

BISPHENOL A: INFORMATION SHEET

SAFETY OF POLYCARBONATE PLASTIC

Summary

Polycarbonate plastic is a lightweight, high-performance plastic that possesses a unique balance of toughness, dimensional stability, optical clarity, high heat resistance and excellent electrical resistance. Because of these attributes, polycarbonate is used in a wide variety of common products including digital media (e.g. CDs, DVDs), electronic equipment, automobiles, construction glazing, sports safety equipment and medical devices. The durability, shatter-resistance and heat-resistance of polycarbonate also make it an ideal choice for tableware as well as reusable bottles and food storage containers that can be conveniently used in the refrigerator and microwave (APME).

Bisphenol A (BPA) is a key building block of polycarbonate plastic. In recent years a number of researchers from government agencies, academia and industry worldwide have studied the potential for low levels of BPA to migrate from polycarbonate products into foods and beverages. These studies consistently show that the potential migration of BPA into food is extremely low, generally less than 5 parts per billion, under conditions typical for uses of polycarbonate products.

Using these results, the estimated dietary intake of BPA from polycarbonate is less than 0.0000125 milligrams per kilogram body weight per day. This level is more than 4000 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 600 kilograms (about 1,300 pounds) of food and beverages in contact with polycarbonate every day for an entire lifetime to exceed the level of BPA that the U.S. Environmental Protection Agency has set as safe.

The European Commission's Scientific Committee on Food (SCF) has also recently confirmed the safety of polycarbonate plastic products for contact with foods and beverages. The SCF estimated total dietary intake of BPA from all food contact sources, including polycarbonate plastic products and 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.

The study data and analyses show that potential human exposure to BPA from polycarbonate products in contact with foods and beverages is very low and poses no known risk to human health. The use of polycarbonate plastic for food contact applications continues to be recognized as safe by the U.S. Food and Drug

SAFETY OF POLYCARBONATE PLASTIC / page 2

Administration, the European Commission Scientific Committee on Food, the United Kingdom Food Standards Agency, the Japan Ministry for Health and Welfare and other regulatory authorities worldwide.

Studies Show Very Low Migration of BPA from Polycarbonate

Polycarbonate is a lightweight plastic with a unique combination of attributes that make it an ideal material for use in a wide variety of applications. Included are a number of home and kitchen applications involving direct contact with food and beverages that take advantage of polycarbonate's inherent shatter-resistance, optical clarity, and heat-resistance. Common examples include reusable 5-gallon water bottles, baby bottles, tableware such as plates and cups, and containers for storing food and reheating in a microwave oven.

The primary building block used to make polycarbonate plastic is bisphenol A (BPA). Many researchers have studied the potential for trace levels of BPA to migrate from polycarbonate into food and beverages under conditions typical for uses of polycarbonate products. These studies include ones conducted by government agencies in the US, Europe and Japan, as well as studies conducted by academic researchers and by industry. These studies generally show that, under typical use conditions, the potential migration of BPA into food is extremely low.

Some of the most notable examples include studies conducted by the:

1. U.S. Food and Drug Administration (FDA) on baby bottles, water bottles and cut portions of baby bottles under "typical/normal use" conditions (Biles *et al*, 1997);
2. U.K. Ministry of Agriculture, Fisheries and Food (MAFF) on baby bottles subjected to as many as 50 cycles of cleaning, sterilizing and simulated use (Mountfort *et al*, 1997; MAFF, 1997);
3. U.K. Department of Trade and Industry (DTI), Consumer Affairs Directorate on baby bottles handled under "realistic worst-case conditions of use" (Earls *et al*, 2000);
4. Japanese National Institute of Health Sciences (NIHS) on tableware and baby bottles under conditions representative of normal consumer use (Kawamura *et al*, 1998); and
5. Society of the Plastics Industry, Inc. (SPI) on polycarbonate discs under the most rigorous conditions recommended by FDA (Howe and Borodinsky, 1998).

These studies are not identical in design but all aimed to measure the potential migration of BPA into foods and beverages under temperature and time conditions considered to be typical of how polycarbonate products are actually used. Study design aspects that vary among the studies are the type of polycarbonate product or article tested (i.e., baby

SAFETY OF POLYCARBONATE PLASTIC / page 3

bottles, water bottles, tableware, molded discs or cut pieces), the nature of the “food” in contact with polycarbonate (i.e., an actual food such as water, fruit juice or infant formula, or a solvent such as 10% ethanol to simulate food), and the specific time/temperature conditions used. Considered together, these studies cover a complete range of polycarbonate food contact products and use conditions, which provides reassurance that the collective results fully represent the potential migration of BPA into foods and beverages. The results of these studies are briefly summarized below in reference to the type of polycarbonate product or article that was tested.

Baby Bottles

Each of the studies conducted by the government agencies included or focused entirely on baby bottles. In most cases, new baby bottles were studied under well-characterized laboratory conditions. In each case, migration of BPA from new baby bottles, when detected, was less than 5 parts per billion.

The Japanese National Institute of Health Sciences (Kawamura *et al*, 1998) conducted the most sensitive study on 4 commercially available baby bottles. Because of the use of food simulants (i.e., water, 20% ethanol, 4% acetic acid, heptane), which facilitate the analytical measurement of BPA, the limit of detection was 0.5 parts per billion. Temperature and time conditions as severe as 30 minutes at 95°C followed by 24 hours at room temperature were examined. With the exception of one data point, migration of BPA was less than 1 part per billion for all test conditions and, for the majority of samples, no BPA was detected at the 0.5 part per billion limit of detection. The one exception involved a new unwashed bottle, which resulted in migration of 3.9 parts per billion. After washing, migration from this bottle decreased to the limit of detection.

A similar study was sponsored by the United Kingdom’s Department of Trade and Industry (DTI), Consumer Affairs Directorate, Consumer Safety Research program and conducted by LGC Ltd (Earls *et al*, 2000). The study examined 21 new baby bottles purchased from various retail outlets in the London area and tested under “realistic worst-case conditions of use.” The bottles were washed and sterilized, filled with either boiling water or 3% acetic acid solution, capped, and placed in a refrigerator for 24 hours at 1-5°C. After warming briefly, the contents were analyzed using a method with a 10 part per billion limit of detection. In every case, no BPA was detected.

The U.S. Food and Drug Administration and the U.K. Ministry of Agriculture, Fisheries and Food (MAFF) both measured migration of BPA from polycarbonate baby bottles into infant formula or fruit juice. In the FDA study (Biles *et al*, 1997), bottles were washed, sterilized, filled with apple juice or infant formula and refrigerated for 72 hours. These conditions were characterized as typical or normal. No BPA was found in any sample with a 100 part per billion limit of detection.

SAFETY OF POLYCARBONATE PLASTIC / page 4

Likewise, in the extensive UK MAFF study (Mountfort *et al*, 1997; MAFF, 1997), baby bottles were repeatedly processed through a sequence in which the bottles were washed, sterilized (three methods tested), filled with fruit juice or infant formula, warmed in a microwave oven, cooled, and analyzed. After as many as 50 cycles, BPA was not detected in any sample with a 30 part per billion limit of detection. In addition, no detectable levels of BPA were found when the bottles were periodically filled with water and held at 40°C for 10 days.

In the UK DTI study, a small number of used baby bottles of uncertain age and history were also tested under the same conditions as the new bottles. For both water and 3% acetic acid solution, no migration was detected in 8 of the 12 bottles tested. In 4 bottles, migration of BPA was detected at levels of 20 to 50 parts per billion. However, the results were inconsistent and there was no correlation between migration levels and the food simulant, estimated age of the bottles or sterilization method reported to have been used. After reviewing all available migration data on new and used bottles as well as other polycarbonate articles, the European Commission's Scientific Committee on Food concluded, "There is no significant effect from repeated-use, abrasion, heating, or chemical sterilization of these plastic articles." (SCF, 2002)

Water Bottles

In the US FDA study, water from several 5-gallon polycarbonate bottles from a bottled water supplier was analyzed with a detection limit of 0.05 parts per billion. In water that had been stored in the bottles for up to 39 weeks, BPA was found only at very low levels ranging from 0.1 to 4.7 parts per billion.

Tableware

The Japanese NIHS study evaluated several mugs and ricebowls along with a measuring cup. As with baby bottles, water and 20% ethanol were used as food simulants, which allowed a 0.5 part per billion limit of detection. No BPA was detected after 3 of 5 articles were exposed to either water (95°C for 30 minutes) or 20% ethanol (60°C for 30 minutes). Migration of BPA was observed from the other 2 articles, but only at levels below 5 parts per billion.

Molded Discs or Cut Pieces

In addition to evaluation of whole baby bottles, the US FDA study also tested migration from baby bottles that had been cut into pieces. The pieces were immersed in a simulant (either water or 10% ethanol), heated to 100°C for 30 minutes and refrigerated for 72 hours. For both simulants, the amount of BPA detected was estimated to be equivalent to migration of approximately 2 ng/ml (equal to 2 parts per billion) from a whole baby bottle. The authors of the US FDA study concluded, "When whole PC baby bottles were

SAFETY OF POLYCARBONATE PLASTIC / page 5

tested by using typical fill conditions and less severe, normal use conditions, neither BPA migration nor hydrolysis were observed (limit of detection was 2 ng/ml).”

The Society of the Plastics Industry, Inc. conducted a study (Howe and Borodinsky, 1998) to measure migration from molded discs that were prepared from a blend of polycarbonate resin from three American manufacturers. The three resins were blended and pressed into small discs such that all surfaces were similar to that of a finished polycarbonate product. The study was conducted according to procedures developed by the US FDA (FDA, 1995, revised 2002) and performed using storage time and temperature conditions recommended by the US FDA.

The discs were immersed in food simulating solvents (water, 3% acetic acid, 10% ethanol, coconut oil) and held at 212°F for 6 hours or at 120°F for 10 days. No BPA migration was detected in any of the samples with a 5 part per billion limit of detection.

Calculation of Potential Exposure and Margin of Safety

The potential dietary exposure to BPA from polycarbonate products that contact food and beverage can be estimated using procedures recommended by the US FDA (FDA, 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 food-contact material, such as polycarbonate plastic. Also in this equation, “f” is the “food-type distribution factor”, the fraction of each food or beverage type that contacts the material, “M” is the migration value for that type of food in contact with the material, and the type is indicated by the subscript description (water-based, acidic, low (<15%) alcohol or fatty).

Migration testing under conditions that are typical of how polycarbonate products are actually used indicates that migration of BPA, when it is detected at all, is generally less than 5 parts per billion. This value (<5 parts per billion) can then be used as the M value for each food type. Standard or “default” values for CF and f are prescribed by the US FDA (FDA, 2002) for food-contact materials for which actual consumer usage data is not available. The default f values for polycarbonate are 0.97, 0.01, 0.01 and 0.01 for water-based, acidic, low alcohol and fatty foods and beverages, respectively. With these parameters, the average concentration of BPA in all food and beverages that contact polycarbonate is <5 parts per billion.

Polycarbonate plastic is classified in the “all other” category for which the CF value is 0.05, corresponding to the estimate that a maximum of 5% of the food and beverages consumed in an average diet are in contact with polycarbonate. Thus, the potential

SAFETY OF POLYCARBONATE PLASTIC / page 6

concentration of BPA in the entire diet from food and beverages that contact polycarbonate is <0.25 parts per billion.

According to FDA, the average individual consumes 3000 grams of food and beverages per day. Based on this value, the potential dietary concentration of <0.25 parts per billion corresponds to a potential daily intake of <0.00075 milligrams per person per day. Based on FDA's estimate that a typical individual weighs 60 kilograms, the estimated dietary intake of BPA is <0.0000125 milligrams per kilogram body weight per day.

This level is more than 4000 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 (EPA, 1993). When the dietary intake of BPA from polycarbonate 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 the US 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 food and beverages that contact polycarbonate of <5 parts per billion (equal to <0.005 milligrams BPA per kilogram food/beverage), an average adult consumer weighing 60 kilograms would have to consume more than 600 kilograms (or about 1300 pounds) of food and beverages in contact with polycarbonate 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 polycarbonate products in contact with food and beverages is over 4000-fold lower than the reference dose, the potential human exposure to BPA from polycarbonate products is minimal and poses no known risk to human health.

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 (SCF, 2002). 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.

SAFETY OF POLYCARBONATE PLASTIC / page 7

Similar to the US EPA reference dose, the TDI represents a lifetime exposure level that is considered to be safe. Based on the existing migration data, total exposure to BPA from all food contact sources, including polycarbonate plastic and epoxy resin coatings, 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. Only a small portion of the exposure was estimated to be from polycarbonate plastic. This assessment confirms that polycarbonate products are safe for use in contact with food and beverage and pose no known risk to human health.

CONCLUSION

Human exposure to BPA from food-contact use of polycarbonate plastic is very low and poses no known risk to human health. The use of polycarbonate plastic for food contact applications has been and continues to be recognized as safe by the U.S. Food and Drug Administration, the European Commission's Scientific Committee on Food, the United Kingdom Food Standards Agency, the Japanese Ministry of Health, Labor and Welfare, and other regulatory authorities worldwide.

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SAFETY OF POLYCARBONATE PLASTIC / page 8

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