TECH BRIEFS

Testing of Plastic Injection Molded Products for Beryllium Transfer

Copper beryllium is used across several industries for its excellent combination of material properties such as high strength, toughness, and formability. In the plastic industry specifically, copper beryllium is used as a mold material for plastic injection molding processes due to its superior strength-conductivity combination. As discussed in this document, a study initiated by Materion's Product Stewardship department demonstrates that the use of copper beryllium as a plastic tooling alloy does not risk the transfer of beryllium to the finished molded, plastic product.

COPPER BERYLLIUM AS A MOLD MATERIAL

When selecting a material for plastic injection tools, a combination of high thermal conductivity and strength is beneficial. The superior thermal properties of a copper base metal aids injection molds by rapidly removing heat from manufactured plastic parts. Beryllium additions to copper provide the increased hardness and strength necessary for plastic molding applications. By using copper beryllium alloys as mold materials, tool life can be extended while plastic products can cool faster and more uniformly. In effect, productivity is improved from shortened cycle times and increased yield.

SAFETY CONSIDERATIONS

Plastic items manufactured by injection molding often have applications that require direct contact with food, such as containers, plastic lids, and bottle caps. When this is the case, there is a potential risk of transferring foreign substances from the plastic articles to the food they contain. At sufficient concentrations, the food's taste, color, or odor may be unacceptably affected. If the amount released into foods reaches an unsafe level, the health of the consumer may even be endangered. Thus, the Food and Drug Administration (FDA) mandates that materials used to construct food contacting surfaces "may not allow the migration of deleterious substances, or impart colors, odors, or tastes to food" (Chapter 4-102.11 and Chapter 4-201.11. FDA code 2013)[1].

ORAL TOXICITY OF BERYLLIUM

Beryllium can be found in drinking water, food, and soil. The average amount of beryllium present in the human body is estimated to be 35 mg or 580 ppb[2]. Although beryllium is a naturally occurring element, it still can be considered a possible contaminant existing in food contact materials.

Research shows varying conclusions of what a normal daily beryllium intake is from food and water. For example, the Environmental Protection Agency estimates that the average person consumes 0.12 µg of beryllium a day from food and 0.3 µg of beryllium a day from water, whereas the World Health Organization states that beryllium is not likely to be found in drinking water.

Although studies have observed that ingestion of beryllium poses no health risks[3], government agencies responsible for food safety remain concerned regarding unidentified toxicological effects of oral consumption of beryllium. As a consequence, there are also discrepancies in what research has concluded as a safe and recommended intake level for humans. One of the most recent conclusions made by the Concise International Chemical Assessment Document (CICAD) in 2001 determined that a tolerable amount to ingest is 0.002 mg/kg of body weight per day. For a 60 kg person, this toxic reference value is 0.12 mg of beryllium ingested from food and water per day. Based on this, the European Council suggested that a reasonably safe oral intake level of beryllium is 10% of the toxicological limit cited by the CICAD (or 0.01 mg of beryllium per kg of food)[4]. For manufacturers who use copper beryllium as mold materials, this specific release limit (SRL) serves as a guide as to how much beryllium can be released from the food plastic containers into the food without endangering the health of consumers.

[1] Food Code. College Park, MD: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, 2013. FDA, 2013. Web.
[2] Emsley, John. "The Elements A-Z." Nature's Building Blocks: Everything You Need to Know about the Elements. Oxford: Oxford UP, 2011.
[3] Strupp, C. "Beryllium Metal I. Experimental Results on Acute Oral Toxicity, Local Skin and Eye Effects, and Genotoxicity." Annals of Occupational Hygiene 55.1 (2010): 30-42.
[4] Metals and Alloys Used in Food Contact Materials and Articles: A Practical Guide for Manufacturers and Regulators. 1st ed. Strasbourg: Council of Europe, 2013. Print.

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The Specific Release (SR) is measured as the difference between the concentration of the element in the food before and after contact with the metal or alloy, so the naturally occurring quantities of the element are also taken into account. If the SR is below the SRL, manufacturers comply with safety guidelines recommended by the European Council.

MOTIVATIONS

As mentioned, when copper beryllium is used as a tooling alloy in the plastic industry, a resulting concern is that residual beryllium could be transferred to the finished parts during the molding process and then further leach into food products. Because of this, some plastic injection manufacturers express concerns about using copper beryllium in mold components.

A study conducted in 1990 concluded that beryllium levels in finished plastic items produced in molds containing copper beryllium alloys are below a detectable limit of 100 ppb[5], but remaining industry concerns suggested the need for updated and more precise data to prove that the use of copper beryllium molds does not pose a health risk to consumers.

The research described in this document was coordinated by Materion's Product Stewardship department in 2015 and further validates the conclusion made in 1990 by executing analytical methods with ten times greater precision than previously applied. In doing so, Materion's findings confirm that the transfer of beryllium to plastic food containers does not occur and serves as relevant data to show that copper beryllium alloys can safely be used in molds utilized to produce articles expected to come in contact with food.

The study's results were also used to confirm that the manufactured parts used in the research adhered to all applicable FDA regulations and European Council guidelines. As previously discussed, the European Council's guide advises manufacturers and regulators that the amount of beryllium released from the plastic materials to the contained food should be limited to 10 ppb, measured as 0.01 mg of beryllium per kg of food. The analysis performed in this study determined that no beryllium was found in the plastic containers with a test detection limit of 10 ppb. Even if beryllium existed at an undetectable level in the plastic materials, these results ensure that the maximum amount of transferred beryllium present in the food would be well under the SRL recommended.

[5] Foley, E. D., Jr., and P. M. Rutter. The Safety of Beryllium Copper Molds. Tech. Maumee, OH: Foley Occupational Health Consulting, 1990.

PROJECT SUMMARY

For this study, various plastic food packaging containers were obtained from manufacturers who use Materion's copper beryllium MoldMAX® alloys in their plastic tooling. Then, samples of the raw materials that comprised the finished products were also collected. Finally, the molded plastic specimens and resin samples were analyzed for the presence of beryllium.

SAMPLING

A total of 157 finished items were collected from food container manufacturers whose molds were made of copper beryllium alloys. The sampling plan followed the Military Standard 414 table guideline which considers sources of variation in transfer and non-transfer situations. The manufacturers were located in seven different sites across Spain, France, Italy, Turkey, and the US. Figure 1 in the Appendix shows how many plastic articles were taken from each manufacturing location. The products sampled included yogurt buckets, ice cream buckets, lids, gallon super lift buckets, food containers of various sizes, and wipe containers. These were made from either PP (polypropylene), HDPE (high density polyethylene), or PS (polystyrene). Often, the specimens were taken directly from the production line or right after fabrication, and then sealed in bags to avoid contamination. In addition, 17 control samples were gathered from the raw materials to identify any background concentrations of beryllium. Figures 2 and 3 quantify how many background samples of each resin type were taken and how many plastic articles were sampled in each product category, respectively.

ANALYSIS

After sampling, a qualified laboratory[6] tested the plastic containers for residual beryllium according to the EPA6010C method[7], a process used to determine trace elements in solution. In this particular analysis, the samples were boiled in a nitric acid solution for twenty minutes, dissolved in solution for twelve hours, and subsequently analyzed by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES). This method is recommended by the European Council as an appropriate analytical technique for release testing of food contact materials made from metals and alloys.

During ICP-AES spectroscopy, atoms are excited and emit electromagnetic radiation. Wavelengths of different sizes can be

[6] Accredited by the American Association of Laboratory Accreditation (A2LA) and meets the requirements of ISO 17025 for elemental chemical analysis.
[7] "EPA Method 6010C (SW-846): Inductively Coupled Plasma - Atomic Emission Spectrometry (PDF)." METHOD 6010C 3rd ser. (2000): n. pag. United States Environmental Protection Agency. Nov. 2000. Web.

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measured from the detected radiation, where each wavelength is specific to a particular element. In this way, beryllium can be identified if it is present in the plastic specimens. Also noteworthy is the Detection Limit (DL) associated with the ICP-AES analysis. The laboratory conducting the elemental chemical analysis supplied this value as 9-10 ppb (measured as ng/g). If any beryllium was present in the plastic materials in amounts above the DL, it could be identified[8]. In comparison to the 1990 investigation, this detection range provided ten times more sensitivity than previously used.

RESULTS & CONCLUSIONS

Of the 63 laboratory analytical test runs on the samples, all were negative for detectable beryllium. These results can be seen in the Appendix under Table 1. The elemental chemical analyses performed verified that beryllium above 10 ppb was not present in any of the plastic items or resins taken from the injection molding manufacturers. Consequently, the study determined that beryllium was not transferred in measurable amounts from the molds to any of the specimens in this study. When using standard injection molding practices and the resins tested, the results further indicate an unlikely possibility that beryllium particulates from molds will be transferred to the plastic. In this regard, using copper beryllium alloys to manufacture plastic products will not lead to violations of food safety standards.

In regard to the regulations and guidelines available on the migration of harmful substances to food from plastic containers, the study's results demonstrated compliance with statements made by both the US Food and Drug Administration and the European Council as no beryllium transfer could be detected.

SAFE HANDLING OF COPPER BERYLLIUM

Handling copper beryllium in solid form poses no special health risk. Like many industrial materials, beryllium-containing materials may pose a health risk if recommended safe handling practices are not followed. Inhalation of airborne beryllium may cause a serious lung disorder in susceptible individuals. The Occupational Safety and Health Administration (OSHA) has set mandatory limits on occupational respiratory exposures. Read and follow the guidance in the Safety Data Sheet (SDS) before working with this material. For additional information on safe handling practices or technical data on copper beryllium, please go to Materion.com or contact Materion Performance Alloys, Technical Service Department at 1-800-375-4205.

[8] Abundance of beryllium below 9-10 ppb could not be identified, but as a reference, levels of beryllium present in plants and legumes can be measured up to 400 ppb.

APPENDIX

Table 1. -- Analysis results of all samples collected

Sample Type	Articles Tested	Detectable Beryllium (ppb)
Lids	70	0
Milk Jugs	23	0
Yogurt Buckets	14	0
Ice Cream Buckets	14	0
Wipe Containers	7	0
Ice Cream Covers	7	0
Gallon Super-lift Buckets	7	0
Food Containers (Cup)	7	0
Food Containers (Quart)	7	0
Resin Sample (PP)	14	0
Resin Sample (PS)	2	0
Background Sample (HDPE)	1	0

Note: Every item in the list was manufactured with plastic injection molding tools made from copper beryllium alloys. Resin samples were taken at each manufacturer location to test the beryllium concentrations present in the resins used for creating the plastic products. As shown in the table, no beryllium could be identified in any of the 157 plastic items or 17 background samples given a test detection limit of 10 ppb.

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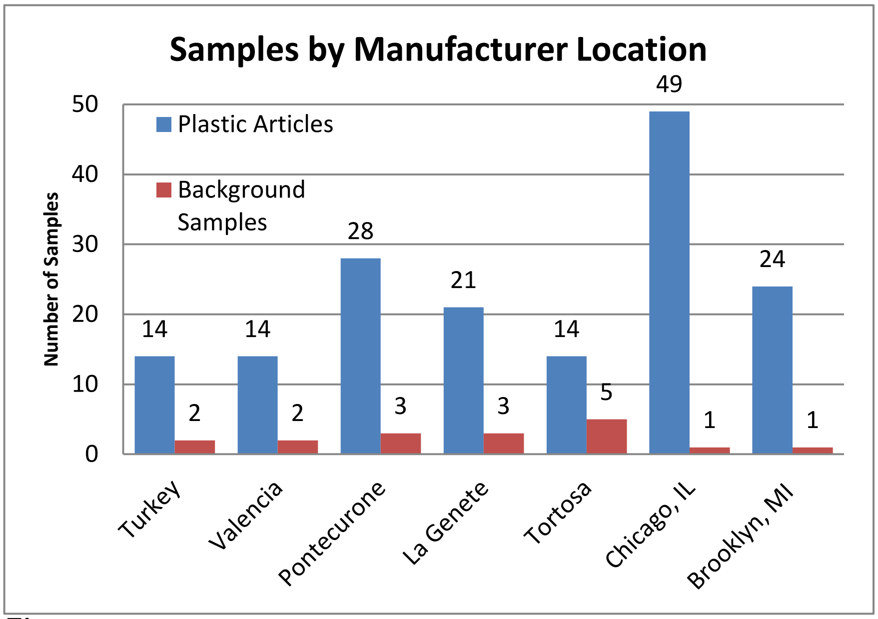

Figure 1. The number of molded products and background samples collected and tested from each manufacturer site.

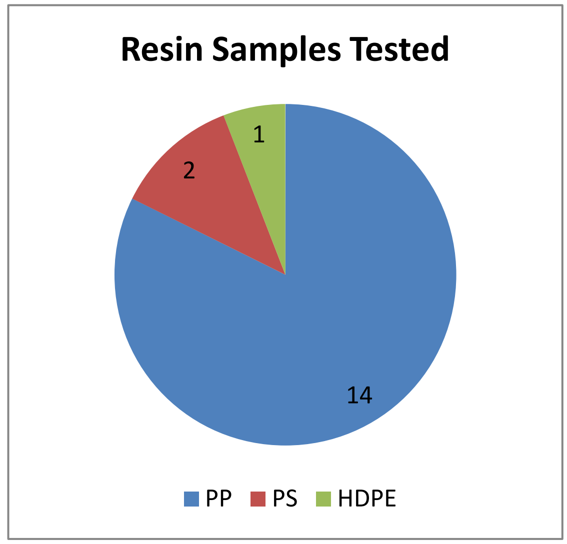

Figure 2. Of the 17 control samples collected from the various manufacturers, 14 were polypropylene, 2 were polystyrene, and 1was high-density polyethylene.

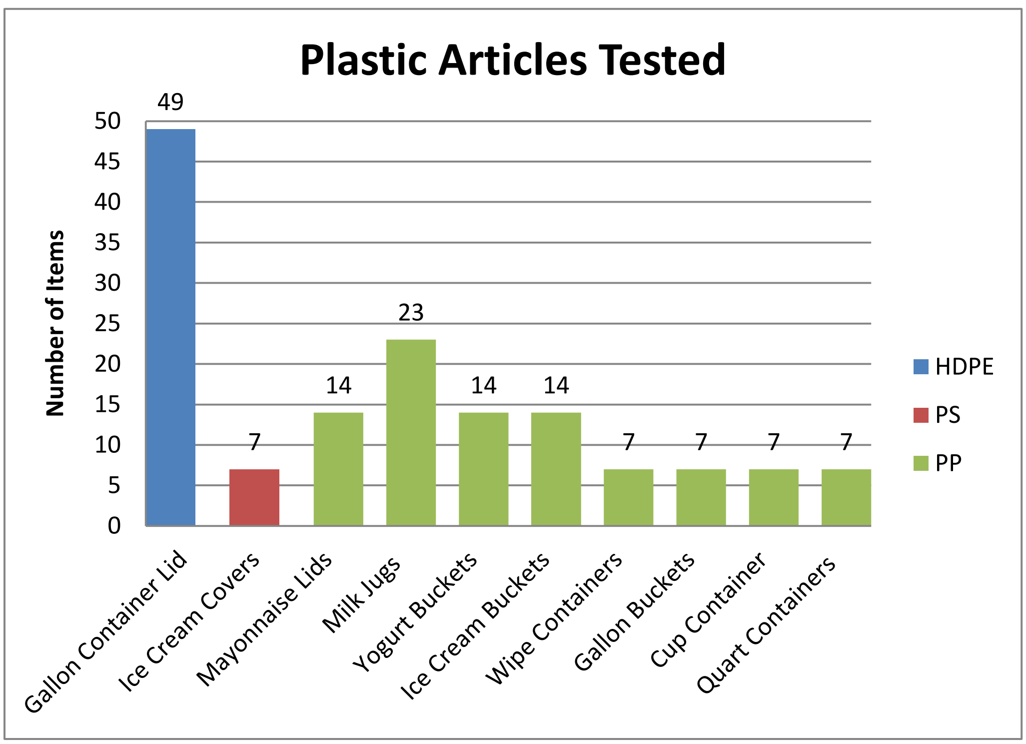

Figure 3. A breakdown of the 157 molded, plastic products collected by item type and resin type.

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