

MIL-A-3248B
4 March 1970
SUPERSEDING
MIL-A-3248A
26 July 1962

MILITARY SPECIFICATION

AMYL NITRITE (INHALANTS)

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

1. SCOPE

1.1 This specification covers amyl nitrite inhalants suitable for use as a coronary vasodilator and as an emergency antidote for cyanide poisoning. (See 6.2).

2. APPLICABLE DOCUMENTS

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

SPECIFICATIONS

Federal

MMM-A-250	Adhesive, Water-Resistant (for Sealing Fiberboard Boxes).
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	Box, Fiberboard.
PPP-B-676	Boxes, Set-Up.
PPP-C-00186a	Containers, Packaging and Packing for Drugs, Chemicals, and Pharmaceuticals.
PPP-C-1266	Container, Thermal, Shipping, for Medical Material Requiring Controlled Temperature Ranges.
PPP-T-76	Tape, Pressure-Sensitive, Adhesive Paper (for Carton Sealing).

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STANDARDS

Federal

Fed. Std. 595 Colors.

Military

MIL-STD-105 Sampling Procedures and Tables
Inspection by Attributes.

MIL-STD-129 Marking for Shipment and Storage.

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

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

AMERICAN PHARMACEUTICAL ASSOCIATION PUBLICATION

National Formulary.

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

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FOOD AND
DRUG ADMINISTRATION.

Federal Food, Drug, and Cosmetic Act and Regulations
Promulgated Thereunder.

(Application for copies should be addressed to the Food and Drug Administration, Washington, D. C. 20204).

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3. REQUIREMENTS

3.1 Material. Material shall be amyl nitrite and shall comply with 4.5.1.

3.1.1 Preservatives. Each ampul shall contain one of the following preservatives, within the limits specified, when tested as required in 4.5.2.

- (a) Not less than 0.0067 gram (g.) and not more than 0.0100 g. of Potassium Carbonate, Anhydrous, U.S.P., reagent grade, or Sodium Carbonate, Anhydrous, U.S.P. reagent grade.
- (b) Not less than 0.0067 g. and not more than 0.0100 g of Diphenylamine, U.S.P. reagent grade.
- (c) Not less than 0.0067 g. and not more than 0.0100 g. of Magnesium Oxide, U.S.P.

3.1.2 The finished product contained in the inhalant ampuls shall comply with the tests, standards, and requirements of the N.F.

3.2 Immediate container. Immediate container for the amyl nitrite shall be an ampul in conformance with the following requirements:

3.2.1 Ampul. Ampul shall be a glass tube having overall dimensions as follows: Diameter of not less than 7/32 inch and not more than 10/32 inch, length of not less than 1 inch and not more than 1-7/16 inches, and a wall thickness of 0.15 to 0.30 millimeters. Ampul shall be hermetically sealed at both ends by heat.

3.2.2 Contents. When tested as specified in 4.5.3, the filled immediate container (ampul) shall contain an average volume of not less than 0.33 cc, with not more than one (1) ampul containing less than 0.30 cc.

3.2.3 Compatibility. The immediate container (ampul) shall be compatible and shall not interact physically or chemically with the amyl nitrite. The strength, quality, purity, and appearance of contents shall not be affected by the immediate container, nor shall the immediate container be altered by the contents in any manner.

3.2.4 Cleanliness. The immediate container shall be free from dirt, foreign matter, or other contaminants, both before and after filling.

3.2.5 Pressure. Ampuls shall not leak and shall be capable of withstanding, in a low-pressure chamber, a pressure of 1.68 pounds per square inch (equivalent to subjecting the ampuls to an altitude of 50,000 feet). When placed in covering specified in 3.2.6, the ampul shall be capable of being crushed easily between thumb and forefinger.

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3.2.6 Covering.

3.2.6.1 Inner covering. Ampul shall be covered with clean, white, absorbent cotton or suitable cotton cloth, which shall be of sufficient thickness to prevent penetration of crushed glass. The cotton or cloth shall provide for the proper distribution of the contents and shall prevent any dripping of amyl nitrite when the ampul is crushed.

3.2.6.2 Outer covering. The absorbent cotton or suitable cotton cloth shall be covered with a woven mesh netting of artificial silk, rayon, or mercerized cotton which shall not fray at the ends. The woven mesh netting shall be securely fastened, or otherwise attached, to prevent unraveling around each cotton or cloth covered ampul.

3.2.7 Overall dimensions. Overall dimensions of the immediate container (ampul with the inner and outer coverings in place) shall not exceed 2 inches in length and shall not exceed 3/8 inch in diameter.

3.2.8 Labeling. Labeling shall be in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act, and shall include the information required below:

3.2.8.1 Immediate containers. Each immediate container (ampul) shall have a label on the outside or inside of the woven mesh netting. The label shall be legibly printed with the following information. However, the information is not required to appear in the sequence indicated:

- (a) the item identification designated as
"AMYL NITRITE"
- (b) the amount contained in each ampul designated as
"0.33 cc (5 minims)"
- (c) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

- (d) the lot or control number designated as
"Lot No. _____" or "Control _____"

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NOTES: Applicable to the immediate container labels only:

1. The date of manufacture need not appear on the immediate container label.
2. Roll feed labels are acceptable.
3. The lot number shall be positioned in the upper quarter of the label. The prefix (i.e., "Lot No.") need not appear.
4. The quantity of contents in the immediate container may be designated as "0.3 cc" in lieu of "0.33 cc."

3.2.8.2 Unit packages. Each unit package shall be labeled on the top face of the package and on the bottom face of the package, as indicated:

3.2.8.2.1 Top face. Top face of the unit package label shall bear the following information:

- (a) the item identification designated as "AMYL NITRITE, N.F., AMPULS, 0.33 cc (5 minims)"
- (b) the stock number designated as "FSN 6505-106-9000" or "Stock No. 6505-106-9000"
- (c) the lot or control number designated as "Lot No. _____" or "Control _____"
- (d) the name and address of the manufacturer. When the manufacturer is not the contractor, the name and address of the contractor shall also appear.

When both names are placed on the label, the following designations shall precede the names:

"MFR" for the manufacturer and
"CONTR" for the contractor.

- (e) the date of manufacture designated as "MFD _____"
- (f) the name and quantity of the preservative used in each ampul
- (g) the word "POISON" in prominent red letters of at least 8-point type.

(No other medical and technical information shall appear in red print).

- (h) the following statements:
 1. PEARLS FOR INHALATION.
 2. FOR CYANIDES.
 3. Store between 2° - 8° C. (35° - 46° F.).
 4. Caution: Federal law prohibits dispensing without prescription.
 5. CAUTION: Flammable.

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3.2.8.2.2 Bottom face. Bottom face of the package label shall bear the following directions:

"AMYL NITRITE FOR CYANIDES
Break two ampuls in piece of cloth and inhale fumes.
Repeat three time if necessary."

3.2.8.3 Overlabeling. Overlabeling is prohibited. The use of a strip label to furnish any of the required information is permitted, provided it does not overlabel.

3.2.8.4 Adhesion of label and permanence of markings.

3.2.8.4.1 Permanence of markings. All markings on the label of each immediate container and each unit package shall be clear and legible. Markings shall remain clear and entirely affixed to the labels after being subjected to the test specified in 4.5.4.1.

3.2.8.4.2 Adhesion of label. All strip labels (if such are used) applied to each unit package shall remain entirely affixed to the unit packages after being subjected to the test specified in 4.5.4.2.

3.2.8.5 Durability. All markings on all containers shall be durable and shall not smear or be removed during handling of the containers with dry hands.

During storage, the labels; the markings on the labels, and the markings directly on the containers; shall remain entirely affixed, and clear and legible; and shall comply with the applicable test specified in 4.5.4.1. If strip labels are used, they shall comply with the test specified in 4.5.4.2.

3.2.9 Size of type for labeling. The printing of any labeling (on the immediate containers and on the unit packages) shall be in an easily readable style of type and of sufficiently large size of type commensurate with the size of the container, but in any event, it need not be larger than 6-point type, except for the word "POISON" which shall be at least 8-point type (see 3.2.8.2.1 (g)).

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3.3 Date of manufacture. The date of manufacture shall be the date when the product is placed within the immediate container.

3.4 Delivery. Not more than 4 months shall have elapsed from the date of manufacture of the product, to the date of delivery to the Government.

3.5 Workmanship. The material and its containers shall be free from any defects which detract from their appearance or may impair their serviceability.

4. QUALITY ASSURANCE PROVISIONS

4.1 Supplier responsibilities for inspection. Such examinations and tests as are set forth in this specification, or as shall otherwise be appropriate or necessary to insure that supplies conform to specification requirements, shall be performed by and at the expense of the supplier. Suppliers who do not have facilities adequate for such tests shall arrange for the use of test facilities acceptable to the Government. Records of examinations and tests performed by the supplier shall be maintained by the supplier and made available to the Government, upon the Government's request, at any time, or from time to time, for a period of 3 years after delivery of the supplies to which such records relate.

4.1.1 Lot. For purposes of this specification, a lot, batch, or control is that single, uniform, and homogeneous quantity of amyl nitrite produced from one formulation, subjected to the same compounding and manufacturing operation, and filled into final (immediate) containers.

4.3 Sampling. Sampling shall be conducted in accordance with MIL-STD-105.

For visual examination	Inspection level	AQL (percent defective)	Unit of product
Major A	II (normal, single)	1.0	Covered ampul
Major B	"	1.0	Unit package
Major C	"	1.0	Intermediate and protective package
Major D	"	1.0	Exterior container
Minor A	S-2	2.5	Covered ampul
Minor B	II (normal, single)	2.5	Ampul

For end item testing. Acceptance number shall be zero (0) for all sample sizes.

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Characteristic	Requirement paragraph	Test paragraph	Inspection level	Minimum sample
Amyl nitrite	3.1	4.5.1	S-4	80 ampuls
Preservative	3.1.1	4.5.2	*	*
Contents	3.2.2	4.5.3	S-3	35 ampuls
Pressure**	3.2.5	---	S-2	10 ampuls
Permanence of markings	3.2.8.4.1	4.5.4.1	S-2	{ 10 ampuls 10 unit packages
Adhesion of label	3.2.8.4.2	4.5.4.2	S-2	10 unit packages

*As necessary.

**If not more than one of the ampuls fails the pressure test, an additional quantity of ampuls shall be sampled and retested using inspection level S-3, minimum sample size 35. All ampuls of the additional quantity tested shall comply with requirement of 3.2.5.

4.3.1 When possible, the same sample shall be used in the determination of two or more tests.

4.4 Examination. The amyl nitrite shall be examined to determine compliance with all requirements contained in this specification.

4.4.1 Classification of defects. Examination shall be conducted in accordance with the following classification of defects:

Categories and Defects***

Major A

101. Ampul not fully covered with absorbent cotton or suitable cotton cloth.
102. Woven mesh netting not adequately secured to enclose ampul.
103. Label not present.
104. Label not complete, not legible.
105. Amyl nitrite and immediate container not free of interaction.
106. Immediate container not free of dirt, foreign matter, or other contaminants.

***Examination is not restricted to the classified possible defects listed above.

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Categories and Defects*** (Continued)Major B

- 151. Material and marking of unit package not as specified.
- 152. Ampul count not as specified.
- 153. Exterior and interior surfaces not coated or finished as specified.

Major C

- 161. Material and marking of intermediate package and protective package not as specified.

Major D

- 171. Material and marking of exterior container not as specified.

Minor A

- 201. Covered ampul does not crush easily under finger pressure.
- 202. Covered ampul overall dimensions not as specified.

Minor B

- 251. Ampul overall dimensions not as specified.
- 252. Ampul wall thickness not as specified.
- 253. Ampul not filled (nonfill or leaker).

4.5 Tests.

4.5.1 Amyl nitrite. The amyl nitrite used in the manufacture of the inhalants shall be in accordance with the tests, standards, and requirements of the N.F.

4.5.2 Preservative. The quantity of preservative shall be determined using an appropriate, accurate, and reproducible method.

***Examination is not restricted to the classified possible defects listed above.

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4.5.3 Contents. Carefully remove the outer and inner coverings of the ampuls. Break each ampul separately in a small beaker (50 milliliters (ml)) with a suitable rod. Immediately pour the solution into a graduated cylinder calibrated to at least 0.02 ml. Alternates: (a) the quantity of solution in each ampul may be measured by drawing the solution from the beaker, by suitable means, into a measuring pipet calibrated to at least 0.02 ml. (b) the quantity of solution in each ampul may be measured by drawing the solution directly into an accurately calibrated hypodermic syringe.

4.5.4 Adhesion and permanence of markings.

4.5.4.1 Permanence of markings. The immediate container labels and the unit packages shall be placed in a bath of water maintained at a temperature of 75° Fahrenheit (F.) \pm 5° F. for a period of 4 hours, during which time the markings shall be completely covered by the water. When the immediate container labels and the unit packages are removed from the water, all of the markings shall be entirely affixed, without distortion, fading of color, or reduction in size of print. After drying, the markings shall still comply with the requirements in the above sentence.

4.5.4.2 Adhesion. If the packages have a strip label, they shall be as described in 4.3.2 of PPP-C-00186a, and shall comply.

5. PREPARATION FOR DELIVERY

5.1 Packaging. Packaging shall be level A or C, as specified (see 6.1).

5.1.1 Unit of issue. Twelve (12) ampuls, as specified, constitute one unit of issue.

5.1.2 Packaging quantities. The number of units of issue indicated in the following table shall be packaged in each unit, intermediate, protective, and exterior container, as applicable, for the required level of protection specified in the procurement document.

Packaging quantities			
Unit package	Intermediate package	Protective package	Exterior container
1 unit	10 units	250 units	500 units

5.1.2.1 Packing variation permitted. If the required number of units in the entire shipment is less than the number of units specified to be over-packed in an exterior container, such units shall be packed in an exterior container of suitable size and design, acceptable to a common carrier which will insure safe delivery to destination.

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5.1.3 Level A.

5.1.3.1 Unit package. Twelve (12) ampuls (1 unit) shall be packaged in a metal container of appropriate size with rounded corners. Container shall have a metal, oblong, seamless, one lug hinged cover with rounded corners, fitted with a nib and catch. Exterior surfaces of metal container shall be painted in a lustreless green (olive drab) color conforming to No. X34087 of Fed. Std. No. 595 (see 6.3). Interior of the body and cover shall be finished with aluminum lacquer.

5.1.3.2 Intermediate package. Intermediate package shall be a carton of appropriate size constructed in accordance with PPP-B-566 or PPP-B-676, except that commercial colors shall be acceptable. Each carton shall be adequately secured to prevent accidental opening.

5.1.3.3 Protective package. Package shall be a box of appropriate size and design constructed in accordance with PPP-B-636, type CF, class weather-resistant. Boxes shall be closed by taping the top and bottom flaps with 2 inch wide tape conforming to PPP-T-76. Closing of bottom flaps with adhesive conforming to MMM-A-250, or metal stitches is permitted.

5.1.4 Level C. Units shall be packaged in standard commercial containers of the size and kind commonly used which will afford the degree of protection required for shipment and use of the product for its intended purpose within the continental limits of the United States of America.

5.2 Packing. Packing shall be levels A, B, or C, as specified (see 6.1).

5.2.1 Level A.

5.2.1.1 Exterior container. Exterior container shall be designed for a type 2 load and constructed in accordance with PPP-B-585, class 3, style 3; PPP-B-601, overseas type; PPP-B-621, class 2; or PPP-B-636, class weather-resistant, grade V3. Closure and strapping shall be as specified in the appendix of the applicable box specification.

5.2.2 Level B.

5.2.2.1 Exterior container. Exterior container shall be designed for a type 2 load and constructed in accordance with PPP-B-585, class 1, style 3; PPP-B-601, domestic type; PPP-B-621, class 1; or PPP-B-636, class domestic. Closure shall be as specified in the appendix of the applicable box specification.

5.2.3 Level C. The subject commodity shall be packed in substantial commercial containers of the type, size, and kind commonly used for the purpose, so constructed as to insure acceptance and safe delivery by common or other carriers, at the lowest rate, to point of delivery called for in the contract or purchase order.

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5.3 Marking. Marking shall be in accordance with all applicable requirements of PPP-C-00186a, except as specified herein:

5.3.1 Intermediate packages and protective packages. Intermediate packages and protective packages shall be marked in accordance with 5.5.3 of PPP-C-00186a, except at end of paragraph, add "Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend: 'STORE BETWEEN 2° - 8° C. (35° - 46° F.).' "

5.3.2 Exterior containers. Exterior containers shall be marked in accordance with 5.5.4 of PPP-C-00186a, except at end of paragraph, add: "Date of manufacture shall be shown in lieu of date packed. Marking shall include the legend: 'STORE BETWEEN 2° - 8° C. (35° - 46° F.).' "

NOTE: The unrefrigerated shipping time for this item shall not be more than 168 hours.

6. NOTES

6.1 Ordering data. Procurement documents should specify the following:

- (a) Number and date of this specification.
- (b) Selection of applicable levels of packaging and packing (see 5.1 and 5.2).

6.2 This specification covers the following Federal Stock No. and Item Identification:

FSN 6505-106-9000 AMYL NITRITE, NF, Ampuls, 0.33 cc, 12s

6.3 Availability of color chips. The individual 3- by 5-inch chip of the color referenced in 5.1.3.1 is available from the General Services Administration, Business Service Center, Region 3, Seventh and D Streets, S.W., Washington, D. C. 20407. Price 5 cents.

6.4 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 - O3

Preparing activity:

Defense Supply Agency - DM
Project No. 6505-1004

Review activities:

Army - MD
Navy - MS
Air Force - O3

Review information is current as of date of this document. For future coordination of changes to this document, draft circulation should be based on the information in the current DODISS.

SPECIFICATION ANALYSIS SHEET		Form Approved Budget Bureau No. 22-R255
<p>INSTRUCTIONS: This sheet is to be filled out by personnel, either Government or contractor, involved in the use of the specification in procurement of products for ultimate use by the Department of Defense. This sheet is provided for obtaining information on the use of this specification which will insure that suitable products can be procured with a minimum amount of delay and at the least cost. Comments and the return of this form will be appreciated. Fold on lines on reverse side, staple in corner, and send to preparing activity. Comments and suggestions submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or serve to amend contractual requirements.</p>		
SPECIFICATION		
MIL-A-3248B		FSN:
ORGANIZATION		
CITY AND STATE		CONTRACT NUMBER
MATERIAL PROCURED UNDER A		
<input type="checkbox"/> DIRECT GOVERNMENT CONTRACT <input type="checkbox"/> SUBCONTRACT		
1. HAS ANY PART OF THE SPECIFICATION CREATED PROBLEMS OR REQUIRED INTERPRETATION IN PROCUREMENT USE?		
A. GIVE PARAGRAPH NUMBER AND WORDING.		
B. RECOMMENDATIONS FOR CORRECTING THE DEFICIENCIES		
2. COMMENTS ON ANY SPECIFICATION REQUIREMENT CONSIDERED TOO RIGID		
3. IS THE SPECIFICATION RESTRICTIVE?		
<input type="checkbox"/> YES <input type="checkbox"/> NO (If "yes", in what way?)		
4. REMARKS (Attach any pertinent data which may be of use in improving this specification. If there are additional papers, attach to form and place both in an envelope addressed to preparing activity)		
SUBMITTED BY (Printed or typed name and activity - Optional)		DATE