

# Technical Information Sheet TIS 27

## Compliance with Food Contact Regulations

### **INTRODUCTION**

Food contact regulations are often viewed as a general purity standard which results in food contact grades being demanded for applications where purity is required but where the material may not necessarily have direct contact with food. Most countries have their own regulations for materials used in contact with food while others refer to long established systems such as the US FDA regulations.

Zotefoams foam products have been comprehensively tested to prove compliance to both the EC food contact regulations and the US FDA regulations. These two regulatory systems use different approaches towards determining articles that are suitable for food contact and those that are not. Due to these different approaches, a material found suitable under EC regulations may not automatically comply with US FDA regulations, and vice versa. It is also important to note that any tests performed on the foam are only valid for the raw foam sheet. Further testing by the converter or end customer would be required on a finished part made from the foam to ensure conversion methods have not affected the overall compliance.

### **EUROPEAN (EC) FOOD CONTACT REGULATIONS**

Requirements for plastics materials used in food contact applications are summarised in the relevant EU directives<sup>1,2,3</sup> documents. These documents combine a set of definitions for suitable plastics with test requirements and extraction limits which ensure that the material is safe under the intended conditions of use and is therefore focussed on the testing of the finished food contact article.

The most likely use of Zotefoams products in food packaging is in the storage and transport of foodstuffs at room temperature. The relevant test conditions chosen for evaluation of the foams were: overall migration for 10 days at 40°C into 3% acetic acid solution, 10% ethanol solution. Since olive oil has been proven to be a poor simulant for testing of fatty food migration into polymer foams the alternative of using iso-octane was chosen and testing performed for 2 days at 20°C. Further tests were undertaken to measure the migration of colour and / or monomer where limits existed. For these tests the highest density of each grade was chosen as this representative of the highest likely source for migration.

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<sup>1</sup> Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

<sup>2</sup> Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs.

<sup>3</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments to date

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Testing was conducted in 2020 on the highest and lowest density available in each product range under investigation to cover the production condition variables as well as taking into account all raw materials currently in use for the production of these grades. The following product ranges and colours were found to comply with EC food contact requirements outlined in Commission Regulation (EU) 10/2011 and its amendments to date:

GRADE	DENSITY	COLOUR
Plastazote® LD	All densities up to 70 kg/m <sup>3</sup>	WE, BK, BE, GN, PK, RD, YW
Plastazote® HD	All densities up to 115 kg/m <sup>3</sup>	WE, BK

Previously materials had been tested to EU directives in 2007. During these tests additional product ranges were tested against the following criteria: The relevant test conditions chosen for evaluation of the foams were: overall migration for 10 days at 40°C into 3% acetic acid solution, 10% ethanol solution and olive oil ('fatty food' simulant). Further tests were undertaken to measure the migration of colour and / or monomer where limits existed. In addition to the grades tested in 2020 the following were shown to be compliant with EU regulation 1935/2004 for the contact with food in storage and transport at room temperature:

GRADE	DENSITY	COLOUR
Plastazote® MP	All densities up to 45 kg/m <sup>3</sup>	WE, BK, BE
Evazote® VA	All densities up to 80 kg/m <sup>3</sup>	WE

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### US FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS

The information listed regarding FDA regulations is based on testing carried out in 2008. The testing was carried out on the foams as they are manufactured by Zotefoams and it is up to the converter to carry out the required tests on the items they supply into the food industry to confirm their processes have not affected compliance.

Materials that come into contact with food in form of packaging or seals on production lines are classed as 'indirect food additives' under US FDA regulations<sup>4</sup>. The US regulations contain definitions of approved 'indirect food additives', sometimes referred to as a 'positive list' - it is the responsibility of the manufacturer to prove that their material matches the definition given in the list.

Zotefoams have, in conjunction with key suppliers, assessed the foam formulations against the 'positive list' and further have had an ongoing dialogue with the FDA, undertaking testing to agreed methods and providing data for assessment.

The following product ranges and colours were found to comply with US FDA regulations:

GRADE	DENSITY	COLOUR	FDA 21 CFR
Plastazote® LD	All densities up to 70 kg/m <sup>3</sup>	WE, BE, PK	177.1520
Plastazote® HD	All densities up to 115 kg/m <sup>3</sup>	WE	177.1520
Plastazote® MP	All densities up to 45 kg/m <sup>3</sup>	WE, BE	177.1520
Evazote® VA	All densities up to 80 kg/m <sup>3</sup>	WE, BE	177.1350
Supazote® EM	All densities up to 26 kg/m <sup>3</sup>	WE	177.1340
ZOTEK® F	All densities up to 30 kg/m <sup>3</sup>	WE	177.2600
ZOTEK® F HT	All densities up to 75 kg/m <sup>3</sup>	WE	177.2600

It should be noted that the paragraph of 21 CFR 177.1520 relevant to the Plastazote® MP resin restricts the suitable uses to conditions of use C through H. This means the material is not approved for applications that require high temperature heat sterilisation (condition of use A) or boiling water sterilisation (condition of use B).

<sup>4</sup> Requirements for these materials are included in Title 21 "Food and Drugs" of the Code of Federal Regulations (21 CFR)

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