

ESA Position Paper regarding the use of carbon/graphite face materials for mechanical seals in food contact

Regulation (EC) No 1935/2004 provides a harmonised legal EU framework for general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odour in an unacceptable way

EC 1935/2004 does not cover carbon/ graphite face materials as used in mechanical seals, but customers of seal suppliers are increasingly requesting certification that seals conform to the regulation.

To determine a possible migration limit for carbon/ graphite seal face materials the analytic laboratory of SQTS (Swiss quality testing services) was enlisted by the Mechanical Seals Division of the ESA to carry out benchmark migration tests.

Four face material suppliers forwarded sample materials which are currently used for applications in the food industry. All materials were conforming to FDA requirements.

SQTS performed migration tests under the following conditions: The migration was set-up according to Commission Regulation (EU) No. 10/2011 and customer instructions. The sample materials were exposed to the simulants as follows:

- Migration preparation: Total immersion as a whole
- Overall migration and specific migration: 95 % Ethanol, 3 x 10 min / 40 °C
- Materials and articles in contact with foodstuffs. Plastics. Guide to the selection of conditions and test methods for overall migration
- The migration was performed according to EN 1186-1:2002: Materials and articles in contact with foodstuffs. Plastics. Guide to the selection of conditions and test methods for overall migration

Chemical analysis: After concentrating, the 95 % ethanol migration solution was analysed using the GC-QTQF-MS/FID screening method (PTV injection, DB-5 column and electron impact ionisation). All relevant substances were compared with the NIST library and SQTS internal library. The concentrations were calculated with the averaged response of the added internal standards IS 1: heptadecane (CAS 629-78-7), IS 3: benzylbutyl phthalate-D4 (CAS 93951-88-3), IS 4: di-nonylphthalate-3,4,5,6-D4 (CAS 1202865-43-7).

Basis of Calculation: The conversion of the measured values to foodstuff is based on the following surface-to-volume ratio (S/V). For any other S/V the resulting migration values are different which might lead to another general assessment of the sample.
Standard S/V: 6 dm² / 1 kg food (EU cube)

The Overall Migration limit (OML) applies to the sum of all substances that can migrate from the food contact material to the food (or food simulant). The overall

migration limit is a measure for the inertness of the material. The limits are 10 mg/dm² and 60 mg/kg food according to Regulation (EU) No. 10-2011 and the Swiss Regulation on Food Contact Materials. The following deviations are tolerated: For all simulants except D2: 10 ± 2 mg/dm² and 60 ± 12 mg/kg food. For simulant D2: 10 ± 3 mg/dm² and 60 ± 20 mg/kg food.

All tested materials showed lower overall migration levels as defined in EU 10/2011.

The possibility of contamination by wear at the seal faces was considered but this was expected to move away from the process not into it. The standard is also about materials in contact with foods not about equipment operation.

Conclusion

The test program showed that carbon or graphite face materials for mechanical seals will perform to stringent limits which are already defined in EU 10/2011 for plastic materials in contact with food as well as Swiss food regulations. The materials from four different suppliers showed similar overall migration values lower than 10 mg/dm² or 60 mg/kg food.

For the adoption of migration limits in future revisions of EC 1935/2004 the ESA would recommend applying the same limits as in EU 10/2011 for other food contact materials including carbon/ graphite face seals.