

§ 1117.1

16 CFR Ch. II (1–1–05 Edition)

§ 1117.1 Purpose.

The purpose of this part is to set forth the Commission's interpretative regulations for reporting of choking incidents required by the Child Safety Protection Act. The statute requires that each manufacturer, distributor, retailer, and importer of a marble, small ball, or latex balloon, or a toy or a game that contains a marble, small ball, latex balloon, or other small part, shall report to the Commission any information obtained by such manufacturer, distributor, retailer, or importer which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on such a marble, small ball, or latex balloon or on a marble, small ball, latex balloon, or other small part contained in such toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional.

§ 1117.2 Definitions.

(a) *Small part* means any part, component, or piece of a toy or game, which, when tested in accordance with the procedures in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR 1501.

(b) *Small ball* means any ball that under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (4.445 cm) in a rigid template .25 inches (6 mm.) thick. For purposes of this designation, the term "ball" includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, or bounced, and is either not permanently attached to another toy or article, or is attached to such a toy or article by means of a string, elastic cord, or similar tether. The term *ball* includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(c) *Choked* means suffered an obstruction of the airways.

(d) A *latex balloon* is a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children's toys that are used in aquatic activities, such as rafts, water wings, life rings, etc.

(e) A *marble* is a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children's games, generally as a playing piece or marker.

(f) *Serious injury* includes not only the concept of "grievous bodily injury" defined in the Commission's rule for Substantial Hazard Reports at 16 CFR 1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred.

(g) *Subject firm* means any manufacturer, distributor, retailer or importer of marbles, small balls, latex balloons, or a toy or game that contains a marble, small ball, latex balloon, or other small part.

(h) *Toy or game* includes any toy or game, including those exempt under 16 CFR 1501.3 from the small parts banning provisions of 16 CFR 1500.18(a)(9).

[60 FR 10493, Feb. 27, 1995, as amended at 60 FR 41801, Aug. 14, 1995]

§ 1117.3 Reportable information.

A subject firm shall report any information it obtains which reasonably supports the conclusion that a reportable incident occurred. Generally, firms should report any information provided to the company, orally or in writing, which states that a child choked on a marble, small ball, latex balloon, or on a marble, small ball, latex balloon or other small part contained in a toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional. Subject firms must not wait until they have investigated the incident or conclusively resolved whether the information is accurate or whether their product was involved in the incident. Firms shall not

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wait to determine conclusively the cause of the death, injury, cessation of breathing or necessity for treatment. An allegation that such a result followed the choking incident is sufficient to require a report.

§ 1117.4 Time for filing a report.

(a) A subject firm must report within 24 hours of obtaining information which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on a marble, small ball, or latex balloon or on a marble, small ball, latex balloon, or other small part contained in a toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional. Section 1117.5 of this part sets forth the information that must be reported.

(b) The Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. Under ordinary circumstances, 5 days shall be the maximum reasonable time for information to reach such an employee, the Chief Executive Officer or the official or employee responsible for complying with the reporting requirements of section 102 of the Child Safety Protection Act.

§ 1117.5 Information that must be reported and to whom.

(a) Reports shall be directed to the Division of Corrective Actions, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20815 (Mailing Address: Washington, D.C. 20207) (Phone: 301-504-0608, facsimile: 301-504-0359).

(b) Subject firms must report as much of the following information as is known when the report is made:

(1) The name, address, and title of the person submitting the report to the Commission,

(2) The name and address of the subject firm,

(3) The name and address of the child who choked and the person(s) who noti-

fied the subject firm of the choking incident,

(4) Identification of the product involved including the date(s) of distribution, model or style number, a description of the product (including any labeling and warnings), a description of the marble, small ball, latex balloon or other small part involved, and pictures or sample if available,

(5) A description of the choking incident and any injuries that resulted or medical treatment that was necessary,

(6) Copies of any information obtained about the choking incident,

(7) Any information about changes made to the product or its labeling or warnings with the intention of avoiding such choking incidents, including, but not limited to, the date(s) of the change and its implementation, and a description of the change. Copies of any engineering drawings or product and label samples that depict the change(s).

(8) The details of any public notice or other corrective action planned by the firm,

(9) Such other information as appropriate.

(c) Retailers or distributors should supply as much of the information required in paragraph (b) of this section as is available to them but are not required to obtain information about product design changes or recall activities from the product manufacturer.

(d) Within ten days of their initial report, subject firms must supplement their reports to supply any of the information required by paragraph (b) of this section that was not available at the time of the initial report.

§ 1117.6 Relation to section 15(b) of the CPSA.

Section 15(b) of the CPSA requires subject firms to report when they obtain information which reasonably supports the conclusion that products they distributed in commerce fail to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, contain a defect which could create a substantial product hazard, or create an unreasonable risk of serious injury or death. The