



Questions and Answers

Elastollan® Food Contact (FC) Grades

What does GMP mean?

EU regulations 1935/2004/EC (framework regulation for materials and articles intended to come into contact with food) and 2023/2006/EC (GMP regulation) state that materials coming into contact with food must not exude substances at levels that endanger human health, change the composition of the product or affect the taste or odor of the food.

Good Manufacturing Practice (GMP) is a quality management (QM) tool intended to provide a comprehensive package of measures to ensure consistently high product quality. In sensitive applications in particular, such as the development and production of medical devices, the production of food contact materials and in the drinking water sector, the GMP quality assurance system is a legal requirement.

The measures relate to all quality-relevant stages in the internal process chain – from procurement of raw materials via production and product approval through to the packaging and shipping sectors.

What measures are implemented within the framework of GMP (extract)?

- Suitability testing of the systems
- Validation of relevant measuring methods
- Documentation of the production steps and analysis results
- Provision of staff training
- Approval of certified suppliers
- Comprehensive information and change management

What advantage can BASF's Elastollan® FC grades offer over the industrial grades?

As one of the leading suppliers of thermoplastic polyurethanes, BASF has always consistently set the highest quality requirements and market orientation. By implementing additional GMP measures and the accompanying quality assurance and risk minimization, BASF ensures the general suitability of the new Elastollan® FC grades as food contact materials in FDA- and EU-regulated markets.

The package of measures linked with the introduction of the products provides, in sensitive areas of application, a more comprehensive minimization of risks with regard to product contamination and thus protection of the end user. For future Elastollan® FC grades, measures will include risk analyses, separate production campaigns and additional cleaning cycles to rule out potential contamination risks, and only starting materials from certified raw material suppliers will be used.

The formulations and technical properties are not affected by the implementation of these additional measures.

All other Elastollan® grades where "FC" is not part of the name are produced as normal to high quality standards. The additional GMP package of measures introduced for the FC grades is not an issue in the so-called industrial grades.

What is the scope of BASF's new FC portfolio and for which applications are they generally suitable?

The new Elastollan® FC portfolio consists of around 20 products and includes both ether- and ester-based grades. This comprehensive portfolio means that BASF can offer its customers the possibility of providing a broad spectrum of TPU applications with food contact – from conveyor belts via films and fabrics through to hoses.

We want to point out that compliance with the processing instructions and application conditions set out in the product data sheet and declarations of conformity is a key basic prerequisite for the suitability tests to be carried out by customers under their own responsibility with regard to the respective end applications.

How does the portfolio look in detail and when will the products be available?

Ether-based Elastollan® FC grades:

- 1170 A 10 FC
- 1180 A 10 FC
- 1185 A 10 FC
- 1190 A 10 FC
- 1195 A 10 FC
- 1198 A 10 FC
- 1154 D 10 FC
- 1174 D 11 FC

Ester-based Elastollan® FC grades:

- B 80 A 11 FC
- B 85 A 11 FC
- B 88 A 11 FC
- B 90 A 11 FC
- B 95 A 11 FC
- B 98 A 11 FC
- 890 A 10 FC
- SP 891 A11 FC

The FC grades listed will be available from January 1, 2016 (typical delivery time: 20 working days).

How long will the declarations of food conformity made in the past apply for Elastollan® grades?

Existing declarations of conformity for food contact applications by BASF for Elastollan® grades which in future will not have "FC" in their nomenclature will no longer be applicable after July 1, 2016.



Note:

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If you have technical questions on the products,
please contact the Elastollan® Infopoint:

Please visit our website:
www.elastollan.de

