



Plastics for contact with food
Information on applicable laws
and regulations





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Competence in plastics

The Röchling Group is a global plastics group. With some 9,000 on the workforce at 88 locations in 25 countries, Röchling today ranks internationally amongst the leading enterprises in the field of plastics processing. With our Industrial, Automotive and Medical divisions, annual sales revenue from business in Europe, the Americas, and Asia amount to approximately EUR 1.7 billion.

Röchling Industrial

The **Industrial** Division covers the range of technical plastics and high-performance plastics within the Röchling Group. With world-wide subsidiaries as well as sales and distribution offices, the Industrial Division has a leading position internationally in producing and machining thermoplastics and composites for the capital goods industry. The product range covers extruded, polymerised and pressed semifinished products, such as round rods, plates and sheets, foils, tubes, extruded profiles, special polyamide cast parts, fibre-reinforced plastics and machined finished components.

www.roechling.com

Plastics for contact with food

Wide range from PE to PEEK

Röchling offers a broad spectrum of plastics for direct contact with food, from standard plastics to high-temperature plastics. They comply with the requirements of Regulation 10/2011/EU, which has been in force since May 2011, its amendment 1282/2011/EU, Framework Regulation 1935/2004/EC and Regulation 2023/2006/EC. Many of Röchling's plastics for direct contact with food also meet the requirements of the US Food and Drug Administration (FDA).

Strictest test conditions

Evidence of suitability for food is provided by means of migration tests pursuant to Regulation 10/2011/EU which were carried out on our products with all the necessary simulants under the toughest test conditions with regard to temperature and the duration of testing.

This means you can be confident that the tested plastics are considered suitable for contact with all kinds of food as stated in our declarations of compliance. Declarations of compliance for our materials can be found on our website at www.roechling.com

Good Manufacturing Practice

It goes without saying that our manufacturing processes are in line with "Good Manufacturing Practice" (2023/2006/EC).

Greatest safety

We ensure that our plastic products intended for contact with food meet the requirements of Framework Regulation 1935/2004/EC. This means they do not have any negative influence on:

- the health of consumers and
- the composition, taste, aroma and appearance of the food

Wide range

The wide range of our materials covers almost all requirements in terms of temperature and time in the production of food. Many of our food-compliant materials are available directly ex stock in different sizes or can be produced at short notice.



Wide range from PE to PEEK

Material	Colour	EU: 10/2011/EU	USA: FDA Code of Federal Regulation [21 CFR] or FDA FCN
PE-LD	Polystone® E	natural	●
PE-300	Polystone® G	natural, blue	●
		white UV, black	●
		light grey	●
	Polystone® GV	natural	●
	Foamlite® G	grey, blue	●
	Polystone® Cut Ride	black, grey, royal blue	●
PE-100	Polystone® G schwarz B 100	black	●
PE-HMW	Polystone® D	marmor, white, marmor white, black	●
		natural, blue, red brown	●
	Polystone® D FDA	black	●
	Polystone® D microbloc	natural	●
PE-UHMW	Polystone® M	natural, blue, blue grey	●
		black	●
	Polystone® M FDA	black	●
	Polystone® M AST	black	●
	Polystone® M AST-FDA	black	●
	Polystone® M EHS	dark blue, light blue, white	●
	Polystone® M MDT	blue	●
	Polystone® M slide	natural	●
	Matrox FC	natural	●
	PP	Polystone® P Homopolymer	natural, grey
white, black			●
Polystone® P UTG		natural	●
Polystone® P SSAG		natural	●
Polystone® P Copolymer		natural	●
		grey, bicolor white	●
	Polystone® P MG	yellow, orange, red, pink, blue, green, brown, white	●
LubX®	LubX® S	grey	●
	LubX® C	blue	●
	LubX® CV	blue	●
PVC	Trovidur® EC-FG	white, light grey, dark grey	●
	Trovidur® NL	red	●
PA6	SUSTAMID 6	natural	●
	SUSTAMID 6 FG	natural	●
PA66	SUSTAMID 66	natural	●
	SUSTAMID 66 FG	natural	●
PA6G	SUSTAMID 6G	natural*	●
POM C	SUSTARIN C	natural, black, yellow, red, green, blue	●
	SUSTARIN C FG	natural, black, blue	●
	SUSTARIN C MG	natural, red, yellow, grey, green, blue, brown, black	●
	SUSTARIN C MDT	blue	●
	SUSTARIN C GDL 160	natural	●
	SUSTARIN C GDL 350	blue	●
POM H	SUSTARIN H	natural	●
PC	SUSTANAT PC	natural	●
PET	SUSTADUR PET	natural	●
	SUSTADUR PET FG	natural	●
	SUSTADUR PET GLD 130	natural	●
PVDF	SUSTAPVDF	natural	●
	SUSTAPVDF FG	natural	●
	Polystone® PVDF	natural	●
PSU	SUSTASON PSU	natural	●
PES	SUSTASON PES	natural	●
PPSU	SUSTASON PPSU	natural, black	●
	SUSTASON PPSU MG	natural, black, blue, green, red, yellow, grey, brown, ivory, rust-colored	●
PEI	SUSTAPEI	natural	●
PPS	SUSTATRON PPS	natural	●
	SUSTATRON PPS GF 40	natural	●
PEEK	SUSTAPEEK	natural	●
	SUSTAPEEK FG	natural	●
	SUSTAPEEK MG	natural, black, copper, blue, green, yellow	●
	SUSTAPEEK GLD 140 FG	natural, blue	●

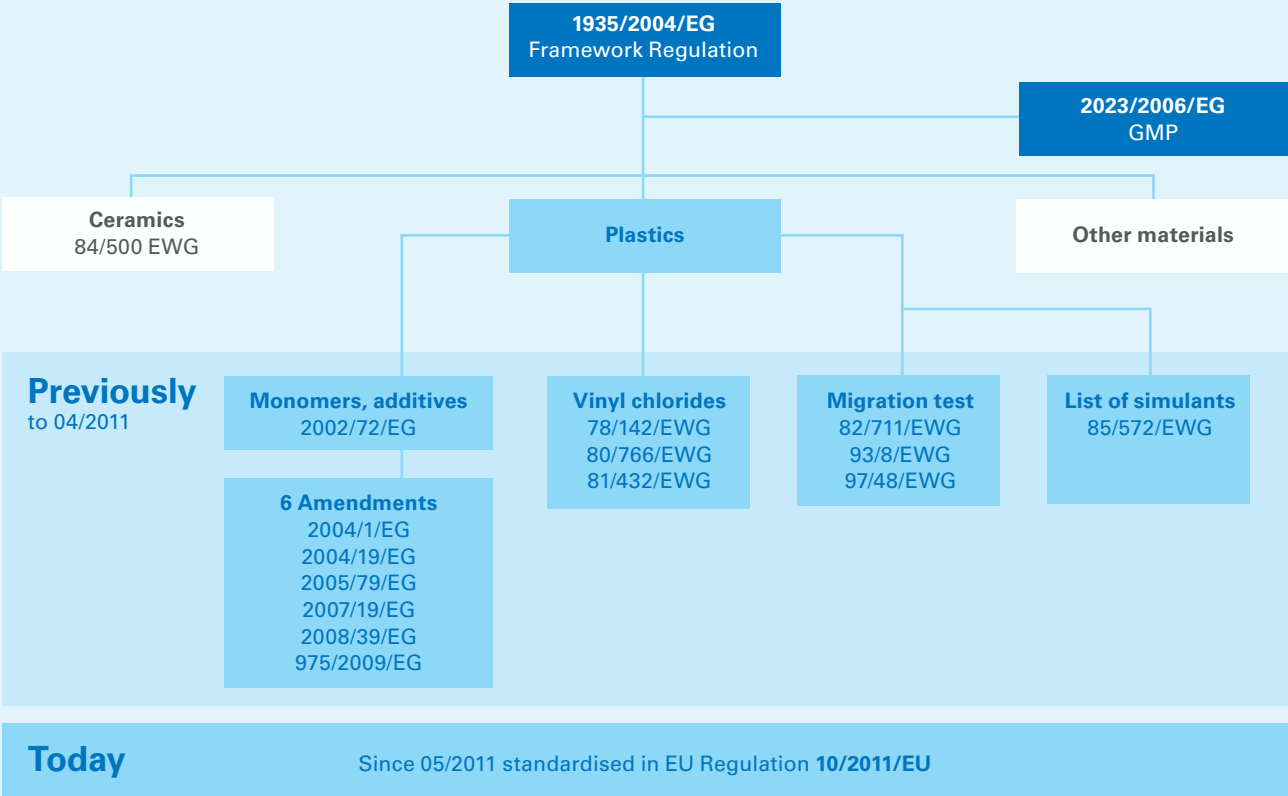
*More colours on demand | Meets suitability requirements
The list is constantly updated. Please visit our website: www.roehling-industrial.com/characteristics/food-contact

Applicable laws and regulations for contact with food

In the industrial processing foodstuffs necessarily come into contact with machine parts made of different materials. Freight containers, slide rails, conveyor screws, scrapers or filling equipment – which often consist of plastic. Packaging materials used include paper, glass, aluminium, composites and, in particular, plastic. The European Union and the United States have a number of laws governing contact between foodstuffs and the materials, and companies are required to comply with these when manufacturing the materials.

In the European Union the contact of plastics with food is governed by Framework Regulation 1935/2004/EC, Regulation 2023/2006/EC and Regulation 10/2011/EU.

Which regulations have to be observed in the European Union for contact with food?



Framework Regulation 1935/2004/EC

The most important primary European law is Framework Regulation 1935/2004/EC: According to article 3, any material or item intended to come into contact directly or indirectly with food must be sufficiently inert. This means that substances may only be transferred to food in quantities that are small enough to ensure that:

- human health is not endangered
- the change in the chemical composition of the food is acceptable
- the organoleptic properties – the aroma, taste, appearance and colour – of the food do not deteriorate

Regulation 2023/2006/EC

This Regulation is based on Framework Regulation 1935/2004/EC and concerns Good Manufacturing Practice (GMP). Companies that make materials for contact with food must establish and maintain a quality assurance and quality control system as well as documentation in accordance with Good Manufacturing Practice guidelines.

Regulation 10/2011/EU

In order to satisfy the requirements of Framework Regulation 1935/2004/EC, companies must also observe other Regulations which refer to the type of material. These are known as specific measures. For plastics in contact with food, this is Regulation 10/2011/EU, frequently referred to as the Plastic Implementation Measure (PIM), which has been in force since May 2011, and its amendment 1282/2011/EU. It summarises a whole raft of Directives and consolidates and extends the previous Directive 2002/72/EC including its six amendments. (See graphic on p. 5)

The most important content of Regulation 10/2011/EU is the following:

Sole use of substances from the “Union list”:

Only the substances listed in the “Union list” of Regulation 10/2011/EU may be used in the manufacture of the plastic. This is a positive list with originally 885 substances that is updated regularly.

It consists of the following areas:

- monomers and other starting substances
- additives excluding colorants
- production aids excluding solvents

Compliance with the overall migration limit (OML):

What is measured is the total amount of non-volatile substances that migrate from the material into the food, regardless of its chemical nature. This limit (10 mg/dm² contact surface or 60 mg/kg food) is intended to ensure that the chemical composition of the food is not changed unacceptably. The overall migration limit applies equally for all plastics.

Compliance with the specific migration limit (SML):

A maximum permitted amount of given substances that can migrate from the material into the food must not be exceeded. The limits are intended to ensure that human health is not endangered. A plastic may contain no, one or more substances that have to be tested.

Binding issuance of a declaration of compliance:

The information required in the declarations of compliance for the materials for contact with food is precisely defined. The information to be provided includes precise details of the nature of the food in question, the contact temperatures and contact times. This information is based on migration experiments conducted with a variety of food simulants. The Regulation distinguishes between five different food types (dry, aqueous, acidic, fatty, alcoholic) that are tested with the simulants. A wide range of contact times and temperatures is also available. This means that the migration experiments can be very complicated and expensive.



What do the Regulations of the European Union mean for national legislation?

European Regulations are legislative acts and apply in all member states. Their content is integrated into national legislation. In Germany the content is correlated as follows:

Europe

Article 3 of Regulation 1935/2004/EC

Regulation 10/2011/EU (formerly Directive 2002/72/EC)

Germany

§§ 30, 31 of the LFBG (= Food and Feed Code, since 01.09.2005) The predecessor of the LFBG was the LMBG (Food and Commodities Law) of 1974

Consumer Goods Ordinance The Consumer Goods Ordinance is in the process of being updated from Directive 2002/72/EC to Regulation 10/2011/EU

Even if the technical content of the national laws corresponds to that of European law, they are necessary because criminal aspects can only be dealt with in national law.

Recommendations of the Federal Institute for Risk Assessment (BfR)

In Germany the recommendations of the Federal Institute for Risk Assessment (BfR) – “BfR Recommendations on Food Contact Materials” – are recognised and represent the current state of scientific and technical knowledge with regard to the health safety of plastics.

The Recommendations have been published by the BfR or its predecessor institutions (Federal Institute for Consumer Health Protection and Veterinary Medicine, BgVV, and Federal Health Office, BGA) since 1958. They were thus formerly known as BgVV or BGA Recommendations.

The BfR-Recommendations must always be adapted to current legislation of the European Union and Germany. Over the course of time,

much of the content originally contained in the Plastics Recommendations (BGA, BgVV, BfR) has been incorporated into European directives and norms or the Consumer Goods Ordinance and subsequently deleted from the BfR-Recommendations. A large part of the current Union list in Regulation 10/2011/EU has its origins in the BfR-Recommendations.

Like all national provisions, the BfR-Recommendations still apply today for substances that have not yet been added to the Union list (see p. 6).

What food contact laws in the United States of America need to be observed?

The Food and Drug Administration (FDA) is the supervisory authority for drugs and food additives in the United States.

All relevant provisions for drugs and food additives are published in Title 21 of the Code of Federal Regulations (CFR). In contrast to the EU, the precise requirements are very material-specific. The fundamental assumption is that all components of a material can migrate into

food. Plastics, colorants and other contact materials are therefore referred to as “indirect food additives”.

Title 21 is divided into various chapters (Parts). Information on plastics is provided in “Part 177 Indirect food additives: Polymers”. The type of plastic is identified by means of a four-digit number, e. g. 1520 for polyolefins or 1500 for polyamides. The section relating to polyamides is thus headed “21 CFR, Part 177, Paragraph 1500”. Colorants are regulated in “21 CFR, Part 178.3297” (Colorants for Polymers).

These paragraphs set out the requirements on the particular plastic for contact with food – in terms of both the ingredients and the additional requirements such as extraction limits.

Substances from the Gras-list (generally recognised as safe) may also be used as additives for materials intended for contact with food.





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