

smooth. good. advised.



PLASTICS THAT ARE APPROVED
FOR USE IN THE FOOD INDUSTRY
– the food-safe [FS] product world of Murtfeldt



**Food
Safe**



THE DEVELOPMENT OF REGULATION (EU) NO. 10/2011

15.01.2011

Regulation (EU) No. 10/2011
decreed

04.02.2011

Regulation (EU) No. 10/2011
comes into force

01.05.2011

Regulation (EU) No. 10/2011
becomes applicable
Directive 2002/72/EC repealed

31.12.2012

Period of grace for selling
plastic materials manufactured
before 1 May 2011 ends.
Transition period for amended
migration tests and documen-
tation commences.

31.12.2015

Temporary regulation for
certain new compositional
requirements ends. Transition
period for migration tests ends.

REGULATION (EC) NO. 1935/2004

What's allowed in food products?

Plasticisers in olive oil or pesto sauces, heavy metals from ceramic glazes, and ink components in drinks: Unappetising or even unhealthy examples of food impurities that really make consumers see red. But in fact, there are justifiable and functional reasons why foods come into contact with certain substances. This might be during production with special machines, during filling, whilst being transported in designated containers, during storage, or whilst being delivered.

Nevertheless: There are risks involved in the interaction of foods and impurities, and these risks must be kept to a minimum. Since 2004, Regulation (EC) No. 1935/2004 – which is still in force today – has governed these risks. Its most important relevant statement here: Raw materials and items must be manufactured in a way that ensures that – in normal, foreseeable usage conditions – their components only pass into foods in levels that cannot endanger the health of the consumer.



REGULATION (EU) NO. 10/2011

New requirements for manufacturers of plastics

In January 2011, the European Commission adopted a new regulation on materials and items made from plastic and intended to come into contact with foods. This new regulation – Regulation (EU) No. 10/2011 – is in force since the 1st of May 2011 and forms part of Regulation (EC) No. 1935/2004.

Its most important content?

A list of source materials (monomers) and a list of auxiliary materials (additives) that can be used to manufacture plastics

Migration processes based on limit values and purity specifications

Conformity declarations

Batch tracking

Manufacturing as per Regulation (EC) No. 2023/2006 (Good Manufacturing Practice)

EU CONFORMITY

It is confirmed by the manufacturer/entity placing materials on the market in accordance with Regulation (EU) No. 10/2011.

Constituent substances must comply with the Union List as set out in the regulation.

Specific and global migration must be tested on the finished product by an independent, accredited laboratory.

Traceability must be assured at every stage.

It is compulsory within the EU.

FDA CONFORMITY

It is confirmed in accordance with Title 21 of the Code of Federal Regulations (CFR) issued by the U.S. Food and Drug Administration (FDA).

The recipe/constituent substances are deemed and confirmed as individual substances in accordance with the Positive List.

It is compulsory within the United States of America.



LET'S GET DOWN TO THE NITTY-GRITTY!

Which source materials and additives can be used?

The substance lists for monomers and additives contain more than 900 source materials that are approved at EU level. Only these substances may be used to manufacture materials and plastic products in accordance with their specific migration values.



What happens in the “migration process”?

For plastics, there are substance-specific limit values for the transition of these substances to foods. These are called “migration values”. These values are determined by means of migration tests that are carried out by independent institutions. If the result of a migration process is successful, the manufacturer is entitled to issue the required certificate of conformity for the outgoing goods.

A declaration of conformity is valid until changes are made to the composition of the material or to the production process that consequently alter the migration of substances from the material or plastic product or until new scientific knowledge is available. The migration process consists of two tests:

Part of the migration process is the overall migration limit test (OML) and the specific migration limit test (SML). In the case of the overall migration limit, the total of all migrating substances may not exceed 60 ppm. The specific migration test determines specific migration values for individual monomers and additives cited in the regulation on plastics.





THE DECLARATION OF CONFORMITY

In accordance with the stipulations of the new EU regulation, each manufacturer or importer of commodities that are made from plastic and that come into contact with foods must enclose a written declaration of conformity with each product.

The main aim of this declaration of conformity is to enable the easy identification and thus traceability of the used materials for which it is issued. It should ensure that there is sufficient information on the substances used and their decomposition products over the entire supply chain as well as information on the use of the material.

THE TRACEABILITY

**In other words: Where did the plastic come from?
And where is it going to?**

The following was mentioned already in the section on the declaration of conformity: Traceability. This refers to the mandatory requirement to identify an item and enable the tracing of its manufacturing, processing, and sales stages. In each case, at least one prior and one subsequent stage must be identifiable. This is achieved by labelling the plastic and placing information on the manufacturer, date of production, production process etc. on the label.

GOOD MANUFACTURING PRACTICE (GMP)

Quality management

Good Manufacturing Practice (GMP) – which means ensuring good production by means of quality assurance – emanates from Regulation (EC) No. 2023/2006, which is embedded in Regulation (EC) No. 1935/2004. According to this concept, manufacturing is a part of a quality system that ensures the safe and traceable production of products in the pharmaceutical and food industries. In practice, an ISO quality system that is already in place must be supplemented by the GMP directives.





If you would like to receive more technical information on our materials that are approved for use in the food industry, please request our general product overview.

If you require more detailed information on the content of Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011, please visit us at murtfeldt.com!



The pages above have made one thing clear: The new regulation requires companies to make a high investment in time, employee know-how, and capital. Murtfeldt Plastics has risen up to meet these challenges, and was able to conclude the required migration processes for its products that are intended for use in the food industry in August 2011.

Overview of Murtfeldt PE plastics that are approved for use in the food industry as per Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011

Original Material "S" green® [FS]®
Production based on PE-UHMW SG 1.2

Original Material "S" black antistatic [FS]®
Production based on PE-UHMW SG 1.2

Original Material "S" natural [FS]®
Production based on PE-UHMW SG 1.2

Muralen® natural [FS]®
Production based on PE-HMW SG 2.1

Muralen® plus + AB [FS]® (sky-blue)
Production based on PE-HMW SG 2.1

Original Material "S" plus+® AB [FS]® (sky-blue)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® TLS [FS]® (ruby red)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® LF [FS]® (cobalt blue)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® ESD [FS]® (black)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® LF ESD [FS]® (black)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® FP [FS]® (pastel blue)
Production based on PE-UHMW SG 1.2

Original Material "S" plus+® GB [FS]® (light-green)
Production based on PE-UHMW SG 1.2

Overview of Murtfeldt technical plastics that are approved for use in the food industry as per Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011

Murylon® B natural [FS]®
Production based on PA6

Murylon® A natural [FS]®
Production based on PA66

Murytal® C natural [FS]®
Production based on POM-C

Murytal® C gentian blue [FS]®
Production based on POM-C

Murlubric® blue [FS]®
Production based on PA6G/Öl

Murylat® [FS]® (natural)
Production based on PET

Murylat® SP [FS]® (light-grey)
Production based on PETP

Overview of Murtfeldt high-performance plastics that are approved for use in the food industry as per Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011

Murinyl® [FS]® natural
Production based on PVDF

Murinit® SP [FS]® (blue)
Production based on PPS-SP

Murpec® natural [FS]®
Production based on PEEK

[FS] ("food-safe") will be added to the names of these products. In addition, on request Murtfeldt is able to carry out individual migration tests for customers for other colours or types of technical plastics.





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