

MIL-F-36043C
 12 December 1978
 SUPERSEDING
 MIL-F-36043B
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MILITARY SPECIFICATION

FIRST AID KIT, EYE DRESSING

This specification is approved for use by all Departments and Agencies of the Department of Defense.

1. SCOPE

1.1 Scope. This specification covers a kit suitable for first aid treatment of eye injuries.

2. APPLICABLE DOCUMENTS

2.1 Issues of documents. The following documents of the issue in effect on date of invitation for bids or request for proposals, forms a part of this specification to the extent specified herein.

SPECIFICATIONS

FEDERAL

L-P-378	- Plastic Film (Polyethylene Thin Gage).
CCC-G-101	- Gauze, Absorbent.
PPP-B-566	- Boxes, Folding, Paperboard.
PPP-B-585	- Boxes, Wood, Wirebound.
PPP-B-601	- Boxes, Wood, Cleated-Plywood.
PPP-B-621	- Boxes, Wood, Nailed and Lock-Corner.
PPP-B-636	- Boxes, Fiberboard.
PPP-B-676	- Boxes, Setup.

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MIL-L-10547	- Liners, Case, and Sheet, Overwrap; Water-Vaporproof or Waterproof Flexible.
MIL-S-36586	- Sterilization Test Strip Set, Bacterial Spore.

Beneficial comments (recommendations, additions, deletions) and any pertinent data which may be of use in improving this document should be addressed to: Headquarters, Defense Personnel Support Center, ATTN: Directorate of Medical Materiel, CODE ATT, 2800 So. 20th Street, Philadelphia, PA 19101, by using the self-addressed Standardization Document Improvement Proposal (DD Form 1426) appearing at the end of this document.

FSC 6545

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STANDARDS

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

DRAWING

Defense Personnel Support Center (DPSC)

- | | |
|-------|------------------------------------|
| 24211 | - Bag, First Aid Kit, Eye Dressing |
|-------|------------------------------------|

(Copies of specifications, standards and drawing required by contractor in connection with specific procurement functions should be obtained from the procuring activity or as directed by the contracting officer).

3. REQUIREMENTS

3.1 Component parts. The kit consists of two sterile, camouflaged eye pads, eight adhesive tape strips (two pieces of 4 strips each), and two tubes of ophthalmic ointment, contained in a recloseable, plastic bag bearing instructions for use as specified in 3.6.2.

3.2 Materials.

3.2.1 Eye pad. Eye pad shall be 2 inches in diameter and shall be composed of a filler of a suitable quantity (approximately 0.8 gram) of U.S.P. grade absorbent cotton, covered top and bottom with single thicknesses of type I, 44-36 gauze, camouflaged, in accordance with the requirements of Specification CCC-G-101. The eye pad shall be free from loose threads and ravelings.

- * 3.2.2 Adhesive tape. The adhesive tape shall be a clear, hypo-reactive, porous, conforming, plastic surgical tape having nominal dimensions of 7/16 inches wide by 5 inches long. Eight (8) adhesive strips shall be placed on an easy-to-separate backing material. The backing material shall be split or tabbed to facilitate separation of the backing from the tape. Each piece of adhesive tape and backing shall be joined by perforation, cutting or rouletting so that individual adhesive tape strips may be easily pulled apart from the adjoining strip.

- * 3.2.3 Sulfacetamide sodium ophthalmic ointment, USP, 10%, 1/8 oz. (3.5 Gm). Shall be NSN 6505-00-183-9419. Not less than 18 months of expiration date shall remain at time of delivery to the government.

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- * 3.2.4 Plastic bag (container for kit components). The plastic bag used to contain the components of the kit shall be a sealed, recloseable, polyethylene bag. Shall be fabricated from 0.004 inch clear polyethylene, conforming to L-P-378, type I, class 1, grade A, finish 2. Shall be fitted with a 3-1/8 inch recloseable, interlocking closure for easy opening and reclosing by finger pressure. Shall have a sealed overflap above the interlocking closure, which shall be readily removable by tearing. Shall be in accordance with DPSC Drawing 24211. The lot number printed on the kit container shall correlate the Sterilization Lot Number of the eye pads contained therein, see 3.4.1. Expiration date indicated on tubes of ophthalmic ointment shall be indicated on bag adjacent to ophthalmic ointment.
- * 3.2.5 Polyethylene bags. The polyethylene bags specified herein shall be made from extruded stainless "layflat tubing". Polyethylene shall have average wall thickness of 0.003 inch. Minimum thickness at any point shall be not less than 0.00225 inch. Both seam and closure shall be heat sealed to prevent moisture from entering or to prevent escape of fluid contents in the event of leakage; excess air shall have been excluded from the sealed bag so that bag conforms to the shape of the component therein. To insure a minimum of excess material, the width of commercially available tubing shall be of a dimension which shall closely fit the individual component to be enclosed. The length of the tubing between seals shall be the minimum to contain the component. Excess tubing beyond the seals shall be cut off. Each sealed bag containing an individual item shall be capable of passing the leakage test specified (see 4.4.1).
- * 3.3 Eye pad packaging. Each eye pad (3.2.1) shall be individually packaged in an envelope fabricated of natural kraft-colored glassine or parchment paper and sealed. The envelope shall be so constructed and sealed that sterility of the content is maintained until the envelope is opened. Individually packaged eye pads shall be sterilized by steam sterilization. Eye pads shall be sterile when tested as specified in 4.4.2.
- * 3.4 Certificate of sterility. A certificate of sterility, stating that samples from each sterilizer lot have been tested and found to be sterile, shall be submitted to the procuring activity. The certificate of sterility shall include:
 - a. Item identification.
 - b. National Stock Number.
 - c. Contract or purchase order number.
 - d. Sterility lot or control number.
 - e. Date of sterilization.

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- f. Quantity of product in sterilizer lot.
- g. Type of sterilization (gas, radiation, dry heat, steam, etc.).
- h. Form of biological indicator (i.e., inoculated paper spore strip or carrier, inoculated product, or inoculated simulated product).
- i. Test organism(s) and population density used.
- j. Test medium, incubation temperature, incubation time, and dates of tests.
- k. Number of test units.
- l. Statement that samples comply with sterility tests.
- m. Signature of head of laboratory or a designated qualified alternate.

When inspection is made at destination, the certificate of sterility shall be submitted by the contractor to the Directorate of Medical Materiel, ATTN: DPSC-ATQ, Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, PA 19101, and a copy forwarded with each shipment to the consignee. When inspection is made at source, certificate of sterility shall be furnished to the cognizant Government Quality Assurance Representative for submission to the procuring activity.

- * 3.4.1 Sterility lot. A sterility lot is that single quantity of product subjected to the same manufacturing operation and simultaneously sterilized in the same sterilizer chamber. Each sterility lot shall be traceable to the pertinent manufacturing lot(s) (see 3.2.4).

3.5 Assembly of components.

3.5.1 Ophthalmic ointment. The contractor shall remove each tube of ophthalmic ointment (3.2.3) from its cardboard carton, and insert it in a polyethylene bag as specified in 3.2.5.

3.5.2 Adhesive tape strips and eye pad. The contractor shall tear off a unit of 4 adhesive strips (3.2.2) and insert it together with one eye pad (3.3) in a 3 mil polyethylene bag and heat seal as specified in 3.2.5.

- * 3.5.3 Final assembly. The contractor shall place two (2) bagged tubes of ophthalmic ointment (3.5.1), two (2) bagged units of adhesive tape strips, instruction sheet (3.6.2), and eye pad (3.5.2) in one recloseable plastic bag specified in 3.2.4. The contractor shall heat seal the recloseable bag and trim excess material from the heat seal.

3.6 Marking for identification.

- * 3.6.1 Eye pad. Each envelope containing the eye pad (3.3) shall bear the sterility clause: "STERILITY IS NOT GUARANTEED IF INDIVIDUAL ENVELOPE HAS BEEN DAMAGED OR OPENED", or similar statement and the name or registered trademark of manufacturer. When the contractor is not the manufacturer, the contractor's name shall also appear.

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3.6.2 Plastic bag (kit container). The list of components and instructions shall be printed in waterproof black ink on white background directly on the plastic bag, with English on same side as the colored line side and French on the other, reading from the top down. Alternately, the list of components and instructions may be printed in waterproof black ink on white paper and inserted in bag in a manner such that the English printing is clearly visible through the plastic on the colored line side, and the French printing is clearly visible through the plastic on the other side, with both printings reading from the top down. The English printing and the French printing shall be as indicated on the drawing. When printing is on paper, no component shall be placed between the paper and the bag so as to obscure the printing. Instructions for opening and closing the bag shall be printed on the bag as shown in the drawing. Opposite NSN 6505-00-183-9419, shall be printed "EXP DATE". Expiration date shall be that of the ophthalmic ointment enclosed in the plastic bag.

3.7 Workmanship. Workmanship shall be first class throughout. The individual components, as well as the completely assembled First Aid Kit, Eye Dressing, shall be free from defects which detract from their appearance or impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Responsibility for inspection. Unless otherwise specified in the contract, the contractor is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract, the contractor 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 to assure supplies and services conform to prescribed requirements.

- * 4.1.1 Records. Records of examinations and tests performed by or for the contractor shall be maintained by the contractor and made available to the Government, upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of three years after delivery of the supplies to which such records relate.

4.1.2 Inspection. Inspection, as used in this specification, is defined as both examination (such as visual or auditory investigation without the use of special laboratory appliances or procedures) and testing (determination by technical means of physical and chemical properties) of the item.

- * 4.1.3 Certificates of quality. Certificates of quality, supplied by the manufacturer of the component material, may be furnished in lieu of actual performance of such testing by the contractor, provided lot identity has been maintained and can be demonstrated to the Government and provided also that the test methods and the results obtained comply with those described in their specification. The certificate shall include the name of the contractor, the contract number, the name of the manufacturer or supplier, the NSN, the item identification, the name of the component/material, the lot number, the lot size, the sample size, the date of testing, the test method, individual test results, and the specification requirements.

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* 4.2 Sampling.

* 4.2.1 For examination. Sampling for examination shall be conducted in accordance with MIL-STD-105 and table I. Unit of product for examination purposes shall be one kit.

TABLE I. For examination.

	Inspection level	AQL (percent defective)
For visual examination		
Major A	II	1.0
Major B	II	1.5
Minor	II	4.0
For dimensional examination	S-2	4.0

* 4.2.2 For tests. Sampling for tests shall be conducted in accordance with MIL-STD-105 and table II. The inspection level shall be S-2 and the acceptance number shall be zero. The unit of product for sampling is shown in table II.

TABLE II. For tests.

Component	Characteristics	Requirement	Test procedure
Bagged Components	Leakage test	3.2.5	4.4.1
Eye pad	Sterilization test	3.3	4.4.2*

* Five individually packaged envelopes from each lot shall be tested.

* 4.3 Examination. The first aid kit shall be examined to determine compliance with all requirements contained in this specification.

* 4.3.1 Classification of defects. Examination shall be conducted in accordance with the classification of defects listed in table III. Examination shall not be restricted to the classified possible defects listed below.

TABLE III. Classification of defects.

Categories	Defects
Major A	
101	Plastic bag (kit container) not in conformance with drawing.
102	Plastic bag (kit container) heat seals not continuous.
103	Plastic bag (kit container) not tamperproof type.
104	Plastic bag (component) cut or torn.
105	Any component missing.
106	Marking incorrect, incomplete, illegible, or non-permanent.
107	Ophthalmic ointment tubes leak.
108	Eye pad paper envelope not intact.

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TABLE III. Classification of defects (contd).

Categories	Defects
Major B 109	Polyethylene bag heat sealed in the closure seam of the plastic bag (kit container).
Minor 201	Excess air not removed from polyethylene bag before sealing.
202	Excess material not removed from bottom of polyethylene bag after sealing.
203	Excess material not removed from bottom of plastic bag (kit container) after sealing.
204	Printing on plastic bag (kit container) off center.
205	Complete kit package not flat.

- * 4.3.2 Dimensional examination. The component parts shall be examined for defects in dimensions. Any dimension not within the tolerance specified herein shall be classified as a defect.
- * 4.3.3 Packaging inspection. The inspection of the packaging, packing and marking for shipment and storage shall be in accordance with quality assurance provisions of the applicable container specification and marking requirements of MIL-STD-129.
- * 4.4 Tests. Tests shall be conducted to determine compliance with specification requirements.
- * 4.4.1 Leakage test. Sealed, filled, polyethylene bags (3.2.5) shall be submerged to a depth of one foot in tap water at room temperature for 15 minutes. Bags shall be removed, exterior surface dried, opened, and examined for leakage of water.
- * 4.4.2 Sterility test. The eye pads shall be tested for sterility in accordance with the method specified in the USP for Purified Cotton, Gauze Surgical Dressings, and Related Material using inoculated product, inoculated simulated product, or paper spore strip (carrier). Product containing a biological indicator shall be marked or labeled so that it clearly differentiates from product intended for distribution. The incubation medium and minimum time in each case shall be soybean casein digest for 7 days for inoculated product, inoculated simulated product, or paper spore strip (carrier). The incubation temperature shall be as indicated in paragraph 4.4.2.1. The minimum number of test units, regardless of lot size, shall be 10, except for inoculated carrier which shall be 20 for type I Sterilization.
- * 4.4.2.1 Inoculated product or simulated product. For steam sterilization, the organism used shall be *Stearothermophilus* at an incubation temperature of 55° - 65°C. The number of viable cells shall be sufficient to provide assurance that the product has been sterilized.

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- * 4.4.2.2 Inoculated carrier. Inoculated carriers (paper spore strips) if used shall be in accordance with MIL-S-36586. Other paper carriers shall be inoculated to be of equivalent resistance. The method of incubation and number of test units shall be as indicated in 4.4.2 Sterility test and 4.4.2.1 Inoculated product or simulated product. The method of sterilization will control the organism in the spore strip to be tested for as shown in 4.4.2.1. NOTE: When an inoculated carrier is chosen, product samples must also be tested as required by the USP.
- * 4.4.2.3 Alternate method. Suppliers conducting sterility tests or designating lots in a manner other than that indicated herein shall submit proof that the alternate method provides equal assurance concerning the sterility of the product. However, all sterility tests shall be conducted using biological indicators. Requests for approval of any alternate method of testing for sterility shall be made to the Contracting Officer, and approval obtained before employment of the alternate method on a Government contract.
- * 4.4.2.4 Product testing. Testing for sterility of the product after receipt by the Government shall be without a biological indicator and in accordance with the U.S.P.

5. PACKAGING.

- * 5.1 Packaging. Packaging shall be level A or C, as specified (see 6.2).
- * 5.1.1 Unit of issue. One first aid eye dressing kit constitutes a unit of issue.
- * 5.1.2 Level A.
- * 5.1.2.1 Unit packaging. Each kit shall be packaged in a bag as specified (see 3.2.4).
- * 5.1.2.2 Intermediate package. Twelve unit packages shall be packaged in a box conforming to PPP-B-566 or PPP-B-676. Closure shall be as specified in the appendix of the applicable box specification.
- * 5.1.3 Level C. Kits packaged in bags as specified in 3.2.4 shall be further packaged in a manner that will afford adequate protection against physical damage during shipment from the supply source to the first receiving activity.
- * 5.2 Packing. Packing shall be level A, B or C as specified (see 6.2).
- * 5.2.1 Level A. Forty-eight intermediate packages (576 units) shall be packed in a shipping container designed for a type 2 load and conforming to PPP-B-585, class 3, style 3; PPP-B-601, overseas type; PPP-B-631, class 2; or PPP-B-636, class weather-resistant. Closure and strapping shall be as specified in the applicable box specification.

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5.2.1.1 Waterproofing. Each wood box shall be lined with a waterproof case liner conforming to MIL-L-10547. Closure and sealing of the liner shall be in accordance with the appendix thereto. Fiberboard boxes shall be waterproofed as specified in the appendix of PPP-B-636.

5.2.2 Level B. Forty-eight intermediate packages (576 units) shall be packed in a shipping container designed for a type 2 load and conforming to PPP-B-585, class 1, style 2; PPP-B-601, domestic type; PPP-B-621, class 1; or PPP-B-636, class domestic. Closure shall be as specified in the applicable box specification.

5.2.3 Level C. The packaged kits shall be packed in shipping containers in a manner that will afford adequate protection against damage during direct shipment from the supply source to the first receiving activity. These packs shall conform to the applicable carrier's rules and regulations.

5.3 Marking.

5.3.1 Unit package. Marking shall be as specified in 3.6 and drawing 24211.

5.3.2 Intermediate package. Each intermediate package shall be marked as specified in MIL-STD-129. The sterility lot or control number, contract or purchase order number and name of contractor shall be shown. Type II shelf life marking as specified in MIL-STD-129 shall also be shown (see 3.6.2). The method of sterilization (G-Gas, R-Radiation, C-Cold, S-Steam, D-Dry heat) shall be shown following the level of packaging and date of packaging. Example: "A 5/78-G". Final sterilization shall be on or after indicated packaging date.

5.3.3 Shipping container. Each shipping container shall be marked as specified in MIL-STD-129. The sterility lot or control number and method of sterilization as specified in 5.3.2 shall also be shown. Type II shelf life marking as specified in MIL-STD-129 shall be shown (see 3.6.2).

6. NOTES

6.1 Identification of international standardization agreement. Certain provisions of this specification are the subject of international standardization agreement NATO STANAG 2126. When amendment, revision, or cancellation of this specification is proposed which will effect or violate the international agreement concerned, the preparing activity will take appropriate reconciliation action through international standardization channels including departmental standardization offices, if required.

6.2 Intended use. The First Aid Kit covered by this specification is intended for treatment of eye injuries.

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6.3 Ordering data. Procurement documents should specify the following:

- (a) Title, number, and date of this specification.
- (b) National Stock Number (NSN).
- (c) Selection of applicable level of packaging and packing (see 5.1 and 5.2).

6.4 This specification covers the following item appearing in the Federal Supply Catalog:

National Stock Number

Item Identification

6545-00-853-6309

FIRST AID KIT, Eye Dressing

6.5 Changes from previous issue. The margins of this specification are marked with an asterisk to indicate where changes (additions, modifications, corrections, deletions) from the previous issue were made. This was done as a convenience only and the Government assumes no liability whatsoever for any inaccuracies in these notations. Bidders and contractors are cautioned to evaluate the requirements of this document based on the entire content irrespective of the marginal notations and relationship to the last previous issue.

6.6 This specification does not cover all types, classes, grades, or sizes of the commodity indicated by the title of this specification or those which are commercially available, but is intended to cover the types which are normally procured to meet military requirements.

Custodians:

Army - MD
Navy - MS
Air Force - 03

Preparing activity:

Defense Logistics Agency - DM

Project No. 6545-0040

Review activity:

DoD - MB

GPO 1974-603-850: 8126 2-1

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