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2-GP-51
March 1968
CANCELLATION
April 1980

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL, MILLED CAKE

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

2-GP-51
22 March 1968
AMENDMENT NO. 1
22 November 1968

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL: Milled Cake

Withdrawn/Retirée

7. INSPECTION

7.4 Assay for Hexachlorophene

7.4.2 *Reagents*

(d) *Alkaline Buffer* - Change second sentence to read:

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

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6/2/69

2-GP-51
March 1968
AMENDMENT NO. 2
November 1973
Supersedes
Amendment No. 1

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL, MILLED CAKE

2. APPLICABLE PUBLICATIONS

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

7. INSPECTION

7.4 Assay for Hexachlorophene

7.4.2 *Reagents*

(d) *Alkaline Buffer* - Change 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:

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

*8.7 Add the following and change par. 8.7 and 8.7.1 to read 8.8 and 8.8.1 respectively:

*8.7 The publication listed in par. 2.1.4 may be obtained from Information Canada, Publishing Division, Ottawa, Canada.

* Change from previous amendment.

Withdrawn/Retirée

CANADA

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

STANDARD

FOR

SOAP, SURGICAL: Milled Cake

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Withdrawn/Retirée

2-GP-51

22 MARCH 1968

THIS STANDARD APPLIES TO HIGH-GRADE, MILLED, STABILIZED, THOROUGHLY SAPONIFIED SODA SOAP, OR MIXTURE OF SODA AND POTASH SOAPS, PREPARED FROM SUITABLE FATS, INCAKE FORM AND CONTAINING HEXACHLOROPHENE.

DEPARTMENT OF DEFENCE PRODUCTION, OTTAWA, CANADA

15 CENTS

COMMITTEE ON SOAPS AND DETERGENTS

(Membership at date of approval by the Committee)

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Withdrawn/Retirée

2-GP-51
22 March 1968

CANADIAN GOVERNMENT SPECIFICATIONS BOARD

Standard
for

SOAP, SURGICAL: Milled Cake

1. DEFINITION

1.1 This standard applies to high-grade, milled, stabilized, thoroughly saponified soda soap, or mixture of soda and potash soaps, prepared from suitable fats, in cake form, 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 Pharmacopoeia of the United States.

2.1.3 ASTM Standards on Soaps and Other Detergents.

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

3. GENERAL REQUIREMENTS

3.1 The soap shall be a light uniform color.

3.2 It shall be free from objectionable odor as received, in solution in hot water and during normal storage, and it shall not leave any objectionable odor on the skin after washing and thorough rinsing with water.

3.3 The soap shall lather effectively in cold soft water.

3.4 It shall have no injurious effect on the skin.

3.5 The soap shall contain no visible foreign particles.

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

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4. BASIS OF ANALYSIS

4.1 In the determination of anhydrous soap, as specified in the detail requirements below, 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 an 81 per cent anhydrous soap content.

5. DETAIL REQUIREMENTS

The soap shall comply with the following detail requirements:

		Min	Max	Test Method
5.1	Hexachlorophene, USP, % by wt (Note 1)	1.80	2.40	Par. 7.4
5.2	Moisture and matter volatile at 105°C, % by wt	-	15.0	2-GP-11/13.1
5.3	Alcohol insoluble matter, % by wt	-	see par. 5.6	2-GP-11/9.1
5.4	Sodium chloride, % by wt	-	see par. 5.6	2-GP-11/11.1
5.5	Free alkali calculated as sodium hydroxide (NaOH), % by wt	-	0.1	2-GP-11/6.1
5.6	Sum of free alkali, total matter insoluble in alcohol, and sodium chloride, % by wt	-	3.0	
5.7	Matter insoluble in water, % by wt (Note 2)	-	1.0	2-GP-11/10.1
5.8	Unsaponified saponifiable matter, % by wt	-	0.3	ASTM D460
5.9	Anhydrous soap (calculated as sodium soap), % by wt (Note 3)	81.0	-	2-GP-11/3.1
5.10	Rosin, % by wt	-	1.0	2-GP-11/5.2
5.11	Sugar, % by wt	-	NIL	2-GP-11/12.1

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: Proceed as in determination of total matter insoluble in alcohol (see Method 9.1, 2-GP-11), 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 (see Method 10.1, 2-GP-11).

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Note 3: The correction necessary for the presence of hexachlorophene and its attendant acidity, in the anhydrous soap, may be made by the following calculation:

$$\text{Anhydrous Sodium Soap} = \left[\left(W_2 - \frac{HW_1}{100}\right) + \left(V - \frac{HW_1}{100 \times 0.407N}\right) \times N \times 0.022\right] \times \frac{100}{W_1}$$

where W_1 = Wt of soap sample taken (g)

W_2 = Wt 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.

Correction should also be made by deducting the unsaponified and unsaponifiable matter as determined by ASTM D460.

6. PREPARATION FOR DELIVERY

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

7. INSPECTION

7.1 Sampling - Sampling shall be in accordance with Method 1.1 of CGSB 2-GP-11, Methods of Testing and Analysis of Soaps and Detergents.

7.2 Testing - The methods of test shall be those in CGSB 2-GP-11, ASTM Standards on Soaps and Other Detergents, or as follows, using the method specified with each requirement. Preparation of samples in the laboratory shall be in accordance with Method 2.1 of 2-GP-11.

7.3 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.

7.4 Assay for Hexachlorophene

7.4.1 Preparation of Sample - Disintegrate and mix the sample by running it through a suitable chopper. Treat samples that cannot be handled in this manner as follows: quarter a cake of average weight by cutting at right angles in the center; equally shave sufficient soap for analysis from all freshly cut surfaces. With either method, promptly mix and weigh out all portions for analysis. Preserve any sample not immediately utilized in an air-tight container in a cool place.

7.4.2 Reagents

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

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(b) Hexachlorophene Reference Standard - U.S.P. Hexachlorophene Reference Standard or equivalent.

(c) 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 ethyl alcohol, and dilute with 90% methanol to volume. Preserve in an air-tight container.

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

(e) Acidified Methanol - 50 ml of 6N acetic acid, 3 ml hydrochloric acid (S.G. 1.18) and dilute to 1,000 ml with 90% methanol.

7.4.3 Standard Hexachlorophene Graph

(a) 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.

(b) 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.

7.4.4 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 hexachlorophene in the sample taken.

8. NOTES

8.1 Intended Uses - 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.

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

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

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

Withdrawn/Retirée

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 departments and agencies may also obtain information regarding availability of qualified products from the above address.

8.4 The publication listed in par. 2.1.1 may be obtained from the CGSB Secretary.

8.5 The publication listed in par. 2.1.2 may be obtained from the U.S. Pharmacopoeial Convention Inc. Publications, 46 Park Avenue, New York, N.Y., U.S.A.

8.6 The publication listed in par. 2.1.3 may be obtained from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa., 19103, U.S.A.

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

8.7.1 U.S. Federal Specification P-S-615, SOAP, SURGICAL, CAKE AND LIQUID.

Withdrawn/Retirée