

LINKING THE LABEL COMMUNITY

**FINAT INFORMATION FOR USERS  
OF SELF-ADHESIVE LABELS**

# **CONFORMITY OF SELF-ADHESIVE LABELS FOR FOOD PACKAGING**

**JUNE 2015 – VERSION 1.0**



LINKING THE LABEL COMMUNITY

translated from the VskE document  
„Information für Verwender von Haftetiketten“

# CONFORMITY OF SELF-ADHESIVE LABELS

## INFORMATION AND ACKNOWLEDGEMENTS

FINAT would like to extend its thanks to the VsKE for providing their original document and to BPIF Labels, UNFEA and Gipea for their input and their collaboration in the Food Contact working group, a joint initiative of FINAT and the national self-adhesive label associations in Europe.



[www.vske.de](http://www.vske.de)



[www.britishprint.com](http://www.britishprint.com)



[www.gipea.net](http://www.gipea.net)



[www.unfea.org](http://www.unfea.org)

The message of this text is interwoven with the message taken from the original German version and translated into English by technical experts from the self-adhesive labelling industry. The translation into English cannot lay claim to be 100% or legally exact. It should reflect, without any legal obligation, the best knowledge and understanding of industry experts.

# CONFORMITY OF SELF-ADHESIVE LABELS

## IMPORTANT INFORMATION ON THE ORIGINAL VSKE DOCUMENT

The association has endeavoured to present the requirements for realising “conformity” according to its best knowledge and understanding.

However, these guidelines do not purport to be complete. They reflect the current legal requirements, as well as the scientific and technological status at the time of publication. These are non-binding guidelines from which it is not possible to derive any warranty claims. Manufacturers and users of self-adhesive labels remain obligated to inform themselves of the current legal situation and ensure that they are compliant.

The VskE would like to thank the participants in the VskE Compliance working group for their collaboration on these guidelines. The following were involved:

**Uwe Jannasch** (Bizerba GmbH & Co. KG),  
**Dr. Harry Johlke** (CCL Label GmbH),  
**Sabine Feifel** (Ero-Etikett GmbH),  
**Dr. Manfred Oßberger** (Fabes Forschungs GmbH),  
**Günter Schneider** (Flint Group Winterbach GmbH),  
**Dr. Ulli Nägele** (Herma GmbH),  
**Stefan Feil** (IST Metz GmbH),  
**Joachim Müller-Straub** (Pago Etikettiersysteme GmbH),  
**Dominique Elsen** (Rako Etiketten GmbH & Co. KG),  
**Rolf Heitmann** (Rako Etiketten GmbH & Co. KG),  
**Michael Geiger** (Siegwerk Switzerland AG),  
**Bernd Miller** (Siegwerk Switzerland AG),  
**Elke Rutzinger** (Bandfix AG),  
**Klemens Ehrlitzer** (VskE),  
**Thomas Pfeiffer** (WPV),  
**Andreas Rascher** (Zeller+Gmelin GmbH & Co. KG),  
**Dr. Heinz Schweiger** (Zeller+Gmelin GmbH & Co. KG)

# CONFORMITY OF SELF-ADHESIVE LABELS

## TABLE OF CONTENTS

	<b>Page</b>
Information and acknowledgement	2
Important information on the original VskE document	3
Table of contents	4
Foreword	5
<b>1. Legal foundations</b>	
1.1 Specification hierarchy	6
1.2 General valid (intra-material) regulations	7
1.2.1 European framework ordinance (EU) no. 1935/2004	7
1.2.2 European ordinance (EU) no. 2023/2006 (GMP)	7
1.2.3 German Food and Feed Code (LFGB)	7
1.2.4 Swiss Ordinance 817.023.21 on Materials and Articles in Contact with Food	7
1.3 Material-specific regulations	8
1.3.1 Paper	8
1.3.2 Plastics	8
1.3.3 Printing inks and lacquers	8
1.3.4 Adhesives	8
<b>2. Packaging in contact with foods</b>	
2.1 Mass transfer with packaged foods	9
2.2 Why does migration take place?	11
2.3 Definitions	12
2.4 Evaluation of potential migration	13
2.5 Labelled packaging	13
2.6 Peculiarities of packaging production	14
2.7 Barriers	14
2.8 Summary	14
<b>3. Declaration of conformity and/or description of properties</b>	
3.1 Declaration of conformity for labels based on the plastic ordinance	15
3.2 Description of properties for labels	16
3.3 Further explanations	16
Closing word	16
<b>4. Annex</b>	
4.1 Sample description of properties	17
4.2 Checklist - packaging details questionnaire	19
4.3 Example 1: supporting document - certificate of compliance	22
4.4 Example 2: supporting document - declaration of conformity	26
4.5 Links to relevant websites	28

# CONFORMITY OF SELF-ADHESIVE LABELS

## FOREWORD

In many areas of a functioning society it is necessary to issue generally applicable specifications and value these higher than individual needs or requirements. The term conformity denotes compliance with these applicable societal standards, in particular in the food industry.

The “conformity of food packaging” and the associated legal foundations are intended to clearly regulate this area for the benefit of the consumer. As such, all persons are beneficiaries of these ordinances.

Commonly with packaging, different types of labels are used. These guidelines describe the fundamental interrelations and serve users as a basis for information on the subject of the conformity of self-adhesive labels.

Conformity to the stipulations of the legislation rests with the end-user who places the product into the market place to ensure that safe products exclusively are brought to the market. However, companies participating across the entire supply chain are obligated to make the requisite information available to the respective downstream bodies. The VskE therefore appeals to all participants to constantly organise communication along the entire supply chain effectively and transparently for the purpose of stepwise accountability.

VskE, AK Compliance  
Höchberg, April 2014

# CONFORMITY OF SELF-ADHESIVE LABELS

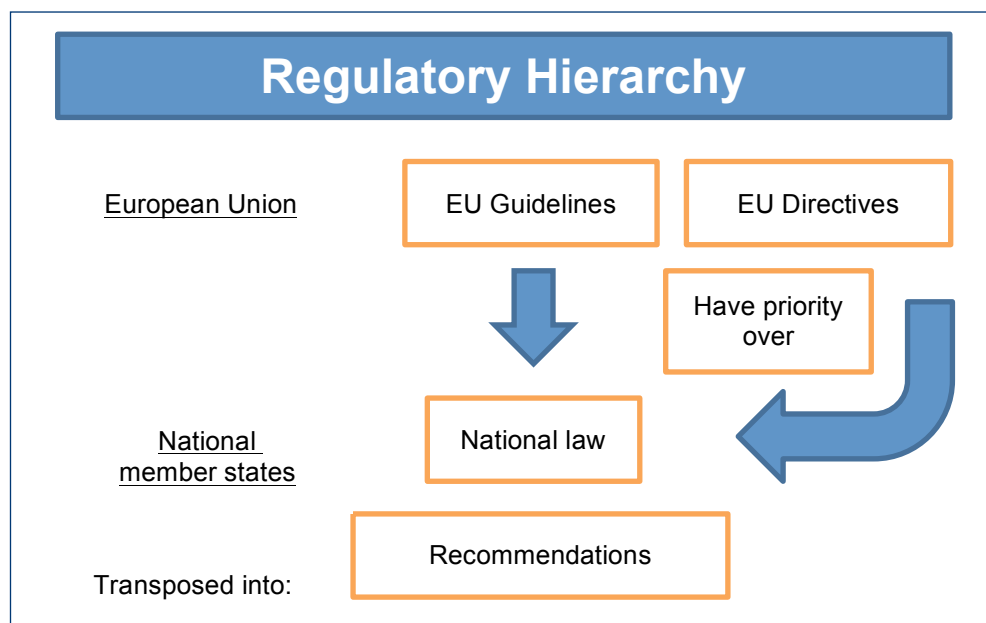
## 1. LEGAL FOUNDATIONS

Legal regulations apply to the production of food packaging, which all participants in the production chain (incl. paper, film or ink suppliers, as well as the print shop) must observe. The label is part of the packaging.

The valid regulations - status April 2014 - are presented in the following in shortened form and reference is also made here to future regulations. Links indicate the publication of the respective regulations on the internet.

### 1.1 Specification hierarchy

The legislators are the European Union and the national member states.



**EU ordinances** take precedence over national law and are legally binding regulations for all member states.

**EU directives** are binding through implementation in national law.

**National laws** of the member states are also legally binding in the respective countries.

**Government/official recommendations** have a quasi-legal nature and aid the interpretation of legal regulations that are not defined in greater detail.

Voluntary commitments, guidelines and standards can be applied as standards in jurisdiction.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 1.2 General valid (intra-material) regulations

### 1.2.1 European framework ordinance (EU) no. 1935/2004

<http://eur-lex.europa.eu/legal-content/EN/ALLI?uri=CELEX:32004R1935>

UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN>

Food packaging in the European Union is regulated by **ordinance (EU) no. 1935/2004, dated October 2004**. This framework ordinance applies to all materials and products that come or are intended to come into contact with foods. It stipulates general requirements that must be fulfilled by all materials that come into contact with food.

**Article 3 of the ordinance (EU) no. 1935/2004** requires that materials and articles (in this case packaging materials) must not endanger human health, must not cause any unacceptable change to the composition of the food and must not impact the organoleptic characteristics of the food.

**Article 5** of this framework ordinance contains individual measures for food contact materials, including a list of substances approved for production. Such an individual measure applies e.g. to plastic materials (see 1.3.2), although not to paper, printing inks or adhesives for example.

Within the framework of the so-called Roadmap 2014, the EU Commission assesses the need for further individual measures according to **ordinance (EU) no. 1935/2004**. Printing inks and paper have higher priority here.

### 1.2.2 European ordinance (EU) 2023/2006 (GMP)

<http://eur-lex.europa.eu/legal-content/EN/ALLI?uri=CELEX:32006R2023>

UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R2023&from=EN>

This so-called **GMP ordinance (Good Manufacturing Practice)** defines the requirements applicable to individual participants in the manufacturing process of materials and articles that are intended for contact with food.

### 1.2.3 German Food and Feed Code (LFGB)

<http://www.gesetze-im-internet.de/bdggstvl/index.html>

The German Food and Feed Code is the national implementation of the European framework **ordinance (EU) no. 1935/2004**.

### 1.2.4 Swiss Ordinance on Materials and Articles in Contact with Food (EDI 817.023.21)

[http://www.admin.ch/ch/d/srlc817\\_023\\_21.html](http://www.admin.ch/ch/d/srlc817_023_21.html)

**The Swiss Commodity Ordinance** includes the regulation of materials and articles for contact with food. When the ordinance was amended on the 1<sup>st</sup> April 2008, regulations for printing inks ("packaging inks") were included. According to this ordinance, since the 1<sup>st</sup> April 2010 it is only permissible to provide consumers with packaging that has been printed with printing inks that comply with this ordinance.

Printing inks must consist exclusively of substances that are listed in Annex 1 and Annex 6. The lists in Annex 6 consist of two parts: Part A contains a list of substances that have been subjected to officially recognised scientific testing. Insofar as this list contains limit values for migration, these must be observed. If no limit value is provided, global migration applies. Part B contains substances that have not been subjected to officially recognised scientific testing. Migration of these substances must not be detectable or must not exceed 10 ppb (0.01 mg per kilogram of food).

Basically inks must be produced and used according to GMP.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 1.3 Material-specific regulations

### 1.3.1 Paper

<http://bfr.zadi.de/kse/faces/resources/pdf/360.pdf>

Food contact materials, which are produced from paper, cardboard and paperboard, are regulated in the **recommendation XXXVI of the Federal Institute for Risk Assessment (BfR)**, which lists the raw, auxiliary and refinement substances approved for use in the production of paper materials that are intended to come into contact with food.

### 1.3.2 Plastics

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011R0010-20140324>

UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0010-20140324&from=EN>

Amending and correcting regulations: [http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl\\_list\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm)

**The plastic ordinance (EU) no. 10/2011 (Plastic Implementation Measure - PIM)** stipulates regulations for materials and articles manufactured from plastic, which must be applied for safe use in contact with food. These guidelines contain limit values for the migration of substances in food, which must not be exceeded. The use of mutagenic, carcinogenic or reprotoxic substances (CMR) is prohibited in the production of packaging materials.

### 1.3.3 Printing inks and lacquers

The following regulations are relevant to printing inks and lacquers:

<http://www.lackindustrie.de/druckfarben/lebensmittelverpackungen/Seiten/EuPIA-Leitlinie-Druckfarben-zur-Verwendung-auf-der-vom-Lebensmittel-abgewandten-Oberflaeche-von-Lebensmittelverpackungen.aspx>

**EuPIA Guideline:** The European Printing Ink Association (EuPIA) has developed guidelines for printing inks for application to the non-food contact surface of food packaging materials, which contain a detailed description of the obligations of the printing ink manufacturer. (<http://www.eupia.org/index.php?id=29>)

**Printing ink ordinance:** At the time of publishing these guidelines (April 2014), the fourth draft of a printing ink ordinance had been published by the federal ministry for food and agriculture.

**Swiss Ordinance on Materials and Articles in contact with food: (see 1.2.4)**

### 1.3.4 Adhesives

The following regulations are relevant to adhesives:

EU plastic ordinance 10/2011: (see 1.3.2)

BfR recommendation XIV - plastic dispersions: (<http://bfr.zadi.de/kse/faces/resources/pdf/140.pdf>)

FDA21 CFR 175.105



# CONFORMITY OF SELF-ADHESIVE LABELS

## 2. PACKAGING IN CONTACT WITH FOODS

### 2.1 Mass transfer with packaged foods

Migration is the general collective term for all forms of mass transfer of substances. In order to avoid misunderstandings, the individual forms are described in the following.

Mass transfer can occur between food packaging and the contents due to:

- Migration (transfer between neighbouring layers)
- Permeation (transfer between one or more layers)
- Invisible set off (set-off in a roll or stack)
- Gas phase transfer (e.g. via air)

#### Migration

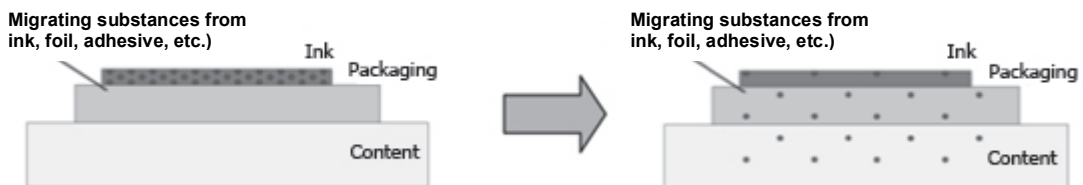
Migration is the transfer of one or more substances between neighbouring layers (e.g. from the packaging to the contents in the diagram below).



*Example of migration*

#### Permeation

Permeation is the transport of one or more substances right through a layer.

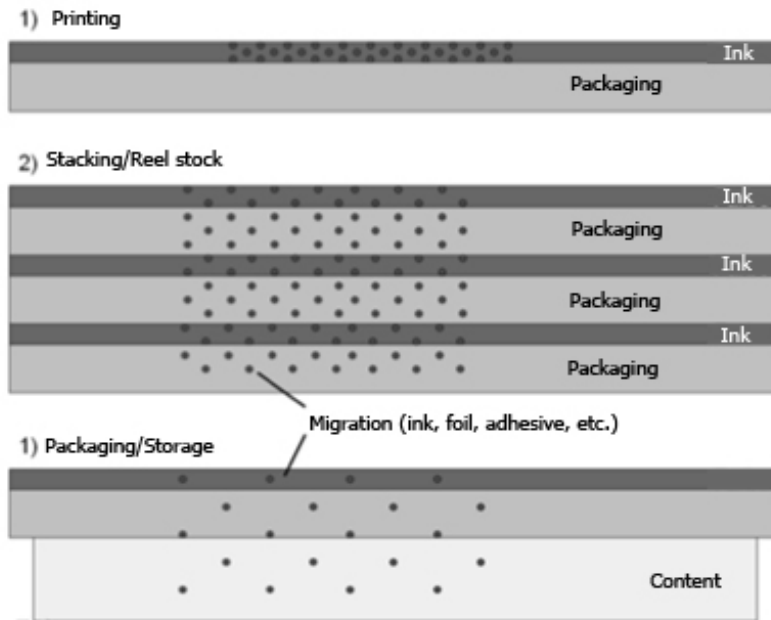


*Example of permeation*

#### Invisible set off

Invisible set off is the - also indiscernible - transfer of one or more substances, which reach the food contact side upon stacking or rolling during the manufacturing process and are transferred to the food in this way.

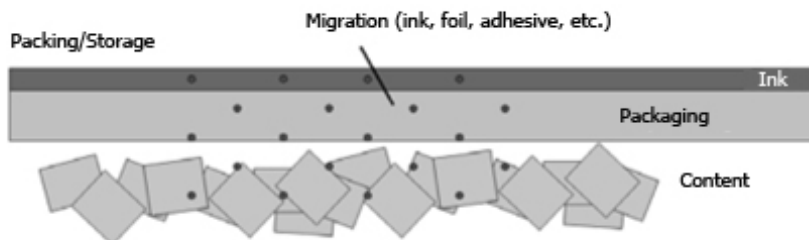
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*Example of invisible set off*

## Gas phase transfer

During a gas phase transfer, substances migrate into the contents via air for example.



*Example of gas phase transfer*

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## 2.2 Why does migration take place?

With the fundamental forces in nature, the greatest degree of stability exists when balance prevails. If a body is at rest, all of the forces acting on it are equal in size. These forces may be gravity, mass inertia, attraction or bond forces, etc.

Atoms and molecules are subject to comparable laws. If the state of a body changes because additional forces act upon it, e.g. due to a supply of energy (heating up) or changes in concentration, the balance of forces shifts. If these forces are sufficiently great, the body starts to move. This continues until balance is restored.

The energy expenditure for the movement of small bodies is less than for the movement of large bodies. In simple terms this can also be transferred to molecules. Large molecules or long molecular chains are therefore slower or even incapable of migration (or only with a high supply of energy/heat). In contrast, low molecular substances (small molecules) possess a higher potential for migration. Migration analyses executed in practice show that substances with a molecular structure greater than 1,000 g/mol (Dalton) possess either a very low or non-existent potential for migration. Critical for a possible mass transfer are therefore low-molecular constituents in the packaging.

Whether and how quickly migration takes place is dependent on the following criteria:

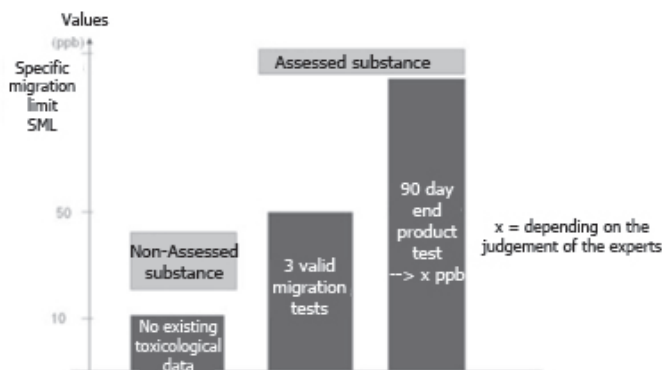
- The initial concentration of migration-capable substances in the packaging
- The speed of migration of migration-capable substances into a material (diffusion speed)
- The distribution equilibrium of the migration-capable substances between two neighbouring layers
- The temperature - because the lower the temperature, the slower the migration process

The highest concentration of a migration-capable substance arises in a medium in which it best dissolves. Fat-soluble substances therefore accumulate in fatty goods (e.g. whole milk, sausage products). The same applies to water-soluble substances, which accumulate in particular in non-cloudy juices or starchy foods.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 2.3 Definition of terms

- GM** (Global Migration): The entire quantity of substances that may transfer to a food during its time in contact with this (mg/kg food).  
The sum of all determined migration instances must not exceed the global migration value.
- QM** (Quantity Maximum): Maximum permissible quantity of a toxicologically evaluated substance in the packaging (mg/kg packaging).
- QMA** Maximum permissible quantity of the substance in the finished material or article expressed as mg/6 dm<sup>2</sup> of the food contact surface.
- ADI** (Acceptable Daily Intake)
- TDI** (Tolerable Daily Intake) in the packaging sector:  
Indicates the quantity of a toxicologically evaluated substance in mg/kg body weight that can be consumed with food on a daily basis without a risk of harm to health (toxicological concentration limit x safety factor of 100).
- SML** (Specific Migration Limit): Specific migration limit value, i.e. the concentration in mg/dm<sup>2</sup> of a toxicologically evaluated substance that must not be exceeded in a foodstuff or in food simulants ( $SML = ADI / TDI \times 60$ ).



The specific migration of a substance must not exceed the following values according to the Note of Guidance of the EFSA (European Food Safety Authority):

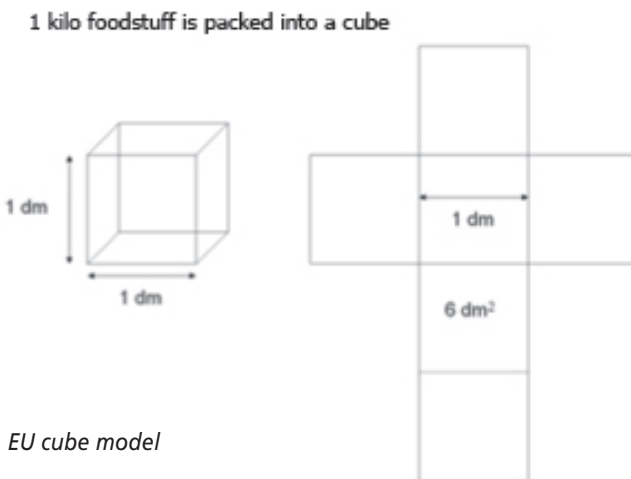
- 0.01 mg/kg (10 ppb) - if no toxicological data is available,
- 0.05 mg/kg (50 ppb) - if three negative mutagenicity tests are available,
- greater than 0.05 mg/kg (50 ppb) - if three negative mutagenicity tests plus one feed study are available.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 2.4 Evaluation of potential migration

Information regarding the concentration of migration is provided in  $\text{mg}/\text{dm}^2$  packaging or  $\text{mg}/\text{kg}$  food. Frequently, the "EU cube model" is used as a basis for packaging with one kilo of food. With an edge length of 10 cm (1 dm) this cube has a surface area per side of  $1 \text{ dm}^2$ . Applied to this surface area, no more than  $10 \text{ mg}/\text{dm}^2$  of the constituents of an article are permitted to transfer to the foodstuff according to the ordinance (EU) no. 10/2011 (global migration).

Applied to the contents as one kilogram of food, no more than  $60 \text{ mg}/\text{kg}$  is permitted to transfer from the packaging cube (six sides) to the food.



Substances that have only been subject to limited toxicological evaluation must not migrate at all, or must only be contained in the packaging up to a stipulated maximum concentration (specific limit value). The respective values can be taken from the positive lists.

The cube model can be applied in the field of labels, in order to estimate the risk of migration. More meaningful is the true ratio of the printed surface to the quantity of contents.

## 2.5 Labelled packaging

Labels that are applied to packaging (e.g. flexible packaging) are deemed an integral component of the packaging. The law makes no distinction between primary and secondary packaging.

Flexible packaging is predominantly produced from substrates that possess an insufficient or non-existent barrier function. Plastics such as polyethylene (LDPE, HDPE) or polypropylene (OPP, PP) constitute no obstacle for low-molecular substances. Packaging from paper, cardboard or paper composites possess no barrier characteristics, whilst composites from paper and plastic only exhibit limited barrier characteristics.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 2.6 Peculiarities of packaging production

Packaging mostly consists of multiple components (e.g. cardboard, plastic, adhesive, printing inks, lacquer, label, etc.) that must each individually comply with the legal stipulations. A new product is produced through their combination in the production process, which must in turn also be tested according to food law specifications.

## 2.7 Barriers

Packaging materials exhibit varying barrier characteristics. In order to prevent migration it is possible to use absolute barriers, which do not permit mass transfer due to their molecular structure. Absolute barriers include glass, metal or aluminium foil from a certain foil thickness. Commonly applicable is a thickness from approx. 7 µm. Aluminium-vaporized foils do not fulfil this prerequisite.

With the following materials it is not possible to speak of an absolute barrier because mass transfer cannot be ruled out: Paper, cardboard, PE, PS/OPS, PP/OPP, PA, PET. However, these materials can certainly constitute a functional barrier. The plastic ordinance defines a functional barrier as follows: A barrier that consists of one or more layers of any type of material and ensures that the material or article in its finished condition complies with art. 3 of the ordinance (EU) no. 1935/2004 and the conditions of the plastic ordinance (art. 3 section 15). It is necessary to test whether a material or material combination constitutes a functional barrier depending on the individual application.

## 2.8 Summary

As a result of the listed requirements, the following consequences arise with respect to communication in the supply chain between the manufacturers and users of labels: Because no individual guidelines presently exist for almost any materials used in the field of self-adhesive labels, it is not possible to issue any declarations of conformity according to ordinance (EU) no. 1935/2004.

This type of declaration of conformity can be issued for:

**Plastics** - ordinance (EU) no. 10/2011 applies as the individual guideline here

No declaration of conformity, but rather a description of properties (see sample in the annex) can be issued for:

**Paper, cardboard, paperboard** - recommendation XXXVI - paper, cardboard and paperboard for food contact - of the Federal Institute for Risk Assessment (BfR) applies here.

**Printing inks** - the following regulations are relevant here:

- German printing inks ordinance (21<sup>st</sup> ordinance for the amendment of the Food and Feed code). Status from April 2014 is available as the fourth draft version from the 23<sup>rd</sup> October 2013.
- Guideline "Printing inks applied to the non-food contact surface of food packaging materials and articles" of the European Printing Ink Association (EuPIA)
- Swiss Ordinance 817.023.21 om Materials and Articles in contact with food (packaging inks ordinance)

**Adhesives** - the following regulations are relevant here:

- Ordinance (EU) no. 10/2011 (contains SML values that must be complied with)
- Recommendation XIV - plastic dispersions - Federal Institute for Risk Assessment (BfR)
- FDA 21 CFR 175.105

# CONFORMITY OF SELF-ADHESIVE LABELS

## 3. DECLARATION OF CONFORMITY AND/OR DESCRIPTION OF PROPERTIES

“It is common usage in the marketing and distribution of food contact materials to issue declarations or certificates on the suitability and the compliance with established food law requirements.” (Quote: Information pamphlet published by the BLL - German Federation of Food Law and Food Science).

Declarations of conformity are written declarations that confirm that the food contact materials comply with the valid specifications. According to article 16 of the framework ordinance (EU) no. 1935/2004 these are obligatory if the provision of a written declaration is stipulated in the “individual measures”. Such an individual measure applies e.g. to plastic (see 1.3.2), although not to paper, printing inks or adhesives for example. It is therefore not possible to issue a declaration of conformity for these materials.

### 3.1 Declaration of conformity for labels based on the plastic ordinance

A declaration of conformity can only be provided for the plastic film components of a label. According to Annex IV of ordinance (EU) no. 10/2011 such a declaration contains the following information:

1. Identity and address of the company issuing the declaration of conformity;
2. Identity and address of the company that produces or imports the plastic materials or articles, or products from intermediate stages of their manufacture or the substances that are intended for the manufacturer of these materials and articles;
3. Identity of the materials, articles, products from intermediate stages of the manufacture or the substances that are intended for the manufacturer of these materials and articles;
4. Date of the declaration;
5. Confirmation that the plastic materials or articles, the products from intermediate stages of the manufacture or the substances meet with the applicable requirements of this ordinance and ordinance (EU) no. 1935/2004;
6. Sufficient information on the substances used or their degradation products, for which Annexes I and II of this ordinance contain limitations and/or specifications, in order that the downstream companies can also assure the compliance with these limitations;
7. Sufficient information regarding the substances, the use in foodstuffs of which is subject to a restriction, obtained from test data or theoretical calculations regarding their specific migration values, and also regarding purity criteria where applicable according to directives 2008/60/EC, 95/45/EC and 2008/84/EC, in order that the users of these materials or articles are able to comply with the valid EU regulations or - if none should exist - the valid national regulations applicable to foodstuffs;
8. Specifications regarding the use of materials or articles, e.g.:
  - i) Type or types of foods that should come into contact with these;
  - ii) Duration and temperature of treatment and storage during contact with the food;
  - iii) Ratio of the surface in contact with the food to the volume, on which basis the conformity of the material or article was determined;
9. If a functional barrier is used in a multi-layered material or article: Confirmation that the material or article complies with the provisions of article 13 sections 2, 3 and 4 or article 14 sections 2 and 3 of this ordinance.

# CONFORMITY OF SELF-ADHESIVE LABELS

With the declaration of conformity, compliance with the valid specifications is confirmed to the user or consumer of the described food contact materials downstream within the chain. According to the stipulations of the legislators, it must be issued anew if significant changes in production result in changes in the migration or if new scientific findings arise.

With the passing on of declarations of conformity, differentiation is made between the "Declaration of conformity" document according to Annex IV of the ordinance (EU) no. 10/2011 and further "suitable documents" for the regulatory authorities, which are frequently also referred to as "supporting documents" or "background documents", e.g. declarations by sub-suppliers and information regarding preliminary products and components ("Confirmation of suitability").

These supporting documents remain with the manufacturer and are not part of the declaration of conformity to be passed on. They serve as a basis for the verification of conformity at internal manufacturer level, and as verification to the responsible authorities of compliance with the applicable legal requirements upon request.

## 3.2 Description of properties for self-adhesive labels

If it is not possible to provide a declaration of conformity, VskE recommends its sample description of properties for self-adhesive labels, which is intended for food packaging (see Annex 4.1)

## 3.3 Further explanations

### "Distributor of the food contact material"

This is generally the customer of the label printer or the foodstuff packer. The label printer is generally a supplier of a component of the food contact material.

### "Type of food contact material"

The user of self-adhesive labels should make available to their suppliers the most detailed information possible regarding the intended use and properties of the product that is to be labelled. The "Checklist: packaging details questionnaire" (see Annex 4.2) is helpful here.

### Closing word

Constant dialogue and the exchange of information within the delivery chain are essential prerequisites for the manufacturers of self-adhesive labels, in order to be able to deliver suitable products to the users for the specific application cases.

This information should make a contribution to supporting this process.



# CONFORMITY OF SELF-ADHESIVE LABELS

## 4. ANNEX

### 4.1. Description of properties

Description of properties for self-adhesive labels/labels [select applicable] from paper/plastic [select applicable] with direct/indirect [select applicable] food contact

We, [name of the company] hereby declare, with respect to the packaging supplied by us

[product designation]

to the company [customer], the following:

This certificate refers to self-adhesive labels/labels [select applicable] from paper/plastic [select applicable] with [describe label construction]

- a printed face,
- without/with printing of the carrier material and
- without/with printing of the rear side (adhesive side),
- whereby no/an [select] absolute or functional barrier exists between the packaging and the contents, i.e. direct/indirect [select] contact exists between the food contact material and the [specified] dry/wet/fatty/non-fatty contents.

This certificate does not constitute any declaration of assurance or guarantee regarding the suitability of the supplied food contact materials produced from paper/plastic composite for the intended use; instead it is a declaration certifying that the supplied packaging complies with the legal requirements in the best possible way.

The central regulations governing food contact materials with a direct legal effect in the European Union are:

- European framework ordinance (EU) no. 1935/2004 regarding “Materials and articles that are intended to come into contact with food”,
- European framework ordinance (EU) no. 10/2011 regarding plastic materials and articles that are intended to come into contact with food,
- European ordinance (EU) no. 2023/2006 regarding “Good manufacturing practice for materials and articles that are intended to come into contact with food”

Testing the suitability of the packaging for the respective contents, the behaviour of the contents during and after packaging and any possible interactions between the contents and the packaging falls under the responsibility of the user (packer, distributor) and requires appropriate measures from the same. The user themselves must check that the packaging is suitable for the intended purpose. The manufacturer of the labels cannot accept any liability for this.

We confirm that we have implemented a suitable and appropriate quality assurance and quality control system according to the principles of good manufacturing practice in conjunction with the ordinance (EU) no. 2023/2006 for the production of (self-adhesive) labels for labelling foods, and that we maintain the associated documentation on a constant basis.

# CONFORMITY OF SELF-ADHESIVE LABELS

With respect to the individual materials used for the manufacture of the self-adhesive labels:

## Adhesive labels

The materials used for the self-adhesive laminates supplied are specifically accompanied by the following certificates from the supplier:

### 1. Face material

#### 1.1 Plastic [designation]

- The plastic film [according to the manufacturer's declaration] fulfils the conditions of the German Food and Feed Code LFGB (in its current valid version)
- A declaration of conformity is available according to the European plastic ordinance (EU) no. 10/2011 (in its current valid version) for the plastic film used [note printing primer!].
- The printing primer/top coat/printing lacquer used [according to manufacturer's declaration] fulfils the requirements of the plastic ordinance (EU) no. 10/2011, as well as the ordinance governing good manufacturing practice and the CEPE raw materials exclusion list.
- The plastic film [according to manufacturer's declaration] complies with BfR recommendation III, polyethylene ..... VII, polypropylene .....

#### 1.2 Paper [designation]

- The paper complies with the BfR recommendation XXXVI, paper, cardboard, paperboard, ....., for direct/indirect/cut edge contact with dry/wet/fatty/non-
- fatty/non-alcoholic ..... foods
- The paper fulfils the conditions of the German Food and Feed Code LFGB (in its current valid version).

### 2. Adhesive [designation]

- The adhesive [according to the manufacturer's declaration] fulfils the conditions of the German Food and Feed Code LFGB (in its current valid version)
- A declaration of conformity is available according to the European plastic ordinance (EU) no. 10/2011 (in its current valid version) for the adhesive used.
- The adhesive complies with the BfR recommendation [according to the manufacturer's declaration] XIV, plastic dispersions .....for ..... direct/indirect/cut edge contact with
- dry/wet/fatty/non-fatty/non-alcoholic ..... foods.

### 3. Inks/lacquers [designation]

Only printing inks and lacquers for application to the non-food contact side are used, for which we have the appropriate certificates as issued to us by the printing ink manufacturers. These declarations pertain to the industry standards of the European Printing Ink Association:

- "EuPIA guideline for printing inks applied to the non-food contact surface of food packaging materials and articles" (in its most recent version)

Our suppliers also confirm that the total proportion of heavy metals mercury, lead, cadmium and chrome VI in their products is less than 100 ppm.

We therefore fulfil the stipulations of the **European packaging directive 94/62/EC**, implemented in **§ 13 of the German packaging ordinance (VerpackVO)**.

*[Date, signature of an authorised representative]*

# CONFORMITY OF SELF-ADHESIVE LABELS

## 4.2. Checklist: Packaging details questionnaire

### CUSTOMER INFORMATION:

Customer: \_\_\_\_\_

Contact: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

Project: \_\_\_\_\_

Other: \_\_\_\_\_

### INFORMATION ON THE PACKAGING MATERIAL:

Will the contents be enclosed by an absolute or functional barrier:

Absolute barrier (Glass, metal, 7  $\mu\text{m}$  aluminium)

Functional barrier, description:

\_\_\_\_\_  
\_\_\_\_\_

What type of packaging is it?

\_\_\_\_\_

Precisely how is the packaging material constructed?

Designation of the layers with thickness information (foil(s), adhesive, print, lacquer, etc.)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The following surface (packaging) / volumetric ratio (food) is considered:

\_\_\_\_\_  $\text{dm}^2$  packaging / \_\_\_\_\_ ml food

# CONFORMITY OF SELF-ADHESIVE LABELS

## INFORMATION ON THE CONTENTS / FOOD:

What type of contents / food is it?

\_\_\_\_\_

- Details:
- liquid
  - dry
  - containing fat / fat content \_\_\_\_\_ %
  - acidic / acid content \_\_\_\_\_ %
  - containing alcohol \_\_\_\_\_ %
  - dry with fat coating
  - \_\_\_\_\_

What is the shelf life of the contents / food?

\_\_\_\_\_

The smallest quantities of food to be packaged are \_\_\_\_\_ g

## INFORMATION ON THE FILLING:

- Filling takes place before / after labelling     before     after
- The contents are hot at the time of filling     no     yes, for \_\_\_\_\_ with \_\_\_\_\_ °C
- The packaging is pasteurised with the label     no     yes, for \_\_\_\_\_ with \_\_\_\_\_ °C
- The packaging is sterilised with the label     no     yes, for \_\_\_\_\_ with \_\_\_\_\_ °C
- The packaging is microwave-treated with the label     no     yes, for \_\_\_\_\_ with \_\_\_\_\_ °C

# CONFORMITY OF SELF-ADHESIVE LABELS

## INFORMATION ON STORAGE AND TRANSPORT:

The packaged food is stored under the following conditions: \_\_\_\_\_ °C \_\_\_\_\_ % rel. humidity

The packaged food is stored under the following conditions for  
\_\_\_\_\_ days transportation: \_\_\_\_\_ °C \_\_\_\_\_ % rel. humidity

Does the outside of the packaging come into contact with the inside of the packaging prior to filling?

- Yes
- No

## LEGAL INFORMATION:

In addition to the applicable legal regulations, is it necessary to comply with other specifications?

- Special customer stipulations

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## OTHER REMARKS:

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Recorded/completed by:

on the:

---

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# CONFORMITY OF SELF-ADHESIVE LABELS

## 4.3. Example 1: Supporting document - certificate of compliance

<b>DR. RALPH DERRA</b> Öffentlich bestellter und vereidigter Sachverständiger für Verpackungsmaterialien, Boden- und Luftanalysen	Akkreditiert gemäß DIN EN ISO / IEC 17025 DIN EN 45011 <b>DACH</b> DAC-PL-0035-97-20 DAC-ZE-002-08	<b>ISEGA – Forschungs- und Untersuchungs- Gesellschaft mbH</b> Aschaffenburg
		63704 Aschaffenburg, Postfach 100565 63741 Aschaffenburg, Zeppelinstr. 3-5 Germany Telefon +49 (0) 60 21 / 49 89-0 Telefax +49 (0) 60 21 / 49 89-30 Email info@isega.de http://www.isega.de
		09.10.2013 Dr. Dr/bk-ml
<b>UNBEDENKLICHKEITSERKLÄRUNG CERTIFICATE OF COMPLIANCE CERTIFICAT DE CONFORMITE</b>		
eingetragen registered no. registré	36457 U 13	
für Firma for Messrs pour MM	HERMA GmbH - Geschäftsbereich Haftmaterial Fabrikstraße 16 70794 Filderstadt	
Produkt Product Produit	Adhesive quality 62Gpt	

The product manufactured by the aforementioned company is an adhesive quality that is used for the rear-side coating of labels and for laminating various materials.

Samples coated with the product have been used by us

according to the methods for testing plastics, insofar as they are commodities in the sense of food and commodities law, including the 62nd notification of the BfR for the testing of high polymers, Federal Health Bulletin 50, 524 (2007), status from April 2007,

for the composition of the adhesive and the absence of constituents harmful to health,

and according to the

- 2 -

Geschäftsführer: Dr. Ralph Derra · Handelsregister: Aschaffenburg HRB 3329  
Die Veröffentlichung von Ergebnissen unserer Arbeiten und Gutachten sowie die Verwendung für Werbezwecke bedürfen – auch auszugsweise – unserer schriftlichen Genehmigung.  
Erfüllungsort und Gerichtsstand Aschaffenburg

# CONFORMITY OF SELF-ADHESIVE LABELS

Page 2 of the document dated 09.10.2013 ISEGA Forschungs- und  
Untersuchungs-Gesellschaft mbH Aschaffenburg

36457 U 13

“Methods for testing commodities, basic rules for determining migration in test foods”, per  
specification no. 80.30, 1 - 3 (EC) in the official publication of test processes according to  
§ 64 of the Food and Feed Code - LFGB, status from April 2008,

and according to the

standard series EN 1186, EN 13130 and CEN/TS 14234 “Materials and articles in contact with  
foodstuffs - plastics”, current status,

for the migration behaviour.

The tests on the coated samples led to results that guarantee that the packaging materials for  
food coated with the adhesive are able to fulfil the specifications of the

ordinance (EC) no. 1935/2004 of the European Parliament and the Council dated the 27<sup>th</sup>  
October 2004 regarding materials and articles, which are intended to come into contact  
with food and for rescinding directives 80/590/EEC and 89/109/EEC, official gazette of the  
European Union L 338/4 dated the 13.11.2004, amended by Annex no. 5.17 of the ordinance  
(EC) no. 596/2009 dated the 18<sup>th</sup> June 2009, official gazette of the European Union L 188  
dated the 18.07.2009. Article 3

and the

Food, Commodities and Feed Code (Food and Feed Code - LFGB) in its version published on  
the 3<sup>rd</sup> June 2013 (BGBl. I p. 1426), most recently amended by article 4 section 20 of the act  
dated the 7<sup>th</sup> August 2013 (BGBl. I p., 3154), §§ 30 and 31,

insofar as this pertains to the influence of the adhesive.

The technical suitability of the adhesive must be checked on an individual case basis. This also  
includes a possible sensory impact of the food.

Limit values of the

ordinance (EU) no. 10/2011 of the commission dated the 14<sup>th</sup> January 2011 regarding plastic  
materials and articles, which are intended for contact with food, official gazette of the  
European Union L 12/1 dated the 15 01.2011, most recently amended and corrected by the  
ordinance (EU) no. 1183/2012 of the commission dated the 30<sup>th</sup> November 2012, official  
gazette of the European Union L 338/11 dated the 12.12.2012,

and

the Commodity Ordinance in its version as published on the 23<sup>rd</sup> December 1997 (BGBl.  
1998 I p. 5), most recently amended by article 1 of the ordinance dated the 24<sup>th</sup> June 2013  
(BGBl. I p. 1682),

are complied with by the samples coated with the adhesive.

# CONFORMITY OF SELF-ADHESIVE LABELS

Page 3 of the document dated 09.10.2013 ISEGA Forschungs- und  
Untersuchungs-Gesellschaft mbH Aschaffenburg

36457 U 13

Adhesive 62Gpt per the sample material presented can therefore be used without concern for coating the backs of labels. The adhesive layer may be in direct contact with such dry, wet and greasy foodstuffs as can be assigned a correction factor of at least 2 according to ordinance (EU) no. 10/2011. Furthermore, the adhesive may be used for laminating various materials. In this case, cut edge contact with foods is harmless.

This declaration of harmlessness constitutes the latest technical status and is based on the declaration of harmlessness no. 32415 U 11 dated the 30.09.2011, in conjunction with a renewed part testing of the product.

It has a validity period of 2 years and comprises 4 pages.

*Staatlich anerkannter Sachverständiger*

Staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Weißblech und  
sonstigen Metallverpackungen auf ihre  
Lebensmittelrechtliche Unbedenklichkeit.



(Burkardt)  
Staatlich geprüfter und  
zugelassener Lebensmittel-  
chemiker



The translation of the above stamps is given on page 4.  
La traduction des estampilles est donnée en page 4.



# CONFORMITY OF SELF-ADHESIVE LABELS

Page 4 of the document dated 09.10.2013 ISEGA Forschungs- und  
Untersuchungs-Gesellschaft mbH Aschaffenburg

36457 U 13



Staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Weissblech und  
sonstigen Metallverpackungen auf ihre  
lebensmittelrechtliche Unbedenklichkeit.

Dr. Ralph Derra

Authorized expert for the analyses of  
packaging materials, attested by the  
Aschaffenburg Chamber of Industry and  
Commerce.

Expert autorisé pour l'analyse des maté-  
riaux d'emballage, assermenté par la  
Chambre d'Industrie et de Commerce  
d'Aschaffenburg.

State registered expert for the analysis of  
contrasting samples of packaging materi-  
als of paper, board, plastics, glass, tin  
plate and other metallic packaging materi-  
als as to their suitability for use with food-  
stuffs.

Expert public pour l'étude du control des  
contre-échantillons d'emballages de pa-  
pier, cartons, plastiques, verre, fer-blanc et  
d'autres emballages métalliques concer-  
nant leur conformité alimentaire.



Dr. Ralph Derra

Authorized expert for the analyses of soil  
and air, attested by the Aschaffenburg  
Chamber of Industry and Commerce.

Expert autorisé pour l'analyse du sol et de  
l'air, assermenté par la Chambre  
d'Industrie et de Commerce d'Aschaffenburg.

---

Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.  
A file sample of the tested material is kept at the expert's office.  
Réserve du matériel analysé est gardée au bureau de l'expert.

# CONFORMITY OF SELF-ADHESIVE LABELS

## 4.4 Example 2: supporting document - declaration of conformity



**FABES Forschungs-GmbH**  
für Analytik und Bewertung von Stoffübergängen  
Schragenhofstrasse 35 | 80992 München

### DECLARATION OF CONFORMITY (\*)

for the compliance of the migration behaviour with the European and German legislation applicable to materials in contact with food

Certificate no.: CON XXXX/20XY Date: xx.xx.2013

Number of pages:  
actual page: 1

Supplier/  
manufacturer: VskE  
Luzer Strasse 6  
97204 HÖCHBERG

Product: UV-printed and lacquered self-adhesive paper labels on PE material with the following specifications:

- PE material (thickness >0.25 mm) with a capacity of at least XY g;
- Maximum X labels (paper "Code No. 001") per XY cm<sup>2</sup>;
- UV printing ink used "Code No. 002";
- Maximum application quantity of the printing ink: XY g/m<sup>2</sup>, UV-dried with XY Watt/cm<sup>2</sup> etc.

Application: Intended for contact with all types of foodstuffs and storage with refrigeration or at room temperature. The migration results based on the assumption that.... With lower quantities of foodstuffs the migration results can change accordingly and must be recalculated and possibly re-evaluated.

Samples and information: --

Migration tests: Global and specific migration, as well as screening, have been carried out in accordance with the directives 82/711/EEC, 93/8/EEC, 97/48/EC and 85/572/EC and in agreement with ordinance (EU) no. 10/2011 and its amendments.

Test report: (\*)... dated XX.XX.20XY.

\* FABES Forschungs-GmbH is a test laboratory accredited by DAkkS according to DIN EN ISO/IEC 17025. The accreditation applies to the test processes listed in the certificate. Generation of the conformity certificates is not a component of accreditation.

Registered court Munich  
HRB115656  
Jurisdiction and  
place of fulfilment:

Company head office: Munich  
VAT no.:DE185 445 952  
Managing Directors:  
Dr. Monika Rüter,  
Munich Dr. Otto Piringer

HypoVereinsbank Munich  
S/C 700 202 70  
Acc. No.: 46770277



# CONFORMITY OF SELF-ADHESIVE LABELS

Certificate no.: CON XXXX/20XY

Page 2 of 2

This certificate has been generated in agreement with the ordinance (EC) no. 1935/2004 of the European Parliament and the Council (dated the 27.10.2004) ....

The tested samples comply with the conditions of the ordinance (EU) no. 10/2011... ordinance (EC) no. 1935/2004 of the European Parliament and the Council (dated the 27.10.2004)... under the aforementioned application conditions.

This declaration of conformity applies to the test samples presented to FABES, the migration and/or extraction tests carried out....

This certificate has a validity period of XY years from its date of issue...

Munich, XX.XX.20XY

FABES Forschungs-GmbH

\* FABES Forschungs-GmbH is a test laboratory accredited by DAkkS according to DIN EN ISO/IEC 17025. The accreditation applies to the test processes listed in the certificate. Generation of the conformity certificates is not a component of accreditation.

FABES Forschungs-GmbH | Schragenhofstrasse 35 | 80992 München | Tel.: (0)89-149009-50 | [www.fabes-online.de](http://www.fabes-online.de)

# CONFORMITY OF SELF-ADHESIVE LABELS

## 4.5 Links to current websites (status August 2015)

### LINKS TO THE EUROPEAN UNION WITH ITS OFFICES AND INSTITUTIONS

#### European Chemicals Agency (ECHA)

- <http://www.echa.europa.eu>

#### Candidate list - substances of very high concern (SVHC):

- <http://www.echa.europa.eu/web/guest/candidate-list-table>

#### The European Parliament:

- <http://www.europarl.europa.eu/portal/en>

#### The European Council:

- <http://www.consilium.europa.eu/en/home/>

- <http://ec.europa.eu>

#### The European Union:

- <http://europa.eu>

- <http://europa.eu/poll/food>

#### European Food Safety Authority (EFSA):

- <http://www.efsa.europa.eu>

### LINKS TO GERMAN FEDERAL MINISTRIES, AS WELL AS SUBORDINATE OFFICES AND FACILITIES RELATED TO CONSUMER HEALTH PROTECTION

#### Federal Office of Consumer Protection and Food Safety (BVL):

- <http://www.bvl.bund.de>

- [http://www.bvl.bund.de/DE/03\\_Bedarfsgegenstaende/bgs\\_node.html](http://www.bvl.bund.de/DE/03_Bedarfsgegenstaende/bgs_node.html)

#### Federal Ministry for Food and Agriculture:

- <http://www.bmel.de>

- [http://www.bmel.de/cln\\_135/DE/Startseite/startseite\\_node.html](http://www.bmel.de/cln_135/DE/Startseite/startseite_node.html)

#### Federal Ministry for the Environment, Nature Conservation and Nuclear Safety:

- <http://www.bmub.bund.de/en/>

#### Federal Environmental Agency (UBA):

- <http://www.umweltbundesamt.de/en>

#### BfR - Federal Institute for Risk Assessment:

- <http://www.bfr.bund.de/en/home.html>

- [http://www.bfr.bund.de/en/database\\_bfr\\_recommendations\\_on\\_food\\_contact\\_materials\\_\\_for\\_merly\\_\\_plastics\\_recommendations\\_\\_-1711.html](http://www.bfr.bund.de/en/database_bfr_recommendations_on_food_contact_materials__for_merly__plastics_recommendations__-1711.html)

# CONFORMITY OF SELF-ADHESIVE LABELS

## LINKS WITH INTERNATIONAL ORGANISATIONS RELATED TO CONSUMER HEALTH PROTECTION

### Codex Alimentarius:

- <http://www.codexalimentarius.net>
- [http://www.bmel.de/DE/Ernaehrung/SichereLebensmittel/Codex-Alimentarius/\\_Texte/CodexInfo.html](http://www.bmel.de/DE/Ernaehrung/SichereLebensmittel/Codex-Alimentarius/_Texte/CodexInfo.html)

## LINKS WITH LAWS AND LEGAL ORDINANCES IN GERMANY AND EUROPE, WHICH ARE RELATED TO CONSUMER HEALTH PROTECTION OR COMMODITIES

### EC official gazette:

- <http://eur-lex.europa.eu/homepage.html?locale=en>
- <http://eur-lex.europa.eu/JOIndex.do?ihmlang=de>

### Federal Law Gazette (I) with all German laws in recent months:

- <http://www.bundesanzeiger.de>

### The law of the European Union: EUR-Lex homepage:

- <http://eur-lex.europa.eu>

### Commodity Ordinance (BedGgstV):

- <http://www.gesetze-im-internet.de/bedggstv/index.html>

### Food, Commodities and Feed Code (LFGB):

- <http://www.gesetze-im-internet.de/lfgb/index.html>

### Food commodities (ordinance EC no. 1935/2004). Ordinances regarding materials and articles that are intended to come into contact with food:

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l21082a>
- UK= <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN>

### Food commodities (ordinance EC no. 282/2008). Ordinance regarding materials and articles that are intended to come into contact with food:

- <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0282>
- UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0282&from=EN>

### Food commodities (ordinance EC no. 2023/2006). Ordinance regarding good manufacturing practice for materials and articles that are intended to come into contact with food:

- <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R2023>
- UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R2023&from=EN>

### Plastic ordinance (EU) no. 10/2011 (Plastic Implementation Measure - PIM):

- <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0010>
- UK: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN>

# CONFORMITY OF SELF-ADHESIVE LABELS

## OTHER LINKS

### European Printing Ink Association (EuPIA) Guideline on Printing Inks:

- [http://www.eupia.org/uploads/tx\\_edm/2011-11-14\\_EuPIA\\_Guideline\\_for\\_Food\\_Packaging\\_Inks\\_-\\_November\\_2011\\_\\_corr\\_July\\_2012.pdf](http://www.eupia.org/uploads/tx_edm/2011-11-14_EuPIA_Guideline_for_Food_Packaging_Inks_-_November_2011__corr_July_2012.pdf)

### Confederation of the European Paper Industries (CEPI) and International Confederation of Paper and Board Converters (CITPA)

#### Industry guideline for compliance of paper & board materials and articles for food contact.

- <http://www.cepi.org/system/files/public/documents/publications/foodcontact/2012/Industry%20guideline-updated2012final.pdf>

### U.S. Food and Drug Administration (FDA):

- <http://www.fda.gov>

### BPIF Labels Good Manufacturing Practice Guide

- [http://www.britishprint.com/downloads/managed/BPIF\\_labels\\_-\\_GMP\\_printing\\_of\\_labels\\_for\\_food\\_and\\_drinks2.pdf](http://www.britishprint.com/downloads/managed/BPIF_labels_-_GMP_printing_of_labels_for_food_and_drinks2.pdf)

### Plastic Europe Association of Plastic Manufacturers. Guidelines for good manufacturing practice for plastic materials and articles intended for food contact applications

- [http://www.plasticseurope.org/documents/document/20120112130220-2011\\_06\\_20\\_plasticseurope\\_guidelines\\_for\\_gmp\\_updated\\_june\\_2011\\_final.pdf](http://www.plasticseurope.org/documents/document/20120112130220-2011_06_20_plasticseurope_guidelines_for_gmp_updated_june_2011_final.pdf)

### Flexible Packaging Europe, CITPA. Code for good manufacturing practices for flexible and fibre base packaging for food

- [http://www.flexpack-europe.org/tl\\_files/FPE/downloads/FPE\\_GMP\\_Code\\_6.0.pdf](http://www.flexpack-europe.org/tl_files/FPE/downloads/FPE_GMP_Code_6.0.pdf)

### CAST Guidelines for the application of the Regulation (EC 2023/2006 to the supply of materials and articles intended to come into contact with food, produced by a collaboration of public and private bodies in Italy

- [http://www.iss.it/binary/publ/cont/11\\_37\\_web.pdf](http://www.iss.it/binary/publ/cont/11_37_web.pdf)

### European Carton Makers Association Good Manufacturing Practice

- <http://www.ecma.org/uploads/Bestanden/Publications/GMP/UK%20GMP%20%20Version%201.1%20%2016%2012%202013%20%20-%20FINAL.pdf>

### Association of the European Adhesive and Sealant Industry (FEICA) - Guideline:

- [http://www.feica.com/images/stories/gup-ex-e03-011\\_feica\\_gmp\\_guideline.pdf](http://www.feica.com/images/stories/gup-ex-e03-011_feica_gmp_guideline.pdf)

### German Adhesives Association (Industrieverband Klebstoffe e.V.)

- <http://www.klebstoffe.com>

### German Federation of Food Law and Food Science (BLL):

- [www.bll.de](http://www.bll.de)

### Federal Office of Consumer Protection and Food Safety:

- [www.bvl.bund.de](http://www.bvl.bund.de)

### Association of the German paint and coatings industry (VdL), (Lack- und Druckfarbenindustrie e.V.):

- [www.lackindustrie.de/druckfarben/Seiten/Uebersichtsseite.aspx](http://www.lackindustrie.de/druckfarben/Seiten/Uebersichtsseite.aspx)





World-wide Association for self-adhesive labels and related products

P.O. Box 85612

2508 CH The Hague

The Netherlands

Tel.: +31 (70) 312 39 10

Fax: +31 (70) 363 63 48

E-mail: [info@finat.com](mailto:info@finat.com)

Internet: [www.finat.com](http://www.finat.com)