



INFORMATION SHEET ON POLYCARBONATE AND MEDICAL DEVICES

Polycarbonate and Medical Applications

Polycarbonate plastic resin, which is produced from the chemical building-block bisphenol A (BPA), has a 50-year safety track record in medical applications. In addition, it provides a number of physical properties that are valued in medical applications, such as strength, toughness, shatter-resistance, physical stability during sterilization and glass-like optical clarity. Polycarbonate grades are available that comply with biocompatibility testing standards such as ISO 10993-1 and USP Class VI.

Polycarbonate grades are available that can be sterilized using all major methods: ethylene oxide (EtO), irradiation (both gamma and electron-beam), and steam autoclaving. Polycarbonate can also be disinfected with common clinical disinfectants, such as isopropyl alcohol.

This unusual combination of properties helps to prevent potentially life-threatening material failures and facilitates visibility when required in clinical and diagnostic settings. Medical devices that include PC components are reviewed and approved for use by the U.S. Food and Drug Administration (FDA) and similar authorities worldwide. Such devices must meet stringent performance and safety standards.

Polycarbonate Safety

During polycarbonate resin production, BPA is incorporated into the polymeric structure of the plastic. There is some potential for trace amounts of BPA to migrate from polycarbonate products; multiple studies indicate that when migration occurs, it is typically 5 ppb, which is well below the exposure level recognized as safe by government bodies worldwide.

In addition to migration testing, the safety of polycarbonate and BPA has been extensively studied and tested. Reviews of the scientific data by government bodies such as the FDA, Health Canada, the European Union and Japanese governmental agencies have concluded that:

- consumer exposure to BPA is low;
- the scientific data do not support concerns about potential health effects from exposure to BPA; and
- polycarbonate can be used in medical devices as well as in food-contact applications.

Health Canada's Information Request

Effective June 1, 2008, the Medical Devices Bureau of The Health Products and Food Branch (HPFB) of Health Canada requests that manufactures of licensed Class II, III and IV medical devices to inform the agency of medical devices manufactured from raw materials containing or derived from bisphenol-A (BPA). This information gathering request is not a ban or restriction on the use of BPA-based polycarbonate plastic in medical devices.

Further Information

Additional information about polycarbonate plastic and BPA is available at www.factsonplastic.com and www.bisphenol-A.org. For further inquiries, please contact Dr. Steven G. Hentges of the Polycarbonate/BPA Global Group at 703.741.5588 or steve_hentges@americanchemistry.com.