



HAEMONETICS®
THE Blood Management Company

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Haemonetics Position Paper: DEHP

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Background: To be pliable, vinyl plastic must have added to it a chemical, referred to as a “plasticizer” at up to 30 to 40% of the final weight. The most widely used plasticizer is a phthalic acid ester known as DEHP. DEHP can migrate from the plastic material itself.

DEHP is a widespread environmental contaminant. It has been in use for more than 50 years. It is a common ingredient in plastics made of polyvinyl chloride (PVC). Everyone is exposed to PVC plastic everyday and thus to low levels of DEHP. It is also found in blood stored within plastic containers. Because DEHP has been found to be a carcinogen in rodents, concern has been raised as to its safety for human use. Studies have shown that in animals DEHP can have adverse effects on the reproductive system in young male animals but only at high doses, concentrations which if adjusted for body weight are rarely achieved in human transfusion recipients, (e.g., massive transfusion, neonatal patients). No studies have conclusively shown harm in humans, including blood transfusion recipients.

Plasma Bottle Manufacturing

Haemonetics uses polyethylene for the production of its plasma collection bottles. This plastic material is free of any plasticizer like DEHP. DEHP is contained only in the PVC used for the production of the harnesses of the plasma collection bottle product. Thus the exposure of plasma to the harnesses is limited to the collection process and the post processing in the laboratory.

Regulatory Perspective

Both the FDA and other regulatory bodies have studied the issue of DEHP for materials containing PVC. Following an FDA-sponsored workshop on October 18, 1999, the FDA concluded that rulemaking regarding PVC medical devices was not warranted because there is no compelling evidence suggesting a human safety hazard. A 2008 European Union panel of experts report concluded that toxicity of DEHP appears to be at low levels. Alternative plasticizers may pose increased risk because of the unknown effects which such substances may pose. These experts also stated that alternatives may fail to achieve the same functionality as PVC with DEHP plasticizer (SCENIHR, European Union, 2008).

Haemonetics Position

Based on the scientific evidence, there is no reason to believe that DEHP presents a clear risk to apheresis blood donors. Haemonetics will monitor the scientific and regulatory literature to determine if there is any change in this view. We are conducting ongoing studies to identify possible alternatives.

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