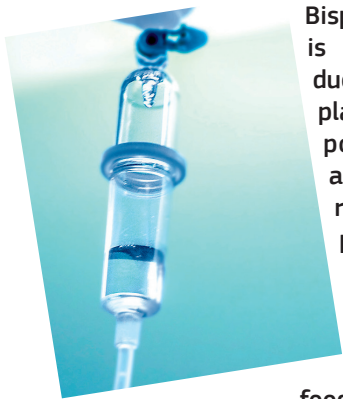


Bisphenol A in medical devices

Is exposure to BPA through the use of medical devices safe for humans?



Bisphenol A (BPA) is used to produce certain plastics such as polycarbonates and epoxy resins. Most people are exposed to it through food, because BPA is used in food packaging.

BPA is also used in the production of polymers for medical devices such as catheters and implants, and some dental devices. Is exposure to BPA via medical devices safe? Are there any risks?

→ WHAT HAPPENS TO BPA ONCE IT IS IN THE BODY?

When BPA is ingested, it is absorbed by the digestive system and efficiently metabolized by the liver into a non-toxic product that goes into the bloodstream. It is then quickly filtered out by the kidneys into the urine.

When BPA comes into the body through the use of medical devices, such as catheters or polymer materials used for hemodialysis equipment, the efficiency of the metabolism to form a non-toxic metabolite is lower. But, its elimination is also relatively fast, so that BPA is not able to accumulate in the body.

→ WHAT ARE THE HEALTH RISKS FROM EXPOSURE TO BPA THROUGH FOOD AND VIA MEDICAL DEVICES?

There is an ongoing debate in the scientific community as to how much BPA people are exposed to and what its effects on health might be.

Many studies on the effects of BPA on health show that there is no significant risk at

the actual level of exposure through food, but there are some other studies showing specific effects at low doses. For example, BPA shows hormone-like effects at relatively high doses, but there are some experimental data suggesting that BPA might have similar effects also at very low doses. BPA might also have specific effects on the metabolism and weight gain, on the development of mammary glands and on behavior and anxiety. But the findings about these effects remain controversial. So far, there are no clear conclusions from available and ongoing research.

For its risk assessment of BPA in medical devices, the SCENIHR took as reference point the temporary tolerable daily intake derived by EFSA, which is 4 µg per kg of body weight per day. The SCENIHR considers this an appropriate basis for evaluating the risk from BPA exposure via medical devices.

→ EXAMPLES OF MEDICAL DEVICES MADE WITH BPA

BPA is a key building block of some plastics or derivatives used in a range of medical applications such as adhesives and sealants used in dentistry, neonatal care incubators, hemodialysers and cardiopulmonary bypass machines.

The risk of BPA exposure from medical devices is associated with the release of BPA from these devices. The actual level of exposure has been investigated for various use scenarios. In most of these applications, including use in dentistry, the amount of BPA people are exposed to is deemed safe, because it does not exceed the limit of the tolerable daily intake of 4 µg per kg body weight per day. Moreover, exposure to BPA through medical devices is usually only for a short period of time, while the tolerable daily intake assumes lifelong, continuous daily exposure.

→ ARE THERE APPLICATIONS WHERE THERE IS A RISK FROM EXPOSURE TO BPA?

The highest estimated exposure to BPA occurs during prolonged medical procedures especially for neonates in intensive care units, for infants undergoing prolonged medical procedures and for dialysis patients. Based on the available data, the SCENIHR concludes that risk of adverse effects from BPA might exist in such cases, since the exposure exceeds the reference value and the exposed population can be particularly vulnerable.

→ SHOULD BPA BE BANNED FROM MEDICAL DEVICES?

The benefit of medical devices should also be taken into account: e.g. the survival of premature infants often depends on them. The possibility of finding alternatives for BPA-containing materials needs to be evaluated in terms of effectiveness of the treatment as well as of potential toxicity of the alternatives. This is something that is not yet possible because there is not enough information on potential alternative material.

This fact sheet is based on the opinion of the independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on "The safety of the use of bisphenol A in medical devices". **February, 2015**

This opinion is available at:
http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm