

Fresenius Kabi

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REACH - Information according to Article 33 - Medical devices

Dear customer,

On October 28, 2008 the European Chemical Agency (ECHA, <http://echa.europa.eu>) released the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 (REACH). According to Article 33 of REACH suppliers of articles are obliged to communicate information on substances which are on the candidate list to customers.

To our current knowledge the following medical devices contain more than 0.1% (w/w) of Bis(2-ethyl(hexyl)phthalate) (DEHP, EC number: 204-211-0):

- Gravity infusion sets, pump dedicated infusion sets, extension lines with PVC tube (except: PE- or PUR tubing)
- Veinsets (Butterflies)
- Compoflex standard blood bag systems
- Composelect in-line filtration blood bag systems
- Stemcare cord blood collection and processing set
- Compoflex transfer bag systems
- BioR and BioP leukodepletion filters
- Platelet additive solution
- SAG-M red cell preservation solution
- Red cell freezing solution
- Red cell washing solution

Information on the safe use of these products can be found in the related instructions for use.

Yours sincerely,

Fresenius Kabi



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