



Appendix 48 (Revised May 2004)

INVESTIGATION GUIDELINE

Small Parts Associated with Children's Products, Small Balls, Toy Balloons and Marbles

I. Introduction

A. Background Information

Small parts associated with nursery and children's products (including toys) are covered under a mandatory Federal regulation, 16 CFR Part 1501 and 1500.50-53 of the Federal Hazardous Substances Act (FHSA) that became effective on January 1, 1980. The goal of the regulation is to prevent small parts-related injuries and deaths to children less than 3 years of age from choking on, inhaling or swallowing small objects. The regulation bans toys and other products intended for children under 3 that are small objects, have small parts or that become small parts when broken.

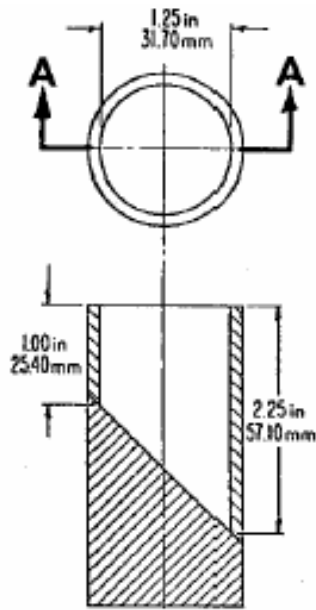
The Child Safety Protection Act of 1994 (CPSA) amended the Federal Hazardous Substances Act (FHSA) with the addition of a new Section 24 that imposes labeling requirements on small balls, toy balloons, marbles and certain toys and games containing these items. The amendment also bans certain balls intended for use by children under 3. The purpose of the labeling is to warn consumers that these products can pose a choking hazard to children under 3. The CPSA also requires that any choking incidents involving small balls, balloons, marbles and toys or games containing these items or other small parts must be reported to CPSC.

New children's products are entering the marketplace daily, especially in the toy industry. Although the major manufacturers of children's products are likely to be aware of these standards, there may still be some manufacturers and importers who are unaware of the inherent dangers of small parts/objects, small balls, marbles and balloons.

B. Product Category Description

1. Definitions and General Description

The definition of a small part is any object that fits completely into a truncated test cylinder with a minimum interior depth of 1 inch and a maximum interior depth of 2.25 inches, and an interior diameter of 1.25 inches (see the diagram on Page 2). Objects with a greater diameter can not readily pass the anterior dental or jaw segment of a 3-year-old child. A small part can be a whole object (such as a small toy); a part of a toy, game or object; or a piece of an object that has broken off through use or abuse by a child.



Small Parts Test Fixture

If a small object or part of a product intended for use by children under 3 fits completely into the test cylinder, then it is considered a banned small part.

The rule uses three factors to determine whether a product is intended for use by children under 3 years:

- a.) The manufacturer's stated intent, such as the age stated on a label.
- b.) The product is advertised, promoted or marketed for use by children under 3.
- c.) The product is commonly recognized as being intended for use by a child under 3.

The wide range of products that the regulation covers can include toys, nursery equipment and nursery furniture. A more detailed list of the products covered can be found in 16 CFR 1501.2.

There are some toys and products that are exempt from the small parts regulations (see 16 CFR Part 1501.3&4(b)). They include the following:

- a.) Balloons, books made of paper, pencils, pens, and most art supplies are exempt because they cannot be manufactured in a manner that would prevent these products from breaking into small parts when subjected to use and abuse testing. NOTE: Many books contain interactive features for a child to manipulate. These are usually not made of paper and are not excluded from the small parts regulations.
- b.) Children's clothing and clothing fasteners; and grooming, feeding and hygiene products are exempt because many of these products must be small to perform their intended purpose or may break easily (e.g., glass baby bottles and ceramic dishware).
- c.) Rattles and pacifiers are subject to their own requirements (16 CFR 1510 and 1511).

The testing requirements for small parts specify that the products must not release pieces that fit into the test cylinder after impact, flexure, torque, tension and compression testing. These tests are designed to represent the forces that these products are subject to during normal use and abuse by young children.

There are also labeling requirements for toys and games that are, or contain small parts, and are intended for use by children from 3 to less than 6 years of age. For the purpose of these labeling requirements, a small part is defined as any object which fits entirely within the test cylinder and is present without subjecting the toy or game to the use and abuse test procedures under 16 CFR 1500.50-53. These products require labels that warn consumers not to buy these products for children under 3, because those children could choke on the small parts.

The requirements under Section 24 of the FHSA, 16 CFR 1500.18(a)(17), and 16 CFR 1500.19 are that a cautionary statement warning the consumer of choking hazards must be used with the following products:

- a.) Any toy or game for children 3 to less than 6 years of age which includes a small part. The labeling should read: **“WARNING: CHOKING HAZARD-Small parts. Not for children under 3 yrs.”**
- b.) Any latex balloon, or toy or game that contains a latex balloon. The labeling should read: **“WARNING: CHOKING HAZARD-Children under 8 yrs can choke or suffocate on uninflated or broken balloons. Adult supervision required. Keep uninflated balloons from children. Discard broken balloons at once.”**
- c.) Any small ball with a diameter of 1.75 inches or less intended for children 3 years and up. The labeling should read: **“WARNING: CHOKING HAZARD-This toy is a small ball. Not for children under 3 yrs.”**
- d.) Any toy or game intended for children 3 years old to less than 8 years old that contains a small ball with a diameter of 1.75 inches or less. The labeling should read: **Warning: CHOKING HAZARD-Toy contains a small ball. Not for children under 3 years.”**
- e.) Any marbles intended for children 3 years or older. The labeling should read: **WARNING: CHOKING HAZARD-This toy is a marble. Not for children under 3 yrs.”**
- f.) Any toy or game intended for children at least three years and less than 8 years of age that contains a marble. The labeling should read: **WARNING: CHOKING HAZARD-Toy contains a marble. Not for children under 3 years.**

These labeling requirements apply to the products described that have been imported into the United States or manufactured in the U.S. on or after 1/1/95. The cautionary statement must appear on the product’s packaging, descriptive material and if unpackaged then on any bin/container or vending machine in which the product is placed.

Additionally, any small ball intended for children under the age of 3 that passes entirely through a circular hole of 1.75 inches in diameter is banned under the FHSA and 16 CFR 1500.18(a)(17).

The following products intended for children are exempt from CPSA requirements under 16 CFR 1500.19 (b)(1):

- a.) Books and other articles made of paper

- b.) Writing and art materials such as, crayons, chalk, pencils, pens, modeling clay, fingerpaints, watercolors and other paint sets
- c.) Grooming, hygiene and feeding products such as diaper pins/clips, barrettes, toothbrushes, drinking glasses, dishes, and eating utensils
- d.) Children's clothing and accessories
- e.) Phonograph records

2. Specific Items of Interest

Field investigators shall conduct an on-site investigation, if the product is available. Otherwise, conduct a telephone interview. On-site investigations are the most desirable, since they afford the investigator the opportunity to gather the best information possible.

- a.) Document all manufacturer brand and serial/model information, including production dates if available.
- b.) Identify all labels regarding certification, testing or conformance with the standards.
- c.) The text of any warning and age labeling on or accompanying the product is also of interest and should be documented and photographed, if possible.
- d.) The exact dimensions of the object involved should be documented if the object is a small ball, marble, or does not pass the small parts test. Each investigator should have a small parts test cylinder for this purpose.
- e.) Identify the type of material from which the object was made and whether the object is rigid, flexible or compressible.
- f.) If the object detached from a product, describe what part of the product it was. Also, determine how the small part detached. Did it break, tear, or twist off, for example? Did the child cause the part to detach?
- g.) If the object was a product such as a small toy that fits entirely within the test cylinder, a small ball or a marble, describe the type of object. Was it a toy premium from a fast food restaurant, a toy from a vending machine, etc.? Was it obtained separately or as part of another product.
- h.) If possible, establish a timeline of the incident events, such as what time the child was discovered choking, what time the object was recovered from the child, etc.
- i.) If the child aspirated, swallowed or choked on the small part/object, please describe where the object lodged before removal (e.g., back of the mouth, larynx, trachea, esophagus, etc). If possible, describe the position of the object when it was found (sideways, straight up and down, etc.) This information will most likely be available in autopsy reports or from statements of persons who were on the scene at the time of the incident. Also, describe the method by which the object was removed from the child. If medical intervention was needed for removal of the object, please obtain any relevant medical records.
- j.) If a toy balloon was involved in the choking incident, describe whether the balloon was whole or a portion of a broken/popped balloon.

- k.) Determine if the product was purchased new by the user, obtained as a gift or obtained second hand. If the product was purchased new ask for the name and address of the retailer. If the product was obtained second hand, please determine how it was obtained and if warning or use instructions accompanied the product. Also, determine whether the object was intended for/belonged to an older child.

C. Headquarters Contacts

Joyce McDonald, EPHA 301-504-7331
Debbie Tinsworth, EPHA 301-504-7307

II. Instructions for Collecting Specific Information

For an on-site or telephone investigation, it is essential to provide a detailed narrative description of the incident in order to provide a clear understanding of the sequence of events, before, during, and after the incident, and the circumstances involved. If a telephone investigation (rather than an on-site investigation) is done, it is still important to obtain as much information about the product as possible. Ask the respondent to describe the product to you in detail, including features that are unique to that product and product identification, such as the model and date of manufacture. If the respondent does not have the product, determine whether it was returned to the store or manufacturer, or if it was destroyed or discarded. Timely contact with the victim's family will improve the likelihood of accurate recollection by the respondent of the circumstances involved in the incident.

Many investigations concerning small objects/parts associated with children's products are initiated by the Recalls and Compliance Division. For guidance on collecting samples, refer to the current year "Toy and Children's Products Field Compliance Program".

A. Synopsis

Describe the sequence of events, report the product(s) involved, the victim's activity during the incident and how the victim became injured. Include the victim's age, sex and type of injury. Specify the location (e.g., home, childcare, etc.) where the incident occurred.

For data retrieval purposes, please include the following key words in the synopsis as appropriate: CHOKED, ASPIRATED, INGESTED, SWALLOWED, MOUTHED, ASPHYXIATED, OBSTRUCTED AIRWAY

B. Description of the Product

1. Product Involved

- a.) Describe the specific type of product involved. Was it a toy or a nursery product?
- b.) Was the product a whole product or part of a product?
- c.) What material(s) was the product made out of, such as wood, plastic, etc? If the product was plastic, describe the type of plastic to the best of your knowledge, i.e., soft/pliable, hard, brittle, vinyl, polystyrene, etc.
- d.) If it was part of a product, describe what it was in relation to the whole and its function, if any. Was it an intact piece or an irregular piece due to tearing, breaking, etc.?
- e.) Measure and document the complete dimensions of the small part/object. If a small ball or marble was involved measure the diameter.

- f.) What were the manufacturer, brand, model and serial number of the product? If this was an imported item make sure to document who the importer/distributor was. If possible, identify the retailer from whom the item was purchased.
- g.) How old was the product? (Include date of purchase, if known.) Was the product obtained new or used? If used, how old was the product when it was obtained?
- h.) How often was the product used (e.g., daily, weekly, etc)? Had the product been used by more than one child and if so, how many?
- i.) Describe the condition of the product (e.g., like new, well used, damaged, etc.).
- j.) Had the product been modified, repaired or altered in any way? If so, please describe how, why and by whom. Had the product ever been disassembled or taken apart? How and for what purpose?
- k.) It is very important to document if the manufacturer specified any age limitation for the product involved.
- l.) Where was the product primarily used and stored? Was it exposed to the elements or adverse conditions, such as heat, rain, sunlight, snow, etc? Did the child chew, mouth, twist or pound the product on a regular basis? Where any cleaners used on the product that might have caused it to deteriorate?

2. Labeling and Instructional Literature

- a.) Describe any labeling on the product or product's packaging, especially age labeling. Indicate where the labeling was located and its exact wording. Determine if there was any certification seal on the product packaging.
- b.) Obtain any instructional literature that came with the product. If the consumer no longer has the literature, did they review it when the product was first obtained? Was there any warning or cautionary statements in the literature?

3. Guidance on Investigating Specific Products

- a.) Toys given out at fast food restaurants and as prizes in food containers (such as cereal boxes) are referred to as toy premiums. Some fast food restaurants give out toy premiums regularly. CPSC staff recommends that restaurants offering toy premiums EITHER make sure the premium is appropriate for children of all ages they are marketing to OR that they use two premiums—one appropriate for children under 3 and one for children 3 and over. Ask the consumer if they remember if there was a choice of toy premiums available, and if so, then ask if there were any age recommendations on the package labeling. Document the age labeling described.
- b.) Game pieces are often small and can present a choking hazard to a young child. It is important to obtain the age recommendation from the box or container. There are some games marketed for children under 3, but the majority will be aimed at older children.
- c.) Vending machine toys are another type of toy product that inherently present a problem since they must be small to fit into their plastic containers and into the machine itself. Documenting these toys may present a problem. They may not be labeled and information about the manufacturer may have to be obtained through the vendor who owns the machine. To obtain the vendor identification it may be necessary to visit the site of the vending machine. Vending machines with toys for children from 3 to under 6 years of age that are or contain small parts must be labeled.

C. Description of Interaction between Injured Person(s) and Product

1. Describe how the product was being used at the time of the incident.
2. Determine to whom the product belongs and the age of the owner.
3. Describe how the child obtained the product. Was it given to the child by an adult, by another child or was it simply within reach of the child?

D. Description of the Victim

1. What was the age of this child (in years and months) at the time of the incident?
2. What were the height and weight of the child at the time of the incident?
3. What is the sex of the child?
4. What developmental abilities did the child display? Could the child walk, roll over, sit up, pull up to a standing position, stand alone, etc.?
5. Please describe injury diagnosis associated with the incident, including the part of the mouth, throat/airway or gastrointestinal tract involved. If the incident resulted in a fatality, please determine the official cause of death.
6. Describe the medical treatment (e.g., tests, x-rays, observation, oral or topical medication, etc.) received by the injured child and include the long-term prognosis. Specify whether the treatment was at home, in a doctor's office/clinic or at a hospital. If the child was hospitalized, document the length of the stay.

E. Description of Environment

1. Determine if the child was playing alone or with other children.
2. Were any adults nearby? Were they actively watching the child or were they distracted?

III. Instructions for Photographing and/or Diagramming the Product

Photograph and/or diagram the entire product and obtain relevant measurements of product components related to the incident. Components of the product that were specifically involved in the incident should be photographed in detail, including close-ups. Try to provide visual cues to indicate the size of items in the pictures. For instance, the object can be placed next to a ruler to help document the measurement. A coin placed next to the object is also a good visual cue.

If the incident product or broken part fits entirely within the Small Parts Test Cylinder, if possible, document it with several photographs of the object resting in the cylinder. The same can be done with a small ball passing through the test template for small balls.

Product labeling should also be photographed or diagrammed, indicating the position of the labeling on the product and the content of the labeling.

IV. Instructions for Obtaining Documents Related to the Investigation

If the incident resulted in a death or serious injury, obtain copies of any official reports such as, police, EMS or coroner's/medical examiner's reports that are available. Also obtain copies of any assembly instructions and owner's or safety manuals that came with the product.

