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2-GP-50
May 1968
CANCELLATION
April 1980

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL, LIQUID

This standard is cancelled because as far as can be determined, it is no longer being used.

2-GP-50
31 May 1968
AMENDMENT NO. 1
22 November 1968

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL: LIQUID

Withdrawn/Retirée

7. INSPECTION

7.2.2.1 Assay for Hexachlorophene

(b) *Reagents*

Alkaline Buffer - Change the second sentence to read:

Add 25.0 ml of IN sodium hydroxide, dilute to 1 liter with water, and mix.

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6/2/09

2-GP-50
Mai 1968
MODIFICATIF N° 1
Novembre 1968

OFFICE DES NORMES DU GOUVERNEMENT CANADIEN

Norme

SAVON LIQUIDE DE QUALITÉ CHIRURGICALE

7. INSPECTION

7.2.2.1 *Dosage de l'hexachlorophène*

(b) *Réactifs*

Tampon alcalin - Remplacer la dernière phrase par la suivante:

Ajouter 25.0 ml d'hydroxyde de sodium IN. diluer jusqu'à 1 litre avec de l'eau et mélanger.

Withdrawn/Retirée

2-GP-50
May 1968
AMENDMENT NO. 2
November 1973
Supersedes
Amendment No. 1

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard

for

SOAP, SURGICAL, LIQUID

2. APPLICABLE PUBLICATIONS

* 2.1.3 Food and Drugs Act and Food and Drug Regulations.

7. INSPECTION

7.2.2.1 Assay for Hexachlorophene

(b) *Reagents*

Alkaline Buffer - Change the second sentence to read:

Add 25.0 mℓ of IN sodium hydroxide, dilute to 1 liter with water, and mix.

8. NOTES

* 8.1 Intended Uses

Add the following sentence to this clause:

It must be noted that products containing more than 0.75% hexachlorophene are on schedule F of the Food and Drug Regulations under the Food and Drug Act, and therefore are obtainable only on prescription.

8.6 Add the following and change par. 8.6 and 8.6.1 to read 8.7 and 8.7.1 respectively.

* 8.6 The publication listed in par. 2.1.3 may be obtained from Information Canada, Publishing Division, Ottawa, Canada.

Withdrawn/Retirée

* Change since previous amendment.

2-GP-50
Mai 1968
MODIFICATIF N° 2
Novembre 1973
Remplace le
Modificatif n° 1

OFFICE DES NORMES DU GOUVERNEMENT CANADIEN

Norme

SAVON LIQUIDE DE QUALITÉ CHIRURGICALE

2. PUBLICATIONS APPLICABLES

*2.1.3 Loi des aliments et drogues et Règlements des aliments et drogues.

7. INSPECTION

7.2.2.1 *Dosage de l'hexachlorophène*

b) *Réactifs*

Tampon alcalin - Remplacer la deuxième phrase par la suivante:

Ajouter 25.0 mℓ d'hydroxyde de sodium 1N, diluer jusqu'à 1 litre avec de l'eau et mélanger.

8. REMARQUES

*8.1 Utilisations prévues

Ajouter la phrase suivante à ce paragraphe:

Il est à souligner que les produits renfermant plus de 0.75% d'hexachlorophène figurent à l'annexe F des Règlements de la Loi des aliments et drogues et par conséquent ne s'obtiennent que par ordonnance.

8.6 Ajouter le paragraphe suivant et remplacer 8.6 et 8.6.1 par 8.7 et 8.7.1 respectivement.

*8.6 La publication mentionnée à l'alinéa 2.1.3 est diffusée par Information Canada, Division de l'édition, Ottawa, Canada

Withdrawn/Retirée

* Changement effectué depuis le modificatif précédent.

CANADA

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

STANDARD

FOR

SOAP, SURGICAL: LIQUID

Withdrawn/Retirée

2-GP-50

31 MAY 1968

THIS STANDARD APPLIES TO A THOROUGHLY SAPONIFIED POTASSIUM SOAP IN LIQUID FORM, PREPARED FROM EITHER VEGETABLE OILS OR DISTILLED VEGETABLE OIL FATTY ACIDS, AND CONTAINING HEXACHLOROPHENE.

DEPARTMENT OF DEFENCE PRODUCTION, OTTAWA, CANADA

25 CENTS

COMMITTEE ON SOAPS AND DETERGENTS

(Membership at date of approval by the Committee)

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Ammann, P.J.	G.H. Wood and Company Limited
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Withdrawn/Retirée

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL: LIQUID

1. DEFINITION

1.1 This standard applies to a thoroughly saponified potassium soap in liquid form, prepared from either vegetable oils or distilled vegetable oil fatty acids, and containing hexachlorophene.*

1.2 For more detailed information on uses see par. 8.1.

2. APPLICABLE PUBLICATIONS

2.1 The following publications are applicable to this standard:

2.1.1 CGSB 2-GP-11 Methods of Testing and Analysis of Soaps and Detergents.

2.1.2 ASTM D460 Sampling and Chemical Analysis of Soaps and Soap Products.

2.2 Reference to the above publications, or to test methods therein, is to the issues in effect on the date of invitation to tender, unless otherwise specified.

3. GENERAL REQUIREMENTS

3.1 The soap shall be a clear homogeneous solution at room temperature (68°F).

3.2 The soap shall not contain visible foreign matter, and shall be free from objectionable odor (e.g., rancidity or odor of decomposition) as received, in solution in hot water, and during storage. The soap shall not leave any objectionable odor on the skin after washing followed by thorough rinsing with water.

3.3 The soap shall have no injurious effect on the skin.

3.4 The soap shall not contain any dye.

4. BASIS OF ANALYSIS

4.1 In the determination of anhydrous soap, as specified in the following detail requirements, the result shall be expressed on the basis of the sample as received. The results of all other determinations shall be expressed on the basis of a sample having a 20 per cent anhydrous soap content.

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* Other germicides may be used providing the conditions in par. 5.1 Note 1 are complied with.

Withdrawn/Retirée

5. DETAIL REQUIREMENTS

The soap shall comply with the following detail requirements:

		Min.	Max.	Test Method
5.1	Hexachlorophene, USP, % by wt (Note 1)	0.9	1.10	Par. 7.2.2.1
5.2	Anhydrous Soap (calculated as potash soap), % by wt (Note 2)	20	-	2-GP-11/3.1
5.3	Free Alkali (calculated as KOH), % by wt	-	0.05	2-GP-11/6.1
5.4	Free Fatty Acid (as oleic), % by wt	-	0.1	2-GP-11/6.1
5.5	Matter Insoluble in Water, % by wt (Note 3)	-	0.1	2-GP-11/10.1
5.6	Alcohol-Insoluble Matter, % by wt	-	0.5	2-GP-11/9.1
5.7	Chlorides (calculated as KCl), % by wt	-	0.17	2-GP-11/11.1
5.8	Rosin, % by wt	-	1.0	2-GP-11/5.2
5.9	Sugar, % by wt	-	NIL	2-GP-11/12.1
5.10	Acid number of fatty acids derived from the soap (Note 4)	215	-	2-GP-11/3.1

5.11 Low-Temperature Stability - The soap shall exhibit no evidence of cloudiness or gelatinization when frozen and then returned to room temperature. Par. 7.2.2.2

Note 1: If a supplier desires to use a germicide other than hexachlorophene, he shall (a) certify the chemical name and concentration of the germicide, (b) provide a suitable method for identifying the germicide and determining its concentration, (c) provide evidence that the effectiveness of the finished product in use-dilution, against pathogenic staphylococci, is at least equal to that of an acceptable product containing hexachlorophene, and (d) provide evidence that the finished product is safe to use and commercially acceptable.

Note 2: Correction necessary for the presence of hexachlorophene and its attendant acidity, in the anhydrous soap, may be made by the following calculation:

$$\text{Anhydrous Potassium Soap} = \left[\left(W_2 - \frac{HW_1}{100}\right) + \left(V - \frac{HW_1}{100 \times 0.407N}\right) \times N \times 0.0381\right] \times \frac{100}{W_1}$$

where W_1 = weight of liquid soap sample taken (g)

W_2 = weight of fatty and rosin acids and hexachlorophene (g)

H = per cent of hexachlorophene, found in assay

V = volume of standard alkali used in titration (ml)

N = normality of standard alkali

Also, correction should be made by deducting the unsaponified and unsaponifiable matter as determined by ASTM D460.

Withdrawn/Retirée

Note 3: For par. 5.5 proceed as in determination of total matter insoluble in alcohol (see 2-GP-11, Method 9.1) starting with a fresh sample of soap but omitting the drying and weighing of matter insoluble in alcohol, and then proceeding with the extraction in boiling water (Method 10.1).

Note 4: Correction necessary because of presence of hexachlorophene and its attendant acidity in the extracted fatty acids may be made by the following calculation:

$$\text{Acid Number} = \left[V - \frac{HW_1}{100 \times 0.407N} \right] \times \frac{N \times 56.1}{(W_2 - 0.01\ HW_1)}$$

where W_1 = weight of liquid soap sample taken (g)

W_2 = weight of fatty and rosin acids and hexachlorophene (g)

V = volume of standard alkali used in titration (ml)

N = normality of standard alkali

H = per cent of hexachlorophene in assay.

6. PREPARATION FOR DELIVERY

6.1 Packaging, Labelling, Packing and Marking - Unless otherwise specified, commercial packaging, labelling, packing and marking shall be acceptable.

6.2 Labelling

6.2.1 The label information shall also indicate that the material shall not be allowed to freeze at any time. The arrangement and wording of the information shall be at the supplier's discretion.

6.2.2 The supplier shall declare on the label the chemical name and minimum proportion of germicide used in the soap.

7. INSPECTION

7.1 Sampling - Sampling shall be in accordance with Method 1.3 of CGSB 2-GP-11, Methods of Testing and Analysis of Soaps and Detergents.

7.2 Testing

7.2.1 Qualification Tests - Qualification tests are those tests that are performed on samples submitted for qualification as a satisfactory product. They shall consist of the tests necessary to establish compliance with all the requirements of this standard.

7.2.2 Test Methods - The methods of test shall be those in CGSB 2-GP-11, ASTM D460 or as follows, using the method specified with each requirement. Preparation of samples in the laboratory shall be in accordance with Method 2.3 of 2-GP-11.

Withdrawn/Retirée

7.2.2.1 Assay for Hexachlorophene

(a) Preparation of Sample - Thoroughly mix the soap. Liquid soap received during very cold weather shall be allowed to stand at least 1 hour after it has been warmed to room temperature (20 to 30°C, 68 to 86°F), before it is tested.

(b) Reagents

Methanol - A. C. S. Reagent Grade (diluted, 1 part distilled water and 9 parts methanol).

Hexachlorophene Reference Standard - U. S. P. Hexachlorophene Reference Standard or equivalent.

Standard Preparation of Hexachlorophene - Place about 50 mg of Hexachlorophene Reference Standard, previously dried at 105°C for 4 hours and accurately weighed, in a 250 ml volumetric flask, dissolve in 10 ml of alcohol, and dilute with 90% methanol to volume. Preserve in an airtight container.

Alkaline Buffer - Dissolve 6.07 gm of tris-(hydroxymethyl) aminomethane (THAM), M. P. 170 to 172°C, in 900 ml of methanol. Add 25.0 ml of 1N hydrochloric acid, dilute to 1 liter with water, and mix.

Acidified Methanol - 50 ml acetic acid (6N) and 3 ml hydrochloric acid diluted to 1,000 ml with 90% methanol.

(c) Standard Hexachlorophene Graph

To 50 ml volumetric flasks add by pipette and in duplicate, 0, 5, 10 and 15 ml portions of the Standard Preparation. To one flask of each pair of duplicates add acidified methanol reagent to volume. To the second flask of each pair add Alkaline Buffer to volume.

Arrange the two series of standard hexachlorophene solutions in pairs according to their hexachlorophene content and determine the absorbance of the alkaline solutions at 312 mu, with a suitable spectrophotometer, using the corresponding acid solution as the blank. Plot the observed absorbance on the ordinate scale against the corresponding concentration of hexachlorophene, in mg per 100 ml, on the abscissa scale.

(d) Procedure - Weigh accurately in a 100 ml volumetric flask approximately 10 g of the sample. Add ethyl alcohol to volume and mix. Transfer 25.0 ml of this solution to a 100 ml volumetric flask, add 90% methanol to volume, mix and filter if necessary. Add 10.0 ml of this solution to each of two 50 ml volumetric flasks, and fill one to volume with the acidified methanol reagent. Fill the other flask to volume with Alkaline Buffer.

Determine the absorbance of the alkaline solution at 312 mu, with the same spectrophotometer used in preparing the Standard Hexachlorophene Graph, using the corresponding acid solution as the blank. From the observed absorbance calculate the weight of hexachorophene in the sample taken.

Withdrawn/Retiree

7.2.2.2 Low-Temperature Stability - Place from 8 to 16 fluid ounces of the product in each of three cylindrical, colorless, clear-glass, stoppered cylinders so that the height of sample in each container is at least 5 inches. Freeze the soap solution. After the soap has been frozen, allow it to return to room temperature. Examine for cloudiness, gelatinization and separation.

8. NOTES

8.1 Intended Uses - Surgical liquid soap to this standard is intended for use in the preparation of the operative field of the skin and for scrubbing by surgical personnel prior to surgery. (In storage the usual precautions against freezing should be taken.)

8.2 Ordering Data - Invitation to tender for liquid surgical soap according to this standard should state the following:

(a) Packaging, packing, marking and labelling required if commercial practice is not acceptable (par. 6.1).

(b) Whether a qualified product is required (par. 8.3).

8.3 Qualification

8.3.1 Qualification Procedure - Details regarding procedure for qualification of material to this standard may be obtained by writing to:

Quality Assurance Branch,
Department of National Defence,
Ottawa 2, Ontario.

The laboratories are located in the Canadian Government Printing Bureau Building, Sacré-Coeur Blvd., Hull, P.Q.

8.3.2 Qualified Products - Federal Government department and agencies may also obtain from the above address information regarding availability of qualified products.

8.4 The publication listed in par. 2.1.1 may be obtained from the Canadian Government Specifications Board.

8.5 The publication listed in par. 2.1.2 may be obtained from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa., 19103, U.S.A.

8.6 Related Specification - At the time of publication, the undernoted document was a corresponding specification (but not necessarily equivalent):

8.6.1 U.S. Federal Specification P-S-615, Soap, Surgical, Cake and Liquid.

Correspondence regarding this standard should be addressed to the Canadian Government Specifications Board, c/o Department of Defence Production, Ottawa 4, Canada.

Withdrawn/Retired