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Information Sheet: Safety of BPA-derived Can Liners

Summary

- The use of bisphenol A (BPA)-derived epoxy resins to make protective coatings for metal food and beverage packaging helps provide safe, wholesome and nutritious food and beverages for people throughout the world.
- Human exposure to BPA from the use of protective liners in cans is exceedingly low, many times lower than the safe exposure levels set by United States and international regulatory agencies, which in turn are based on comprehensive reviews that include safety factors of 100-fold or more.
- Recent and comprehensive reviews of the science, including low dose studies, by regulatory agencies (including the U.S., the European Union, Canada, Japan, Germany and the United Kingdom) have affirmed that BPA-derived can liners are safe for use in food contact applications. They are approved for this use by all food regulatory agencies around the world.
- In addition to the specific research on the safety of BPA-derived can liners, regulatory agencies have conducted their own research as well as assessed the available scientific data on BPA. The conclusions of these comprehensive and up-to-date assessments – which consistently affirm the safety of BPA use - provide assurance to the public that all of the available science has been considered and that the safety of BPA has been thoroughly examined.

Use of BPA-derived Can Liners Protects the Food Supply

- The use of BPA-derived can liners helps provide food for people throughout the world by maintaining the safety, wholesomeness and nutritional value of canned foods and beverages.
- Canning is one of the most significant innovations in the preservation of food in human history. The metal food can, now more than 200 years old, remains one of the most recyclable, economical and above all, safe and energy-efficient modes of food distribution and packaging because it enables food sterilization and long-term preservation.
- Due to the metal-corroding effects of foods and beverages during processing (one hour at 250°F) and long-term storage, metal containers and lids are coated to:
 - Ensure the safety of canned food by protecting the integrity of the container from corrosion, and
 - Prevent deleterious effects on food quality, wholesomeness and nutritional value due to metal migration.
- In the manufacture of can liners, BPA and other materials are reacted to form high molecular weight epoxy polymers which are further cross linked during the curing process to form a chemically resistant coating.
- The high nutritional value of foods packaged using current canning technology, including can liners, has been demonstrated in studies conducted at the University of Illinois¹ and the University of Massachusetts.²
- Today's use of BPA-derived epoxy resins is the result of over 60 years of industry research to develop and provide can liners with the safest and most effective food contact performance.

¹ <http://www.mealtime.org/default.aspx?id=326>

² <http://www.mealtime.org/default.aspx?id=325>

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Human Exposure to BPA from Can Liners is Low

- Human exposure to BPA from use of protective liners for food cans is exceeding low, hundreds or more times lower than safe exposure levels set by U.S. and international regulatory agencies.
- For example, a recent highly publicized survey³ of BPA levels in U.S. canned foods reported a geometric mean of 2.4 micrograms BPA per kilogram concentrated liquid infant formula (a BPA level equivalent to 2.4 parts per billion⁴). Using the assumption in the report that **100 percent of the infant's diet is from concentrated liquid formula**, the estimated BPA intake for a three-month old infant⁵ is only 0.17 micrograms per kilogram body weight per day. This value is **300 times lower** than the most up-to-date Tolerable Daily Intake, the amount of a substance that can be ingested daily over a lifetime without posing a significant risk to health.
- This TDI (50 micrograms per kilogram body weight per day) was set by the European Food Safety Authority⁶ earlier this year after a comprehensive review of the latest and most reliable data and includes a 100-fold safety factor to account for the extrapolation from laboratory animal studies to human health.
- This same survey also reported a geometric mean of 7.9 micrograms BPA per kilogram food (7.9 parts per billion⁴) in 97 canned foods. Using the assumption in the report of **one serving of canned foods per day for life**, the estimated BPA intake from canned foods for adults⁷ is 0.046 micrograms per kilogram per day, a value that is **over 1000 times lower** than the Tolerable Daily Intake value set by the European Food Safety Authority earlier this year.
- The finding that BPA intake is 300 to over 1000 times lower than the TDI is reassuring and confirms that residual levels of BPA in canned foods do not pose any significant risk to health.

Regulatory Agency Reviews Affirm the Safety of BPA-derived Can Liners

- The safety of BPA-derived protective coatings in food and beverage containers have undergone independent reviews of the science by multiple regulatory agencies, including the U.S. Food and Drug Administration, the United Kingdom Food Standards Agency, the Research Center for Chemical Risk Management of the National Institute for Advanced Industrial Science and Technology of Japan, and most recently the European Food Safety Authority. Every regulatory review conducted to date has affirmed that BPA-based can liners are approved for use in food contact applications and safe for use.
- In the United States, the Food and Drug Administration, which approved the use of BPA-derived can liners a number of years ago, conducts periodic studies on human exposure⁸ and monitors the extensive database of studies. Agency officials have repeatedly affirmed that "...FDA sees no reason to change [its] long-held position that current [BPA] uses with food are safe."⁹ This most recent assurance was provided in November 2005 by the Associate Director for Science and Policy of FDA's Office of Food Additive Safety, who at that time was Dr. George Pauli.

³ <http://www.ewg.org/reports/bisphenola>

⁴ One part per billion is the time equivalent of one second in 31 years, 8 months.

⁵ Using the assumptions in the report that a three-month old infant has a body weight of 6 kilograms or 13 pounds and formula consumption of 0.84 kilograms or 30 ounces per day.

⁶ http://www.efsa.europa.eu/en/science/afc/afc_opinions/bisphenol_a.html

⁷ Using the assumptions in the report of an adult body weight of 60 kilograms or 132 pounds, and using the largest adult serving size in the survey, 12.5 ounces or 350 grams.

⁸ Biles, J. E., McNeal, T. P. and Begley, T. H. Determination of bisphenol A migrating from epoxy can coatings to infant formula liquid concentrates. J Agric Food Chem 1997; 45: 4697-4700.

⁹ Letter from George Pauli, Associate Director for Science and Policy, FDA's Office of Food Additive Safety, to California Assemblymember Greg Aghazarian. November 28, 2005.



- Internationally, the U.K. Food Standards Agency surveyed the levels of BPA in canned foods in Britain and concluded, on the basis of a review by the independent Committee on Toxicology of Chemicals in Food, Consumer Products and the Environment, that “the levels of BPA identified in canned foods analyzed in this survey are unlikely to be of concern to health.”¹⁰
- In Japan, the Research Center for Chemical Risk Management of the National Institute for Advanced Industrial Science and Technology reviewed the health hazards of BPA and provided an assessment report in 2006 that concluded low risk from BPA use in food contact applications.¹¹
- The most recent assessment of BPA-derived can liners is that of the European Food Safety Authority, cited above. In conducting this assessment, the EFSA directed the independent Scientific Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food to re-evaluate the use of BPA in articles intended to come into contact with food, giving particular attention to the exposure of infants.
 - This assessment in turn builds on the comprehensive Risk Assessment Report for BPA conducted by the European Union and published in 2003 and the 2002 assessment by the E.U. Scientific Committee on Food.
- Because of its high relevance to the safety of BPA-derived can liners, **the findings of the EFSA Scientific Panel regarding claimed low dose effects of BPA** are quoted here:
 - “In reviewing the earlier and the recently published studies on BPA, the Panel noted that some studies indicated differences in behavior or reproductive parameters between control and treated animals at dose levels lower than the previously accepted overall no observed adverse effect level (NOAEL) of 5 milligrams per kilogram body weight per day. However, the Panel had considerable reservations both about the biological significance of the reported observations and the robustness of the studies.
 - “The Panel noted that the changes observed were often not sustained through adulthood. The biological consequences of many of the changes in the affected animals are unknown and some, such as small increases in prostate weight, are not considered as precursors of pathological change. While some of the changes may be indicative of biomarkers of effect in very sensitive species and strains, in the light of present knowledge, they cannot be readily interpreted as adverse effects.
 - “The Panel also noted that the results of the studies reporting low-dose effects are in contrast to the results of other studies using comprehensive protocols developed for testing both structure and reproductive function in parents and offspring and performed following internationally recognized guidelines with regard to study design and animal model selection. A two-generation reproductive toxicity study has recently been reported in an estrogen-sensitive strain of mice administered a wide range of BPA doses in the diet. BPA administration in the low-dose range did not result in changes in reproductive organs or performance and gave an overall NOAEL of 5 milligrams per kilogram body weight per day, with liver toxicity as the most sensitive endpoint. The positive control substance, 17 β -estradiol, resulted in reproductive and developmental toxicity.
 - “The Panel considered that low-dose effects of BPA in rodents have not been demonstrated in a robust and reproducible way, such that they could be used as pivotal studies for risk assessment.”
- **The overall conclusions of the EFSA Scientific Panel on BPA-derived can liners are:**
 - “The Panel concluded that the overall NOAEL of 5 milligrams per kilogram body weight per day, based on the results of a comprehensive three-generation study in the rat, is still valid, and in the

¹⁰ <http://www.food.gov.uk/science/surveillance/fsis2001/bisphenols?view=printerfriendly>

¹¹ http://unit.aist.go.jp/crm/mainmenu/e_1-10.html

Panel's view is further supported by the NOAEL of 5 milligrams per kilogram body weight in a recent two-generation reproductive toxicity study of BPA in mice.

- "The Panel now considers that the database concerning reproduction and development has been considerably strengthened and that the additional uncertainty factor of 5, introduced in 2002 for the uncertainties in the database on reproduction and development, is no longer required.
 - "The Panel also concluded, in view of the well described species differences in toxicokinetics, showing a low level of free BPA in humans compared with rats, that a default uncertainty factor of 100 applied to the overall NOAEL from the rodent studies can be considered as conservative.
 - "The Panel therefore established a full TDI of 50 micrograms BPA per kilogram body weight, derived by applying a 100-fold uncertainty factor to the overall NOAEL of 5 milligrams per kilogram body weight per day."
- In short, the European Food Safety Authority concluded not only that studies claiming low dose effects are not sufficiently reliable for risk assessment, but also that the studies no longer justify any additional uncertainty factor beyond the standard 100-fold safety factor used for extrapolation from laboratory animal studies to human health.

Extensive Research and Review Provides Assurance of Safety

- In addition to the specific research on the safety of BPA-derived can liners reviewed above, extensive research and review of the scientific data provides assurance to the public that all of the available science has been considered and that the safety of BPA has been thoroughly examined.
- While research and review of claimed low dose effects have been on-going for over 10 years, only the most recent reports are referenced below:
 - In March 2005, the Japanese Ministry of Environment reported the results of their own tests on BPA, including an enhanced one-generation reproductive and developmental study in lab rats.¹² BPA was tested at four doses representing estimated human exposure levels. The Ministry of Environment reported that the study found no clear evidence of effects at any of the BPA doses tested.
 - In January 2006, the German Federal Institute for Risk Assessment released a statement with their views on the safety of BPA in which they noted that some of the trials reporting low dose effects "are difficult to interpret and occasionally they are contradictory."¹³
 - In June 2006, a panel of U.S. scientific experts reported the results of their weight-of-the-evidence evaluation of low-dose reproductive and developmental effects of bisphenol A. Considering studies published through February 2006, the panel concluded "the weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health."¹⁴
 - In January 2007, Dr. Michael A. Kamrin of the Center for Integrative Toxicology of Michigan State University published a review of the available data on BPA in a peer-reviewed international science

¹² http://www.env.go.jp/en/chemi/ed/extend2005_full.pdf

¹³ <http://www.bfr.bund.de/cd/7294>

¹⁴ Goodman, J. E., McConnell, E. E., Sipes, I. G., Witorsch, R. J., Slayton, T. M., Yu, C. J., Lewis, A. S., and Rhomberg, L. R. 2006. An Updated Weight of the Evidence Evaluation of Reproductive and Developmental Effects of Low Doses of Bisphenol A. *Critical Reviews in Toxicology*, vol. 36, pages 387-457.

journal.¹⁵ The paper concludes that “these ‘low dose’ effects have yet to be established, that the studies purported to support these cannot be validly extrapolated to humans, and the doses at which the studies have been performed are significantly higher than the levels to which humans are exposed.”

- In April 2008, Health Canada officials clearly stated that the very low levels of BPA exposure experienced by most people presents negligible risk.¹⁶
- In April 2008, the National Toxicology Program (NTP) released its Draft Brief on BPA.¹⁷ The Draft Brief presents NTP’s draft conclusions on the possible effects of BPA on human development and reproduction.. The Draft Brief includes the following conclusions:
 - Negligible concern that exposure of pregnant women to BPA will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring;
 - Some concern for neural and behavioral effects in fetuses, infants, and children at current human exposures;
 - Some concern for BPA exposure in these populations based on effects in the prostate gland, mammary gland, and an earlier age for puberty in females;
 - Negligible concern that exposure to BPA causes reproductive effects in non-occupationally exposed adults; and
 - Minimal concern for workers exposed to higher levels in occupational settings.

Conclusions

- The use of BPA-derived can liners helps provide essential food to feed the world by maintaining the safety, wholesomeness and nutritional value of canned foods and beverages.
- Human exposure to BPA from use of food protective can liners is much lower than safe exposure levels set by U.S. and international regulatory authorities.
- The safety of BPA-derived can liners has undergone recent scientific reviews by U.S. and international regulatory agencies, who have rejected low dose studies as not reliable for risk assessment and affirmed the safety of BPA-derived can liners.
- Extensive research and review of the scientific data on BPA provides assurance to the public that all of the available science has been considered and the safety of BPA-derived can liners thoroughly examined.

¹⁵ Kamrin, M.A. 2007. The “Low Dose” Hypothesis: Validity and Implications for Human Risk. *International Journal of Toxicology*, vol. 26, pages 13-23.

¹⁶ http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2008/2008_59_e.html

¹⁷ http://cerhr.niehs.nih.gov/chemicals/bisphenol/BPADraftBriefVF_04_14_08.pdf