

Bis(2-ethyhexyl) phthalate (DEHP) and Bisphenol A (BPA) Questions & Answers

August 15, 2008

DEHP

- Q1. Why is Health Canada requesting information on devices that contain $\geq 0.1\%$ w/w DEHP?
- A. When Bill C-307 is passed, Health Canada is required to produce a list of all medical devices that contain $\geq 0.1\%$ w/w DEHP
- Q2. When considering the mass of DEHP in a device, is it 0.1% of the mass of a whole system (i.e. the whole CT system), or the mass of any individual parts (i.e. each part of CT such as Gantry, Patient couch, or for Ultrasound, Transducers)?
- A. - If the part is assembled in the finished device then the % mass is calculated using the mass of the finished device
- If the part is not assembled in the finished device (infusion set or disposable tubing for example) then the % mass should be calculated based on the part alone.
- Q3. If Diagnostic X-ray equipment contains DEHP, is it sufficient only to investigate the parts and materials in accessible surface by patients and operators?
- A. The requirement to report on medical devices that contain DEHP is based on Bill C-307 which is currently before the parliament. The Bill does not specify whether the device comes into contact with patients or not, so all devices that contain $\geq 0.1\%$ w/w DEHP need to be included.

BPA

- Q4. Why is Health Canada requesting information on devices that contain BPA?
- A. Health Canada is taking a proactive approach in gathering information on devices that contain BPA in light of the Bill that is currently before Parliament regarding BPA. Health Canada does not currently have concerns regarding the safety of medical devices containing BPA.
- Q5. BPA as trace amounts are contained in in-vitro diagnostic devices and many plastic casings that house device components that do not come into contact with the patients. Given that we are being proactive, should it only be devices that come into contact with patient and user's body fluids, tissue and skin?
- A. For BPA, manufacturers will only be asked to report on devices that come into contact with the patient or patient fluids (e.g. via intravenous, inhalation, oral exposure, contact with the skin, or as an implant).

DEPH & BPA

- Q6. With regards to the notice issued May 2, 2008 pertaining to devices containing DEHP or BPA, will manufacturers be forced to do anything else (i.e. recalls or provide special labeling instructions) other than disclose whether or not the device contains more than 0.1% w/w DEHP or BPA?
- A. At this time Health Canada is only requesting that manufacturers report as to whether or not their devices contain 0.1% w/w DEHP, or BPA that comes into contact with patients or patient fluids.
- Q7. Also, do manufacturers of Class I devices that may or may not contain 0.1% w/w DEHP or BPA required to do anything at this time or in the future?
- A. At this time Health Canada is only requesting DEHP and BPA information on Class II, III and IV medical devices.
- Q8. Are there certain mandatory measuring procedures or testing methods?
- A. Health Canada has not prescribed any specific measuring procedures or testing methods, but official, recognized methods are required.
- Q9. Do manufacturers have to submit test reports on DEHP and BPA to Health Canada?
- A. At this time Health Canada is not requesting that manufacturers submit test reports on DEHP and BPA. On September 1, 2008 Health Canada will be sending out a survey to ALL manufacturers of licensed Class II, III and IV medical devices. In this survey the manufacturer will only be asked to check a box as to whether their devices contain $\geq 0.1\%$ w/w of DEHP or BPA (if the device comes into contact with the patient or patient fluids).
- Q10. Is there a rationale that will allow us to continue to sell in Canada, or do we need to just let our license expire, and discontinue offering these devices in Canada?
- A. At this time, Health Canada does not intend to ban the sale of medical devices that contain DEHP or BPA. Health Canada is just being proactive in gathering this information.