

..... keeping disinfectants simple

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CE and Disinfectants

We are frequently asked if our disinfectants carry the 'CE Mark' or if they should do so in order to meet compliance as Medical Devices.

The CE marking scheme is a self administered one, in which manufacturers indicate, by displaying the appropriate logo, that their product fully meets the requirements of an EC directive. The number of the relevant directive is quoted below the logo.

Disinfectants employed on hard surfaces, as in the fabric of cleanrooms, are not medical devices per se. Those same disinfectants become medical devices (by association) if they are employed in order to assist or otherwise support the function of a medical device. For example, a sterilant solution used in the preparation or recycling of an invasive implement is itself a medical device, by association.

Agma has discussed this subject with a several recognised authorities on the subject of disinfection and, without exception, they have indicated to us that the use of environmental disinfectants is held to be distinct and free of any association with medical devices. In other words, they should not carry a CE mark.

Interestingly, as the Biocidal Products Directive (see next page) gains integrated enforcement to embrace user preparations, it may become appropriate for disinfectants to be CE marked in compliance with EC Directive 98/8. However, this would not in itself replace the Medical Devices Directive (EC 93/42 and amendments), which is quite separate in its intent. This is all some way away and to date no guidance has been published.

STERILE TRIGGER SPRAYS

Sterile ethanol (IMS) is now available in both 450 ml and 900 ml trigger sprays, to suit differing levels of usage.

Sterile alcohol, 'Proceine' and 'Qceine' sprays are all fitted with non-venting trigger heads and employ an inner bag to facilitate the balancing of air pressure without compromising sterility.

All types of trigger spray, together with wipes, RFU fluids and alcohol aerosols are available ex stock for prompt delivery throughout the British Isles.



BIOCIDAL PRODUCTS DIRECTIVE [BPD]

Several readers of 'The Agma Way' have asked us to clarify the implications of the BPD and we are happy to do so.

The Biocidal Products Directive (EC 98/8) is a directive issued by the European Parliament and concerns the 'placing on the market' of products promoted for the purpose of killing, disabling or deterring living organisms.

It is intended to control the effects of such products on the environment by measures which include identification, registration, comprehensive testing and data publication. The onus and costs of compliance are placed upon whoever brings such a molecule, mixture or preparation to market, i.e. the pyramid of researchers, manufacturers, compounders and traders engaged in commerce at any level within the EC.

The large number of different materials and that broad definition are broken down into groups of commercially available products defined by their advertised functions, for example rodenticides; marine anti fouling paints; bactericides; wood preservatives and so on.

Registration is step-wise, starting with original 'actives', that is the single molecules or elements claimed to exhibit biocidal effects, such as phenol or ethanol. It will eventually progress through the supply chain to compounders, blenders and traders – anyone who alters, names or presents those molecules in a commercial format, whilst making any claims for efficacy.

Certain classes of applications are excluded or exempt on the basis that adequate registration and documentation already exists. Medicines and antibiotics are examples.

So what does this all mean in practice?

- Supporting an 'active' substance will cost manufacturers anything up to £2 million.
- Manufacturers will inevitably rationalise the number of products they wish to support, leading to the disappearance of many quite well known products. New developments are also likely to be limited.
- Original research into biocides will be confined to organisations with global resources.

What do I need to do?

For the sake of continuity, you should seek assurance from your immediate supplier that compliance has been established right back to the original manufacturer of 'actives'.

An unexpected complication has occurred with Quaternary Ammonium Halides (QUATs or QACs). This term includes hundreds of similar and related molecular species, made by hundreds of synthesisers worldwide but only a small number was notified and registered before the closing deadline, Sept 2006. This means that many disinfectants still on the UK market are, strictly speaking, illegal under the Biocidal Products Regulations (BPR) – the UK enactment of BPD. HSE is currently considering this position but if you are offered QAC based products ask the question!

Agma worked closely with its suppliers when developing 'Proceine' and 'Qceine' to ensure that its chosen 'actives' would be fully supported and we are confident of ongoing compliance with BPR.

One particular aspect of BPR came into force on 6th April 2007 and this requires all advertising material promoting any product which falls within the scope of the Directive to include the phrases 'Use biocides (or disinfectants) safely. Always read the label and product information'. These phrases must be 'stand alone' and be clearly distinguishable from other text.

Under the terms of this rule, suppliers must not mislead in respect of the risks of a product to humans, animals or the environment and advertising must not contain, in relation to the biocide product, the words 'low risk biocide product', 'non toxic' or 'harmless'.

These requirements refer specifically to advertising and do not cover packaging or labelling – which are regulated by other legislation.