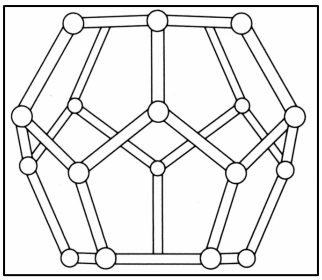
Zotefoams plc

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 would be required on a finished part made from the foam.

EUROPEAN (EC) FOOD CONTACT REGULATIONS

Requirements for plastics materials used in food contact applications are summarised in the relevant EU directives[1,2] 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 on 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 and olive oil ('fatty food' simulant). Further tests were undertaken to measure the migration of colour and / or monomer where limits existed.

The following product ranges and colours were found to comply with EC food contact regulations:

GRADE	DENSITY	COLOUR
Plastazote® LD	All densities up to 70 kg/m^3	WE, BK, BE, GN, PK, RD, YW
Plastazote® MP	All densities up to 45 kg/m^3	WE, BK, BE
Plastazote® HD	All densities up to 115 kg/m^3	WE, BK
Evazote® VA	All densities up to 80 kg/m^3	WE

[1] 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.

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

US FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS

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[3]. 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^3	WE, BE, PK	177.1520
Plastazote® HD	All densities up to 115 kg/m^3	WE	177.1520
Evazote® VA	All densities up to 80 kg/m^3	WE, BE	177.1350
Supazote® EM	All densities up to 26 kg/m^3	WE	177.1340
ZOTEK® F	All densities up to 30 kg/m^3	WE	177.2600
ZOTEK® F HT	All densities up to 75 kg/m^3	WE	177.2600

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ISO 9001:2000
FM 01870

ISO 14001
EMS 36270

[3] Requirements for these materials are included in Title 21 "Food and Drugs" of the Code of Federal Regulations (21 CFR)