Designation: F 1926~~17~~ – 99~~00~~

Standard ~~Test Method~~ Consumer Safety Performance Specification for ~~Evaluation of the Environmental Stability of Calcium Phosphate Coatings~~ Infant Bedding and Related Accessories[1]

This standard is issued under the fixed designation ~~F 1926;~~ F 1917; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

This consumer safety performance specification addresses incidents associated with infant bedding and related accessories that were reported to the U.S. Consumer Product Safety Commission (CPSC). These incident reports involved entanglement or strangulation on decorative ribbons, bumper guard ties, wall hangings, fitted sheets, and threads resulting from unraveled seams. It also addresses potential suffocation on decorative pillows placed in cribs.

In response to the incident data developed by the CPSC, this consumer safety performance specification attempts to minimize the problems listed above. This effort is accomplished through the establishment of performance requirements and warning labels for infant bedding and accessories. This specification cannot prevent incidents that occur as the result of unforeseeable abuse and misuse.

NOTE—This consumer safety performance specification is not intended to address incidents and injuries resulting from the interaction of other persons with children using these products or the incidents resulting from unforeseeable abuse and misuse.

This consumer safety performance specification has been written based on current state-of-the-art softgoods technology. This consumer safety performance specification will be updated whenever substantive information becomes available.

1. Scope

1.1 This consumer safety specification establishes safety performance requirements, test ~~method covers calcium phosphate coatings intended~~ methods, and requirements for ~~use in surgical implant applications.~~

~~1.2 Aspects of~~ labeling to minimize the ~~biological response~~ identified hazards to ~~calcium phosphate materials in soft tissue~~

[1] This ~~test method~~ consumer safety performance specification is under the jurisdiction of ASTM Committee ~~F04~~ F-15 on ~~Medical~~ Consumer Products and ~~Surgical Materials and Devices and~~ is the direct responsibility of Subcommittee ~~F04.13~~ F15.19 on ~~Ceramic Materials~~ . Infant Bedding.

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children presented by infant bedding and bone have been reported from laboratory studies and clinical use **(1-10)**.[2]

1.3 The requirements related accessories as identified in the introduction.

1.2 No infant bedding or related accessory produced after the approval date of the consumer safety performance specification shall indicate, either by label or other means, compliance with this specification apply unless it conforms to calcium phosphate coatings such as calcium hydroxyapatite (see Specification F 1185), beta-tricalcium phosphate (see Specification F 1088), all applicable requirements contained herein.

1.3 The inspection and biphasic mixtures thereof with or without intentional addition of other minor components (< 10 %).

1.4 The coating(s) test procedures contained herein shall be representative used to determine the conformance of products to the requirements of this consumer safety perfodurmanced specification. The relevant tests for sale. It shall have been produced and processed under standard manufacturing conditions.

1.5 The coatings an infant bedding product or related accessory can be done in any order, except where specified. Each test may be conducted on a different sample, unless otherwise specified. The tests can be considered as qualification tests and not necessarily as quality control tests. These tests shall also be conducted when there is a design or material change in the infant bedding or related accessory item. Each producer or distributor who represents any products as conforming to porous, nonporous, textured, this specification may utilize statistically based sampling plans that are appropriate and other implantable topographical substrate forms representative shall keep such essential records as are necessary to document that all of the end-use product.

1.6 The calcium phosphate coating may constitute requirements of this specification have been met. Any test methods that are made mandatory by the only coating on a substrate CPSC, or any applicable governmental agencies, shall supersede any applicable test methods in this specification.

1.4 These tests are intended to simulate normal use conditions, so as to ensure that hazards are not generated through normal use. The tests shall be one of carried out in a multiple coated device.

1.7 This test method is limited normal use environment. For example, bumper guards should be secured in a crib as a customer would in actual end use situations. Ties should be tied and untied. While no specific requirements are defined here, the evaluator shall perform enough testing to simulate normal use during the laboratory evaluation estimated lifetime of the dissolution rate of a calcium phosphate coatings. No correlation of the results product. The infant bedding product or related accessory shall be inspected after such tests and shall be evaluated according to in vivo performance is implied.

1.8 The the relevant requirements listed within this specification.

1.5 The values stated in both inch-pound and SI units are to be regarded separately as the standard. The values given in parentheses are for information only.

1.96 The following safety hazards caveat pertains only to the test method portion, Section 7, of this consumer safety performance specification: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

~~E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[2]~~
F 1088169 Specification for ~~Beta Tricalcium Phosphate~~ Full-Size Baby Crib[3]
2.2 *Federal Standards:*[2]

[2] ~~*Annual Book*~~*Code of ~~ASTM Standards~~ Federal Regulations*, ~~Vol 14.02.~~ available from U.S. Government Printing Office, Washington, DC 20402.
[3] ~~The boldface numbers given in parentheses refer to a list~~
[3] *Annual Book of ~~references at the end of the text.~~ ASTM Standards*, Vol 15.07.

16 CFR Part 1508 Full-Size Baby Crib
16 CFR Part 1509 Non-Full-Size Baby Crib
16 CFR Part 1500.50–1500.53 Test Methods for ~~Surgical Implantation[4]~~
~~F 1185 Specification~~ Simulating Use and Abuse of Toys and Other Articles Intended for ~~Ceramic Hydroxylapatite for Surgical Implantation[4]~~ Use by Children
2.3 *ANSI Standard:*[4]

~~*Annual Book of ASTM*~~
[4] Available from American National Standards~~, Vol 13.01.~~ Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

ANSI Z535.4 Product Safety Signs and Labels

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 ~~*calcium phosphate*—any one of~~bumper ties, *n*—flexible ribbons, strings, and ties attached to a ~~number~~ bumper for the purpose of ~~inorganic chemical compounds containing calcium and phosphate ions as its principal constituents.~~ attaching to a crib.

3.1.2 ~~*coating*—a layer of material mechanically or chemically adhering to~~infant bedding and related accessories, *n*—includes the ~~surface of~~ following items intended for use in a ~~s~~ nursery: fitted sheets, blankets, dust ruffles, covers and drapes for canopies, pillows, mattress covers, diaper stackers, fabric wall hangings, bumper guards, headboard bumper guards, and comforters.

4. ~~Dissolution Media~~

~~4.1 Any water used for preparing reagents or dissolution media shall be deionized or distilled~~General Requirements

4.1 *Ribbons, Strings, and ~~have less then 0.1 ppm each of residual Ca^{++}, phosphorus~~, Ties*—Ribbons, strings, and ~~total solids.~~ ties shall comply with the length requirements in 6.1.

4.2 ~~*Unbuffered Water Media*—Deionized or distilled water containing 8×10^{-5} M NaCl, 8×10^{-5} M $CaCl_2$, and 5×10^{-5} M $K_3(PO_4)$.~~

~~4.3 *pH 5.5 MES Buffer Media*—1.0 M MES, [2-(N-morphplino)ethanesulfonic acid] having a pH~~Threads—Use of ~~5.5 at 37 °C ± 0.5 °C and containing 8×10^{-5} M NaCl, 8×10^{-5} M $CaCl_2$, and 5×10^{-5} M $K_3(PO_4)$.~~

~~4.3.1 A buffer concentration of 1.0 M will usually provide sufficient buffer capacity to keep~~ monofilament thread in the ~~solution within ± 0.1 pH units~~ construction of ~~the initial value. If this~~ infant bedding and related accessories is ~~not the case, the buffer capacity should~~ prohibited.

4.3 Bumper guards shall be ~~adjusted accordingly.~~

~~4.3.2 The pH must be adjusted to 5.5 at 37 ± 0.5° C.~~

~~4.4 *pH 7.4 TRIS Buffer Media*—1.0 M TRIS, [Tris(hydroxymethyl)aminomethane] having a pH~~ capable of ~~7.4~~ being secured at ~~37 °C ± 0.5 °C~~ or near all corners and ~~containing 8×10^{-5} M NaCl, 8×10^{-5} M $CaCl_2$, and 5×10^{-5} M $K_3(PO_4)$.~~

~~4.4.1 A buffer concentration~~ at the midpoints of ~~1.0 M will usually provide sufficient buffer capacity to keep~~ the ~~solution within ± 0.1 pH units~~ long sides of the ~~initial value. If this is not the case, the buffer capacity should~~ crib. Bumper guards intended for circular cribs shall be ~~adjusted accordingly.~~

~~4.4.2 The pH must be adjusted to 7.4~~ capable of being secured at ~~37 ± 0.5° C.~~ intervals not exceeding 26 in. (660 mm).

5. ~~Analytical Parameters~~

~~5.1 The following procedure should~~Performance Requirements

5.1 *Normal Use Testing*—Simulation of normal use conditions are described in 1.4.

5.2 *Unsupported Vinyls*—Unsupported vinyl shall be ~~performed with each~~ 0.012-in. (0.30-mm) nominal thickness or thicker gage. No minimum thickness is specified for supported vinyl. Any infant bedding or related accessory item composed entirely or in part of ~~the media listed:~~

~~5.1.1 The dissolution rate~~ unsupported vinyl shall be ~~measured under~~ tested in accordance with 6.2.

5.3 If during the ~~conditions~~ course of conducting tests in accordance with this specification, a ~~constant ratio of initial coating mass (mg) to total dissolution media volume (mL), and initial pH. The milligrams of coating to millilitres of dissolution media ratio~~ test sample sustains any permanent deformation or damage, an additional test sample shall ~~typically~~ be ~~between 1.0 and 0.1.~~

~~5.1.2 The pH of~~ used for the ~~dissolution media (±0.01 pH units), dissolved Ca++ concentration (± 1 ppm), and dissolved phosphorus (as P) concentration (± 1 ppm) shall be measured as soon as practical after the start~~ remainder of the ~~experiment and at appropriate time intervals thereafter to allow the determination of their changes with time.~~ tests.

6. ~~Analytical Procedures~~

~~6.1 Make pH measurements with an appropriately calibrated pH meter~~Test Methods

6.1 *Ribbons, Strings, and ~~probe~~.*

~~6.2 Measure Ca++ concentrations potentiometrically, colorimetrically, by atomic absorption (AA)~~ Ties—Flexible ribbons, strings, or ~~inductively coupled plasma (ICP) spectroscopy,~~ ties attached to any infant bedding or ~~by inductively coupled plasma mass spectroscopy (ICP/MS).~~

~~6.3 Total phosphorus concentrations~~ related accessory item, with the exception of ties on bumper guards and headboard bumper guards, shall ~~be~~ not exceed 7 in. (180 mm) when measured ~~by an appropriate method (for example, inductively coupled plasma (ICP) spectroscopy, inductively coupled plasma mass spectroscopy (ICP/MS),~~ to the maximum length under a force of 5 lbf (22 N). Ribbons, strings, and ~~phosphomolybdate complex method)~~ **~~(11)~~**.

~~6.4 It~~ ties on bumper guards and headboard bumper guards, shall not exceed 9.0 in. (230 mm). If ribbons, strings, or ties can tangle to form a loop, then the perimeter of the loop shall not exceed 14 in. (360 mm) under a force of 5 lbf (22 N).

6.2 *Rationale*—The neck circumference of a 5th percentile 0-3 month old infant is ~~recommended that an appropriate bacteriostat (for example, 0.1 v/v % Hibiclens~~ 7.2 in. (183 mm), as stated in the University of Michigan final report to the CPSC dated January 1986. Based on this measurement, the Infant Bedding and Related Accessories Subcommittee has mandated the maximum

allowable length of flexible ribbons, strings, or ~~0.1 w/v % sodium azide) be added~~ ties attached to any infant bedding or related accessory item, with the ~~dissolution media prior~~ exception of bumper guards and headboard bumper guards, to be 7.0 in. (180 mm). The maximum allowable length of flexible ribbons, strings, or ties, or a combination thereof, attached to bumper guards and headboard bumper guards for the ~~start~~ purpose of securing it to a crib rail is 9 in. (230 mm). Flexible ribbons, strings, or ties of 9 in. on bumper guards and headboard bumper guards will allow the product to be sufficiently secured to the crib rails by the parent or care provider. On some cribs, shorter ribbons, strings, or ties may not allow the parent or care provider to be able to sufficiently secure the bumper guard or headboard bumper guard, or both, to the crib rail.

6.3 *Vinyl Thickness Measurement*—Using a paper micrometer, measure the thickness at four locations, one at each end and two in a location near the middle.

7. ~~Dissolution Apparatus~~

~~7.1 The dissolution vessel (see Fig. 1)~~Product/Package Marking

7.1 Each product shall ~~be of such design to easily accommodate~~ have a permanent conspicuous label that identifies the ~~test specimen (see Fig. 2)~~ name and ~~stirrer assembly (see Fig. 3), the specific ion-electrode assembly,~~ address (city, state, and ~~the pH electrode assembly. It shall also be capable~~ zip code) of ~~being isolated from~~ the ~~atmosphere by an oxygen and carbon dioxide free inert gas purge.~~

~~7.2 It shall be of appropriate dimensions to contain the required volume of dissolution media at~~ manufacturer, distributor, or seller, or a ~~level to facilitate sufficient stirring action from~~ label that identifies the ~~stirrer blades.~~

~~7.3 The stirrer assembly shall consist of a stirrer motor capable of maintaining a constant stirring rate of at least 80 rpm. The distal end of the stirrer shaft shall be threaded to mate with the male threaded portion of the test specimen and also allow for the placement of the stirrer propeller~~ Registered Identification Number (RN) or Wool Products Labeling Act Number (WPL).[5] ~~immediately above the test specimen (see Fig. 3).~~

~~7.3.1 *Stirrer Propeller*[5]—(2.5 in. (63.50 mm) diameter, 0.875 in. (22.22 mm) blades, three blades, 45° pitch, stainless steel).~~

~~7.3.2 A different type of stirrer design and stirring rate may be used provided equivalence in experimental results can be demonstrated. Any modification must be reported in 10.1.1.~~

~~7.4 The dissolution vessel~~

7.2 *Product Warning Labels*—A permanent conspicuous label(s) shall be ~~thermostatically controlled at 37 ± 0.5 °C.~~

~~7.5 The dissolution apparatus may include various data recording and storage devices, strip chart recorders, computers, etc., to facilitate continuous monitoring throughout the duration of the experiment.~~

~~8. Preparation of Test Specimens~~

~~8.1 The standard test specimen for coating evaluation is defined in Fig. 2.~~

~~8.2 The test specimen~~ on each headboard/bumper set, bumper, wall hanging, decorator pillow (label shall be ~~manufactured from the same materials and processes as substrates produced for sale.~~

~~8.3 The test specimen shall have the upper shank threaded so as to mate with the stirrer shaft described in Fig. 3.~~

~~8.4 By appropriate masking, or other techniques, the coating shall be~~ applied ~~only~~ to ~~the central 0.5 ± 0.005 in. of the test specimen.~~

~~8.5 The coating shall be applied to the test specimen,~~ insert and ~~receive all processing steps as the actual product.~~

~~9. Procedure for Monitoring Changes in pH, Calcium~~, cover, if cover is removable), diaper stacker, and ~~Phosphorus Concentrations~~

~~9.1 Prepare the test specimen as described in Section 8.~~

~~9.2 Procure the appropriate volume of dissolution media needed for the experiment and equilibrate at 37 ± 0.5 °C.~~

~~9.3 Calibrate the pH probe, the ion-selective probes, and any other analytical instrumentation to be used immediately before starting the experiment as recommended by the manufacturers.~~

~~9.4 Adjust the stirrer-test specimen assembly to at least 80 rpm.~~

~~9.5 Assemble the dissolution apparatus (see Fig. 1).~~ fitted sheet. The ~~dissolution media, all calibrated sensing electrodes, and the stirrer should~~ label(s) shall be in ~~place and operating. However, do not~~ the ANSI format, which would include a delineated signal word panel containing the ~~test specimen. Then equilibrate this assembly at 37 ± 0.5 °C.~~

~~9.6 Set~~ safety alert symbol before the ~~experiment timing device to zero.~~

~~9.7 When ready to begin the experiment, add the test specimen to the stirrer~~ signal word and ~~dissolution vessel. Start the timer and stirrer, and make any necessary adjustments to the equipment.~~

~~9.8 As soon as practical after the introduction of the test specimen to the dissolution media, record the initial pH and the dissolved Ca++ and phosphorus concentrations.~~

~~[5] The sole source of supply of the apparatus known to the committee at this time~~

[5] RN/WPL is ~~VWR Scientific, Item 58957-116, P.O. Box 66929, O'Hare AMF, Chicago, IL 60666. If you are aware of alternative suppliers, please provide this information to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend.~~ Registration Number/Wool Products Labeling Act under the Federal Trade Commission.

9.9 Repeat the measurement of the pH, dissolved Ca^{++}, and dissolved phosphorus concentrations at appropriate time intervals to define their dissolution rate curves.

9.9.1 A typical initial sampling rate a contrasting background. The label(s) shall be at least every 15 min for begin with the first 2 h. More frequent sampling may be necessary for some materials in order to accurately determine word "WARNING," the slope letters of the initial linear portion of the dissolution curve.

9.9.2 A typical final sampling rate which shall be at least every hour for the last 8 h of the experiment.

9.9.3 The total volume of all aliquots taken during the course of the experiment shall not comprise more be less than 5 % of the initial volume.

9.9.4 The duration of a typical experiment 0.2 in. (5 mm) high. The remaining text shall be at least 48 h. Longer times may be needed in letters not less than 0.1 in. (2.5 mm) high.

7.2.1 The warning label(s) for some materials if their measured pH a headboard/bumper set or concentrations of dissolved Ca^{++} bumper shall read as follows:

or phosphorous continue to change by more than 10 % over a 3 h period.

⚠ **WARNING**

10. Report

++ and phosphorus at the end of the experiment.

10.1.5 Plots of the pH and concentrations of total dissolved Ca^{++} and phosphorus versus time data be

To prevent entanglement or strangulation, position ties to outside of crib and be

10.1 Report the following results for each of the media systems used:

10.1.1 All procedural details that differ from those described in this test method.

10.1.2 The identity of the dissolution media, the substrate material, and the mass-to-volume ratio used.

10.1.3 The pH and concentrations of dissolved Ca++ and phosphorus recorded at the start of the experiment (see 9.8).

7.2.2 The warning label for the duration of the experiment.

10.1.6 The calculated initial dissolution rates (R_i) a fabric wall hanging shall read as follows:

10.1.6.1 Calcium phosphate coatings typically display two quasi-linear regions in their dissolution rate curves. The initial dissolution rate is usually distinguished from the final dissolution rate by a significantly higher rate of increase in the concentrations of dissolved Ca^{++} and phosphorus. The final dissolution rate occurs later in the experiment.

10.1.6.2 The initial dissolution rate (R_i) of a coating is expressed in terms of the initial changes in total Ca^{++} or phosphorus concentrations with time:

$(R_i)_{Ca}$ = Initial slope of the Ca^{++} concentration versus time curve expressed in terms of the total milligrams of Ca^{++} dissolved per milligram of coating per millilitre of media per hour.

⚠ **WARNING** = Initial slope of the Ca^{++} concentration versus time curve expressed in terms of the total milligrams of Ca^{++} dissolved per milligram of coating per millilitre of media per hour.

$(R_i)_P$ = Initial slope of the phosphorus concentration versus time curve expressed in terms of the total milligrams of phosphorus dissolved per milligram of coating per millilitre of media per hour.

To prevent entanglement or strangulation, do not place within a child's reach (including a standing child).

Not intended as a toy.

10.1.7 The calculated final dissolution rates (R_f)

7.2.3 The warning label for a pillow shall read as follows:

10.1.7.1 The final dissolution rate of a coating expressed in terms of the final changes in Ca^{++} and phosphorus concentrations:

$(R_f)_{Ca}$ = Final slope of the Ca^{++} concentration versus time curve expressed in terms of the total milligrams of Ca^{++} dissolved per milligram of coating per millilitre of media per hour.

⚠ **WARNING** = Final slope of the Ca^{++} concentration versus time curve expressed in terms of the total milligrams of Ca^{++} dissolved per milligram of coating per millilitre of media per hour.

$(R_f)_P$ = Final slope of the phosphorus concentration versus time curve expressed in terms of the total milligrams of phosphorus dissolved per milligram of coating per millilitre of media per hour.

a crib or near an area where an infant may sleep.

To prevent suffocation, do not put any pillow in terms of the total milligrams of phosphorus dissolved per milligram of coating per millilitre of media per hour.

a crib or near an area where an infant may sleep.

Pillows are a decorator item only and are not intended for an infant's use.

11. Precision

7.2.4 The warning label for a diaper stacker shall read as follows:

⚠ **WARNING**

Prevent strangulation or entanglement.
Never place on or attach to a crib.

7.2.5 The warning label for a fitted sheet shall read as follows:

⚠ **WARNING**

Prevent possible strangulation or entanglement.
Never use crib sheet unless it fits securely on crib mattress.

7.3 *Package Warning Statement*—A warning statement shall be on each fitted sheet retail package. The warning statement shall be in the ANSI format as stated in 7.2.

7.3.1 The warning statement for a fitted sheet retail package shall read as follows:

⚠ **WARNING**
Prevent possible suffocation or entanglement. Never use crib sheet unless it fits securely on crib mattress.

7.4 *Rationale*—Warning labels for headboard/bumpers, wall hangings, pillows, fitted sheets, and ~~Bias~~

~~11.1 Precision and bias~~ diaper stackers have been created to warn the consumer of ~~this test method will be determined after interlaboratory tests~~ the hazard that can exist if the product is not used as intended. In most cases, the hazards identified in each warning label are ~~carried out and~~ substantiated by data from in-depth investigations of accidents or fatalities, or both, involving the ~~results tabulated. The interlaboratory tests will be carried out following Practice E 691.~~

~~12.~~ use of the aforementioned products. Based on these facts, the word "prevent," instead of "possible," is used in order to stress the importance of compliance with the stated warning. In addition, the word "Warning" is used as the signal word for these warning labels as ANSI Z535.4 states that "Warning" indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

8. Keywords

~~12.1 calcium-phosphate ceramic; coating; dissolution rate; environmental stability~~

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8.1 bumper guard; diaper stacker; fitted sheet; infant bedding; wall hanging ~~*Trans. Soc. Biomaterials*, 1986.~~

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