18 January 2018, Strasbourg, France

The Ph. Eur. revised its general chapters on plasticised PVC materials

At its 159th Commission session (November 2017) the Ph. Eur. Commission adopted the following revised general chapters:

- 3.1.1.1/90001. Materials based on plasticised poly(vinyl chloride) for containers for human blood and blood components;
- 3.1.1.2/90002. Materials based on plasticised poly(vinyl chloride) for tubing used in sets for the transfusion of blood and blood components;
- 3.2.4. Empty sterile containers of plasticised poly(vinyl chloride) for human blood and blood components;
- 3.2.5. Sterile containers of plasticised poly(vinyl chloride) for human blood containing anticoagulant solution.

These chapters had been revised to include four new PVC plasticisers:

- cyclohexane 1,2-dicarboxylic acid, diisononyl ester;
- butyryl tri-n-hexyl citrate;
- tris(2-ethylhexyl) trimellitate;
- bis(2-ethylhexyl) terephthalate.

Another 2 general chapters were also indirectly impacted by the revision:

- 3.1.13. Plastic additives: the list of additives has been updated with the 4 additives mentioned above;
- 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion: the quantification of plasticisers (including DEHP) is now performed by gas chromatography/mass spectrometry.

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Note for the Editor: Further information is available on the internet site **https://www.edqm.eu/**
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[1]There are thirty-nine members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine, United Kingdom and the European Union.*

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