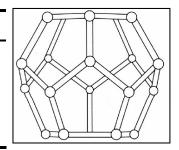
# Zotefoams plc

## Technical Information Sheet – TIS 20 (previously BTI5)

# Toxicity Testing of Azote Foams



## **INTRODUCTION**

Zotefoams plc do not use any halocarbon gases (e.g. CFCs, HCFCs, HFCs) or volatile hydrocarbons (eg pentane, isobutane) at any stage in the production of any of its polyolefin foams. Plastazote<sup>®</sup>, Evazote<sup>®</sup>, Propozote<sup>®</sup> and Supazote<sup>®</sup> are manufactured using a high pressure nitrogen gas process which produces a pure, chemically and biologically inert material.

All formulation additives are non-toxic except for the polymer bound antimony and halogen compounds used to impart flame retardant properties to FR grades. No cadmium based pigments are used.

## **TESTS AGAINST SPECIFIC REQUIREMENTS**

## Safety of toys

Analytical tests have been carried out on most products and confirm compliance with the toxicity requirements of BS EN 71:Pt 3:1995 (BS 5665 Pt3:1995; Safety of Toys: Migration of certain elements). Details are given in Bulletin BTI-4.

#### Food contact

The following grades have been shown to comply with FDA food contact regulations ref: 21 CFR 177.1520:

Plastazote<sup>®</sup> grades: LD White at all densities, LD45 Pink

Article 2 of the EEC Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs measures global migration after 10 days at 40°C in a food simulant. There are 3 aqueous simulants and olive oil.

The following grades have been shown to comply when tested using both agueous and olive oil simulants:

- Plastazote® grades LD24 White, LD33 LC White, LD45 White, LD45 Yellow Other Plastazote foams would be expected to meet the full requirements but have not been tested. The following grades have been shown to comply when tested using the aqueous simulants ONLY:
  - Plastazote® MP45
  - Evazote<sup>®</sup> EV50
    Evazote<sup>®</sup> VA35

It is expected that all grades of Plastazote® and Evazote® would meet the requirements when tested using an aqueous simulant.



## Contact with potable water

The following grades have been shown to comply with BS6920 1988/90 (Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on water quality):

- Plastazote® grades: LD White and Black at all densities
- Evazote® grades: EV50 White and Black

The above grades are Approved Products by the Water Byelaws Scheme and appear in the Water Fittings and Materials Directory, Part 2 under listing number 9903512.

## Cytotoxicity/irritancy

A representative range of Zotefoams plc products has been subjected to cytotoxicity tests based on BS EN 30993-5:1994/ISO 10993-5:1994, "Biological evaluation of Medical Devices part 5: Tests for cytotoxicity, in vitro methods." This test has been validated as a test for irritancy. Foams tested were:

Plastazote <sup>®</sup>	LD24 White, LD45 White, LD45 Pink, LD45 FR
	Charcoal, MP45 White, HD115 White, HD115 Black
Evazote <sup>®</sup>	EV50 White, VA35 White
Supazote <sup>®</sup>	EM26 White
Propozote <sup>®</sup>	PPA30 White

Results showed that none of the foams (or foams of identical formulation differing only in density) were cytotoxic in this assay, and hence none would be expected to have an irritant effect on living tissue.

## **CONEG** regulations

The following grades have been analysed and shown to meet the full CONEG regulations. (lead, cadmium, mercury, hexavalent chromium concentrations less than 100 part per million)

- Plastazote® grades: LD white, black, blue, FR Charcoal and CN Black at all densities
- Evazote® grades: EV CN Black at all densities

A statement regarding compliance with packaging regulations is available on the website or on request.

#### Azo dves

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 2nd Decree of the German Ministry of Health. The representative grades tested were:

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

#### **General Note**

Reference to specific grades does not infer that other grades may not meet test requirements.



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