POSITION PAPER

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Use of Copper Beryllium Alloy for Medical Devices

Copper Beryllium (Cu-Be) is an excellent material for components for oxygen service such as springs and diaphragms because of its very high mechanical strength, its good resistance to fatigue and its high copper content (about 98% making it very resistant to oxygen ignition). However, because it contains approximately 2% of Beryllium which, as a pure metal, is classified as carcinogenic, the use of Cu-Be for medical components and accessories within such devices as valves and regulators has been questioned.

Whilst literature searches show numerous references to studies demonstrating a causative link between beryllium metal and clinical disease states, a review of medical databases reveals few papers identifying any association between beryllium-copper alloys and Chronic Beryllium Disease (CBD)[1]. The first papers proposing a link were published in the 1950s and 60s [Tepper 1961, Jackson 1964, Sneddon 1950] but they utilised crude tests to establish the diagnosis of CBD – investigations that would fail to fulfil modern CBD diagnostic criteria (e.g. a positive beryllium lymphocyte transformation test) and therefore raising doubts as to the nature of the clinical syndrome described.

There appear to be only 4 documented cases of exposure to 2% beryllium-copper that have resulted in confirmed cases of CBD [Tarlo 2001, Balkissoon 1999]. Without exception all of the patients had been exposed to very high concentrations whilst working in beryllium foundries for prolonged periods without respiratory protection. More recently, a study by Kreiss in 1997 of a beryllium manufacturing facility also described cases of CBD amongst beryllium copper alloy workers; the authors were however, forced to acknowledge that the workers may also have been exposed to other forms of beryllium [Kreiss 1997] known to precipitate CBD.

[1] CBD is the only beryllium induced clinical disease encountered today and has an estimated prevalence of between 1% to 16% in individuals exposed whilst working directly with beryllium and its alloys during processing and finishing [Maier 1998]. It is an immunologically mediated systemic disease characterized by the development of noncaseating granulomas in multiple organs –most commonly the lungs. Clinically and pathologically it closely resembles sarcoidosis with the diagnosis dependent on both a history of beryllium exposure and an abnormal beryllium lymphocyte transformation test [Mroz 1991]. The susceptibility to developing CBD following beryllium exposure appears to at least partly genetically determined [Richeldi 1993, Newman 1996, Wang 1999]
In its early stages, CBD may be either completely asymptomatic or associated with non-specific respiratory symptoms such as mild dyspnoea and a non productive cough. Eventually, the majority of patients develop more characteristic symptoms: cough, chest pain, progressive exertional dyspnoea, fatigue, anorexia, weight loss and acrocyanosis with digital clubbing. Advanced disease may be associated with the development of Cor Pulmonale (right heart failure secondary to acquired pulmonary hypertension).
The first characterised form of beryllium induced disease was actually an acute syndrome however environmental legislation limiting permissible exposure limits (PEL) for beryllium of 2 µg m^{-3} (averaged over an 8 h period) has consigned this disease to the annals of medical history (only 15 cases have been noted by the US Beryllium case registry since 1950). Furthermore a high level of compliance with the current Occupational Safety and Health Administration PELs also appears effective in reducing the incidence of CBD [Johnson 2001, Hardy 1946, Kriebel 1988].

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By contrast no cases at all of CBD (or any other beryllium related disease) have been documented as a result of contact with finished beryllium copper alloy products.

EIGA does not envisage any scenario that a finished beryllium copper alloy component as used in cylinder valves could liberate free beryllium.

Note: Patient Exposure Limit (PEL) for free beryllium is 2 µg m^{-3} for 8 hours

EIGA CONCLUSION

Considering its excellent mechanical properties as indicated in the introduction of this position paper and that, unlike pure beryllium metal, the risk of initiating CBD is extremely unlikely, EIGA supports the use of beryllium copper for finished components such as springs and diaphragms within valves, regulators and similar accessories used for medical applications.

References

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