

# Disinfectants by design



A harmonised approach to the design, specification and application of sterile disinfectants achieves the best results, satisfies the regulators and engages the user, says Andrew Philpotts, technical director of AGMA

When asked about disinfectants, disinfectant delivery systems and the ways in which they serve the cleanroom user, most operators and their staff will admit to an element of confusion, tinged with dissatisfaction.

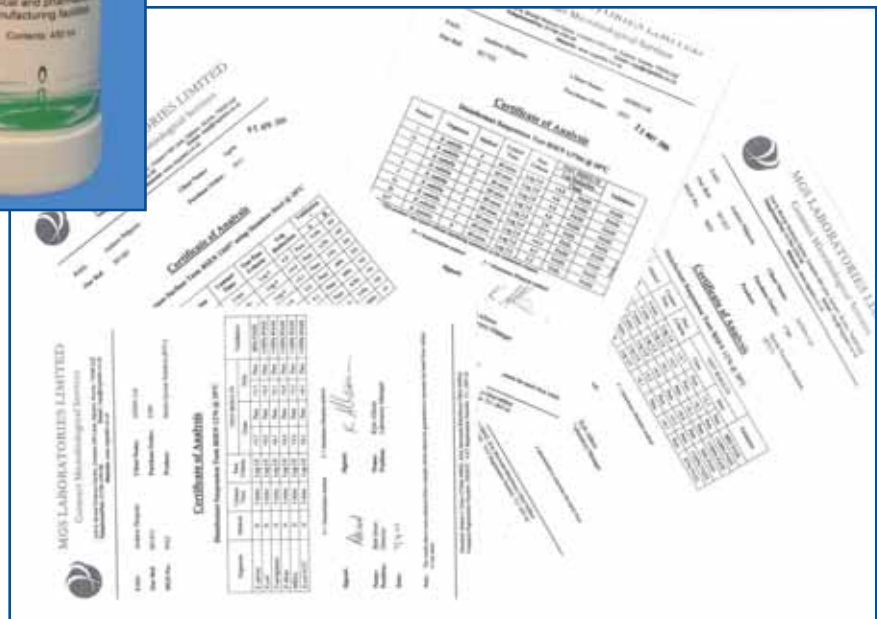
The desirable and necessary characteristics of cleanroom disinfectants are in the process of being redefined, ever since this vital aspect of operational maintenance attracted, circumstantially perhaps, the deserved attention of the regulators.

A clear set of criteria is emerging that satisfies not only those regulators in their pursuit of zero risk, but also the users in their desire for assurance, simplicity and operability.

The influences driving this minor revolution in practice are primarily regulatory.

The European Biocides Directive (EBD) is enacted in the UK as the Biocidal Products Regulations (BPR) and comes into force in September 2006. By this act, all chemicals substances (actives) that are promoted as having adverse material effect on living organisms are required to be registered, along with a hugely detailed dossier of their behaviour.

In effect, this brings to the disinfectant



Above: More sterile certificated products are being specified for use throughout cleanrooms  
Top left: Two rotationally compatible mainline disinfectants and a sterile alcohol

market something approaching the duty of disclosure and care already familiar to the pharmaceuticals industry. It is illegal to bring to the market any unregistered 'active' substance after 1 September 2006.

## Sterile certification

Guidelines now insist upon the certified sterile status of disinfectants employed in medical cleanrooms within the critical A and B zones. In practice, this means that it is operationally practical and advisable to employ sterile disinfectants throughout the facility, including zones C and D.

The practice of disinfectant rotation has its supporters and at the same time attracts a considerable proportion of sceptics. It is, however, gaining ground and is increasingly acknowledged in risk assessment and mitigation analyses. The practice is not mandatory – at least, not yet – but an air of inevitability pervades.

Criticism is increasingly focussed upon those disinfectants whose residues during and after use might give rise to contamination issues. Consideration of residues is then intertwined with the discussion of disinfectant rotation since a

Right: Sterile Proceine, Zyceine and 70% v/v pure alcohol ready-to-use wipes from the Agma product range

further dimension to the (potential) problem arises from the risk of adverse interactions resulting from inadequately clear-cut rotational interchange.

Harmonisation of the protocols employed in the evaluation of disinfectants across Europe has reached fruition via the standards published by an EC working group under CEN 216 (Committee European Normalisation No 216). Although further work is being undertaken on some aspects of the standard, a pan-European consensus has emerged in the form of a graded, step-by-step assessment procedure forming the clear basis for disinfectant registration, whether by mandate or by popular consent.

The limitations and strictures flowing from occupational health and safety continue to bear down on the creative formulator by proxy for his/her intended end-user.

## Future legislation

Beyond current legislation, REACH (Registration, Evaluation and Authorisation of Chemicals) legislation will bring to all known chemical materials marketed in the European Union the same kind of documentary requirements that are presently being enacted for biocidal products. Only the prodigal will dare to ignore the impending costs and constraints that will ensue.

The specialist disinfectant formulator, such as AGMA, occupies a unique position at the heart of the triangle formed by the interests of the working cleanroom, the legislator/regulator and the international chemicals industry.

The formulator's role is that of sympathetic interpreter, listening to the needs of the end user while fully acknowledging the regulator's position. They then seek to select, arrange and present, from the building blocks of the international chemical industry, the most appropriate solutions that will be fit for purpose in the eyes of the end user – a difficult and often laborious task in which a multi-disciplinary approach is required involving considerations derived variously from chemistry, microbiology, materials science, physics, statistics and occupational health.

## Formulation challenge

The responsible formulator enjoys a hard-won position of trust with all parties, based on a sound reputation, ethical track record and the ability to change, when appropriate,



in order to pursue and maintain conformance linked to assurance.

The changing profiles of disinfectant expectations and user protocols represent a significant challenge to the formulator and the marketer alike, giving rise to questions such as:

- When to abandon the outmoded?
- When to embrace the product of your r&d and launch it on a trusting and essentially conservative user base?
- How best to involve customers in the logic process?
- How much "science" do users really need in order to employ the system effectively and how much is to be held, in trust, for the more academic enquirer?
- Can less be more, if your technology is robust?
- How best to capture the support for change?

AGMA has watched carefully the shifts and trends in thought and practice and has now relaunched its branded disinfectants as a compact, acutely effective and sustainable line of sterile disinfectant products promising unique conformance with cleanroom users' needs.

The main features of the new product range include:

- Two rotationally compatible mainline disinfectants – Proceine and Qceine
- A uniquely presented stable, sterile sporicide (patent applied for) – Zyceine
- All three of the products have been

certified sterile, in-pack

- All three products forming a CEN 216 compliant system
- Three different but complementary user formats – wet wipes, trigger sprays and bulk fluid
- All-round mutual compatibility – freely interchangeable at will
- Very low residuals and no interactions
- Maximum shelf-life in hermetic packaging
- Batch coded and traceable throughout
- User friendly – safe in storage, dispensing and use
- BPR compliant – continuity assured
- REACH compliant as far as can be anticipated.

Throughout the project AGMA has sought to use objectivity and technical strength to absorb the burden of compliance and to pass on to the user a simple, engaging system that will serve every cleanroom operator and employee. ■

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