Bisphenol A (BPA) is safe for consumers – that is the overall outcome of the core “CLARITY-BPA” study, the largest-ever scientific investigation on the basic chemical building block used to produce the high-performance materials polycarbonates and epoxy resins.

CLARITY – Consortium Linking Academic and Regulatory Insights on BPA Toxicity – is a large-scale US study program on BPA. It has been conducted by a consortium of US government scientists¹ and several specialized academic research groups, and is fully funded by US government institutes.

BPA is already one of the best researched industrial chemicals. Many comprehensive guideline studies respecting Good Laboratory Practices (GLP) are available, as well as an enormous amount of exploratory studies which are often not GLP-compliant. Some of these question the safety of BPA for human health.

CLARITY-BPA now merges elements of proven guideline compliant study protocols with the exploratory approach of academia to generate new scientific insight into hotly debated areas of potential concern, such as alleged adverse hormonal effects of BPA or the so-called low-dose hypothesis.

CLARITY-BPA has two components:
- chronic (lifetime) guideline compliant toxicity study conducted by FDA scientists (core study), and
- 14 grants to academics using in their studies samples from the chronic study to test their hypotheses (grantee studies)

“Our initial review supports our determination that currently authorized uses of BPA continue to be safe for consumers.”

Dr. Steven Ostroff, Deputy Commissioner for Foods and Veterinary Medicine, US Food and Drug Administration (FDA)

The core chronic study specifically investigated the areas in which there is continuous debate about the interpretation of available data. With respect to low dose exposure in particular, it found

- no biologically relevant health effects from low dose exposure to BPA
- no evidence of non-monotonic dose-responses, often referred to as “low dose effects”
- no evidence of endocrine disruption
- no evidence of effects from developmental exposure to BPA later in life

Re-Assessment of BPA in Europe

EFSA has started a re-evaluation of the safety of BPA for food contact applications in 2017. The re-evaluation process assesses the newly generated scientific information since 2013. The results of the CLARITY-BPA core study and of the grantee studies will form an important piece of the re-evaluation process.
CLARITY-BPA: UNPRECEDENTED REGIME, SCOPE AND MAGNITUDE

CLARITY-BPA is the capstone study program completing a long-term research effort of the US government to determine the safety of BPA for human health. The goal of the US government was to evaluate certain health parameters, which have been reported to be adversely impacted by BPA exposure in hypothesis-driven studies. To ensure utmost reliability, all scientists worked on samples treated in exactly the same way, and the core chronic study was conducted according to GLP principles.

Study essentials
Three groups of pregnant rats (vehicle control group, BPA-exposed, estrogen-exposed) were used in the study. In the BPA-group the mother animals and their offspring were exposed to different doses of BPA, either on a continuous dose throughout their whole lifespan, or by “stop-dose”, i.e. until weaning. Various target tissues were examined, for example from the brain, heart, kidneys, liver, mammary gland, ovaries, prostate, testis, thymus, thyroid, uterus, and many more.

- The Continuous Dose exposure during pregnancy through offspring’s whole lifespan is directly relevant for human exposure and safety assessment
- The Stop Dose exposure during pregnancy through offspring weaning investigates whether developmental exposure shows adverse effects later in life
- 5 dose levels (2.5 to 25,000 micrograms/kg bodyweight/day) covering a wide span from low doses close to actual human exposure, to doses about 250,000 times higher, focused on examining whether effects at low doses and/or non-monotonic dose-responses could be seen
- The estrogen control (two different doses of ethinylestradiol) served to validate the sensitivity of animals so the animals’ response to a classic estrogen could be compared with response to BPA

Overall, the core chronic study found that BPA is safe at typical consumer exposure levels.
The results from the core chronic study indicate that BPA has very little potential to cause health effects even when people are exposed to it throughout their lives. The study’s Principal Investigator Dr Barry Delclos stated in a webinar in which the study results were discussed in detail that “BPA did not elicit clear, biologically plausible, adverse effects ...” at levels even remotely close to typical, very low consumer exposure levels.

More information on BPA:
Jasmin Bird
Polycarbonate/Bisphenol-A Group PlasticsEurope
Email: jasmin.bird.consultant@plasticseurope.org

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