

FFF-D-191D
 April 16, 1975
 SUPERSEDING
 FFF-D-191C
 April 17, 1972

FEDERAL SPECIFICATION

DENTIFRICE

This specification was approved by the Commissioner,
 Federal Supply Service, General Services Administration,
 for the use of all Federal agencies.

1. SCOPE AND CLASSIFICATION

1.1 Scope. This specification covers toothpaste and tooth powder (see 6.1).

1.2 Classification. Dentifrice shall be of the following types, classes, and sizes as specified (see 6.2 and 6.3).

Type I - Toothpaste
 Class 1 - Regular.
 Class 2 - With fluoride.
 Sizes 1.5 ounces avoirdupois (oz av)
 4.0 oz av
 Type II - Tooth powder.

2. APPLICABLE DOCUMENTS

2.1 The following documents, of the issues in effect on date of invitation for bids or request for proposal, form a part of this specification to the extent specified herein.

Federal Specifications:

PPP-B-636 - Boxes, Shipping, Fiberboard.
 PPP-C-186 - Containers Packaging and Packing for Drugs, Chemicals and
 Pharmaceuticals.

Federal Standard

Fed. Std. No. 123 - Marking for Domestic Shipment (Civil Agencies).

(Activities outside the Federal Government may obtain copies of Federal Specifications, Standards, and Handbooks as outlined under General Information in the Index of Federal Specifications and Standards at the prices indicated in the Index. The Index, which includes cumulative monthly supplements as issued, is for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(Single copies of this specification and other Federal Specifications required by activities outside the Federal Government for bidding purposes are available without charge from Business Service Centers at the General Services Administration Regional Offices in Boston, New York, Washington, DC, Atlanta, Chicago, Kansas City, MO, Fort Worth, Denver, San Francisco, Los Angeles, and Seattle, WA.

(Federal Government activities may obtain copies of Federal Specifications, Standards, and Handbooks and the Index of Federal Specifications and Standards from established distribution points in their agencies.)

Military Specifications:

MIL-L-10547 - Liners, Case, and Sheets, Overwrap; Water-Vaporproof or Water-proof Flexible.

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Military Standards:

MIL-STD-105 - Sampling Procedures and Tables for Inspection by Attributes.
 MIL-STD-129 - Marking for Shipment and Storage.

(Copies of Military Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer.)

Laws and regulations

21 CFR 1 - Federal Food, Drug and Cosmetic Act.

(The Code of Federal Regulations (CFR) and the Federal Register (FR) are for sale on a subscription basis by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. When indicated, reprints of certain regulations may be obtained from the Federal agency responsible for issuance thereof.)

2.2 Other publications. The following documents form a part of this specification to the extent specified herein. Unless a specific issue is identified, the issue in effect on date of invitation for bids or request for proposal shall apply.

American Pharmaceutical Association.

National Formulary (NF).

(Application for copies should be addressed to the Mack Printing Company, Easton, PA 18042).

U.S. Pharmacopeial Convention, Inc.

Pharmacopeia of the United States (USP).

(Application for copies should be addressed to the Mack Printing Company, Easton, PA 18042.)

American Dental Association:

Accepted Dental Therapeutics.

(Application for copies should be addressed to the American Dental Association, 211 E. Chicago Avenue, Chicago, IL 60611.)

American Society for Testing and Materials (ASTM) Standard

E 70 - pH of Aqueous Solutions With the Glass Electrode.

(Application for copies should be addressed to the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.)

National Motor Freight Traffic Association, Inc., Agent:

National Motor Freight Classification.

(Application for copies should be addressed to the American Trucking Associations, Inc., Tariff Order Section, 1616 P Street, N.W., Washington, DC 20036.)

Uniform Classification Committee, Agent:

Uniform Freight Classification.

(Application for copies should be addressed to the Uniform Classification Committee, Room 1106, 222 South Riverside Plaza, Chicago, IL 60606.)

3. REQUIREMENTS

3.1 Materials. All materials used in making the dentifrice shall be USP, NF or pharmaceutical grade and quality.

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3.2 Formulation. The dentifrice provided under this specification shall have the same formulation as a dentifrice sold commercially by the manufacturer. The dentifrice shall be manufactured in the same way as the commercially sold dentifrice using materials of the same or higher quality.

3.2.1 Type I, class 2. Type I, class 2 dentifrice shall contain a fluoride compound and shall have a formulation accepted by the Council of Dental Therapeutics of the American Dental Association as an effective decay-preventing dentifrice. For each lot, the manufacturer shall provide test results verifying presence and concentration of fluoride in the toothpaste.

3.3 Flavor. The flavor of the dentifrice shall be distinct and pleasant, or as specified in the applicable procurement documents.

3.4 Color. The color of the dentifrice shall be white, a light pastel shade, or as specified in the applicable procurement documents. Type I dentifrice may be translucent.

3.5 pH. The pH of the dentifrice shall be not less than 4.5 and not greater than 8.9 when tested as specified in 4.3.1.

3.6 Abrasiveness. The dentifrice shall not be excessively abrasive when tested as specified in 4.3.2.

3.7 Irritation. The dentifrice shall not irritate the mucous membrane of the mouth.

3.8 Safety. When used in the normal manner, the dentifrice shall not cause injury to the teeth, gums, mucous membrane of the mouth, or the body in general.

3.9 Federal Food, Drug and Cosmetic Act. Dentifrice shall conform in all respects to the provisions of the Federal Food, Drug and Cosmetic Act.

3.10 Unit container.

3.10.1 Type I toothpaste. Not less than the specified weight of type I toothpaste shall be packaged in collapsible tubes conforming to PPP-C-186, group B, class 1 or 2, type A, closure A, B, E, or H.

3.10.2 Type II tooth powder. Not less than 4 oz av of type II tooth powder shall be packaged in a metal or plastic container. The container shall have a reclosable dispensing feature and shall not leak when closed.

3.11 Labeling, type I, class 2. The name of the fluoride compound that the type I, class 2 toothpaste contains shall be marked on the tube.

3.12 Consistency. Dentifrice shall be a homogeneous mixture and shall be free of lumps or particles which are palpable in the mouth as separate or discrete particles.

3.12.1 Type I dentifrice.

3.12.1.1 Viscosity. Type I toothpaste shall have a viscosity between 130,000 and 360,000 centipoise.

3.12.1.2 Ease of extrusion. It shall be possible to extrude not less than ninety-five percent of the toothpaste from the tube in a continuous mass at a temperature of 10°C without the application of excessive force which would cause injury to the tube.

3.12.1.3 Cohesiveness. A 10 millimeter ribbon of toothpaste, extruded from a tube held vertically with the neck down at a temperature of 20°C, shall remain attached to the tube for at least 15 seconds.

3.12.2 Type II dentifrice. Type II tooth powder shall be free flowing and without lumps.

3.13 Stability of type I dentifrice. Type I toothpaste shall not segregate, ferment, or deteriorate when cooled to a temperature of -15°C for one hour or when heated to a temperature of 45°C for 72 hours. The filled tube and lining (if present) shall not be corroded or otherwise injured by the toothpaste or the temperature itself when heated to 45°C for a period of 72 hours.

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3.14 Certificate of compliance. The manufacturer shall certify that his product meets the requirements of paragraphs 3.1, 3.2, 3 2.1 (for type I, class 2 only), 3.8, and 3.9.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or order, the supplier may use his own or any other facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure that supplies and services conform to prescribed requirements.

4.1.1 Certificates of compliance Where certificates of compliance are submitted, the Government reserves the right to check test such items to determine the validity of the certification.

4.2 Quality conformance inspection.

4.2.1 Inspection of the end item. In accordance with 4.1 above, components and materials shall be inspected and tested in accordance with all the requirements of referenced specifications, drawings and standards unless otherwise excluded, amended, modified or qualified in this specification or applicable purchase documents. Where failure of any requirement is reported, report description of failure or numerical point of failure, as applicable.

4.2.2 Examination of preparation for delivery Packaging, packing, and marking shall be examined for compliance with the requirements of section 5. Defects shall be scored in accordance with table I. The sample unit shall be one shipping container fully prepared for delivery. The lot size shall be the number of shipping containers offered for inspection at one time. Sampling and acceptance shall be in accordance with MIL-STD-105, inspection level S-2, Acceptable Quality Level (AQL) 4.0 percent defective.

TABLE I. Examination of preparation for delivery

| Examine | Defect |
|-------------|--|
| Containers | Not as specified |
| Contents | Not as specified. |
| Markings | Omitted; incorrect; illegible; improper size, location, sequence or method of application. |
| Materials | Component missing or damaged |
| Workmanship | Bulging or distortion of containers Cushioning inadequate, improper, or missing. |

4.2.2.1 Examination of closure, waterproofing and banding. When shipping containers are required to comply with PPP-B-636, examination for defects in closure, waterproofing and banding shall be in accordance with the appendix of that specification.

4.2.3 Examination of the end item. The end item shall be examined for defects as listed in table II. The sample unit shall be one tube of type I dentifrice or one container of type II dentifrice. The lot shall consist of all dentifrice of the same type, grade and size manufactured during one 24 hour period, under the same processing conditions, using the same raw material lots and offered for delivery at one time. Sampling and acceptance shall be in accordance with MIL-STD-105, inspection level S-4, AQL of 4.0 percent defective.

TABLE II. Examination of the end item

| Examine | Defect |
|------------|--|
| Containers | Not as specified; leaking, bulging, distorted, broken. |
| Dentifrice | |
| Type I | Lumps or particles. |
| Type II | Not free flowing, lumps or particles. |
| Color | Not as specified. |
| Flavor | Not as specified. |
| Net weight | Less than specified. |

4.2.4 Testing of the end item. The end item shall be tested as specified in table III. The sample unit shall be four tubes of type I toothpaste or one container of type II tooth powder. The lot shall consist of all dentifrice of the same type, grade and size manufactured during one 24 hour period, under the same processing conditions, using the same raw material lots and offered for inspection at one time. Sampling shall be in accordance with MIL-STD-105, inspection level S-1. Failure of any sample unit to meet any of the requirements of table III shall be cause for rejection of the lot.

TABLE III. Instructions for testing the end item

| Characteristic | Specification reference | | Results reported | |
|-------------------|-------------------------|-------------|------------------|------------------------|
| | Requirement | Test Method | Pass/Fail | Numerically to nearest |
| pH | 3.5 | 4.3.1 | | 0.05 unit |
| Abrasiveness | 3.6 | 4.3.2 | X | |
| Irritation | 3.7 | 4.3.3 | X | |
| Viscosity | 3.12.1.1 | 4.3.4 | | 1000 centipoise |
| Ease of extrusion | 3.12.1.2 | 4.3.5 | X | |
| Cohesiveness | 3.12.1.3 | 4.3.6 | X | |
| Stability | 3.13 | 4.3.7 | X | |
| Tube inertness | 3.13 | 4.3.8 | X | |

4.3 Test methods

4.3.1 pH. Dissolve one part by weight of dentifrice in four parts by weight of freshly distilled water. Determine the pH by ASTM Standard E 70

4.3.2 Abrasiveness. Place a portion of the toothpaste or a paste made of the tooth powder and distilled water on a clean, new glass microscope slide. Rub the glass slide covered with paste with a metal instrument having the hardness and curvature of a 5-cent coin (Rockwell hardness of $B 60 \pm 4$, radius of curvature of 1 ± 0.1 cm). Press the instrument against the slide with a pressure of 16 ounces and make 100 double strokes. Make a control test of the metal instrument and glass slide using a lubricant such as glycerine, petroleum jelly, or a known nonabrasive paste. Make this test near where the dentifrice test was made. Clean the slide in hot nitric acid to remove particles of alloy from the glass. View the slide in transmitted and reflected light without the use of a microscope. If the dentifrice test shows more scratching on the glass than the control, repeat the test. If the repeat test shows more scratching by the dentifrice than by the control, the lot shall be rejected. Ignore apparent polishing effects which may in some illuminations appear to be changes in surface, but which are not line scratches.

4.3.3 Irritation. Apply approximately one gram of the undiluted dentifrice to the mucous membrane of the cheeks and gums for a period of two minutes. The dentifrice shall not cause any irritation.

4.3.4 Viscosity. Place the toothpaste in a 600cc low form Griffin beaker and measure the viscosity with a Brookfield Model RVF viscometer (Brookfield Engineering Laboratories, Inc., Stoughton, MA), the Helipath stand and T-D spindle. Operate at 4.0 RPM.

4.3.5 Ease of extrusion. Cool the tube of toothpaste to 10°C. Apply pressure to the tube to extrude the toothpaste. It shall be possible to extrude not less than ninety-five percent of the toothpaste in a single mass without applying excessive force which would injure the tube.

4.3.6 Cohesiveness. Cool the tube to 20°C. Hold the tube in a vertical position with the mouth downward. Squeeze out a 10 mm ribbon of toothpaste. The ribbon shall remain attached to the tube for at least 15 seconds.

4.3.7 Stability. Place portions of the toothpaste into four glass test tubes and stopper them. Heat two of the test tubes to 45°C for 72 hours. Examine the toothpaste for separation and fermentation. Cool two of the test tubes to -15°C for one hour. Examine the toothpaste for separation.

4.3.8 Tube inertness. Heat the tube of toothpaste to 45°C for 72 hours. Extrude a part of the toothpaste and examine for contamination on the paste. Slit the tube, remove the toothpaste and examine the surface of the tube and cap for corrosion, chemical attack, or other injury.

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5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A, B or C, as specified (see 6.2).

5.1.1 Levels A and B.

5.1.1.1 Type I. Each tube of toothpaste shall be packaged in a carton commercially used for the item.

5.1.1.2 Type II. Either six or twelve unit containers of tooth powder (at the option of the supplier) shall be packaged in a box commercially used for the purpose. The box shall be secured to prevent accidental opening.

5.1.2 Level C. Dentifrices shall be packaged to afford adequate protection against damage during shipment from the supply source to the first receiving agency.

5.2 Packing. Packing shall be level A, B, or C, as specified (see 6.2)

5.2.1 Level A.

5.2.1.1 Type I. Thirty-six (36) tubes of type I toothpaste, packaged as specified in 5.1.1.1 shall be packed in a box conforming to PPP-B-636, class weather resistant. The box shall be closed, waterproofed and banded in accordance with the appendix of the box specification.

5.2.1.2 Type II. One hundred forty four (144) unit containers of type II tooth powder, packaged as specified in 5.1.1.2, shall be packed in a box conforming to PPP-B-636, class weather resistant. The box shall be closed, waterproofed and banded in accordance with the appendix to the box specification.

5.2.2 Level B

5.2.2.1 Type I. Thirty-six (36) tubes of type I toothpaste, packaged as specified in 5.1.1.1, shall be packed in a box conforming to PPP-B-636, class domestic. The box shall be closed in accordance with the appendix of the box specification.

5.2.2.2 Type II. One hundred forty four (144) unit containers of type II tooth powder, packaged as specified in 5.1.1.2, shall be packed in a box conforming to PPP-B-636, class domestic. The box shall be closed in accordance with the appendix of the box specification.

5.2.3 Level C. Dentifrice in quantities as specified (see 6.2), packaged as specified in 5.1, shall be packed in containers to assure carrier acceptance and safe arrival at destination in compliance with Uniform Freight Classification or National Motor Freight Classification, as applicable

5.3 Marking.

5.3.1 Unit containers. Containers shall be marked in accordance with 3.11 and with commercial markings to include net weight, name or tradename of contents and name or trademark of contractor. Marking shall be clear, legible, durable and nonfading. In the absence of commercial marking, the containers shall be marked in accordance with 3.11 and Fed. Std. No. 123 for civil agencies or MIL-STD-129 for military agencies as specified (see 6.2).

5.3.2 Intermediate packages. Packages specified in 5.1.1.1 shall be marked in accordance with 5.3.1. Packages specified in 5.1.1.2 shall be marked in accordance with 5.3.3.

5.3.3 Shipping containers. In addition to any special marking required by the contract or order, the containers shall be marked in accordance with Fed. Std. No. 123 for civil agencies or MIL-STD-129 for military agencies as specified (see 6.2).

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6. NOTES

6.1 Intended use. The dentifrice covered by this specification is intended for use with a toothbrush to remove the usual daily accumulation of food and tartar from the teeth.

6.2 Ordering data. Purchasers should select the preferred options permitted herein, and include the following information in procurement documents

- (a) Title, number, and date of this specification.
- (b) Type, class and size required (see 1.2).
- (c) Selection of levels of packaging and packing required (see 5.1 and 5.2).
- (d) Marking document required (see 5.3).
- (e) Quantities required (see 5.2).

6.3 Classification change. Type I under FFF-D-191C has been changed to type I, class 1. Type III under FFF-D-191C has been changed to type I, class 2. Type IV has been combined with type I.

MILITARY INTEREST:

CIVIL AGENCY COORDINATING ACTIVITIES:

User Activity:

Army - GL

GSA-FSS
HEW-NIH, FDA
VA-DMS

PREPARING ACTIVITY GSA-FSS

Orders for this publication are to be placed with General Services Administration, acting as an agent for the Superintendent of Documents. See Section 2 of this specification to obtain extra copies and other documents referenced herein. Price 30 cents each.