. Pressure sensitive adhesives (PSA) are characterised by an infinite open time and normally remain sticky at room temperature. A certain pressure is needed to allow the wetting of the substrate surfaces. As a result of the pressure, the molecules in the cohesive film of the adhesive
come into contact with the substrate, finally resulting in adhesion. In the case of food contact applications that do not have an appropriate barrier, only paraffinic purified white mineral oil should be used. For tape or labelling applications of for example metal cans or glass bottles, other qualities such as purified naphthenic or paraffinic oils can be used.

- **Additives / Others**
  
  **Antioxidants / UV stabilisers**

  These additives inhibit or decrease oxidisation processes. They act as radical scavengers. The most common antioxidants are sterically hindered phenols, thioether and phosphites. Typical UV stabilisers are substituted benzotriazols.

  **Antiblocking agents**

  These additives are used to protect hotmelt pellets against agglomeration during transport. Typical antiblocking agents are talc, various amides and stearates.

**Manufacturing process of hotmelt adhesives**

The production of a packaging hotmelt does not feature a chemical reaction. It is mainly a blending process, which often takes place in heated vessels. In a first step the wax is melted, resin, polymers and additives are added accordingly. A vacuum can be used to help remove foam and air bubbles. After the filtration, the product can be either extruded to form pellets or directly filled into various packaging units.

PSA hotmelts are produced by heating up oil with antioxidants, adding the styrene block copolymer followed by mastication. Afterwards the resins are incorporated into the mixer and the product is homogenised before filling.

### 2.3 Precoated systems

#### 2.3.1 Coldseals

**General description**

Coldseals are adhesives which form an elastic film on a wide range of different substrates such as paper, PP, Coex PP, PE (see figure 10). They are applied via printing processes, including pattern application, to allow different seal characteristics to be achieved. As pressure-reactivated systems, no heating is required to obtain adhesion: two coated substrates only have to be pressed together. With a release lacquer or a release layer on the opposite side of the substrate, the coated material can be stored in reels or stacks without sticking together and then simply unwound for application.

*Figure 10: Typical coldseal applications as monoweb (left) and laminate (right)*
Depending on the application, seal strength can be adjusted by variation of the coating weight or of the polymer content within the formulation. Due to the chemical nature of the polymer used (see below), coldseals will exhibit a shelf life determined by oxidative degradation.

**Ingredients / Composition**

Coldseals are generally composed of natural rubber latex dispersions, polymers (e.g. acrylics, EVAs) and additives (e.g. antiblocking agents, stabilisers / antioxidants, defoaming agents, wetting agents).

Natural latex is obtained from the plant Hevea brasiliensis and consists primarily of the polymer cis-1,4-polyisoprene. As for all natural raw materials, a certain variation in the chemical composition of natural latex cannot be avoided. More importantly, the potential presence of allergenic latex protein traces has to be evaluated case-by-case for sensitive applications.

Natural rubber can now be replaced with synthetic rubber, based on various polymer types such as isobutylene-isoprene or styrene-butadiene copolymers and styrene block polymers. These synthetic grades offer a number of potential advantages over natural rubber latex such as being non-allergenic and offering high seal strengths, low odour and extended shelf life.

**Manufacturing process of the adhesive**

Manufacturing of coldseals is generally a cold blend batch process. The ingredients are added individually to the mixer whilst stirring and once all components are added, further stirring is required to ensure full homogenisation. Coldseals are non-reactive products.

**2.3.2 Heatseals**

**General description**

Heat sealing refers to the combining of two different substrates via heat and – to a certain extent – pressure. At least one of the substrates has to be heat sealable (either by an applied heat sealable layer or by being heat sealable itself), which means that it can be activated via heat.

Heat sealable layers can be formed on non-sealable substrates by coating them with heatseal adhesives or via coextrusion in the course of film processing.

*Figure 11: Typical heat seal applications: aluminium (left) and PET/paper lid (right).*
Heatseal adhesives are in most cases solvent-based or water-based products which are applied and dried on the substrate, resulting in a tack-free, block-resistant and solid coating for convenient storage of the coated substrate, for example in reels (technical industrial term, used also in the GMP regulation, where set-off is mentioned). In some cases, heatseal adhesives are solvent-free hotmelt products, which are applied to the substrate by coating.

Heatseal coatings can be applied to various substrates such as PE, PP, PS, PET, PVC or aluminium (see figure 11). Compared to coldseals, where only pressure has to be applied for bonding, but no heat, the bonding strength of heatseals typically is higher. In addition, heatseals are in most applications applied to the entire surface of the substrate.

**Ingredients / Composition**

Heatseals are generally composed of a solvent (water or organic solvent such as ethyl acetate), thermoplastic resins and additives (waxes, antioxidants, antifoam, pigments/fillers).

Water-based systems are also known as heatseal dispersions, whereas solvent-based systems are called heatseal lacquers. Thermoplastic resins are based on various chemistries, for example acrylates, styrene / acrylates, polyolefin / acrylates, vinylic compounds (PVC, PVDC), waxes, polyesters, or polypropylene dispersions or EVA.

**Manufacturing process of the adhesive**

Heatseal products are generally made via batch-wise, non-reactive blending of the individual components in water or in solvent. Ingredients are added to the reactor and blended till the product is homogeneous. Depending on the raw materials, the blending operation may require elevated temperatures.
3. TYPICAL APPLICATIONS OF ADHESIVES

Adhesives are suitable for a wide range of applications depending on their technology. Typical applications of adhesives are listed in annex I of this document.

3.1 Typical applications of reactive polyurethane adhesives in food packaging

Adhesives based on reactive polyurethanes are indispensable in the production of flexible packaging. Most of this packaging is composed of two or more layers held together by laminating adhesives.

Figures 12 and 13 illustrate the typical flexible packaging production process. While solvent-based polyurethane adhesives need a drying unit before going through the lamination process, solvent-free polyurethane adhesives can be used without this production step.

Figure 12: Solvent-based PU adhesives lamination (source: Bostik™)

Figure 13: Solvent-free PU adhesives lamination (source: Bostik™)
Because polyurethane adhesives have high flexibility and bonding strength, they are widely used throughout the packaging industry. Food packaging containing polyurethane adhesives (such as bags for coffee powder and chips) can be used for applications at room temperature and below, but some formulations are also suitable for elevated temperatures such as those found in pasteurisation or retort applications (for example flexible packaging of aggressive foodstuff such as fruit juices or liquid petfood). The technical information provided by the adhesive manufacturer should be followed to ensure complete curing. Time, temperature and humidity are the most important factors for the curing process. With regard to the curing conditions, the advice of the adhesive supplier should be followed to avoid the possible migration of primary aromatic amines. (See chapter 2.1.1).

3.2 Typical applications of adhesives based on natural polymers in food packaging

Adhesives based on colloidal solutions of natural polymers in general dry slowly and therefore need a very long setting time. Water-based adhesives containing starch, dextrin and / or casein are primarily used in labelling applications. Pure starch and dextrin glues are mostly used in less demanding standard labelling applications. Starch glues are also widely used in the production of corrugated board.

Casein adhesives show a very high increase in viscosity as the temperature decreases, which makes them suitable for labelling cold and wet bottles on high speed labelling machines, where a high wet tack is required. Because casein glues can be easily removed in caustic soda solutions, they are ideal for returnable glass bottles. Adhesives based on colloidal solutions containing tackifier resins are also suitable for plastic bottles.

Water-based adhesives containing cellulose or cellulose derivatives are often used for bonding paper in tissue and towel applications for the tail-tie bonding of toilet and tissue paper rolls and in cigarette applications for cigarillo leaf wrapping.

3.3 Typical applications of adhesives based on dispersions / emulsions

The most important applications for vinyl acetate based homo- and copolymer dispersions are the production and processing of packaging made of paper (e.g. sugar bags, salt boxes), cardboard and corrugated board, (e.g. for fruits, vegetables) folding boxes (side seam), bags (e.g. for bread), pouches and sacks (e.g. multiwall for milk powder, flour), core and tube winding (e.g. cling film, aluminium foil), etc. PVAc homopolymers normally need plasticisers and therefore are mostly used in secondary packaging applications while PVAc copolymers are used for primary packages. Because copolymers show better adhesion properties than homopolymers, they are suitable for bonding paper to other substrates such as foil or aluminium.

Pressure-sensitive adhesives: these adhere to a surface when gentle pressure is applied. As precoated systems, they have permanent tack and adequate cohesion. Typical applications are self-adhesive paper and film labels or tapes. These paper labels can be directly applied on food, such as fruits and vegetables, as well as sausages.

Laminating adhesives for flexible packaging: acrylic dispersions can be used to produce multi-layer lamination of various films. These water-based adhesives offer high green strength, have short curing times and are free of primary aromatic amines.

For retort applications, acrylic dispersions can be cross-linked with water-dispersible aliphatic polyisocyanates.
Glossy film lamination: acrylic dispersions are used to laminate clear, high-gloss polymer films onto printed paper or board. The polymer film protects the printed surface and enhances the optical appearance of the print. To increase the resistance to grooving and embossing, such adhesives are often self-crosslinking after drying.

Polyacrylate dispersions can also be used as reseal adhesives, synthetic coldseal or protective film adhesives.

3.4 Typical applications of hotmelt adhesives

Various grades of hotmelts are available, optimised for different applications. Hotmelts can be used for carton and case closing, tray erection (for fruits and vegetables) and wrap around boxes among other applications such as labelling. The most common packaging application is case and carton sealing (e.g. cereals), closing of folding boxes (primary or secondary packaging, e.g. confectionery, biscuits, frozen meals), wrap around (e.g. chocolate) or corrugated cartons (tertiary packaging).

Other hotmelt applications include the attachment of straws or bonding of plastic caps onto bricks (e.g. milk) or even bag-in-box (juices, wine).

Hotmelt pressure sensitive adhesives are used for labelling and to manufacture a wide range of tapes, labels and specialty products, where the adhesion can be permanent, or semi-permanent (repositionable) removable and dry peel. In the packaging industry, PSA hotmelts are often used for reclosable food packs and double-sided tapes. Permanent closure of PE, PP or paper bags is also a typical PSA application.

Heat-sealable hot melt adhesives are used for packaging applications on high speed machines, where hot tack and very good sealing properties are required. Substrates can be paper, film, cardboard, aluminium or combinations thereof.

3.5 Typical applications of coldseals in food packaging

Coldseal are typically handled within a temperature range of 15 to 25 °C and the absence of heat makes them ideal for packaging temperature-sensitive foodstuff such as ice cream, chocolate or biscuits. In addition, high packaging speeds in horizontal form fill seal (HFFS) machines can be achieved, without compromising tailored solutions for specific pack opening characteristics. This includes high performance applications such as reclosable food packaging (e.g. chocolate bars).

Figure 14: Coldseal typically applied in frame pattern (source: Henkel)
3.6 Typical applications of heatseals in food packaging

Heatseals are predominantly used for lidding applications, where aluminium or plastic lids are bound to food containers, for example, packaging of dairy products such as yogurts, plastic trays and instant noodle cups. Heatseals are also used for pharmaceutical blister applications or flexible laminated foil packages.

Special attention has to be paid to the opening behaviour in lidding applications. On the one hand, bonding has to be strong enough to ensure reliable closure of the package during storage and transportation. On the other hand, smooth opening of the food container is required when removing the lid: it should not rupture, but be removed completely.

4. LEGAL BACKGROUND SURROUNDING ADHESIVES INTENDED TO BE USED FOR FOOD CONTACT APPLICATIONS

This chapter explains how adhesives intended to come into contact with food are regulated at the European level. Normally adhesives are not intended for direct food contact since they are meant to stick together packaging materials. However, adhesives as components of the packaging material might contribute to the migration of constituents into foodstuffs.

Additional details and a more comprehensive explanation with decision trees for manufacturers can be consulted directly on the FEICA website.

Adhesives, like all food contact materials, are subject to the EU Framework Regulation (EC) No. 1935/2004 and, where existing, to relevant Member State national legislation. Plastic materials and articles are additionally regulated by a specific measure, the Plastics Regulation (EU) No. 10/2011, and thus harmonised at EU level. This regulation provides, among other requirements, a list of authorised substances. Adhesives do not have such specific harmonised legislation yet and the industry uses this extensive list of evaluated substances as the main regulatory reference whenever possible. As an alternative and when relevant, reference is made to the opinions of the European Food Safety Authority, to Resolutions of the Council of Europe, to national legislation, and even to non-European legislation for risk assessments.


Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food provides general principles to regulate any type of food contact material and is known as the Framework Regulation. It indicates that specific measures (EU harmonised legislation) may be adopted for certain food contact material groups as defined in Annex I. Currently, no specific measure has been issued to regulate adhesives.

Article 3 of the Framework Regulation stipulates the core requirements that any type of material intended for food contact application should meet.

ARTICLE 3:
Materials and articles, including active and intelligent 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;

b) bring about an unacceptable change in the composition of the food; or

c) bring about deterioration in the organoleptic characteristics thereof.

In addition to these requirements, Regulation (EC) No. 1935/2004 establishes some specific provisions on traceability, the authorisation process for new substances, the Declaration of Compliance (DoC) for those substance groups already regulated by a specific measure, as well as supporting documentation applicable to all materials covered under the Regulation.

It must be emphasised that full compliance with Article 3 of the Regulation can only be achieved through adequate exchange of information between players along the whole value chain. The information flow needs to go both ways because, in addition to information on substances and materials being shared from upstream to downstream players, it is key that end-users share information on the real or foreseeable conditions of use to their suppliers.

**4.2 Regulation (EC) No. 2023/2006 as amended – Good Manufacturing Practice**

Commission Regulation (EC) No. 2023/2006, on Good Manufacturing Practice for materials and articles intended to come into contact with food sets out general principles to ensure the suitability of the material or article for the intended end use. It is obligatory for all actors in the food contact supply chain and focuses mainly on the principles of a quality assurance system, quality control and appropriate documentation within the manufacturing process.

The general intention of this regulation is to ensure that all business operators acting in the area of food contact materials are able to demonstrate that the materials they place on the market are in compliance with the Framework Regulation requirements and thus do not endanger human health. This means that the starting materials shall also be selected according to pre-established specifications to ensure compliance. Although the regulation does not refer to any standards, a majority of requirements of the GMP regulation can already be covered through an established and implemented Quality Management System (such as ISO 9001 and equivalent procedures).

The FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in reference to Regulation (EU) No. 2023/2006 recommends procedures to assure the safety of adhesives for food contact applications and focuses particularly on the specific needs of GMP for adhesives intended to be used in food contact applications.

**4.3 Regulation (EU) No. 10/2011 as amended – Plastics Regulation**

The Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food defines several compositional requirements for substances used in plastics. Where possible, it is also common practice to use these requirements for a first evaluation of substances in adhesives.

The Regulation also defines provisions on Declaration of Compliance (DoC) and supporting documents (SD) (Articles 15 and 16). It applies not only to the plastic food contact material production chain and the final article, but also to intermediate stages down to the starting substances. It should be available at all marketing stages other than the retail stage. It should also be available at the importer stage = marketing stage for imports. The DoC represents information in the supply chain necessary to ensure the compliance of the final article. The supporting documentation can include all types of documents (e.g. raw materials, information/certificates, analytical data, risk assessment data, etc.) to support the final DoC. Supporting information has to be available at all stages for all declarations of compliance and should be kept in-house and made available to the authorities upon request.

---

6 Article 2 of Regulation (EC) No. 2023/2006 - “This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.”

7 Covering the suitability of starting materials, operation processes, premises and equipment and the qualification of the staff.

When substances in the Union list are used in adhesives, the specific limits / restrictions should be followed and information on such limitations / restrictions should be given in the Food Contact Status Declaration. The declaration should also contain information about dual-use additives and substances that are not listed in the Union list in case these are used in the formulation. The suitability of those substances will have to be demonstrated as explained in subsequent chapters of this document.

On the subject of Migration Testing, Regulation (EU) No. 10/2011 defines Specific Migration Limits (SML) and the Overall Migration Limit (OML), which need to be met by the final material or article; it defines the simulants in accordance with the food in question and sets the test conditions in correlation to the intended food contact application.

The migration testing conditions for plastics are not always appropriate for use with adhesives. A specific FEICA guidance paper on migration testing of adhesives intended for food contact materials explains the points to consider when testing adhesives for migration. Alternatively, the use of a worst-case calculation or migration modelling is an option to show compliance, provided the method is recognised as scientifically sound.

4.4 EU Member States’ legislation

For substances in an adhesive not listed in EU regulations, EU Member States national legislation may be applied to evaluate their suitability for the intended use.

National legislation is legally binding in the specific country where it is issued. It is generally structured following the concept of positive lists. In some instances, listing of catalysts and/or processing aids is also included. Currently there is little national legislation regulating adhesives specifically. However, positive lists relating to other food contact materials can also be used to assess compliance of substances that are not listed in the Union list. The relevant national legislation and restrictions should be referenced in the Food Contact Status Declaration.

The Mutual Recognition Principle

In intra-EU trade in goods, mutual recognition is the principle that a product lawfully marketed in one Member State and not subject to Union harmonisation should be allowed to be marketed in any other Member State, even when the product does not fully comply with the technical rules of the Member State of destination. In practical terms this means that a product that complies with certain legislation in one of the Member States should be considered compliant also in the rest of the EU territory. However, each Member State can still impose restrictions or bans at national legislation level should any concern for health or the environment be posed in that Member State by the use of that product (e.g. BPA in France).

9 http://www.feica.eu/our-priorities/key-projects/food-contact.aspx
10 List of substances authorized to be used in the manufacture of materials intended to be used in the regulated application and their restrictions and/or limitations.
4.5 Others: recommendations, resolutions, etc.

For substances in the adhesive neither listed in EU regulations nor in national legislation, non-legally binding texts such as the ones listed below can provide useful reference for the safety assessment:

- EFSA Opinions
- German BfR Recommendations
- Resolutions of the Council of Europe

Non-EU legislation

If a substance is not listed in any EU Regulation or reference document in the EU (as described above), non-European legislation can be used for further evaluation.

One example of non-EU legislation that is cited often is from the US Food and Drug Administration – FDA – an agency of the US Department of Health and Human Services. Among other areas, the FDA is responsible for protecting public health through regulation and supervision of food safety. Some examples of FDA sections relevant for adhesives in food contact are:

- 21CFR175.105 Adhesives, where INDIRECT Food Contact Compliance implies that the material is separated from the foodstuff by another material (functional barrier)\(^ {11} \)
- 21CFR175.125 Pressure-sensitive adhesives, used for labels and tapes
- 21CFR175.300 Resinous and polymeric coatings, where DIRECT food contact of coatings is regulated

Due to the different approaches of FDA and EU regulations and the complexity of this subject, it will not be covered in detail here.

An example of European but non-EU legislation is the Swiss Ordinance. Section 817.02 can be considered the equivalent of the EU Framework Regulation 1935/2004/EC - its Article 34 is the equivalent of Article 3, making the same requirements. Section 817.023.21 deals with commodities for food contact and covers various areas (plastics, silicones, inks, etc.), but no specific provisions for adhesives are made. It contains several positive lists for various material groups, for example, plastics are covered in (Annex 2) (the restrictions are similar to those in the Union list in the EU). Its Annex 10 deals with substances permitted for use in printing inks. This list goes beyond what is used in plastics both from the EU and the Swiss point of view and is used in particular if adhesives are used as coatings (coldseals, heatseals).

An update of the Swiss Ordinance came into force in May 2017. This now also contains rules on compliance testing. The test conditions and simulants used (in Annex 4) follow largely what is described in (EU) No. 10/2011. It now also demands a DoC, similar to what is required for harmonised areas in the EU.

---

11 Functional barrier in the context of FDA is defined differently from the functional barrier in the context of EU legislation.
5. EVALUATION OF ADHESIVE INTENDED TO BE USED IN FOOD CONTACT APPLICATIONS

To assist users with the evaluation of their adhesives, FEICA has published a guidance paper, including a decision tree on how the downstream user might evaluate specific adhesives. Important issues to consider such as migration modelling and testing is covered briefly in this chapter.

5.1 Migration

Substance transfer from the packaging material into foodstuff is known as migration, and adhesives may contribute to this substance transfer. The lower the molecular weight of the substance, the more likely it is to migrate into the food, either in direct contact by diffusion or indirect via the gas phase (vapour phase transition). Typically, compounds below 1,000 dalton show migration potential, whereas pure polymers of several thousand dalton and above do not need to be considered.

Several measures can be taken to reduce the risk of migration. On the one hand, reducing low molecular weight compounds of less than 1,000 dalton within the adhesive formulation may help to reduce the general substance transfer. On the other hand, packaging design can be an appropriate tool: installation of barrier layers prevents migratable packaging constituents from being transferred into the food. Such layers may reduce or even inhibit migration under defined conditions of use (functional barriers that offer protection under defined storage conditions, e.g. PET layers), or may even act as an absolute barrier (e.g. glass, aluminium).

5.2 Estimating migration

Analysis of the packed foodstuff gives answers to the following questions:

- Identity: what type of packaging constituents (including the contribution of the adhesive) have migrated into the food?
- Quantity: how much of each of these different substances migrated into food?
- Are all legal limits being respected under the intended conditions of use?

Although analysis of real foodstuff gives the most realistic information about migration in these food contact scenarios, it is time-consuming, complex and its results are only valid for the investigated application. To simplify these investigations, three different approaches to estimate migration have been established:

- Calculation: some constituents can be ruled out by taking their maximum concentration in the formulation and assuming a total substance transfer in the real application. If under these most severe conditions the limits are not exceeded, the formulation can be assumed to be safe with regard to these substances. Further investigations for these compounds typically are not required.
- Migration modelling: as migration follows the law of diffusion, computer models have been established to predict the expected migration of defined compounds under defined conditions.
- Migration testing (see chapter 5.3).

5.3 Migration testing

Migration testing is an appropriate and accepted way to estimate substance transfer from a packaging material into foodstuff. Standardised test conditions (incubation time, incubation temperature, food simulants) simulate the real food contact scenario. Not being limited to only

12 FEICA guidance for a food contact status declaration for adhesives: http://www.feica.eu/our-priorities/key-projects/food-contact.aspx
one type of foodstuff, these results are applicable for extended ranges of food types. Numerous regulations and guidelines have been developed that describe how to perform migration testing on packaging materials, especially concerning plastic materials. However, there is no adhesives regulation available at the European level.

Due to this lack of legislation, test conditions applicable only for plastics are often taken as guidance to test adhesives. In this case, the procedure is prone to error because the material specific properties and the way adhesives are used are different compared to plastics and polymer films. Amongst others, these differences include:

- Adhesives are mostly applied in small quantities and at defined locations within the packaging material.
- Adhesives intentionally contain low molecular weight fractions that would be re-dissolved when applying liquid food simulants directly to the adhesives.
- Adhesives intentionally contain fractions with low softening points that would soften when being treated at elevated migration test temperatures e.g. 60 °C.

For further advice on the migration testing of adhesives, reference is made to an available testing guideline from FEICA, the Association of the European Adhesive and Sealant Industry.

5.4 NIAS (Non-intentionally added substances)

The European Commission defines NIAS in the production of food contact plastic materials as: “Non-intentionally added substances are either impurities in the substances used or reaction intermediates formed during the polymerisation process or decomposition or reaction products which can occur in the final product”. Yet it is generally accepted that only compounds <1,000 Da are risk assessed as NIAS, since substances with greater molecular weight usually cannot be absorbed by the body (see EFSA note for Guidance\textsuperscript{13}). An exception to this would be polyfluoro and perfluoro compounds, for which a cut-off value of 1,500 Da could be appropriate because the molecular volume of C-F is smaller than that of C-H molecules of the same molecular mass\textsuperscript{14}. However, polyfluoro and perfluoro compounds are not used in food packaging adhesives.

By understanding the adhesives’ raw materials and manufacturing process, including the chemical reactions during the production of adhesives, NIAS can be identified, monitored and risk-assessed. The raw material supplier should assist in sharing the information, and an experienced adhesive chemist can determine the risk assessment.

For more guidance on risk assessment of NIAS, both ILSI Europe and FCA (the “Food Contact Additives” Sector Group of Cefic – the European Chemical Industry Council) have published guidance\textsuperscript{15,16}.

5.5 Substance-specific risk assessment

NIAS or not, it is important for European adhesive suppliers to comply with the Food Contact Materials Framework Regulation (EC) No. 1935/2004, especially Article 3: “Materials and articles … do not transfer their constituents to food in quantities which could: (a) endanger human health”.

To meet this requirement, two approaches are possible:

1. Understand all possible raw materials, contaminants and reaction products of the adhesive or;
2. Perform adequate testing of the adhesive to understand which possible substances could transfer from the adhesive into food, and perform risk assessments for these.

\textsuperscript{13} https://www.efsa.europa.eu/de/efsajournal/pub/21r
\textsuperscript{14} http://www.bfr.bund.de/cm/343/migration_of_perfluorchemicals_from_food_contact_materials.pdf
\textsuperscript{15} Koster S. et al, Guidance on best practices on the risk assessment of non-intentionally added substances (niass) in food contact materials and articles. ILSI Europe Report Series. 2015;1-70.
\textsuperscript{16} http://fca.cefic.org/images/Documents/FCA.pdf
Risk assessment of a food contact chemical can be carried out using many different approaches or methodologies. Knowing the migration behaviour of substances included in the adhesive formulation, the producer can substitute or reduce the concentration of those substances which migrate over the required limits. This is called “safety by design”.

In the absence of EU harmonised specific measures for non-plastics, the adhesive manufacturer may also use non-listed substances. In this case it needs to perform a specific risk assessment. A useful tool to assist adhesives manufacturers in their risk assessment is the FCA guideline on non-listed substances.
SOURCES


Reckziegel, Spließ, Onusseit, published by Bundesverband Druck und Medien, DWV33_0507.doc, Vers. 1.02, 31.05.2007.


https://www.tappi.org/content/enewsletters/eplace/2006/06PLA50.pdf, date of access January 19, 2018.
## ANNEX I

### Technology / application matrix

<table>
<thead>
<tr>
<th>Natural polymers Casein</th>
<th>Natural polymers Starch</th>
<th>Natural polymers Cellulose</th>
<th>Reactive polyurethane (PU) adhesives</th>
<th>Adhesives based on acrylic polymers and (VAE) copolymers, including styrene acrylate terpolymers and reactive systems</th>
<th>Coldseals (latex)</th>
<th>Dispersions / emulsions: Adhesives based on vinyl acetate polymers (PVAc)</th>
<th>Hotmelt PSA</th>
<th>Heatseals</th>
<th>Coldseals</th>
<th>Flexo</th>
<th>Laminating</th>
<th>Reclosable lidding for trays</th>
<th>Blister sealing: lidding for dairy products, trays</th>
<th>Bag closure</th>
<th>In mould labelling</th>
<th>X Lidding on chocolate bars for ice cream</th>
<th>X Lidding on aluminium, glass, paper, pouches</th>
</tr>
</thead>
<tbody>
<tr>
<td>X Paper to foil laminating</td>
<td>X Laminating</td>
<td>X Laminating</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

- Flexible packaging
- Laminating
- Reclosable lidding for trays
- Blister sealing: lidding for dairy products, trays
- Bag closure
- In mould labelling
- X Lidding on chocolate bars for ice cream
- X Lidding on aluminium, glass, paper, pouches
ANNEX II

Abbreviations:

BPA  Bisphenol-A
BOPP  Bi-oriented polypropylene
CFR  Code of Federal Regulation
Coex  Coextruded
DoC  Declaration of Compliance
EC  European Commission
EN  European Norm
EU  European Union
EVA  Ethylene vinyl acetate
FCA  Food Contact Additives Association
FDA  Food and Drug Administration
FEICA  Association of the European Adhesive and Sealant Industry
GMP  Good Manufacturing Practice
HDMI  Hexamethylene diisocyanate
IPDI  Isophorone diisocyanate
ISO  International Organization for Standardization
IUPAC  International Union of Pure and Applied Chemistry
MDI  Methylene diphenyl diisocyanate
NCO  Functional group of isocyanates
NIAS  Non-intentionally added substance(s)
OH  Functional group of alcohols / Glycols
OML  Overall Migration Limit
PE  Polyethylene
PET  Polyethylene terephthalate
PP  Polypropylene
PS  Polystyrene
PSA  Pressure sensitive adhesives
PU / PUR  Polyurethane
PVAc  Polyvinyl acetate
PVC  Polyvinyl chloride
PVDC  Polyvinylidene chloride
PVOH  Polyvinyl alcohol
SD  Supporting Documents
SML  Specific migration limit
TDI  Toluene diisocyanate
VAE  Vinyl acetate ethylene
ILSI Europe Reports Series

- Addition of Nutrients to Food: Nutritional and Safety Considerations (1999)
- Animal-Borne Viruses of Relevance to the Food Industry (2009)
- Applicability of the ADI to Infants and Children (1997)
- Application of the Margin of Exposure Approach to Compounds in Food which are both Genotoxic and Carcinogenic (2009)
- Approach to the Control of Entero-haemorrhagic Escherichia coli (EHEC) (2001)
- A Scientific Basis for Regulations on Pathogenic Microorganisms in Foods (1993)
- Assessing and Controlling Industrial Impacts on the Aquatic Environment (2001)
- Beta-Carotene, Vitamin E, Vitamin C and Quercetin in the Prevention of Degenerative Disease: The Role of Foods (1994)
- Campylobacters as Zoonotic Pathogens: A Food Production Perspective (2007)
- Emerging Technologies for Efficacy Demonstration (2009)
- Evaluation of the Risks Posed in Europe by Unintended Mixing of Food Crops and Food Crops Developed for Non-Food Uses (2011)
- Exposure from Food Contact Materials (2002)
- Foodborne Protozoan Parasites (2003)
- Food Consumption and Packaging Usage Factors (1997)
- Food Safety Management Tools (1998)
- Food Safety Objectives – Role in Microbiological Food Safety Management (2004)
- Frontiers in Food Allergen Risk Assessment (2011)
- Guidance for Exposure Assessment of Substances Migrating from Food Packaging materials (2007)
- Impact of Microbial Distributions on Food Safety (2010)
- Markers of Oxidative Damage and Antioxidant Protection: Current status and relevance to disease (2000)
- 3-MCPD Esters in Food Products (2009)
- MCPD and Glycidyl Esters in Food Products (2012)
- Micronutrient Landscape of Europe: Comparison of Intakes and Methodologies with Particular Regard to Higher Consumption (2009)
- Mycobacterium avium subsp. paratuberculosis (MAP) and the Food Chain (2004)
- Overview of the Health Issues Related to Alcohol Consumption (1999)
- Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications- Updated version (2017)
- Packaging Materials: 5. Polyvinyl Chloride (PVC) for Food Packaging Applications (2003)
- Packaging Materials: 8. Printing Inks for Food Packaging Composition and Properties of Printing Inks (2011)
- Persistence and Survival of Pathogens in Dry Foods and Dry Food Processing Environments (2011)
- Recontamination as a Source of Pathogens in Processed Foods – A Literature Review (2005)
- Recycling of Plastics for Food Contact Use (1998)
- Risk Assessment Approaches to Setting Thermal Processes in Food Manufacture (2012)
- Safety Assessment of Viable Genetically Modified Microorganisms Used in Food (1999)
- Safety Considerations of DNA in Food (2001)
- Safety Implications of the Presence of Nucleic Acids of Inactivated Microorganisms in Foods (2013)
- Significance of Excursions of Intake above the Acceptable Daily Intake (ADI) (1999)
- The Enterobacteriaceae and Their Significance to the Food Industry (2011)
- Threshold of Toxicological Concern for Chemical Substances Present in the Diet (2001)
- Transmissible Spongiform Encephalopathy as a Zoonotic Disease (2003)
- Using Microbiological Risk Assessment (MRA) in Food Safety Management (2007)
- Validation and Verification of HACCP (1999)
- Water Use of Oil Crops: Current Water Use and Future Outlooks (2011)
ILSI Europe Reports can be downloaded from:
http://ilsi.eu/publications/report-series/

ILSI Europe publishes also Concise Monographs in its Concise Monograph Series. They can be downloaded from:
http://ilsi.eu/publications/concise-monograph-series/

Predominantly, ILSI Europe publishes articles and proceedings in peer-reviewed journals. Most of them can be downloaded from:
http://ilsi.eu/publications/peer-reviewed-publications/

Keep up-to-date with all the latest activities from ILSI Europe by checking out our website at www.ilsi.eu, connecting with us on LinkedIn and following us on Twitter.