United States
Consumer Product Safety Commission

November 28, 2023

Ms. Joan Lawrence, ASTM F15.22 Subcommittee Chair
Mr. Jos Huxley, ASTM F15.22 Task Group Chair
ASTM International
100 Barr Harbor Drive
West Conshohocken, PA 19428

Dear Ms. Lawrence and Mr. Huxley:

On September 11, 2023, ASTM 15.22 held an emerging hazards working group meeting on expanding materials, specifically water beads. One topic of discussion was possible toxicity levels associated with those products. Other discussion topics included modification of the performance requirements, test results interpretation, and test method modification. At that meeting CPSC staff[1] agreed to provide information on acrylamide levels in water beads as well as provide feedback on the other areas.

Staff outlines here three incidents where varying levels of medical intervention were required to treat victims after water bead ingestion. The first incident involved a one-year-old female, who was able to successfully pass a water bead less than 25.4 mm in diameter with the aid of a barium enema. This incident seems to indicate that the bead was likely able to pass into the large intestines before full expansion occurred. In this incident, a second ingested bead of 32 mm was surgically removed. The second incident involved a three-year-old female who ingested approximately 1200 water beads (approximately 1 tablespoon before expansion). The victim successfully passed all of these through her system with the aid of a mineral oil enema. The product was identified, and a separate package was purchased for testing. Seventeen (17) water beads were hydrated for 72 hours per the standard, and then measured in their expanded state. The smallest beads measured approximately 9.3 mm, while the largest measured approximately 15.2 mm. However, staff has also reviewed a third incident involving a 13-month-old female, who ingested a water bead at least 13.2 mm in diameter, as determined by similar testing. The water bead caused a gastrointestinal blockage that required surgical removal.

Regarding acrylamide levels, CPSC staff performed a series of extractions to simulate three phases of human ingestion. Twenty-four samples from 14 water bead products were tested. Some of the products included more than one size of water beads. The water beads were characterized by their pre-expanded size (small (≤ 2 mm), medium (between 2-3 mm), or

[1] The views expressed in this letter are those of CPSC staff, and they have not been reviewed or approved by, and may not reflect the views, of the Commission.

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

large (≥ 3mm), as well as their pre-expanded hardness (soft or hard)).

CPSC staff measured the expanded sizes of various water beads. The small water beads expanded to between 12 mm and 15 mm, the medium water beads expanded to between 15 mm and 18 mm, and the large firm water beads measured between 35 mm and 56 mm. The large, soft water beads also measured between 35 mm and 56 mm.

During the acrylamide extraction testing, small/medium beads were tested in sets, while large beads were tested individually. Two samples of the 24 samples tested were observed to be both large and soft (partially hydrated) prior to any expansion.

The beads were extracted first in simulated saliva (tap water, 5 mL) at room temperature with no shaking for five minutes. The beads were then transferred to a simulated stomach acid (0.07 mol/L HCl, made in tap water, 10-20 mL) at 37 °C shaking at 60 RPM for two hours. Finally, the beads were transferred to a simulated small intestine fluid (tap water with pH adjusted to approximately 7.4, 45-50 mL) at 37 °C shaking at 30 RPM where they were left for up to seven days. Aliquots of the extraction solutions were taken at various time intervals as work schedules permitted (after 5 minutes in saliva, 2 hours in stomach acid, and 6, 24, 48, 72, 96, and 168 hours in small intestine fluid) and analyzed for acrylamide concentration using a Liquid Chromatography-Triple Quadrupole Mass Spectrometer (LC-TQMS). In most samples, the cumulative extraction of acrylamide peaked within the first 26 hours. The subsequent timepoints did not show substantial additional extraction of acrylamide. The two large, soft beads released concerning levels of acrylamide within the first 26 hours of extractions.

The Agency for Toxic Substances and Disease Registry (ATSDR) has published an acute-duration oral minimal risk level (MRL) of 0.01 mg/kg-day for acrylamide.[2] CPSC staff recommends that ASTM set limits, such that ingestion of multiple beads should not exceed the acute-duration oral MRL in children aged 6 months to 10 years. The acrylamide exposure could be assessed using a 24-hour extraction in pH neutral water. The number of beads ingested in an exposure scenario can be based on case reports and/or anthropomorphic estimates for the relevant age groups. As an example, considering the weight of a 5th percentile 6-8-month-old of 7.0 kg and assuming an incident of ingesting 100 beads, staff recommends that water beads be tested by extracting in pH neutral water for 24 hours and that a performance standard be set such that the amount of acrylamide extracted in 24 hours shall not exceed 70 µg per 100 beads, considering the MRL (7.0 kg x 0.01 mg/kg-day = 0.070 mg/day = 70 µg extracted in water for 24 hours).

[2] Acrylamide | Toxicological Profile | ATSDR (cdc.gov)

Staff is also aware of incidents as well as reports of children inserting water beads in their nose[3] or ear canals.[4] Studies have indicated that some of these incidents caused serious injuries, requiring surgical intervention to remove the beads, but no fatalities have been associated. Taking this information collectively, CPSC staff recommends the gauge size be substantially reduced from 20 mm and stands ready to work with the Committee to determine the recommended size.

CPSC staff also requests modification of the test method that involves use of a push rod with a 4.5 lb force. In the current standard, the force is applied through a 10 mm rod with a hemispherical end, which is a concentrated load, and less like compressive pressure, which is more representative of the gastrointestinal tract action. The test rod will impart a shearing force, breaking up the water bead into smaller pieces which is not representative of the incident data where the beads remain whole. Staff requests that the push rod approach force be removed from the test method entirely. Instead of a push rod applying a force, a test gauge should be supported horizontally in air and the expanded water bead placed on top after 72 hours of expansion in water. To aid in placing the water bead on the gauge, the opening above the X mm diameter hole (with a tolerance of (+0,-0.1 mm)) can be formed in a funnel shape to facilitate placing a single water bead (Appendix A). In addition, staff recommends that the funnel shaped gauge be made of aluminum to maintain dimensional stability.

CPSC staff also sees a need to clarify the testing and disagrees with the current interpretations of the test results in section 8.30 of the current standard. In cases where the water bead breaks, but does not go through the gauge, staff's interpretation is that that is a failure. However, some have proposed an interpretation that states the force should be applied to the broken pieces of water beads. Proponents of this view have opined that the muscular action of the gastrointestinal tract would break the bead into smaller pieces, and that they would be able to pass. However, incident data has not identified a reoccurring pattern of incidents of water beads breaking when ingested nor have proponents provided data supporting this position. ASTM's current interpretation of the standard could result in water beads passing the standard, regardless of size, unintentionally creating a hazard. Revising the test method as proposed above will eliminate this discrepancy in interpretation, resulting in a lower likelihood of potentially hazardous beads passing the test when they would have otherwise failed.

---

[3] Han., et al, *Superabsorbent polymer balls as foreign bodies in the nasal cavities of children: our clinical experience*

[4] Zalzal, et al., Managing the Destructive Foreign Body: Water Beads in the Ear (A Case Series) and Literature Review

United States
Consumer Product Safety Commission

CPSC staff requests a working group meeting by December 20, 2023, to discuss the information in this letter and develop a schedule for ASTM to revise the requirements for these products. If you have any questions, or need additional information, you can contact me at: bmordecai@cpsc.gov, or (301) 987-2506.

Sincerely,

Benjamin Mordecai

Benjamin Mordecai Mechanical Engineer
Project Manager, F963

Cc: Molly Lynyak, ASTM F15 Staff Manager
Susan Bathalon, Children's Program Area Risk Manager
Daniel Taxier, Children's Program Manager
Jacqueline Campbell, CPSC Voluntary Standards Coordinator

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

Appendix A. New Concept Expanding Material Gauge Test Methods

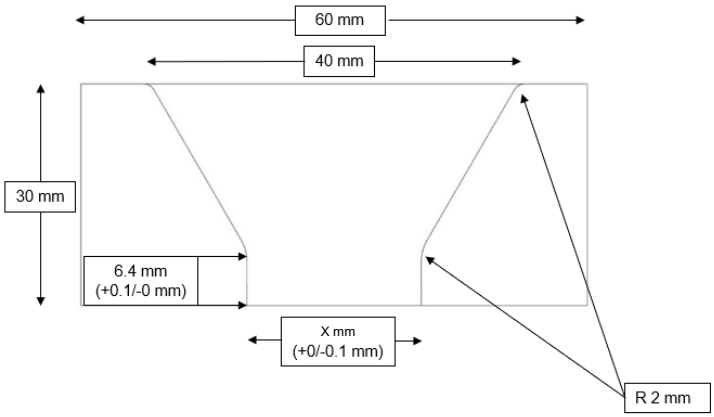

Figure 1. New Expanding Material Gauge Concept (Aluminum)

Step 1) Position the gauge horizontally off of a capture surface or container, with the larger opening on top.

Step 2) Place the expanded water bead on top of the gauge's opening.

Step 3) Release the water bead and let it travel down until it reaches the lower opening.

Step 4) Allow up to 5 seconds to take place. If the water bead passes through the lower opening, then it meets the requirements of the standard. If it does not pass through, then it does not.