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# Zotefoams plc

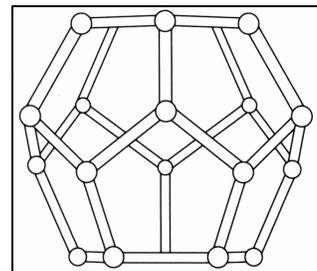
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## Technical Information Sheet – TIS 20

(previously BT15)

### Toxicity testing of Zotefoams materials

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#### INTRODUCTION

For an increasing number of applications testing to confirm the absence of certain regulated or banned chemicals has become vital in recent years. Furthermore applications that include close skin contact and products intended to be used by young children often require further testing to ensure that they are not causing skin irritations, sensitisation or contain chemicals that could be leached out by sweat or saliva.

Zotefoams plc do not use any halocarbon gases (e.g. CFCs, HCFCs, HFCs) or, unlike chemical blowing processes, volatile hydrocarbons such as pentane or isobutane during any production stage of their Azote<sup>®</sup> and Zotek<sup>®</sup> foams. All Azote<sup>®</sup> and Zotek<sup>®</sup> foams are manufactured using a unique high pressure nitrogen gas process which produces a pure, chemically and biologically inert material. A statement confirming compliance with the Montreal protocol with regard to the substances is available on the website.

All formulation additives are non-toxic, except for the polymer bound antimony and halogen compounds used to impart flame retardant properties to 'FR', 'FM' and 'FB' grades.

This document aims to provide a summary of the tests performed in relation to the safety and toxicity of the foam for a wide range of applications. To avoid the document becoming too large topics that require more in depth discussion have been covered by separate technical information sheets which will be referred under the appropriate headings. There is also a range of application specific statements available on our website covering the following topics:

- Use of Evazote<sup>®</sup> in gymnastics mats
- Use of Plastazote<sup>®</sup> in the conservation industry
- The purity of Plastazote<sup>®</sup>
- Substances of concern in medical footwear

The listing of performed tests below is complete at the time of writing. Most tests performed on Zotefoams materials are in relation to European regulations and ISO standards as information on these is most commonly requested by our customers. If you require information regarding compliance with a standard or regulation not listed in this document please contact our technical support team.

## **EUROPEAN DIRECTIVES**

Many hazardous chemicals are regulated by European directives and regulations with a view to protecting the consumer. The most commonly quoted directive is the so called RoHS directive ('Directive 2002/95/EC of the European Parliament and of the council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment'). Zotefoams plc does not utilise any chemicals regulated by this directive in its production processes for foam materials. A statement confirming this is available on the website.

For plastics the main concern is on the presence of lead, mercury, cadmium and chromium VI which are found in many dyes as well as brominated flame retardants belonging to the polybrominated biphenyl and polybrominated diphenyl ether classes. Zotefoams plc has undertaken a number of tests using different methods to confirm the absence of these chemicals. Most of these analyses were part of test programmes to confirm compliance of the foams with international standard such as Oekotex 100, or EN71-3.

Other directives or guidelines that cover the same types of chemicals or refer to the RoHS directive:

- CONEG regulations for packaging
- 2000/53/EC "ELV" directive
- 2002/96/EC "WEEE" directive
- 2003/11/EC (Brominated diphenyl ethers)
- 2006/122/EC (perfluorooctane sulfonates)
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Statements confirming compliance for all of these materials are available on the website.

## **REACH REGULATION**

This regulation does not strictly deal with toxicity of a product but is included in this document as some parts of the regulation cover toxicity and similar testing. Zotefoams is not a producer of chemicals but uses chemicals to produce foams. Therefore we are not required to register any chemicals but only ensure that all our raw materials are registered and approved (in the coming years) under this regulation. For a detailed statement regarding our responsibilities and the status of the products used in the manufacture of our foams please see the separate statement on this topic.

## **AZO DYES**

No azo dyes are used for the manufacture of any of Zotefoams plc products. The absence of these in representative grades has been confirmed by independent analytical test for MAK amines according to the 2<sup>nd</sup> Decree of the German Ministry of Health. The representative grades tested were:

Plastazote <sup>®</sup>	LD45 Blue LD45 Red, LD45 Black, LD24 FR Charcoal, LD32 CN Black
Evazote <sup>®</sup>	VA35 Orange, EV50 Violet, EV30 Gold

## **MONTREAL PROTOCOL**

The Montreal Protocol was drawn up by the United Nations Environment Program to control the use of substances that are known to deplete the ozone layer. Most of these substances are halogenated hydrocarbons which were used widely as blowing agents, cooling agents and similar applications. Zotefoams does not utilise any of the substances controlled or banned under this protocol. A statement is available confirming the absence of all substances listed in the Montreal Protocol.

## **OEKOTEX 100**

The Oekotex 100 standard has been developed by the German textiles industry. It aims at marking textiles and products that are used in the textiles industry which are considered particularly non-hazardous and environmentally friendly because of the absence or limitation of a wide range of chemical classes. There are four product classes ranging from textiles and textile toys for babies (Class I) to textiles for decoration such as curtains (Class IV). The test requirements are based on the likely exposure of humans to products leaching out of textiles and the vulnerability of groups of people to chemicals (Class I babies and small children, Class II general clothing) with requirements for class I the most stringent.

The test methods cover absorption through the skin, ingestion and inhalation of fumes. Based on the formulation of a product the following chemical classes and properties are analysed:

- pH
- formaldehyde content
- heavy metals content (limits for antimony, arsenic, lead, cadmium, chromium, cobalt, copper, nickel and mercury)
- pesticides
- chlorinated phenols, benzenes and toluenes
- phthalates
- organic tin compounds
- other chemical residues (e.g. PFOA, PFOS)
- flame retardants
- biologically active products
- dyes and pigments (no toxic, carcinogenic etc.)
- colour fastness (against sweat, saliva and rubbing)
- volatile compounds
- odour
- banned fibres

A range of Azote<sup>®</sup> products has been tested against this standard and the certification is maintained by annual retesting of random samples. White, black and coloured products from the Plastazote<sup>®</sup> LD, Evazote<sup>®</sup> EV and Evazote<sup>®</sup> VA ranges were found to comply with the requirements for class one. The certificate number is 19553. This can be

verified on the Oekotex homepage and a scanned copy of the current certificate is available on our website.

## **SAFETY OF TOYS**

There are a range of standards available from different standardisation bodies which cover the safety requirements for toys. Most of these tests are finished article tests that ensure the toy does not endanger a child's health through chemicals leaching, parts causing choking or strangling hazards or flammability hazards. Therefore only limited test to confirm the absence of chemicals of concern (heavy metals) have been carried out on Zotefoams materials. For more information on toy standards and the tests carried out on the foam please refer to Technical Information Sheet 19.

## **FOOD CONTACT**

Various Zotefoams grades have been tested to confirm compliance with European regulations on food contact and FDA regulations. The two approaches are very different and tests performed on the material are outlined in a separate Technical Information Sheet. (TIS 27)

## **POTABLE WATER CONTACT**

Zotefoams maintains two product listings for materials under the Water Regulations Advisory Scheme (WRAS). Items listed under this scheme need to pass the test requirements given in BS 6920 - Suitability of Non-metallic Products for Use in Contact with Water Intended for Human Consumption with Regard to Their Effect on the Quality of the Water.

Product listing 0405512 covers materials suitable for hot and cold water use up to 50°C. This listing includes the following grades:

- Plastazote<sup>®</sup> grades: LD White and Black at all densities
- Evazote<sup>®</sup> grades: EV50 White and Black

Product listing 0604526 covers materials suitable for hot and cold water use up to 85°C. This listing includes the following grades:

- Plastazote<sup>®</sup> grades: LD70 black and HD White and Black at all densities
- Evazote<sup>®</sup> grades: VA and EV White and Black at all densities

## **MEDICAL APPLICATIONS**

Zotefoams materials are widely used in medical applications where the foam comes into contact with the patients skin. To confirm that our materials are suitable for these applications representative samples have been tested against the requirements for medical devices in contact with skin as outlined in ISO 10993. For information on the tests that have been carried out and the materials that have been tested please refer to Technical Information Sheet 25.

All tests reports related to the toxicity of Plastazote® LD materials in all densities and the colours white, blue and pink have been filed with the Food and Drug Administration (FDA) in the USA in form of a Type III Drug Master File. Letters granting reference to this file can be provided upon request by the Technical Support Team.

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