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Purity of Plastazote® Products

For many applications the assurance of the purity of the materials employed is essential to avoid contamination or complications during intended use. The process utilised by Zotefoams plc for the production of its crosslinked polyolefin foams uses only nitrogen gas for the expansion of the solid material into the foam. Where there is a necessity to use additives, such as pigments, etc., then the additives, as with the raw polymers, are carefully selected and tightly specified.

There are many tests that can be used to demonstrate suitability of a material for an application requiring high purity. This document summarises the tests that have been performed on materials in the Plastazote® LD range with a special emphasis on the medical grade Plastazote® LD45 Pink. The tests, performed over a number of years, have been aimed at identifying organic compounds or heavy metals that could leach out of the foam under various conditions.

Heavy Metals and Inorganic Substances

Leaching of heavy metals has always been a concern for applications where the foam is in direct contact with humans or where leached substances can add to the contamination of the environment. Within the European Union the use of certain heavy metals, Lead (Pb), Mercury (Hg), Cadmium (Cd) and hexavalent Chromium (Cr⁶⁺) has been restricted in packaging and in electrical and electronic equipment by EU directives 1994/62/EC and 2002/95/EC respectively. Other industries such as the automotive industry have adopted these restrictions and most have their own “black lists” of banned or restricted hazardous substances.

Plastazote® LD foams have been repeatedly tested for extractable metals using aqueous and acidic media for the extraction process. Furthermore analysis of the residues after wet-ashing were analysed for their metal content. All tests have been performed by independent test houses and the reports can be made available upon request.

Studies on aqueous extracts were performed in accordance with the textile standard Ökotex 100 (May 2006), the medical standard ISO 10993-18 and USP <661> (2005) and Potable Water regulations compliance to BS 6920 (repeated tests since 1999 at various temperatures). In all of these studies the heavy metal content was below the detection limit.

A study (June 2002) using acidic extraction (Hydrochloric acid used to mimic conditions after accidental ingestion) was performed to show compliance with the requirements of the European toy standard EN 71-3 for heavy metal migration. Again values for all tested materials (including a wide range of colours and densities from the Plastazote® LD range) were below the detection limit.

A further study (June 2002) was performed on analysis of the material after wet-ashing to BS 6810. This study also did not detect the heavy metals banned under the RoHS directive in the Plastazote® LD range.

Organic Compounds

As well as heavy metals and other inorganic compounds, many organic compounds are causes of concern due to their potential effects on humans and the environment. The components of most concern vary between industries.

Azodyes have been a concern in many coloured products. Their use has been banned within the European Union and pigments used in Plastazote® materials do not contain any of such substances. An independent test report from September 2002 also confirms the absence of any azo compounds.

In the textile industry certain amines and chlorinated phenols have been restricted in their use. Tests performed as part of the Ökotex 100 certification process confirmed that these materials are not present in Plastazote® LD materials.

General migration studies (March 1991, April 1993, December 1994) of substances from the foam into various food simulants (representing aqueous, fatty, alcoholic and acidic food types), carried out in accordance with EU directive 90/128/EEC, have shown compliance of Plastazote® LD White and Pink foams with the quoted directive.

More recently general studies (2005) of organic extractables have been performed. As part of the testing to ISO 10993-18 aqueous and isopropanol extracts of the foams were analysed by chromatographic methods using mass spectrometry as detection systems. While Gas chromatography (GC) detected only shorter chain hydrocarbons, High Performance Liquid Chromatography (HPLC) analysis did not show any extractables in samples of Plastazote® LD45 Pink and Plastazote® LD70 Black.

Further tests (February 2004) on Plastazote® LD45 Pink were performed after concerns from the medical footwear industry regarding suitability of the material in shoes designed for patients with diabetic foot. These tests compared extractables from Plastazote® LD45 Pink with those found in two competitor's materials also commonly used for this application. These independent studies confirmed that potentially hazardous substances such as Acetophenone, Methyl Styrene and Semicarbide could be detected in the competitor's materials while they were absent from Plastazote® LD45 Pink. For more information on these tests please refer to the statement titled "Concerns Over Foams Used in Medical Footwear".

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November 2006

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**ISO 9001:2000
FM 01870**



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EMS 36270**

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November 2006