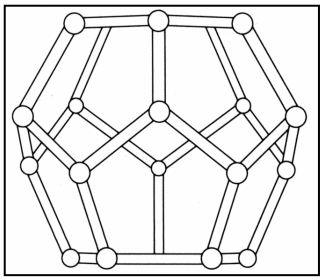
Zotefoams plc



Technical Information Sheet – TIS 24 Cleaning, Disinfecting and Sterilisation of Azote® Foams

INTRODUCTION

Foams from the Azote® product ranges find use in many applications that may require regular cleaning, disinfection or sterilisation of finished articles. Especially in the medical and food industries surface contamination is an issue that needs to be addressed. Some cleaning and sterilisation method can affect the properties of the foam. This technical information sheet aims to give a summary of suitable cleaning and sterilisation practises and summarises the effects observed during trials of some of these treatments.

CLEANING

Azote® products can be washed using household soaps and detergents in warm water. If automatic washing cycles are used a cool wash cycle, not exceeding 40 ℃, is recommend. Drying of the materials after the cleaning process can either be achieved by application of towels or similar absorbent materials or air drying at room temperature.

It should be noted that heating the material either through use of hot cleaning fluids or hot air in the drying process can affect the properties of the foam. Such effects can include densification, shrinkage and deformation in extreme cases. The extent of the effect of heat treatments will depend on the temperatures involved and the exposure time. For more information on the effect of heat on the foams please refer to TIS 08.

No tests have been performed by Zotefoams with regard to resistance of Azote® foams to industrial cleaning fluids. As these are often mixtures of active agents it is difficult to predict the effect of such cleaning fluids on the foam as interactions can enhance or reduce the effect of any of the single ingredients. For guidance on the general chemical resistance of Azote® foams please refer to TIS 06. Where contact with industrial cleaning fluids can not be avoided it is advisable to perform tests on small samples to ascertain suitability.

DISINFECTION

The following method is suggested for Plastazote®, Evazote® and Supazote® where soiling of these materials occurs and cleaning or disinfection is required.

- Fill 5-10 litres (1-2 gallons) of water, hand-hot, into a suitable container.
- Add 30 ml (1/2 fluid oz) of a commercially available detergent/ hypochlorite preparation e.g. Domestos.
- Using a dry clean cloth, thoroughly wash the appliance.
- If the appliance has a cellular surface i.e., it does not possess a continuous skin, rinsing should be repeated. However, it is not necessary to dry the appliance between the rinses.

This method of disinfection is based on that described by Boycott. (Boycott J.A. Lancet; September 29, 1956. p.678-9)

If other disinfectants are used suitability should be tested prior to wide ranged use. Drying can either be achieved by use of a clean cloth or air drying at ambient or slightly elevated temperatures.

STERILISATION

Common sterilisation techniques can be summarised in three groups:

- Heat sterilisation
- Chemical Sterilisation
- Irradiation sterilisation

Heat Sterilisation

Direct heat sterilisation or steam sterilisation in an autoclave requires a material to be exposed to elevated temperatures and/or pressures for a certain amount of time to ensure that the heat (and steam) will kill of all pathogens within a device/ material. These conditions are typically severe enough to cause shrinkage and deformation as well as changes in the mechanical properties of Azote® foams. The extent of the effect such treatment has on Azote® materials will vary between grades and will depend on the conditions of the sterilisation process. Due to their higher melting point Plastazote® materials will be less affected than Evazote® or Supazote® foams but even though some grades may withstand the procedure this method is not recommended for use on devices that incorporate Azote® foams or the foams themselves.

Chemical Sterilisation

Ethylene Oxide is used for sterilisation for certain (medical) applications. In this process the material is subjected to ethylene oxide at a slightly elevated temperature. Since Ethylene Oxide is highly toxic and potentially carcinogenic, this process requires degassing of the material after the exposure, which is typically done in a vacuum environment. Due to the safety regulations the process is fairly time consuming when compared to sterilisation by irradiation and is becoming less common for materials that can be sterilised by irradiation.

The combination of pressure cycles, elevated temperature and the ethylene oxide itself result in a degradation of Azote® foams. Especially the lower density grades and the softer Evazote® grades are severely affected by this process and it is therefore not recommended.

Trials of the extent of degradation after exposure to a 'mild EtO cycle' (50 °C, shallow vacuum, 2 hours exposure) have been performed on half sheets of material that were packaged in a PE wrapping at the Isotron facility in Thorne.

Assessing the changes induced during this type of sterilisation and their impact on the suitability of the material for applications that require sterilisation by ethylene oxide. The density of the treated foam increased for all tested Azote® foams, in some cases by more than 30%. These changes in density resulted in changes in the mechanical properties. While the compressive strength of the materials remained comparable to that of the original material compression set behaviour, tear and tensile strength decreased significantly for all materials indicating a softening of the polymer structure through the interaction with the ethylene oxide. If you require a detailed report of these trials or information regarding a specific product please contact the technical support team.

Irradiation Sterilisation

Three different types of irradiation sterilisation are currently available, namely, electron beam irradiation, gamma irradiation and x-ray irradiation. While the first two types are commonly used, the third, x-ray irradiation, is still a new development and few facilities are in operation that can offer this treatment.

The amount of irradiation, an article is subjected to, is measured in megarads (Mrads) or more commonly kilo Grays (kGy). For applications in the food and medical industries a radiation dose of 2.5 Mrads or 25 kGy is typically used. If articles are intended for repeat use they may be irradiated to this level several times and the effects of the irradiation on the structure of the material are cumulative.

When the irradiation process is set-up great care is taken to ensure that every part of the articles receives the required dose. As penetration of the radiation varies with the material of an article and the thickness of the material most processes are set up so that the amount receiving the least radiation is subjected to the minimum required dose.

During the electron beam (or e-beam) irradiation process an electron beam will bombard the item with electrons of low penetration. Consequently, the density and/or thickness of the item needs to be low and will require consideration in relation to the power of the electron beam. The process is normally quick and the item does not suffer from any significant oxidative degradation.

For the gamma irradiation process gamma rays are generated from radioactive cobalt and are highly penetrating. The radioactive substance is produced especially for this process and the radiation sources have a lifetime of 15-20 years after which they can be reprocessed to be used in radiation therapy or diagnostic tests. In the gamma irradiation process the actual 'work' is done by the photons emitted during the radioactive decay.

Therefore Azote® foams cannot become radioactive when subjected to radiation sterilisation. As photons exhibit better penetration in comparison to electrons this technique tends to be used for dense items. The process is slower than electron beam and ozone is produced by the action of the gamma rays on air. There may consequently be some oxidative degradation of the surface.

Both radiation techniques can also be used for modification of the surface structure, and are indeed used to achieve crosslinking of the solid polymer used in the production of some Zotefoams grades. Higher crosslinking generally leads to a stiffer, more brittle product, which should be kept in mind if an article is likely to receive multiple irradiation doses throughout its useful life.

Trials have been performed on a wide range of Azote® products using 25 kGy and 50 kGy irradiation doses respectively. In the past various products have also been irradiated to up to 100 kGy without showing significant deterioration of the material or loss of colour. Therefore irradiation sterilisation is the recommended sterilisation method for products containing or being packaged in Azote® foams.

The recent trials where performed on samples of A4 size and a thickness of 1 cm. These were packed in stacks (10 samples per stack) and wrapped in polyethylene foil. The treated material showed minor decreases in density to the untreated control samples. Tensile Strength, Elongation at Break and compressive strength also decreased. There was however no trend in the data with regard to increased radiation. A more detailed report is available upon request from the technical support team.

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ISO 9001:2000
FM 01870

ISO 14001
EMS 36270

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May 2007