

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^{1,2,3} 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.

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.

³ 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

Technical Information Sheet TIS 27

Compliance with Food Contact Regulations

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:

PRODUCT RANGE	GRADE	COLOUR
Plastazote® LD	LD15, LD24, LD33, LD45, LD60, LD70	BK, BE, GN, PK, RD, WE, YW
Plastazote® HD	HD30, HD60, HD80, HD110, HD115	BK, WE

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:

PRODUCT RANGE	GRADE	COLOUR
Plastazote® MP	MP15, MP24, MP33, MP45	WE, BK, BE
Evazote® VA	VA35	WE

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 regulations⁴. 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.

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

Technical Information Sheet TIS 27

Compliance with Food Contact Regulations

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

PRODUCT RANGE	GRADE	COLOUR	FDA 21 CFR
Plastazote® LD	LD15, LD24, LD33, LD45, LD60, LD70	WE, BE, PK	177.1520
Plastazote® HD	HD30, HD60, HD80, HD110, HD115	WE	177.1520
Plastazote® MP	MP15, MP24, MP33, MP45	WE, BE	177.1520
Evazote® VA	VA35	WE, BE	177.1350
Supazote® EM	EM26	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

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).

Technical Information Sheet TIS 27

Compliance with Food Contact Regulations

Exclusion of Liability

Any information contained in this document is, to the best of the knowledge and belief of Zotefoams plc and of Zotefoams Inc. (together herein referred to as ZOTEFOAMS), accurate. Any liability on the part of ZOTEFOAMS or any subsidiary or holding company of ZOTEFOAMS for any loss, damage, costs or expenses directly or indirectly arising out of the use of such information or the use, application, adaptation or processing of any goods, materials or products described herein is, save as provided in ZOTEFOAMS' conditions of sale ("Conditions of Sale"), hereby excluded to the fullest extent permitted by law. Where ZOTEFOAMS' goods or materials are to be used in conjunction with other goods or materials, it is the responsibility of the user to obtain from the manufacturers or suppliers of the other goods or materials all technical data and other properties relating to those other goods or materials. Save as provided in the Conditions of Sale no liability can be accepted in respect of the use of ZOTEFOAMS' goods or materials in conjunction with any other goods or materials.

Where ZOTEFOAMS' goods or materials are likely to come into contact with foodstuffs or pharmaceuticals, whether directly or indirectly, or are likely to be used in the manufacture of toys, prior written confirmation of compliance with relevant legislative or regulatory standards for those applications may be requested from ZOTEFOAMS, if appropriate. Save as provided in the Conditions of Sale no liability can be accepted for any damage, loss or injury directly or indirectly arising out of any failure by the user to obtain such confirmation or to observe any recommendations given by or on behalf of ZOTEFOAMS.

ZOTEFOAMS MAKES NO WARRANTIES EXPRESS OR IMPLIED, EXCEPT TO THE EXTENT SET OUT IN THE CONDITIONS OF SALE, AND HEREBY SPECIFICALLY EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY GOODS, MATERIALS OR PRODUCTS DESCRIBED HEREIN.

Zotefoams plc Management systems are covered by the following:



Quality
FM 01870
ISO 9001



Safety
OHS 52538
OHSAS 18001 2007



Environment
EMS 36270
ISO 14001 2015

ZOTEFOAMS plc

675 Mitcham Road
Croydon
Surrey
CR9 3AL
United Kingdom

Tel: +44 (0) 20 8664 1600
Fax: +44 (0) 20 8664 1616

ZOTEFOAMS SP z.o.o.

Ul. Parkowa 26
49-318 Skarbimierz
Osiedle
Poland

ZOTEFOAMS inc

55 Precision Drive
Walton
Kentucky
41094
USA

Tel: +1 859 371
Freephone: (800) 362 8358 US only
Fax: +1 859 371 4734

AZOTE®, Ecozote®, Evazote®, Plastazote®, ReZorce®, Supazote®, T-FIT®, Zotefoams®, Zote®, ZOTEK® are registered trademarks of Zotefoams plc.

If you would like more information
email: techsupport@zotefoams.com
or visit our website www.zotefoams.com