

BISPHENOL A: INFORMATION SHEET

SAFETY OF EPOXY CAN COATINGS

SUMMARY

Metal food and beverage cans have a thin coating on the interior surface, which is essential to prevent corrosion of the can and contamination of food and beverages with dissolved metals (UK FSA, 2002). In addition, the coating helps to prevent canned foods from becoming tainted or spoiled by bacterial contamination. The major types of interior can coating are made from epoxy resins, which have achieved wide acceptance for use as protective coatings because of their exceptional combination of toughness, adhesion, formability and chemical resistance. Such coatings are essentially inert and have been used safely for over 40 years. In addition to protecting contents from spoilage, these coatings make it possible for food products to maintain their quality and taste, while extending shelf life.

Bisphenol A (BPA) is a key building block of epoxy resins. In 1995, Brotons and coworkers reported that BPA could migrate from can coatings during the food canning process. Later that same year, the Society of the Plastics Industry, Inc. (SPI), initiated a study to quantify the migration of BPA from can coatings.

Based on the results of the SPI study, the estimated dietary intake of BPA from can coatings is less than 0.00011 milligrams per kilogram body weight per day. This level is more than 450 times lower than the maximum acceptable or “reference” dose for BPA of 0.05 milligrams per kilogram body weight per day established by the U.S. Environmental Protection Agency.

Stated another way, an average adult consumer would have to ingest more than 230 kilograms (or about 500 pounds) of canned food and beverages every day for an entire lifetime to exceed the safe level of BPA set by the U.S. Environmental Protection Agency.

In 2002, the safety of epoxy resin can coatings was confirmed by an analysis of the European Commission’s Scientific Committee on Food (SCF). The SCF estimated total dietary intake of BPA from all food contact sources, including epoxy resin coatings, to be in the range of 0.00048 to 0.0016 milligrams per kilogram body weight per day, which is below the Tolerable Daily Intake set by the SCF of 0.01 milligrams per kilogram body weight per day.

Consequently, the potential human exposure to BPA from can coatings is minimal and poses no known risk to human health. Can coatings have been and continue to be recognized as safe by the U.S. Food and Drug Administration, the U.K. Food Standards Agency, the EU Scientific Committee on Food and other government bodies worldwide.

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THE CAN COATING MIGRATION STUDY

- In 1995, after Brotons and coworkers reported migration of BPA from can coatings during food canning (Brotons *et al*, 1995), the Society of the Plastics Industry, Inc. (SPI) initiated a study of BPA migration from can coatings (Howe *et al*, 1998). In the first phase of this study, the analytical signal was noted to have an unusual or unsymmetrical shape, suggesting that not all of the material detected was really BPA.
- To follow up on the results of the first phase, nine laboratories conducted a series of tests to compare analytical methods for detecting BPA. The analytical methods tested included high performance liquid chromatography (HPLC) and gas chromatography with mass spectroscopy (GC/MS). The results of this second phase confirmed the presence of interfering materials (unidentified substances) that could be mistaken for BPA.
- Two additional series of tests were conducted to identify the HPLC and GC/MS methods that best eliminated the interfering materials and to ensure that these methods could be reliably conducted in an independent laboratory (Wingender *et al*, 1998).
- Using the preferred analytical methodology, fourteen can samples, representing food cans produced by the major American can manufacturers and their coating suppliers, were tested. Nine of the samples were identical to those examined in the initial phase of this study. All cans contained maximum levels of coating formulations using epoxy resin systems.
- Detection of BPA migration was enhanced by using easily analyzed food simulating solvents rather than actual foods – either 10% ethyl alcohol to simulate water-based foods, such as fruit juice, infant formula, and other beverages, or 95% ethyl alcohol to simulate fatty foods, such as meats and other canned foods.
- Storage conditions for sample cans containing the food simulating solvents were those prescribed by the U.S. Food and Drug Administration (FDA, 1995, revised 2002) to exaggerate the normal canning processes used. For “hot-filled” products such as fruit juice, cans were filled with hot solvent (10% ethyl alcohol), held at 212° F for 30 minutes and stored for 10 days at 120° F. For “retorted” products (all other samples), cans were filled with the appropriate solvent (10% or 95% ethyl alcohol), heated under pressure at 250° F for two hours and then stored for 10 days at 120° F.
- Bisphenol A levels in the food simulating solvents from the can samples were quantified using the HPLC and GC/MS analytical methods developed to reliably detect BPA without interference from other materials in the solvents. The lowest amount of BPA that can be detected (the limit of detection) using these procedures is 5 parts per billion.

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RESULTS

- The first phase of the SPI study found no detectable migration of BPA for the three beverage/beer can coatings tested with an analytical method sensitive to 5 parts per billion. Since neither BPA nor interfering materials that could be mistaken for BPA were detected, these results are valid and only food cans were included in the second phase of the study.
- In the second phase of the study, the HPLC and GC/MS methods gave virtually identical results with all food can samples, confirming the accuracy and reliability of the improved analytical methods.
- The measured level of BPA migration in the nine types of food cans analyzed in the first phase and again analyzed in the second phase of the study dropped from an average 63 parts per billion (first phase analytical methods) to an average of 36 parts per billion (second phase analytical methods). This 43% decrease in average levels is due entirely to the use of analytical methods that eliminated interfering (non-BPA) materials.
- The average level of BPA migration from the full set of 14 cans analyzed in the second phase of the study was 37 parts per billion.
- The potential dietary exposure to BPA from canned foods and beverages can be estimated using procedures recommended by the U.S. Food and Drug Administration (FDA, 1995, revised 2002):

$$\text{dietary concentration} = \text{CF} \times [(f_{\text{water-based}} \times M_{\text{water-based}}) + (f_{\text{acidic}} \times M_{\text{acidic}}) + (f_{\text{low alcohol}} \times M_{\text{low alcohol}}) + (f_{\text{fatty}} \times M_{\text{fatty}})]$$

In this equation, “CF” is the “consumption factor,” the fraction of the average individual’s diet that is likely to contact a specific type of packaging material, such as can coatings. Also in this equation, “f” is the “food-type distribution factor”, the fraction of each food or beverage type that contacts a packaging material, “M” is the migration value for that type of food in contact with the packaging material, and the food types are indicated by the subscript description (water-based, acidic, low (<15%) alcohol or fatty).

- Estimates of the CF and f values for canned food and beverages are available from FDA (FDA, 1995, revised 2002). The f values are estimated to be 0.16, 0.35, 0.40 and 0.09 for water-based, acidic, low alcohol and fatty foods. The M-value for acidic and low alcohol foods is the value (< 5 parts per billion) measured for beverage cans, and the value for water-based and fatty foods is 37 parts per billion. With these parameters, the average concentration of BPA in all canned food and beverages together is <13 parts per billion.

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The quantity of food and beverages packaged in polymer-coated metal cans is estimated at 17%, corresponding to a CF value of 0.17. Thus, the potential concentration of BPA in the entire diet from canned foods and beverages is <2.2 parts per billion.

Assuming, as does FDA, that the average individual consumes 3000 grams of food and beverages per day, the potential dietary concentration of <2.2 parts per billion corresponds to a potential daily intake of less than 0.0066 milligrams per person per day. Based on FDA's estimate that a typical individual weighs 60 kilograms, the estimated dietary intake of BPA from can coatings is < 0.00011 milligrams per kilogram body weight per day.

This level is more than 450 times lower than the maximum acceptable or "reference" dose for BPA of 0.05 milligrams per kilogram body weight per day (EPA, 1993). When the dietary intake of BPA from can coatings is combined with other sources of dietary exposure to BPA, the total dietary intake of BPA (<0.00012 milligrams per kilogram body weight per day) from all sources is still more than 400 times lower than the reference dose (BPA INFO, 2002). The reference dose is defined by EPA as an estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

- With an average concentration of BPA in all canned food and beverages of <13 parts per billion (equal to <0.013 milligrams BPA per kilogram food/beverage), an average adult consumer weighing 60 kilograms would have to consume more than 230 kilograms (or about 500 pounds) of canned food and beverages every day for an entire lifetime to exceed the reference dose of 0.05 milligrams per kilogram body weight per day.
- The reference dose for BPA has recently been confirmed by a three-generation study in rats (Tyl *et al*, 2002), which found no adverse effects on reproduction from BPA at doses of 50 milligrams per kilogram body weight per day and lower. The US EPA calculated the reference dose by dividing the Lowest-Observed-Adverse-Effect-Level (LOAEL, 50 milligrams per kilogram body weight per day) from an earlier chronic toxicity study by an uncertainty factor of 1000. Applying that same uncertainty factor to the No-Observed-Adverse-Effect-Level (NOAEL, 50 milligrams per kilogram body weight per day) from the Tyl study confirms the safety of the reference dose, 0.05 milligrams BPA per kilogram body weight per day. Since the maximum estimate of BPA exposure from can coatings is over 450-fold lower than the reference dose, the potential human exposure to BPA from can coatings is minimal and poses no known risk to human health.
- In 2001, the UK Food Standards Agency (FSA) reported the results of a survey of BPA content in canned foods and beverages purchased in the UK (UK FSA, 2001; Goodson *et al*, 2002). The levels of BPA found in foods and beverages are generally consistent with the results reported by SPI (Howe *et al*, 1998), which

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were measured in food simulating solvents. In all but one canned beverage, BPA was not detected at a limit of detection of 2 parts per billion, which is below the 5 parts per billion limit of detection in the SPI study. In most of the canned food samples, BPA, when detected, was found at levels comparable to or lower than the average level of 37 ppb for food cans reported in the SPI study. For all canned foods and beverages, the UK FSA estimated an average upper bound BPA level of 21.7 parts per billion. Using a different methodology that assumes higher consumption of canned foods and beverages than the FDA methodology, the UK FSA estimated a BPA dietary intake of 0.00036 to 0.00038 milligrams per kilogram body weight per day.

- Based on the UK FSA survey data, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) assessed the potential health implications of BPA in canned foods and beverages (COT, 2001; Goodson *et al*, 2002). The COT concluded “that the levels of BPA identified in canned foods analysed in the FSA survey are unlikely to be of concern to health, and that there is no reason for consumers to change their source of foodstuffs as a result of these findings.”
- The Scientific Committee on Food (SCF), which is an independent advisory committee to the European Commission on food safety matters, has recently evaluated the safety of BPA from all food contact sources including epoxy resin coatings. The SCF set a Tolerable Daily Intake (TDI) for BPA of 0.01 milligrams per kilogram body weight per day after a comprehensive review of all robust scientific data covering all aspects of toxicity. Similar to the EPA reference dose, the TDI represents a lifetime exposure level that is considered to be safe. Based on the existing migration data, the total exposure to BPA from all food contact sources was estimated to be in the range of 0.00048 to 0.0016 milligrams per kilogram body weight per day for adults and infants respectively, which is below the TDI value set by the SCF. Similar to the UK FSA analysis, the methodology used by the SCF assumes higher consumption of canned foods and beverages than the FDA methodology. This assessment also confirms that epoxy resin coatings for food and beverage cans are safe for use and pose no known risk to human health (SCF, 2002).

CONCLUSIONS

- Epoxy resins provide an important coating for food and beverage cans that helps to protect food and beverages from contamination with dissolved metals and from spoilage due to bacterial contamination. Can coatings are essential to maintaining the quality and integrity of canned food and beverages.
- Human exposure to BPA from can coatings is minimal and poses no known risk to human health. Can coatings have been and continue to be recognized as safe by the U.S. Food and Drug Administration, the U.K. Food Standards Agency, the EC Scientific Committee on Food and other government bodies worldwide.

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- Care must be taken in selecting an analytical method for measuring the migration of BPA from can coatings. Other materials in food or beverages may interfere with the accurate measurement of BPA, leading to overestimation of migration values.
- Using appropriate analytical methods, no BPA was detected from beverage/beer cans with a limit of detection of 5 parts per billion. Bisphenol A migration levels from food cans averages 37 parts per billion.
- Using FDA recommended values and procedures, which exaggerate canning and storage conditions, the potential dietary intake of BPA from food and beverage cans is less than 2.2 parts per billion and the estimated dietary intake is less than 0.00011 milligrams per kilogram body weight per day. The estimated daily intake of BPA from canned food and beverages is over 450 times lower than the maximum acceptable or reference dose for BPA of 0.05 milligrams per kilogram body weight per day.
- The UK FSA and COT have confirmed that the levels of BPA in canned foods are unlikely to be of health concern. The SCF has also confirmed that exposure to BPA from all food contact sources, including epoxy resin food and beverage can coatings, is below the Tolerable Daily Intake and therefore is safe.

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