

Regulations on papers & boards in Germany

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Germany

- Resolution of the Council of Europe with its adopted parts exists in parallel with national law.
- BfR-Recommendation XXXVI paper and board for food contact.

BfR-Recommendations












































































Issued by BfR since 1958 (“Plastic Recommendations”)

They are not legal norms

They are based on German and European law

They represent the current state of the scientific and technical knowledge

Access via the BfR website is free of charge
(http://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp)

Id	Recommendation	Recommendation(s) Announcement(s) Substance(s)
010	I. High Polymers Containing Plasticizers	  
020	II. Plasticizer-free polyvinyl chloride, plasticizer-free copolymers of vinyl chloride and mixtures of these polymers with other copolymers and chlorinated polyolefins containing mainly vinyl chloride in the total mixture	  
030	III. Polyethylene	  
050	V. Polystyrene Produced exclusively from the Polymerisation of Styrene	  
060	VI. Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers	  
070	VII. Polypropylen	  
090	IX. Colorants for Plastics and other Polymers Used in Commodities	  
100	X. Polyamides	  
110	XI. Polycarbonates and Mixtures of Polycarbonates with other Polymers or Copolymers	  
120	XII. Unsaturated Polyester Resins	  
140	XIV. Plastics Dispersions	  
150	XV. Silicones	  
160	XVI. Polyvinyl Ethers	  
170	XVII. Poly(terephthalic acid diol esters)	  
200	XX. Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers	  
210	XXI. Commodities based on Natural and Synthetic Rubber	  
220	XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers	  
250	XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics	  
280	XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials	  
300	XXX. Conveyor Belts Made from Gutta-Percha and Balata	  
330	XXXIII. Acetal resins	  
340	XXXIV. Vinylidene Chloride Copolymers with a Predominant Content of Polyvinylidene Chloride	  
350	XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters	  
360	XXXVI. Paper and board for food contact	  
361	XXXVII. Cooking Papers, Hot Filter Papers and Filter Layers	  

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Recommendations

Substances

Substances:

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Further Guidelines

Last amendment of the recommendations

Imprint

 [Deutsche Version](#)

A service of the Federal Agency for Agriculture and Food
(BLE).

BfR-Recommendations XXXVI

- XXXVI Paper and board for food contact
(food packaging, kitchen towels, napkins)
- XXXVI/1 Cooking Papers, Hot Filter Papers and Filter Layers
(hot filter papers, tea bags, boil-in-bag packages etc.)
- XXXVI/2 Paper and Paperboard for Baking Purposes
(baking paper, etc.)
- XXXVI/3 Absorber pads based on cellulosic fibres for food
packaging

BfR-Recommendations XXXVI

These Recommendations apply to

- Raw materials, production aids, and special paper refining agents used in the production process for paper, paperboard and board that comes into contact with foodstuffs
- Preservatives that are used to prevent microbial spoilage of formulations and slimicides

These Recommendations do not apply to

- Substances are used to keep manufacturing devices clean and to protect them from corrosion
- Substances that are used for manufacturing of paper raw materials or substances that are used for formulation of active ingredients (e.g. emulsifiers, solvents, set-up chemicals, stabilizer, pH modifiers)

For these substances the manufacturer or distributor of the paper is responsible to comply to food regulations (especially Regulation (EU) No. 1935/2004).

BfR-Recommendations XXXVI

According to European Biocide Regulation (EU) No. 528/2012
→ Removal of slimicides and preservatives from BfR-
Recommendations in 2014

Recommendation	Removal of	
	Slimicides	Preservatives
XXXVI	20	11
XXXVI/1	4	-
XXXVI/2	5	4
XXXVI/3	3	-

BfR-Recommendations XXXVI

Recommendation	Evaluations		No. of listed substances*
	Last 5 years	Pending applications	
XXXVI	27	7	437
XXXVI/1	14	1	152
XXXVI/2	12	3	201
XXXVI/3	4	-	87

*No. includes substances, polymers and monomers

BfR-Recommendations XXXVI

Intended use of newly added substances:

- Surface refining and coating agents
- Slimicides
- Preservatives
- Retention agents
- Sizing agents
- Defoamers
- Dispersion and flotation agents
- Wet-strength agents
- Fillers
- Pigments

BfR-Recommendations

Applications to add new substances to the Recommendation

According to the EFSA Note for Guidance:

<http://www.efsa.europa.eu/de/efsajournal/doc/21r.pdf>

- Characterization of the substance
- Intended use of the substance
- Migration data on the substance into food, including the necessary analytical methods
- Toxicological data
- Reference substance

BfR-Recommendations XXXVI

Special requirements for Paper-Recommendations

- Evaluation includes active substances as well as impurities, reaction, degradation products and oligomers
- The convention that 40 g paper come into contact with 1 kg food according to DIN EN 645 and 647 (cold and hot water extract) is used

All assumptions made must be justified in a comprehensible manner.

BfR-Recommendations XXXVI

Methods for determining the transfer of substances from paper

- Theoretical calculation on the assumption of a complete transfer based on the quantity used in the process
- Theoretical calculation on the assumption of a complete transfer based on the content in the paper
- Migration measurement
 - in simulants
 - in foodstuffs

BfR-Recommendations XXXVI

Migration measurement in simulants (finished paper)

Recommendation XXXVI

- Cold water extract according to DIN EN 645
- Organic solvent extract (isooctane/95 % ethanol) in accordance with DIN EN 15519
- Migration tests according to the provisions of Regulation (EU) No. 10/2011
- Where appropriate determination of the transfer from paper and board using modified polyphenylene oxide (MPPO) as a simulant (DIN EN 14338)

Recommendation XXXVI/1

- Hot water extract according to DIN EN 647
- Organic solvent extract (isooctane/95 % ethanol) in accordance with DIN EN 15519

BfR-Recommendations XXXVI

Migration measurement in simulants (finished paper)

Recommendation XXXVI/2

- Hot water extract according to DIN EN 647
- Organic solvent extract (isooctane/95 % ethanol) in accordance with DIN EN 15519

Or migration tests:

- 2 hrs at 220 °C using modified polyphenylene oxide (MPPO) as a simulant (DIN EN 14338)

or

- 2 hrs at 220 °C with test dough in accordance with DIN 10955, Section 11.2.5.4

For use of paper and board in microwave applications, only, migration test conditions are 30 min at 150 °C.

BfR-Recommendations: toxicological data

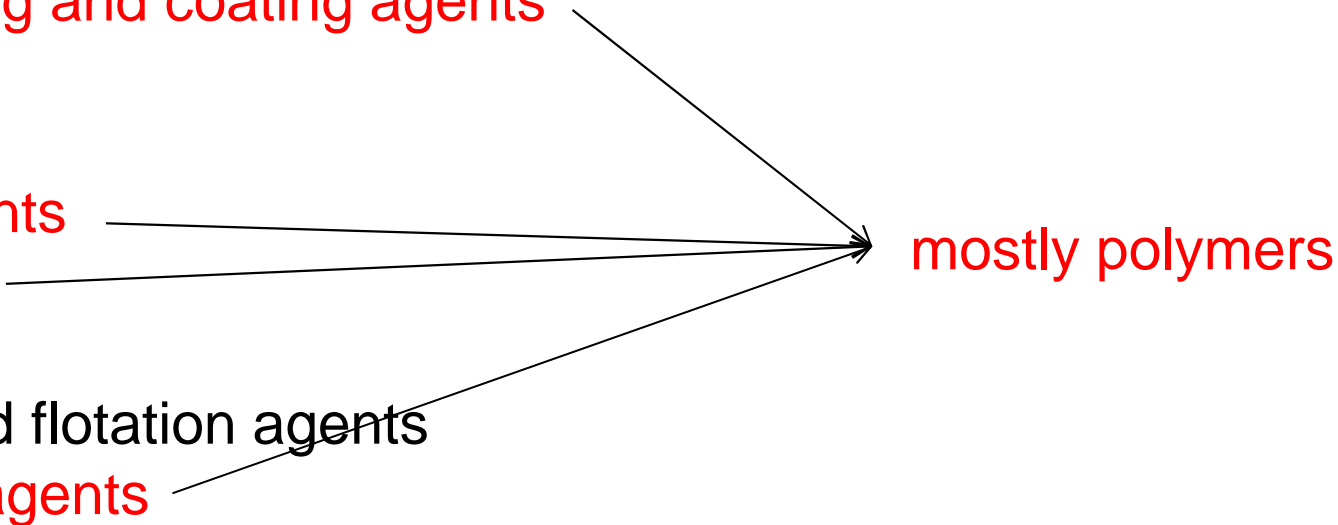
Migration	Required toxicological data*
< 0.05 mg/kg food	2 mutagenicity studies <i>in vitro</i>
0.05 – 5 mg/kg food	<u>additional:</u> 90-day oral toxicity studies, Data to demonstrate the absence of potential for accumulation in man
> 5 – 60 mg/kg food	<u>additional:</u> Studies on absorption, distribution, metabolism and excretion Studies on reproduction in one species, and developmental toxicity Studies on long-term toxicity/carcinogenicity

* EFSA Note for Guidance

BfR-Recommendations XXXVI

Challenges

Intended use of newly added substances:

- Surface refining and coating agents
 - Slimicides
 - Preservatives
 - Retention agents
 - Sizing agents
 - Defoamers
 - Dispersion and flotation agents
 - Wet-strength agents
 - Fillers
 - Pigments
- mostly polymers
- 

BfR-Recommendations XXXVI

Challenges

- Many dossiers for polymeric additives
 - Oligomers should be identified and quantified
 - First step: Measurement in the trade product – calculated migration into food might be high
 - identification of oligomers is needed
 - no toxicological data available
 - substance for toxicological tests not available
 - Second step: Measurement in the cold water extract
 - problems with paper matrix

Thank you for your attention

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