FPE Flexible Packaging Europe

FPE Guideline on Use of Isocyanate-based Adhesives in Packaging Laminates

1.0 Introduction and Scope

Flexible packaging materials used for foodstuffs frequently consist of multi-layer structures. Such materials may utilise isocyanate-based adhesives to bond together different functional layers to give a high performance specification.

These isocyanate-based adhesives use either aromatic (e.g. MDI, TDI) or aliphatic (e.g. IPDI, HDI) systems. It has to be underlined that only the aromatic isocyanates lead to the potential formation of primary aromatic amines which are of concern.

A fundamental aspect of the migration of primary aromatic amines is that it is time-dependent and disappears several days after production of the laminate (curing time). This is in contrast to other migrants of packaging which – once present in the packaging material – generally remain a potential source of migration.

The aim of this document is to provide FPE members with information on why laminates made with isocyanate-based adhesives require a curing time prior to food contact, thus maintaining the safety and quality of the packaged food. It provides an overview of the relevant EU and US legislation, an outline of the basic chemistry and use of isocyanate- based adhesives, and it provides simple guidance that all users of such materials should follow.

2.0 Legislative background

2.1 Regulatory status: Europe
Commission Directive 2002/72/EC as amended by Directive 2007/19/EC states: "Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0.01 mg/kg of food or food simulant)."[1]

2.2 Regulatory status: United States of America
The US Food and Drug Administration (FDA) has specified within the Code of Federal Regulation (CFR) the circumstances under which adhesives may be safely used in food packaging materials and the substances that may be used[2]:

2.2.1 The adhesive is either separated from the food by a functional barrier, which serves as a non-permeable obstacle to migration or used subject to the following additional limitations:

[1] A consolidated version of the Plastic Directive 2002/72/EC including all amendments can be downloaded under the following link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0072:20080327:EN:PDF
[2] Code of Federal Regulation (CFR): Title 21- Food and Drugs; Chapter 1- Food and Drugs Administration, Department of Health and Human Services. Part 175 – Indirect food additives: Adhesives and components of coatings: http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr175_00.html

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2.2.1.1 *For dry foods*, the quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice (GMP).

2.2.1.2 *For aqueous and fatty foods*, where the risk of migration is greatest, FDA has specified that contacts shall not exceed trace amount at the seams and at the edge exposure between packaging laminates that may occur within the limits of GMP.

2.2.2 Packaging seams or laminates must remain firmly bonded without visible separation under normal conditions of use.

FDA has also specified, within the CFR, requirements for migration of isocyanates or diisocyanates from laminate materials at high temperature[3, 4]. This reflects the fact that plastic laminates may not serve as a functional barrier to isocyanates or aromatic amines at high temperature.

3.0 Process overview and Chemistry

Isocyanate based adhesives consist of two components (di-isocyanate and di-alcohol), which when mixed, react and cure to form a stable polyurethane polymer layer, capable of bonding together plastics films, paper, foil, metallised films and other materials.

A reaction occurs between the di-isocyanate and water to form an amine. When the adhesive is fully cured, the amine has completely reacted and the laminate is safe to use. If the laminate is brought into contact with food before curing is complete, the amine formed may be extracted (in the packed product) and as a result is of concern to toxicologists (especially with regard to primary aromatic amines). The actual chemistry of adhesive reactions is complex. This paragraph just concentrates on the potential formation of primary aromatic amines.

Migration is dependent on the materials being used and on the foodstuff being packed, as a dry foodstuff will extract less than will a liquid, acidic food.

4.0 Due diligence

4.1 The flexible packaging industry has studied the issue of primary aromatic amine migration. The curing time of an isocyanate-based adhesive is defined by the adhesive supplier. On the basis of this information converters will specify the curing conditions (time and temperature) required for their products and processing conditions to ensure that the detectable limit as defined in Directive 2002/72/EC for primary aromatic amines is not exceeded.

[3] Code of Federal Regulation (CFR): Title 21- Food and Drugs; Chapter 1- Food and Drugs Administration, Department of Health and Human Services. Part 177 – laminate structure for use at temperatures of 250°F and above: http://a257.g.akamaitech.net/7/257/2422/04nov20031500/edocket.access.gpo.gov/cfr_2001/aprqtr/pdf/21cfr177.1390.pdf

[4] Code of Federal Regulation (CFR): Title 21- Food and Drugs; Chapter 1- Food and Drugs Administration, Department of Health and Human Services. Part 177 – laminate structure for use at temperatures between 120°F and 250°F: http://a257.g.akamaitech.net/7/257/2422/04nov20031500/edocket.access.gpo.gov/cfr_2001/aprqtr/pdf/21cfr177.1395.pdf

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Curing conditions may vary according to the adhesive type, weight used, humidity, curing temperature and laminate make up.

In the following some representative examples are given for solvent-based and solvent-free adhesive systems:

	Reaction temp.	***Curing temp.***	***Curing time***
Adhesive 1	***Room temperature***	***40 °C***	***5 d***
Adhesive 2	***Room temperature***	***40 °C***	***10 d***
Adhesive 3	***40 °C***	***Room temperature***	***7 d***
Adhesive 4	***Room temperature***	***Room temperature***	***3 d***

By increasing the curing temperature for example it is possible to decrease the curing time dramatically, e.g. down to 2 d. The curing time will increase with the weight of adhesive used. Very low humidity (e.g. in winter) increases the curing time.

If a packaging supplier reduces the curing times defined by the adhesive supplier, he has to justify the shorter curing time. This justification may be based on calculations / estimations, based on earlier practical measurements. Best practice is to do a control measurement on the laminate. Currently the most practical method for doing that is the acknowledged “BfR colorimetric test” [5] which currently is the only practical test available and suitable as a screening/quality control technique. More sophisticated methods are available in specialized laboratories.

4.2 Where laminate materials are imported from outside the EU, the packer/filler should ensure that the packaging supplier understands the issue.

4.3 Supplier GMP should include a process control procedure which manages coating weight and component mixing ratio with alarms in case of deviation from the set-point. Quality systems must ensure that significant changes to the adhesive curing time are communicated down the value chain.

4.4 The packer/filler has to remain vigilant with regard to quality problems of the laminate (odour, tackiness, failing heat seal etc.) possibly caused by the adhesive but should be aware that there is no straight-forward relationship between such quality problems and the issue of primary aromatic amines.

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[5] Amtliche Sammlung von Untersuchungsverfahren nach § 64 LFGB, Buchst. L. Nr. 00.00-6: "Untersuchung von Lebensmitteln - Bestimmung von primären aromatischen Aminen in wässrigen Prüflebensmitteln"

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