CONCERNS OVER FOAMS USED IN MEDICAL FOOTWEAR

Recent tests (February 2004 – August 2005) commissioned by Zotefoams plc with an independent analytical test laboratory have revealed concerns for users (converters and end-users, i.e. patients) of chemically expanded, crosslinked Polyethylene (XL-PE) and Ethylene Vinyl-Acetate (XL-EVA) foams in medical footwear applications.

Samples of Plastazote® LD45 Pink foam from Zotefoams plc and two other commonly used foams (one XL-EVA the other an XL-PE) from other manufacturers were compared using analytical techniques. These independent studies confirm the presence of potentially hazardous and potentially harmful substances in the competitors materials, including:

- **Acetophenone**
  
  Although little is known about the toxicology of acetophenone in humans, it is widely regarded as a skin / eye irritant, at least one of the references indicates contact with the material may lead to an ‘acne-like skin rash’.

- **Methyl Styrene**
  
  There are a number of forms (isomers) of methyl styrene and the analysis was unable to be certain of the form, however a common factor is that these substances are all known to be irritant to the eyes, skin and respiratory system.

- **Semicarbazide**
  
  Semicarbazide is a direct by-product of the reaction to decompose Azodicarbonamide (ADCN), the most widely used chemical blowing agent in the manufacture of crosslinked polyethylene, EVA and other polymer foams.

  Semicarbazide was the subject of a health scare in Europe in 2003 when the substance (a suspected carcinogen and genotoxin) was identified in baby foods. Subsequent investigation by industry and the European Food Standards Agency (EFSA) led to the foam seal in baby food and other food jars being identified as the source. The risk to human health was considered small but led to Azodicarbonamide blowing agents being banned by the European Union for use in food contact materials as of August 2005.

  In one of the studies the XL-EVA based foam material (widely promoted for use in medical footwear industry in the USA) also yielded relatively high levels of acetic acid and BHT (Butylated Hydroxy Toluene).

  The studies found the above and other substances present in foams currently in use in the medical footwear industry. Zotefoams plc is concerned since it is possible to envisage a situation whereby these substances can be indirectly ingested or inhaled (via particulates from the fabrication or machining of the foams) or
potentially absorbed to the skin over extended contact periods (as may be expected in the case of patients). Of more concern may be a situation where such foams are in contact with patients with open wounds or sores, in which case they may exacerbate the possibility of harm or interfere in the healing process.

**Plastazote® LD45 Pink was also tested as the control in the studies undertaken and none of the above named species were identified.**

Zotefoams plc employs a unique physical expansion process, utilizing nitrogen gas rather than chemicals to expand the foams, resulting in a wide range of clean, inert foam products. Recent tests have further proven medical compliance to USP and ISO 10993 standards. Plastazote® foam products have for several decades provided comfort, support and a safe healing environment for patients with podiatric complaints.

Dr. Neil Witten  
Director of Technology and Development

**REFERENCES :**

1 Confidential Technical Report No. 42452, 'Comparison Of Foam Samples Pt. 1 - Examination of Volatile Species', RAPRA Technology, Shawbury, UK.  
2 Confidential Technical Report No. 45074, 'Comparison Of Foam Samples', RAPRA Technology, Shawbury, UK.  
3 New Jersey Dept. of Health and Senior Services Website at www.state.nj.us/health/ehs/hitkweb/2961.pdf.  
4 US Environmental Protection Website at www.epa.gov/tnn/atw/hithef/acetophe.html.  
5 US Hazardous Substances Data Bank (HSDB) at National Library of Medicine Toxnet system at http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~a38MJU:1  
6 http://www.osha.gov/dts/chemicalsampling/data/CH_254700.html  
7 http://ull.chemistry.uakron.edu/erd/chemicals/3/2060.html  
12 www.zotefoams.com

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