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GUIDELINE FOR MIGRATION TESTING OF TPS

Test laboratories receive recommendation for an alternative food simulant

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SUMMARY

REGULATION (EU) NO. 10/2011 AND THERMOPLASTIC ELASTOMERS

Regulation (EU) No. 10/2011 sets rules for the migration testing of plastic materials with food contact. It applies to all thermoplastic urethanes (TPU) and thermoplastic styrene block copolymers (TPS), including their additives and processing aids. TPS constitutes more than 90% of KRAIBURG TPE's portfolio.

However, the regulation does not include thermoplastic vulcanizates (TPV) made of ethylene propylene diene monomer (EPDM) with polypropylene, for example. Regulation (EU) No. 10/2011 also does not include natural rubber (NR) and silicones, so these materials cannot comply with it.

The suitability of materials for food contact applications must be reliably verified by migration testing in accordance with Regulation (EU) No. 10/2011. It is not possible in all cases to perform tests with the specified food simulants, and the test sometimes results in the destruction of the materials or overestimates the actual migration.

KRAIBURG TPE has examined the problem and found an alternative simulant that allows easier identification of migration of TPS with fatty food materials.

LEGAL FRAMEWORK FOR PLASTIC MATERIALS WITH FOOD CONTACT

In the European Union, Regulation (EU) No. 1935/2004 regulates the harmonization of existing regulations in relation to materials and objects that come into contact with food. For this purpose, individual regulations have been adopted that apply to groups of materials that are in food contact.

Since January 14, 2011, Regulation (EU) No. 10/2011 has applied to the group of plastic materials. According to Article 1 Paragraph 2, "this regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles

a) intended to come into contact with food; or
b) already in contact with food; or
c) which can reasonably be expected to come into contact with food."

In recent decades, thermoplastic elastomers (TPE), and thermoplastic styrene block copolymers (TPS) in particular, have taken the lead for being used in a large number of different fields of application where they come into contact with food. The range spans from containers and lids through to household appliances and conveyor belts in the food processing industry **(figure 1)**. As a legal framework for materials and articles made of plastics, Regulation (EU) No. 10/2011 contains relevant rules that must be complied with when TPEs are used.

Figure 1: *Examples of food contact applications using TPS that require a risk assessment for the migration of the material's ingredients in accordance with Regulation (EU) No. 10/2011. (Image: KRAIBURG TPE)*

CONSUMER SAFETY

Ensuring consumer safety has top priority. The stipulations of Regulation (EU) No. 10/2011 therefore include that plastic materials must not transfer substances to foods in quantities exceeding the specific or general migration limits. Predefined migration tests imitate the substance transfer that is to be actually expected and thus make the transfer measurable. The regulation also specifies test conditions for different types of food. To facilitate testing, general test simulants **(figure 2)** are used instead of actual food.

Food simulant	Abbreviation
Ethanol, 10% (v/v)	A
Acetic acid, 3% (w/v)	B
Ethanol, 20% (v/v)	C
Ethanol, 50% (v/v)	D1
Vegetable oil with <1% nonsaponifiable components	D2
Poly (2,6-diphenyl-p-phenylene oxide), particle size 60–80 mesh, pore size 200 nm	E

Figure 2: *List of food simulants that are used instead of real food to simplify testing (Regulation (EU) No. 10/2011, Annex 3, Table 1)*

Successful TPE projects are based on a selection of plastic materials that precisely match the intended application as well as on correct handling during processing.

The technical side provides advice services that include construction recommendations and guidance on matters such as the influence of container capacity (the larger, the better) or food contact surface area (the smaller, the better), which both affect migration behavior and can be used as a minimizing factor. At an organizational level, early coordination can decisively reduce the effort required for migration testing, save development costs and tool costs and expedite the product launch.

SPECIAL ASPECTS OF TPS MATERIALS IN MIGRATION TESTING

The Regulation (EU) No. 10/2011 provides for using vegetable oil as a simulant (D2) for fatty food or food containing fat. This involves insurmountable technical obstacles in many cases because TPS tends to swell due to its chemical structure. In addition, the TPE significantly absorbs the vegetable oil simulant. This leads to a change in volume, weight, and density of the compound **(figure 3)**.

The migration of the simulant into the TPS interferes with the testing for components that the TPS might transfer to the food. It is essential to selectively and completely re-extract the simulant from the TPS after the test to achieve a quantitative assessment. For this reason, these tests often produce doubtful migration values, which do not correspond to the facts and are therefore not valid results.

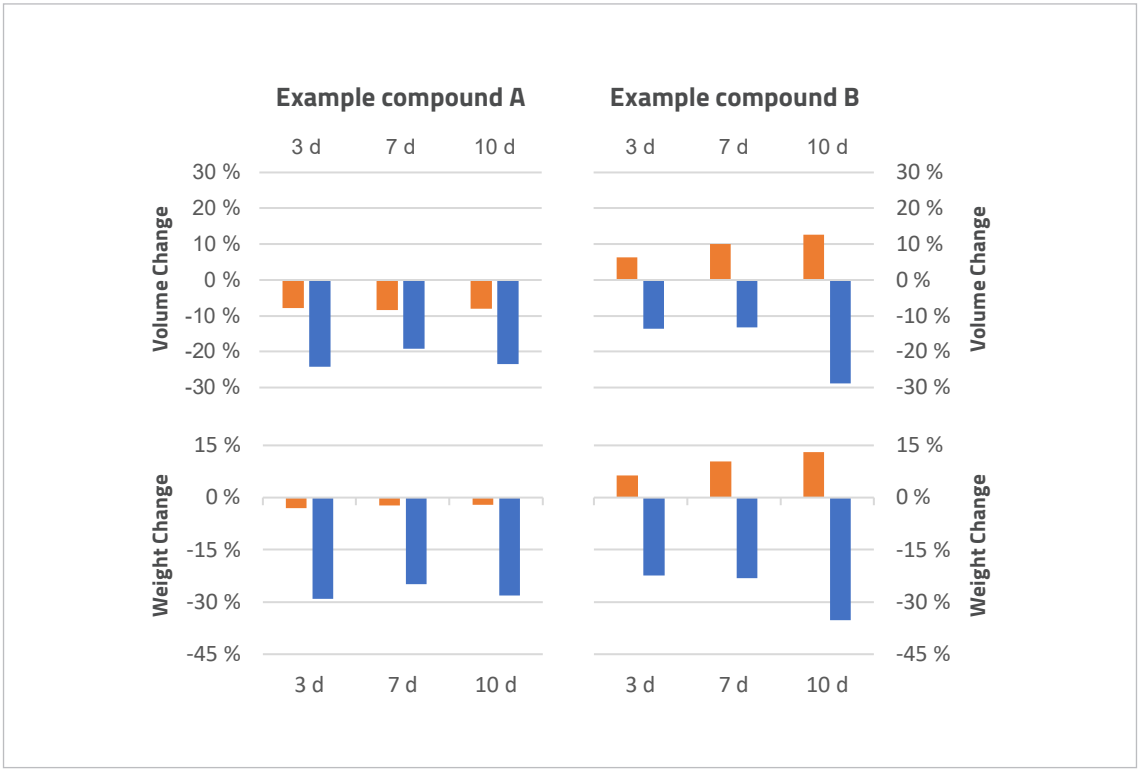

Figure 3: Change in volume and weight of samples of representative THERMOLAST® K materials during storage in olive oil (orange) and isooctane (blue). Volume and weight losses during storage in isooctane, which are attributable to excess extraction of components, are clearly recognizable. For sample compound B with reduced oil content, an increase in volume and weight can also be seen, which is attributable to the absorption of the vegetable oil simulant. For sample compound A with high oil content, this effect is overlaid by an exchange of white oil contained in the compound for the vegetable oil.

Something similar applies to the use of isooctane as a permissible simulant substitute. Here, swelling has a considerable impact on the properties of the TPS including tensile strength, elongation at break and hardness **(figure 4)**. These changes in the material are inconsistent with the basic requirements for migration testing in accordance with Regulation (EU) No. 10/2011 and invalidate the test. Isooctane is thus too aggressive a solvent, which extracts components from TPS that do not migrate into foods under normal conditions. The fast reduction in tensile strength and elongation at break demonstrates how much the solvent damages the TPS.

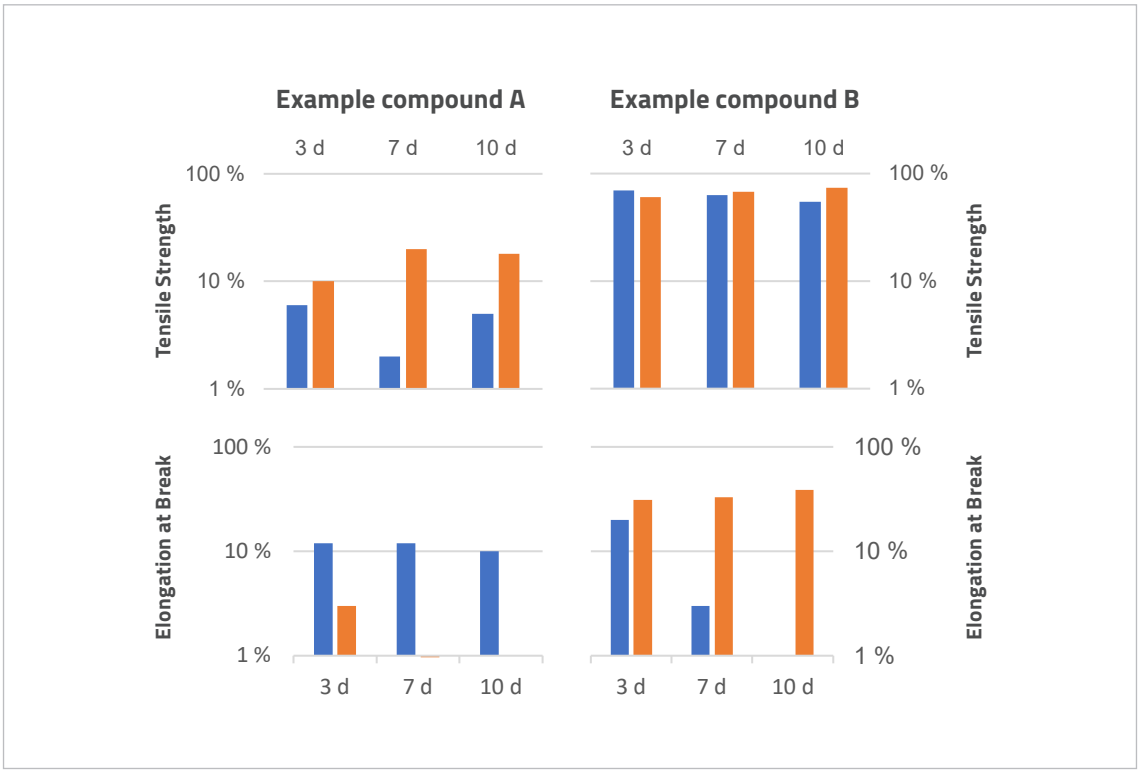

Figure 4: *Isooctane (blue) and vegetable oil (orange) used as food simulants for migration testing lead to significant changes in the properties of TPS even when in contact for only a short time. (Image: KRAIBURG TPE)*

ALTERNATIVE SIMULANT SUITABLE FOR TPS

In cases of this type, Regulation (EU) No. 10/2011 alternatively provides for testing with adjusted conditions such as reduced temperature and/or test duration, among others. In many cases, however, this does not reproduce the actual conditions of the application's use. It would be better to use an alternative simulant that does not have a damaging impact on the TPS, while allowing a realistic migration assessment. The regulation explicitly permits the use of other simulant substitutes, but requires scientific proof that these simulants do not underestimate the migration in comparison the defined simulants **(Figure 2)**. Figure 5 illustrates the approach.

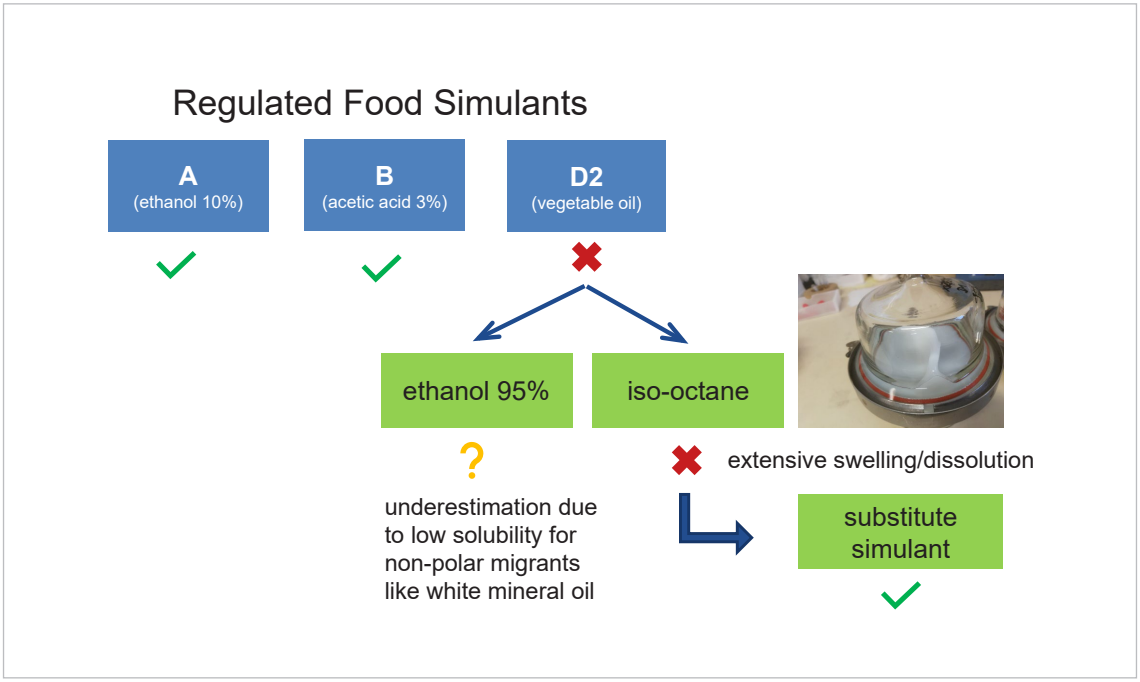

Figure 5: While simulants A and B usually allow reliable assessment of the migration potential of TPS, the use of D2 causes massive interactions with TPS, which often do not allow valid migration assessment. (Image: KRAIBURG TPE)

In contrast to isooctane, ethanol 95% (v/v) would be non-critical. But it is considerably more polar than vegetable oil and can therefore not be used to simulate the migration of nonpolar portions. Basically, all components of the TPS formulation have an impact on migration. The medical white oil contained in many TPEs contributes the biggest share to the global migration in testing with simulants for fatty foods and foods containing fat. Due to its nonpolar nature, this component can migrate into foods to a greater degree than the test with ethanol 95% (v/v) would suggest.

This leads to the actual migration contribution of oil-containing TPS being systematically underestimated. This procedure is irrelevant for oil-free TPS, where no oil migration can occur during testing.

KRAIBURG TPE has therefore carried out a large-scale survey (2020/21) together with MDCTec Services GmbH to identify suitable alternative simulants for TPS. The two crucial criteria were: The alternative simulant must neither damage the TPS test sample nor change the material physically contrary to the requirements of Regulation (EU) No. 10/2011. It must also deliver a realistic migration assessment, while maintaining the predefined test conditions. The outcome of the survey was that an alternative simulant was found that comprehensively meets these requirements. KRAIBURG TPE recommends using only the alternative simulant instead of D2 or isooctane for simulating fatty foods or foods containing fat when testing the migration of TPS.

KRAIBURG TPE has developed several other criteria that need special attention as part of the tests. For example, the expected conditions for the respective application's use, including the food it comes in contact with, should be defined as exactly as possible. Materials tests based on test plates are not a reliable substitute for testing the article in the condition intended; the assessment of multipart products (such as box and cover) must be carried out for each part.

APPROACH TO SOLVING THE PROBLEM FOR TEST LABORATORIES

Test laboratories can request guidance from KRAIBURG TPE to benefit from the latest findings of this survey. In parallel with this, KRAIBURG TPE has developed two series that are targeted specifically at applications in contact with fatty food or food containing fat. Controlled Migration TPE also complies with Regulation (EU) No. 10/2011 as well as the requirements of 21 CFR (FDA) and GB 4806-2016.

In addition, THERMOLAST® K types are available for contact with non-fatty foods, which have been established for a long time in the market due to their latex-free and halogen-free formulation and their good adhesion to various other plastic materials.

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