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Abstract:

Alternatives to DEHP plasticizers are used in various PVC medical devices (MD) for infusion. As they are able to migrate from these MDs into infused solutions, they may come into contact with patient. Different and specific clinical parameters influence their migration in at-risk situations such as infusion.

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In contrast to the regulations for Food Contact Materials (MCDA), there is currently no acceptable migration limits for the use of these plasticizers in clinical situations. In order to assess their migration, and thus control the risks linked to these MDs, we developed a migration model for the plasticizers in MDs. To this end, we applied a cross-disciplinary methodological process similar to that used in the food-processing industry, taking into account the MDs' conditions of use in clinical practice. The simulation model is simple and includes the following conditions: MD should be tested with a dynamic method that respects our established clinical assumption (2L of infused solutions via 13dm2 of plasticized PVC), at a temperature of 25°C and during 24h of contact, using a 50/50 (v/v) ethanol/water simulant.

This model could be proposed as a tool for the safety evaluation of the patients' exposure risk to plasticizers from PVC medical devices for infusions.

Reference:

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