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# ENQUIRY DRAFT

## Baby skin care products
## Part 2: Baby powder



**Guyana National Bureau of Standards**
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# Contents

# Foreword

This Draft Guyana Standard is the first revision of 'GYS 179-2: 1998 Baby skin care products-Part 2: Baby Powder. It was developed by the Guyana National Bureau of Standards through the **Technical Committee- Cosmetics and Pharmaceuticals.**

The standard was originally adapted from the Jamaican Standard, JS 250 Part 2: 2000, 'Specification for baby skin care products-Part 2 Baby powder' to provide guidelines for the manufacturing of baby powder in an effort to ensure that only products of acceptable quality are offered for sale to consumers. This standard was revised to provide detailed requirements for baby powder and update the test method for lead.

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# Baby skin care products Part 2: Baby powder

## 1 Scope

This standard specifies the requirements for baby powder prepared from a blend of material to produce the characteristics set out in **Clause 4**. It applies to baby powder used for newborns (birth to 1 month), infants (1 month to 1 year), and young children (1 year through 6 years). It does not apply to aerosols.

## 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this National Standard. For undated references, the latest edition of the referenced document (including any amendments) applies

GYS 9-1, *Specification for labelling of commodities- Part1: General principles. Guyana Standard.*

GYS 9-2, *Specifications for labelling of Commodities- Part 2: Labelling of pre-packaged goods. Guyana Standard.*

GYS 9-8, *Specifications for labelling of Commodities- Part 8: Labelling of cosmetics. Guyana Standard.*

GYS 11-3, *Cosmetics – Part 3: Raw materials and adjuncts. Guyana Standard.*

GYS 11-4, *Cosmetics-Part 4: Microbiological test method for cosmetics. Guyana Standard.*

GYS 179-1, *Baby skin care products- Part 1: General requirements. Guyana Standard.*

## 3 Definitions

### 3.1 Free flowing

Moving without hindrance, with particles that do not stick together.

### 3.2 Grit

Small loose particles

### 3.3 Off white

A white colour, not pure white with a grey or yellowish tinge

### 3.4 Chafting

Skin irritation that occurs where skin rubs against skin, clothing, or other material.

### 3.5 Baby powder

Finely powdered, free flowing, absorbent innocuous materials such as talc, and may contain a mild perfume and other ingredient consistent with accepted practice in the cosmetic industry

# 4 General requirements

## 4.1 Raw materials

Raw materials shall be dermatologically safe and unless otherwise specified, all raw materials used in the manufacture of baby powder shall be approved by the Ministry of Health and shall conform to the latest version of the **GYS 179-1, Baby skin care products- Part 1: General requirements** and the **GYS 11-3, Cosmetics – Part 3: Raw materials and adjuncts.**

## 4.2 Finished products

**4.2.1** This product shall be finely powdered, free flowing and made from high grade sterile platelet talc, corn starch or any other suitable materials combined with other approved ingredients, so selected and processed that the powder shall:

(a) be loose and free from grit;

(b) be smooth;

(c) be white to off white; and

(d) not have an unpleasant odour within the shelf life of the product

**4.2.2** The product shall also have properties to impart a smooth feel, absorb moisture and adhere to the skin.

## 4.3 Performance

The product shall:

(a) help to control diaper rash;

(b) not clog sweat pore or interfere with normal water loss;

(c) serve as lubricant where skin surfaces are in contact and thus help to prevent chafting;

(d) act as a moisture barrier; and

(e) be non-irritating

# 5 Detailed requirements for finished products

## 5.1 Ingredients and chemicals requirements

**5.1.1** The product shall comply with the requirements prescribed in **Tables 1** and **2**.

**Table 1 Ingredients**

| Ingredients | Percentage of weight |
|---|---|
| Talc or Corn Starch | 90 – 98 |
| Moisture absorber | 2 max |
| Fragrance | 0.2 max |
| Whitening or Opacifying agent | 1 -2 |
| Adhesive Agent | 2 max |
| Neutralising Agent | 2 max |

**Table 2 Chemical Properties**

| Property | Specifications |
|---|---|
| Moisture & Volatile matter (% by wt. Max ) pH (in aqueous suspension) | 2<br>5.5 – 9.0 |
| Particle size, (% by wt.) | |
| Residue on 150-micron sieve | 0.5 |
| Residue on 75 micron sieve | 2.0 |
| **Contaminant (ppm max)** | |
| Lead | 1 |
| Arsenic (as $As_2 0_3$),parts per million, Max | 2 |

**5.1.2** The total amount of heavy metals as lead, mercury and arsenic, in combination in the finished baby powder shall not exceed 10 mg/kg.

### 5.2 Microbiological requirements

**5.2.1** When tested in accordance with the requirements of the latest version of the **GYS 11-4, Cosmetics-Part 4: Microbiological test method for cosmetics** the finished product shall comply with the following microbiological requirements:

(a) total aerobic plate count shall be less than 100 colony forming units per gram or per mL;

(b) yeast and mould shall be absent;

(c) coagulase positive *Staphylococcus* shall be absent;

(d) sterility test results shall be negative; and

(e) gram negative rods shall be absent;

## 6 Packaging and labelling

**6.1.1** The product shall be packed in suitable well- closed containers and labelled in accordance with the latest version of:

1. GYS 9 –1, Specification for labelling of commodities- Part1: General principles.
2. GYS 9 – 2, Labelling of Goods - Part 2: Specific requirements for prepackaged goods; and
3. GYS 9 -8, Specifications for labelling of Commodities- Part 8: Labelling of cosmetics

**6.1.2** Packaging materials shall be compatible with the contents.

## 7 Sampling and testing

### 7.1 Sampling

Representative samples shall be drawn as prescribed in **Appendix B**.

### 7.2 Test

Tests for chemical and microbiological parameters shall be carried out on the composite sample as prescribed in Appendix B.

#### 7.2.1 Interpretation of results

The product shall be taken to conform to the specification if the composite sample passes all the tests prescribed in **Appendix C.**

# Appendix A

## Recommended agents

The following agents are recommended for use in baby powder:

| | | |
|---|---|---|
| Moisture absorbing | - | magnesium carbonate<br>calcium carbonate fumed silica |
| Adhesive agent | - | zinc stearate<br>magnesium stearate |
| Neutralising agent | - | adipic acid<br>malic acid succinic acid |
| Opacifying agent | - | zinc oxide |
| Lubricating agent | - | isopropyl myristate<br>isopropyl palmitate |

# Appendix B

## Guidelines for sampling

### B.1 General requirements

**B.1.1** Sampling shall be done by a qualified person, trained in aseptic techniques.

**B.1.2** Sampling shall be carried out according to written quality control procedures.

**B.1.3** The sampling equipment and sample containers must be sterile.

**B.1.4** Precautions shall be taken to protect the samples, the materials being sampled, the sampling instrument and the sample containers from contamination.

**B.1.5** The material to be sampled shall be mixed as thoroughly as possible by suitable means.

**B.1.6** Each sample container shall be sealed air-tight with a suitable stopper after filling and marking with full details of sampling, to include the date of sampling and year of manufacture of the product.

**B.1.7** Samples shall be stored in such a manner that deterioration of the product is not accelerated.

### B.2 Scale of sampling

**B.2.1** **lot:** All the cases with containers of the same size containing material of the same type, grade, class and composition, manufactured under the same condition and at the same time shall constitute a lot.

**B.2.2** **sample:** All the containers drawn from the particular lot shall be considered a sample for testing purposes.

**B.2.3** Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of the specification.

**B.2.4** The number of containers to be selected from each lot shall be in accordance with that specified for the requirement.

**B.2.5** The containers shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If random number tables are not available, the following procedures shall be used:

Starting from any count 1,2,3,4,…. 'r' in a systematic manner. Each 'rth' case thus counted shall be withdrawn until the desired number is obtained, 'r' being the integral part of N/n. Where 'n' is the number of cases to be selected, one container shall be drawn from each case.

### B.3 Test samples and reference samples

#### B.3.1 Preparation of test samples

Draw with appropriate sampling instrument a small portion of the material from different parts of each container selected as in **B-2.5.** The total quantity of the material drawn shall be sufficient to conduct the test form all characteristics in clauses **4.1** and **4.2** (and shall not be less that 0.2 kg).

**B.3.2** Thoroughly mix all portions of the material drawn from the same container. Out of these portions, equal quantity shall be taken from each selected container and shall be well mixed together so as to form a composite sample weight not less than 0.5 kg. This composite sample shall be divided into three equal parts, one for the purchaser, another for the suppler and the third for referee.

**B.3.3** The reference sample shall be appropriately marked and be retained so that it can be used in the event of any dispute.

## B.4 Sampling plan

**B.4.1** Each of the containers selected in accordance with the specified sampling plan shall be tested for the relevant finished product requirement.

**B.4.2** Sampling plan for microbiological and chemical requirements shall be as follows:

| | | |
|---|---|---|
| Acceptable Quantity Limit (AQL) | = | 2.5 |
| Sample Size | = | 5 |
| Acceptance No. | = | 0 |
| Rejection No. | = | 1 |

**Acceptance**

Where on first sampling and testing a unit fails to meet the requirements, a second sample of the same size shall be taken. If on re-sampling and testing, another until does not comply, the lot shall deem to have failed to meet the requirements.

When more than one unit of the initial sample or one the re-sample fails to meet the requirements, investigations to determine cause of failure and subsequent remedial action shall be necessary.

# Appendix C

## Analysis of Skin Powder

## C.1 Quality of reagents

Unless specified otherwise, pure chemicals and distilled water shall be used in these tests.

## C.2 Determination of moisture (Volatile matter)

### C.2.1 Procedure

Weigh accurately 5g of the material in a porcelain or glass dish, about 6 to 8 cm in diameter and about 2 to 4 cm in depth. Dry in an air oven a temperature of $105^0 \pm 2\ ^0$C to constant weight (within ± 5mg.).

### C.2.2 Calculation

Moisture and Volatile matter, percent by weight $\frac{100Xw}{W}$

Where w = loss in wt. (in g) on drying

W = wt (in g) of material taken for the test.

## C.3 Determination of pH aqueous suspension

### C.3.1 Apparatus -pH meter equipped glass electrode

**Procedure**

Boil about 10g of the powder with 50 mL of water for 30 minutes, adding water from time to time to maintain approximately the original volume of the liquid. Cool and filter. Determine the pH of the filtrate within 5 minutes of filtration.

## C.4 Determination of fineness

### C.4.1 Procedure for material retained on 75 micron IS sieve

Place 10g of powder in 75-micron (IS) sieve and wash by means of slow stream of running tap water and finally with fine stream from a wash bottle until all the powder that can pass through the sieve has passed. Let the water drain from the sieve and then dry the sieve containing the residue on a stream bath. Transfer the residue on to a tared watch glass carefully and dry it to a constant mass 105 ± 2 $^0$C and weigh.

### C.4.2 Calculation

Material retained on specified sieve percent by mass = $100 \frac{m}{M}$

Where m = mass (in g) of the residue retained on the sieve, and M = mass (in g) of the material taken for the test.

### C.5 Test for lead

The method for determining the amount of lead that may be present in pharmaceutical products depends on extraction of lead by solutions of dithizone.

Select all reagents for test to have as low a content of lead as practicable and store all reagents solutions in containers of borosilicate glass. Rinse thoroughly all glassware with warm dilute nitric acid (1 in 2), followed by water.

### C.5.1 Preparation of Sample

1. Transfer 1.0 g of the substance under test to a suitable flask, add 5 mL of sulfuric acid and a few glass beads, and digest on a hot plate in a hood until charring begins.

**Note1**: Other suitable means of heating may be substituted. (Add additional sulfuric acid, if necessary, to wet the substance completely, but do not add more than a total of 10 mL)

2. Add, dropwise and with caution, 30% hydrogen peroxide, allowing the reaction to subside and heat between drops. Add the first few drops very slowly, mix carefully to prevent a rapid reaction, and discontinue heating if foaming becomes excessive. Swirl the solution in the flask to prevent unreacted substance from caking on the walls of the flask.

**Note2**: Add peroxide whenever the mixture turns brown or darkens.

3. Continue the digestion until the substance is completely destroyed, copious fumes of sulfur trioxide are evolved, and the solution is colourless.

4. Cool, and cautiously add 10 mL of water. Evaporate until sulfur trioxide again is evolved, and cool. Repeat procedure with another 10 mL of water to remove any traces of hydrogen peroxide.

5. Cautiously dilute with 10 mL of water, and cool.

### C.5.2 Special reagents

**Ammonia cyanide solution**

Dissolve 2 g of potassium cyanide in 15 mL of stronger ammonia TS and dilute with water to 100 mL.

**Ammonia citrate solution**

Dissolve 40 g citric acid in 90 mL of water. Add 2 or 3 drops of phenol red TS, then cautiously add stronger ammonia TS until the solution acquires a reddish colour. Remove any lead that may represent by extracting the solution with 20 mL portions of dithizone the solution if necessary and add 2 mL of potassium cyanide solution.

### C.5.3 Procedure:

1. Transfer the Test preparation or Sample solution, rinsing with 10 mL of water, or the volume of the prepared sample specified in the monograph to a separator, and, unless otherwise directed in the monograph.

2. Add 6 mL of Ammonium citrate solution and 2 mL of Hydroxylamine hydrochloride solution.

**Note3**: For the determination of lead in iron salts, use 10 mL of Ammonium citrate solution.

3. Add 2 drops of phenol red TS, and make the solution just alkaline (red in color) by the addition of ammonium hydroxide. Cool the solution if necessary, and add 2 mL of Potassium cyanide solution.

4. Immediately extract the solution with 5 mL portions of dithizone extraction solution, draining off each extract into another separator, until the dithizone solution retains its green colour.

5. Shake the combined dithizone solution for 30 seconds with 20 mL of dilute nitric acid (1 in 100) and discard the chloroform layer.

6. Add to the acid solution 5.0 mL of standard dithizone solution and 4 mL of ammonia- cyanide solution and shake for 30 seconds.

### C.5.4 Interpretation of results

The colour of the chloroform layer is of no deeper shade of violet than that of a control made within a volume of diluted standard lead solution equivalent to the amount of lead permitted in the sample under examination, and the same quantities of the same reagents and in the same manner as in the test with the sample.

# Appendix D
## Determination of arsenic/lead by ICP-based methods.

Procedure 1 and 2 are ICP-based procedures and can be used for the determination of arsenic/lead. Procedure 1 can be used for the determination of arsenic/lead by inductively coupled plasma atomic (or optical) emission spectroscopy (ICP–AES or ICP–OES). Procedure 2 can be used for the determination of arsenic/lead by ICP–MS.

Before initial use, verify that the procedure is appropriate for the instrument and sample used by meeting the requirements for procedure validation. Where a monograph specifies a limit for arsenic/lead concentration, the value listed in the monograph should be used as the J value for the purposes of this test. System standardization and suitability evaluation using applicable reference materials should be performed on the day of analysis.

### D.1 Procedure 1

#### D.1.1 Preparation of Sample

1. Dehydrate and predigest 0.5 g of the primary sample in 5 mL of freshly prepared concentrated acid. Allow to sit loosely covered for 30 min in a fume hood

2. Add an additional 10 mL of concentrated acid, and digest using a closed vessel technique until digestion or extraction is complete. Repeat, if necessary, by adding an additional 5 mL of concentrated acid.

**Note4**: Follow the manufacturer's recommended procedures to ensure safe use.

#### D.1.2 Reagents

All reagents used for the preparation of sample and standard solutions should be free of elemental impurities.

a) **Standardization solution 1**

1.5 J of arsenic/lead in a matched matrix

b) **Standardization solution 2**

0.5 J of arsenic/lead in a matched matrix

c) **Sample stock solution**

Prepare as directed in Sample preparation. Allow the sample to cool, if necessary

d) **Sample solution**

Dilute the sample stock solution with an appropriate solvent to obtain a final arsenic/lead concentration of not more than 1.5 J.

e) **Blank**

Matched matrix

f) **Elemental spectrometric system**

g) **Rinse**

Use diluent

h) **Standardisation**

Standardisation solution 1, Standardisation solution 2, Blank

**D.1.3 System suitability**

**Sample:** Standardisation solution 1

**Suitability requirements**

**Drift:** Compare results obtained from Standardisation solution 1 before and after the analysis of the sample solution.

**Suitability criteria:** Note more than 20% for arsenic/lead.

**Note5**: If samples are high in mineral content, rinse the system well before introducing the sample in order to minimize carryover**.**

**D 1.4 Analysis:** Analysis according to the manufacturer's suggestions for program and mass-charge. Calculate and report results on the basis of the original sample size.

**Note6**: Appropriate measures may be taken to correct matrix-induced interferences (e.g., wavelength overlaps).

**D.2 Procedure 2**

Follow procedure 3, with changes made for detector and analysis.

**D.2.1 Detector**: Mass spectrometer

**D.2.2 Analysis:** Analyze according to the manufacturer's suggestions for program and mass-to-charge ratio. Calculate and report results based on the original sample size.

**Note7**: Appropriate measures may be taken to correct for matrix-induced interferences.

**D. 3 Requirements for procedure validation**

The following section defines the validation parameters and the acceptance criteria for performance-based procedures. Meeting these requirements must be demonstrated experimentally using an appropriate system suitability procedure and reference materials. Any alternative procedure (e.g., an atomic-absorption-based procedure) that has been validated and meets the acceptance criteria that follow is considered to be suitable for use. Meeting these validation acceptance criteria is sufficient to demonstrate that the procedure will produce comparable results to those obtained using the procedure prescribed in the monograph.

**D.3.1 Accuracy**
Standard solutions: Prepare solutions containing arsenic at concentrations ranging from 50% to 150% of J using appropriate reference materials.

Test samples: Spike the material under test with the appropriate reference materials before any sample preparation steps (digestion or solubilization). Prepare three replicate samples at concentrations ranging from 50% to 150% of J for arsenic/lead.

**D.3.2 Acceptance criteria**
Spike recovery: 70%–150% for the mean of three replicate preparations at each concentration

**D.3.3 Precision**
Repeatability
Test samples: Six independent samples of material under test (taken from the same lot) spiked with appropriate reference materials for arsenic/lead at the indicated concentration

**D.3.4 Acceptance criteria**
Relative standard deviation: Not more than 20% (N = 6) for arsenic/lead

**D.4 Intermediate Precision (Ruggedness)**
Analysis: Perform the Repeatability analysis again on a different day, with different instrumentation, with a different analyst, or a combination thereof. Combine the results of this analysis with the Repeatability analysis so the total number of analyses is 12.

**Acceptance criteria**
Relative standard deviation: Not more than 25% (N= 12) for arsenic/lead

**Specificity**
The procedure must be able to unequivocally assess arsenic in the presence of components that may be expected to be present, including matrix components.

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