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SUBJECT: Comments on Draft, "Criteria for a Recommended Standard: Occupational Exposures to Metalworking Fluids"

Dear Ms. Manning:

I would like to address the above in the following two areas: (1) 5.3 Biocides, pg. 132; and (2) 6.2 Microbial Contamination, pg. 144.

First, although it may be trivial, I will correct Table 5-1. The biocides Omadine, Proxel, Kathon, and Dowicide-1 are neither formaldehyde condensates nor formaldehyde releasers. Second, although Onyxide-200 and Grotan BK are given slightly different chemical names, they are exactly the same and represent only two of at least five EPA-registered products from different companies. Third, Trisnitro and Bioban P-1487, although formaldehyde condensates, are not frank formaldehyde releasers. In Table 5-2, DBNBA is correctly 2,2-dibromo-3-nitrilopropionamide and Givgard DXN is the correct trivial name. In addition, this biocide releases acetaldehyde which produces cross resistance to formaldehyde.

More substantively, with respect to biocides is the method of dosing. It is obviously most convenient to include biocide in the concentrate package so that when the metalworking fluid (MWF) is diluted for use the biocide will already be present. This approach, though well received by end users, is fraught with many problems, some of which can be anticipated but others not.

Perhaps the simplest scenario deals with extent of dilution, a factor beyond the control of the formulator. For example, triazine is added to MWF concentrate at 3% in anticipation of a 5% or 1:20 use-dilution of the MWF to yield a biocide level of 1,500 ppm, well within the EPA registered dose. If the machine operator opts for 10% we now have 3,000 ppm which exceeds the EPA dose. Is this dangerous?

This is a formaldehyde release agent and the excess is not readily anticipated. The other side, a 2-1/2% dilution, yields 750 ppm with two events occurring (i.e., uncontrolled fungal growth and selection for formaldehyde-resistant bacteria). There are other problems, even with

targeted dilutions. The physical half-life of the MWF may exceed the chemical half-life of the biocide. Thus we repeat the first presented scenario. In addition, more frequently than not, MSDS's do not state exact biocide levels but give only ranges, compounding the problem of concentration.

There is another question with respect to MWF concentrate. Does dilution of biocide by MWF concentrate constitute de jure as well as de facto dilution and repackaging? Without a valid EPA sub-registration this would constitute a violation of F.I.F.R.A. I am not sure that most end users are aware of problems associated with concentrate dosing, only benefits.

The obvious and rational use of biocides is to apply when needed in doses known to achieve a given microbial level (whatever that may be!). This means regular monitoring for viable microbial types, as is done in infectious disease. Stress should be on the use of EPA-registered biocides, emphasizing that this means use-registered. Registration means risk assessment by toxicological testing and environmental impact, with the involvement of the former most severe with MWF biocides. Notice there is no official requirement currently for efficacy, although originally there was. The amended requirement said, "Caveat Emptor," and submittors should keep efficacy data in their files.

It should be pointed out that only claims for prevention of biodeterioration can be made with no claims for prevention of communicable disease. With current concerns over Legionellosis and Hypersensitivity Pneumonitis (HP) of microbial origin, users should be aware that no written claims for efficacy against those organisms can legally be made.

With respect to microbial populations in MWF, the review presented is essentially correct without being judgmental. There is little or no published evidence of frank infection from MWF except for "Pontiac Fever" from an engine plant in 1981 in which sero-conversion of 1:1024 was noted in the afflicted group and 1:512 in the non-afflicted cohort, to a new species, Legionella feelii. Recently Bernstein, et al. reported in Chest (Sept 1995) that diagnosed HP was accompanied in all cases by positive serology to Pseudomonas fluorescens. Unfortunately no serology was available from exposed but non-clinically diagnosed workers. Mattsby-Baltzer, et al. and Hill and Al-Zubaidy both report antibodies to Pseudomonas antigens from MWF. Is this not a normal immunological response? The HP reported by Mullenberg, et al. (Burge) was indeed gram positive but also acid fast and there is some indication that fast-growing acid-fast bacteria have been isolated from MWF in more than one location associated with HP.

There are other signs of changes in MWF microbiota, although not associated specifically with any disease. Specifically, the appearance of gram positive organisms among the dominant groups.

Thirty years ago Marcus Key stated that skin infection from MWF bacteria was non-existent and my laboratory could not sustain Staphylococcus aureus in MWF. Now we find this organism growing in MWF. Bearing in mind that gram positive bacteria in general survive aerosolization better than do gram negative and in addition are more likely to cause respiratory disease, should there be more concern about airborne levels of these organisms as well as gram negative endotoxin producers? It is odd that given the long history of fungal growth in MWF (since the middle 60s) and especially with Cephalosporium that no histories of MWF allergies have developed or been reported.

I pose another question, perhaps rhetorical. Are we at the stage in this industry where we must impose microbial levels and/or restrict type of organisms permitted?

Respectfully submitted,

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HWR/mmh