Appendix 1

Health Protection Agency Guidance on Replacement of Hycolin with other Disinfectants

Clear soluble phenolics (CSPs), of which the prime example is Hycolin, have been withdrawn from sale as a result of the European Biocidal Products Directive. There is now an urgent need to find an effective replacement for laboratories handling mycobacteria.

This appendix contains information gathered by HPA for identifying alternative disinfectants for use in their laboratories. This document is also freely available on the Department of Health website.

HPA Replacement for Hycolin – February 2007

Background
Clear soluble phenolics (CSPs), of which the prime example is Hycolin have been withdrawn from sale as a result of the European Biocidal Products Directive. (This is not because they are ineffective, but because sales levels do not justify the substantial investment needed for registration). The withdrawal of CSPs from the market was abrupt and has taken users by surprise. CSPs were the agent of choice for mycobacterial disinfection. There are established alternatives to CSPs available for every laboratory requirement other than areas where mycobactericidal activity is required where, up until now, they were the sole disinfectant. There is now an urgent need to find an effective replacement for laboratories handling mycobacteria.

Present predicament and what do we require
Disinfection against TB and other pathogenic mycobacteria is required in routine diagnostic laboratories as well as reference and research facilities. Chemical disinfectants are required in case of spills, for routine environmental decontamination, for equipment decontamination (where corrosion can be problematic) and for disinfection of liquid waste, which may contain a high concentration of organic matter. CSPs have the advantage of low corrosivity and high resistance to inactivation by organic matter.

It may be impossible to find all the attributes of CSPs in a single substitute, however the user's situation may have to become more complex, with more than one agent required in a laboratory.

There are no standard tests for laboratory disinfectants. European disinfectant tests are usually for environmental disinfection in the absence of gross soiling, in contrast with a laboratory spill, where there may be very high levels of organic matter; similarly with disinfection of liquid waste. The applicability of other European disinfectant tests to laboratory situations is debatable. Many disinfectant manufacturers will claim, most correctly, that their disinfectants will inactivate mycobacteria. However this is only a starting point for consideration of a replacement for CSPs; many other factors can prevent a chemical disinfectant from working effectively. To assess how effectively an agent will perform in practice, experience and judgement by those experienced in laboratory safety and disinfectant properties will have to come into play.

A small HPA group was convened to review options or alternatives for Hycolin. The results of this review and subsequent recommendations are outlined below. These recommendations were derived from peer review published data (see references) with the additional input of HPA users and experts from across the Agency.

Possible Alternatives to Hycolin
There was a historical general perception that hypochlorites were unreliable against mycobacteria. More recent work indicates this is not the case.

> **Hypochlorites**
> These are the main laboratory disinfectants. Their characteristics are: wide microbicidal spectrum, comparatively rapid action, inactivation by organic matter at low concentrations and corrosive to some metals.
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> Hypochlorites are available from either liquid sodium hypochlorite or as solutions of the solid sodium dichloroisocyanurate (NaDCC). NaDCC has several practical advantages over sodium hypochlorite, mainly the stability of the undiluted disinfectant and the availability of pre-measured tablets of the agent.

Results from a recognised disinfection centre of excellence, the Hospital Infection Research Laboratory (HIRL) at City Hospital in Birmingham, shows hypochlorites from NaDCC to be effective against *Mycobacterium tuberculosis*, a validated substitute for TB, *Mycobacterium terrae*, and atypical mycobacteria such as *Mycobacterium avium-intracellulare* (MAI) though, as with most other disinfectants, activity against atypicals is slower.

At CfI, NaDCC is used at 2500 ppm available Chlorine (ppm av Cl). The work from HIRL showed 1000 ppm to produce a reduction greater than 5 logs in four minutes and 10,000 ppm to produce the same reduction in one minute in dirty conditions (10 percent serum). Similarly, with MAI, those reductions were achieved in 60 and 10 minutes respectively.

From these data we believe that hypochlorites could be used in laboratories handling mycobacteria for disinfection in areas where corrosion is not issue.

Hypochlorites can have their activity checked in use by starch/iodide indicator papers: if sufficient oxidising power is left in a used solution, it will turn the papers blue-black; if there is insufficient oxidising power (showing overloading of the disinfectant), the papers will produce a pallid colour or not change at all. (Care – high concentrations can bleach out the colour change, therefore, if there is no colour change apparent, dilute the test solution to about 1% and retry).

Peracetic acid

Peracetic acid (PA) is a wide spectrum, rapid disinfectant that is more expensive than hypochlorite, but without its corrosivity and degree of inactivation by organic matter. PA is currently used as a disinfectant for flexible fibre optic endoscopes, where corrosion is highly undesirable.

HIRL results show 0.35% PA to produce a 5 log reduction in TB in one minute under dirty conditions. With MAI, the same reduction was achieved in four minutes in dirty conditions. Similar, though less quantitative, work from University College Hospital showed a different PA product (0.2%) to be of similar activity.

From these data we believe that PA could be used in laboratories handling mycobacteria for disinfection in areas where corrosion must be avoided.

Chlorine dioxide

Chlorine dioxide is a wide spectrum, rapid disinfectant that is more expensive than hypochlorite, but without its corrosivity and degree of inactivation by organic matter. Chlorine dioxide is currently used as a disinfectant for flexible fibre optic endoscopes, where corrosion is highly undesirable.

HIRL results show that chlorine dioxide at 1100 ppm produces a 5 log reduction in one minute under dirty conditions. With MAI the same reduction was also achieved in one minute in dirty conditions.

From these data we believe that chlorine dioxide could be used in laboratories handling mycobacteria for disinfection in areas where corrosion must be avoided.

Recommendations

Therefore, based on evaluation of peer reviewed papers, we recommend that the following disinfectants are considered for use in laboratories working with mycobacteria. However, their use must be subject to local assessment of suitability and risk assessments. The recommendations relate only to replacement of Hycolin and are not intended to suggest replacement of other disinfectants currently in use.

- There is a range of hypochlorite products that can be used for the disinfection of liquid waste such as sputum digest supernatant, if steam sterilisation is not feasible. Hypochlorite has the advantage that a highly concentrated initial solution can be diluted by adding liquid waste such that the final volume contains the desired available chlorine concentration. Activity can be checked by starch-iodide paper (see above). Hypochlorites can also be used for spills. Hypochlorite presentations such as absorbent granules are particularly suited to spill clearance. Occasional use of high hypochlorite concentrations should not cause corrosion on most laboratory surfaces. Hypochlorite however, should not be used on laboratory equipment such as centrifuges.

- Peracetic acid and chlorine dioxide products – either or both of these solutions could be used in situations where corrosion must be avoided. Although these are used on endoscopes without corrosion, this does not guarantee they will not have corrosion, including where this might have a significant safety element such as centrifuges. We recommend that users make attempts to ascertain compatibility with equipment manufacturers. We realise this may not always be possible and where it is not, every effort must be made to ensure that centrifuges and components are inspected and maintained in accordance with HPA Centrifuge Guidance. The references describe possible products which may be suitable within this category.

- Chemical disinfectants are an inherently poor quality assurance method of decontamination. Dry discard followed by steam sterilisation has superior quality assurance and should be used wherever feasible. Liquid discards may need to be immobilised with a gelling agent. Safe methods of transport between point of use and point of disposal will also have to be considered.

Summary

	Spills in cabinet	Equipment	Routine surface decontamination	Liquid waste
Method				
Steam sterilisation	NA	x	NA	√
Hypochlorite	√	x	√*	√
Chlorine dioxide	√	√	√	NA
Peracetic acid	√	√	√	NA

* only if surface will withstand repeated hypochlorite use.

References

P. A. Griffiths, J. R. Babb and A. P. Fraise (1998) Mycobacterium terrae: a potential surrogate for Mycobacterium tuberculosis in a standard disinfectant test. Journal of Hospital Infection **38**: 183-192

J. Holton, P. Nye and V. McDonald. (1994) Efficacy of selected disinfectants against Mycobacteria and Cryptosporidia. Journal of Hospital Infection **27**; 105-I 1.5