

January 19, 2024

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 November 28, 2023, CPSC staff¹ sent a letter to ASTM concerning expanding materials, specifically water beads. In that letter, CPSC staff outlined toxicity levels related to those products. ASTM responded with questions, commentary, and requests regarding the incident data as well as the acrylamide study. This letter responds to those questions and requests and provides additional relevant data.

ASTM asked the following numbered questions regarding the incident data CPSC staff provided. CPSC staff's answers are after each question.

1) What are the toy age grade and any warning labeling and/or information related to the products in question?

For the first incident, images provided by the consumer show an age grading on the package of 3+. The consumer states that there was no warning label on the packaging pertaining to water beads. For the second incident, images provided by the consumer show an age grading on the package of 3+. There were no other warning labels on the packaging pertaining to water beads. CPSC staff can provide a brief synopsis of these incidents, which are not reflected in the data spreadsheet, at the next scheduled ASTM meeting. The third incident is 170802CCC3140, provided to ASTM on June 20, 2023 (see data spreadsheet). A redacted IDI was also provided to ASTM on August 2, 2023, because the incident involved a product that was compliant with the standard but caused an intestinal obstruction.

2) The results of the ASTM F963 testing applied to the beads from the products involved in the incidents (where the expanded diameter was more than 20 mm)?

¹ This letter was prepared by the CPSC staff. It has not been reviewed or approved by, and may not represent the views of, the Commission.

Only the first incident is relevant because it contained two different sizes of beads, where one size expanded to over 20 mm. The beads failed to pass through the expanding material gauge during testing.

3) For the second (multiple bead ingestion) incident, was the barium enema applied as a precautionary measure or to remove an obstruction? Based on the information received and the age of the child, these do not appear to be sized such that an obstruction would be likely to occur.

It is unclear whether this was a precautionary measure; however, no obstruction occurred.

4) For the third incident was the water bead referenced of 13.2 mm in diameter the pre- or post-expanded size?

The post-expanded size.

The following were questions/requests regarding acrylamide:

1) Please provide the acrylamide test results that were observed from the referenced testing.

Staff does not believe that these product-specific results—which cannot be shared at this time—are relevant to the development of voluntary standards addressing hazardous levels of acrylamide across all water beads.

2) Please confirm CPSC is or will be initiating a Chronic Hazard Advisory Panel (CHAP) review for acrylamide.

CPSC statutes provide that CPSC must convene a Chronic Hazard Advisory Panel (CHAP) when proposing certain regulations relating to a risk of cancer, birth defects, or gene mutations. Although acrylamide is a carcinogen, staff is currently focused on the acute chemical hazards posed by acrylamide. Therefore, staff does not contemplate convening a CHAP for acrylamide at this time.

3) What was the basis for 100 beads to be applied for a 6-month-old? At this developmental age, the mobility and fine motor skills would not indicate such a



large number of beads to be ingested (ref. <u>CPSC Age Determination Guidelines</u>, p20).

When developing the example in the letter, staff selected 100 small beads (approximately 0.7 mL or 0.14 teaspoon) as a plausible amount that a young child could grasp and ingest. One study that reviewed water bead ingestion cases over a 10-year period reported that children have ingested a varying number of water beads, from "one piece to a handful" (Mehmetoğlu, 2018). Published case reports identify a two-year-old who swallowed 100 small water beads (Jackson et al., 2015). One incident reported to CPSC described an incident where a three-year-old ingested 1,200 small water beads.

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 Jacqueline Campbell, CPSC Voluntary Standards Coordinator