BPA Is Clearly Safe, and Here's How We Know

By Steve Hentges, Ph.D.

No doubt you've heard about bisphenol A (BPA), the key raw material used to make polycarbonate plastic and epoxy resins. BPA has been mentioned in media reports for years and you may have had questions from your customers or colleagues wondering if materials made with BPA are safe. You may have even considered alternatives, just to avoid the BPA controversy.

Before going any further down that path, it's time to step back and consider what we now know about the safety of BPA. Earlier this year, the results of the Consortium Linking Academic and Regulatory Insights on BPA Toxicity (CLARITY) Core study – a scientific study of unprecedented scope and magnitude – were released. If you have any interest in BPA, whether you're concerned about its safety or not, you need to know about the results of this multi-year and multi-million dollar study.

Why are polycarbonate plastic and epoxy resins used?

If you've used these materials, you'll already know that both are widely used because of their exceptional performance.

Polycarbonate is a highly shatter-resistant, lightweight and optically clear thermoplastic. This combination of attributes makes it virtually unique among commercially-available thermoplastics. Markets and typical products that take advantage of these attributes include:

- Medical – surgical and drug-delivery devices, dialyzers, incubators
- Electronic – housing units for cell phones, laptops, game consoles
- Automotive – headlamp lenses, sunroofs, bumpers
- Building/Construction – LED lighting fixtures, architectural and security glazing, signage

Epoxy resins, most of which are made from BPA, are thermoset plastics with an outstanding combination of toughness, chemical resistance and high adhesion. Epoxy resins are well-suited to a wide range of coating applications, and are increasingly used in high-strength/lightweight composites:

- Wind energy – wind turbine rotor blades
- Aerospace – aircraft fuselage and wing structures
- Marine – boat manufacture and repair
- Paints and Protective Coatings – appliance powder coatings, automobile primers, flooring

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700 2nd Street NE • Washington, DC 20002

Resolving the controversy

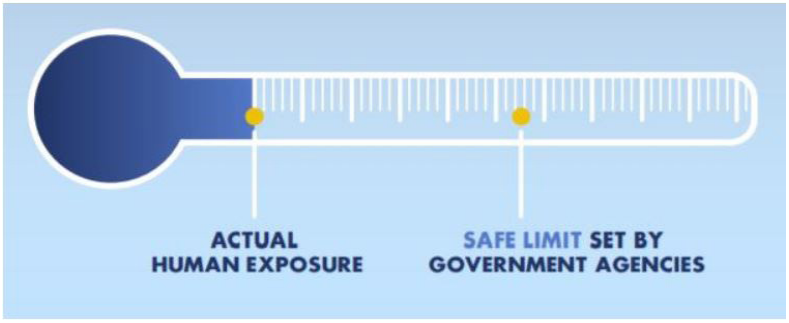
Beginning more than 10 years ago, U.S. federal government scientists began a comprehensive research program aimed at answering key scientific questions and resolving any remaining uncertainties about the safety of BPA. This well-designed scientific program has resulted in more than 30 scientific studies on BPA published to date. In addition, the CLARITY study has funded research at 13 academic centers to further explore potential health effects from BPA.

The research program includes three important scientific elements – exposure, pharmacokinetics, and toxicity – that together allow clear conclusions on whether BPA is safe as it is used, or not. Overall conclusions should be based on reliable scientific data and now we can let the data speak. Key findings from the research program are summarized below.

1. Consumer exposure to BPA is extremely low

To understand the safety of any substance, we first need to know about exposure levels. As said in an age-old maxim – the dose makes the poison – any substance could be harmful if exposure levels are sufficiently high. The U.S. Centers for Disease Control and Prevention (CDC) has conducted a series of six large-scale biomonitoring studies over a 12-year period to measure exposure to BPA in the U.S. population.

From these studies we can be certain that exposure to BPA is extremely low. Importantly, similar studies conducted in China, Europe, Japan and Korea indicate that exposure to BPA around the world is comparably low.



2. BPA is rapidly eliminated from the body

Once exposure has been demonstrated, we next need to know what happens to the substance after it enters the body. Pharmacokinetic studies tell us where the substance goes in the body, in what form, how long it stays, and how it is eliminated.

Numerous studies on laboratory animals conducted by U.S. Food and Drug Administration (FDA) scientists show that BPA is efficiently converted after exposure to an inactive form that is rapidly eliminated from the body. These findings have been confirmed in clinical studies, including an important study conducted by the U.S. National Toxicology Program (NTP), on human volunteers exposed to BPA at levels much higher than typical consumer exposures.

From the results of these studies, we can predict that BPA is not likely to be harmful at typical consumer exposure levels. But to be sure, we need toxicity data from experimental studies. And now, with the results of the capstone study in the research program, the data can give us a clear conclusion on the safety of BPA.

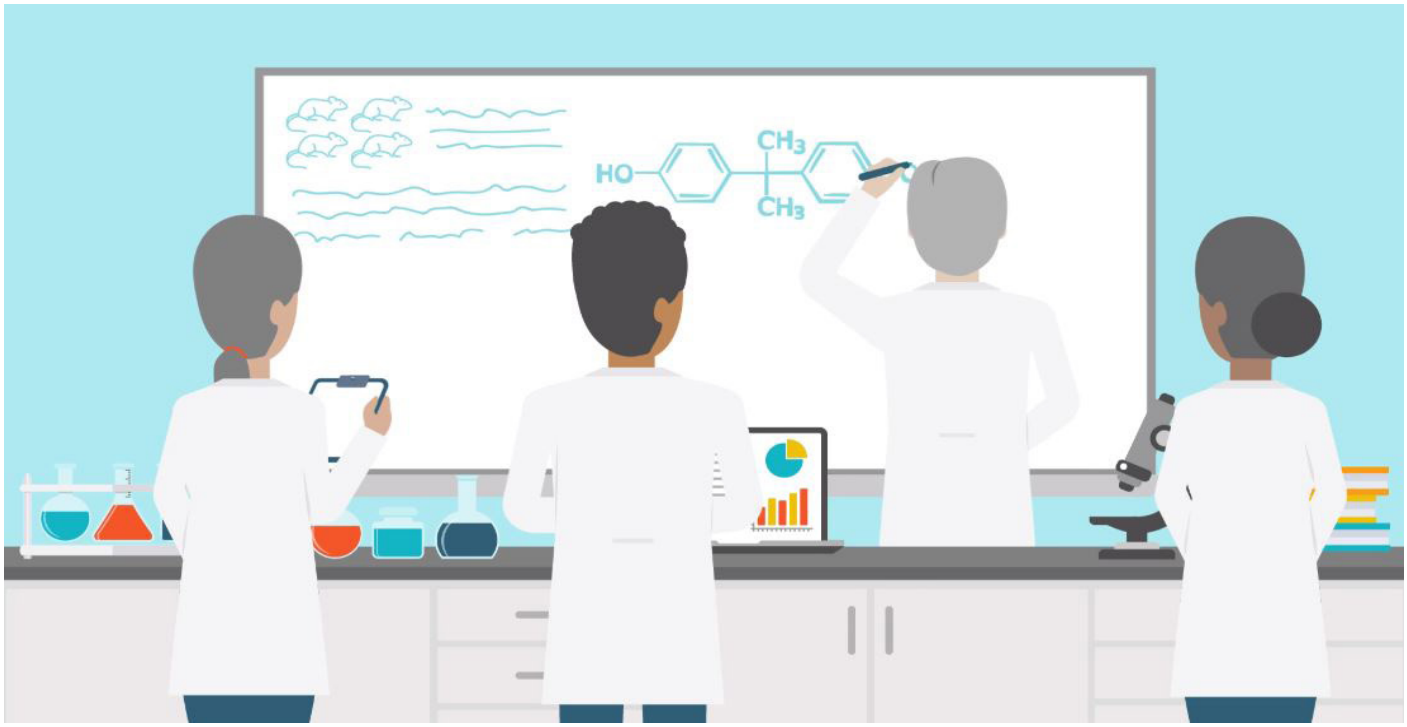
3. No risk of health effects at typical consumer exposure levels

Earlier this year, NTP released the results of the CLARITY Core Study. Senior scientists at FDA's National Center for Toxicological Research (NCTR) conducted the study with funding from NTP.

The study involved exposure of laboratory animals to BPA beginning during pregnancy and continuing in the offspring throughout their entire lifetime. A wide range of dose levels were examined, from low doses close to actual consumer exposure to doses about 250,000 times higher.

The results indicate that BPA has very little potential to cause health effects even when people are exposed to it throughout their lives. As stated in the conclusion of the study report, "BPA produced minimal effects that were distinguishable from background."

Importantly, NTP selected a panel of six independent expert scientists to conduct a formal peer review of the study. In general, the peer review panel supported the design and conduct of the study, and also agreed with the overall conclusion that the study found minimal effects for the range of doses studied.



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What's next?

With the results of the CLARITY Core study now in hand, the U.S. government has substantially met its goal of answering key scientific questions and resolving any remaining uncertainties about the safety of BPA.

As an immediate next step, NTP and FDA will incorporate recommendations from the peer reviewers, as appropriate, into a final CLARITY Core study report that is expected by August 2018. In parallel, the study will also be published in the scientific literature.

More importantly, the CLARITY study results will be globally influential in future government evaluations of the safety of BPA. FDA has already initiated that process. In a statement released in conjunction with the report, Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine at the U.S. Food and Drug Administration (FDA) noted: "our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers."

For more information, please visit FactsAboutBPA.org

About Steve Hentges, Ph.D.

Dr. Steve Hentges, Ph.D., leads the Polycarbonate/BPA Global Group of the American Chemistry Council (ACC). This unit of ACC promotes the business interests and welfare of the global polycarbonate and bisphenol A industry with a comprehensive program that includes health and environmental research along with a wide range of communications and advocacy activities.

In his current position, Dr. Hentges has been deeply involved with the science on bisphenol A for more than 17 years. Prior to joining ACC in 2000, Dr. Hentges spent nearly 18 years with a major plastics and chemical manufacturer, working primarily in a series of assignments that focused on product safety, regulatory compliance and product development.

Dr. Hentges holds a B.S. in chemistry from the University of Minnesota, a Ph.D. in organic chemistry from Stanford University, and has also conducted postdoctoral research at the California Institute of Technology.

Contact:
Steven G. Hentges, Ph.D.
Polycarbonate/BPA Global Group
American Chemistry Council
steve_hentges@americanchemistry.com