SRI LANKA STANDARD 589: 2018

UDC 668.582.22

SPECIFICATION FOR BABY COLOGNE

(*First Revision*)

SRI LANKA STANDARDS INSTITUTION

Sri Lanka Standard
SPECIFICATION FOR BABY COLOGNE
(*First Revision*)

SLS 589: 2018
(AMD 526 Attached)

Gr. 5

SRI LANKA STANDARDS INSTITUTION
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Sri Lanka

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This Standard does not purport to include all the necessary provisions of a contract

Sri Lanka Standard

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FOREWORD

This Standard was approved by the Sectoral Committee on Chemicals and Polymer Technology and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standards Institution on 2018-11-16.

This Specification was first published in 1982. In this first Revision, the requirements for pH and alcohol content have been updated. Microbiological limits and limits for heavy metals have been introduced. The method of test for the determination of ethanol content has also been revised.

After determining the potential categories of product use, habits, practices and exposure routs, it has been recommended to minimize the content of alcohol present in the product.

This Specification is subject to the restrictions imposed under the applicable State Legislative requirements.

For the purpose of deciding whether a particular requirement of this Specification is complied with, the final value, observed or calculated, expressing the result of a test or an analysis, shall be rounded off in accordance with **SLS 102**. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this Specification.

In the formulation of this Specification, the assistance derived from the following publications is gratefully acknowledged :

GS 777 : 2004	Ghana Standard Cosmetics – Specification for Colognes and Perfumes
International Fragrance Association (IFRA) Standards	
ISO 17516 : 2014	Cosmetics – Microbiology – Microbiological limits

1 SCOPE

1.1 This Specification prescribes the requirements and methods of test for baby cologne.

2 REFERENCES

SLS ISO /TR 17276	Cosmetics - Analytical approach for screening and quantification methods for heavy metals in cosmetics
SLS ISO 22716	Guidelines on good manufacturing practices for cosmetics
SLS 102	Rules for rounding off numerical values
SLS 457	Cosmetics - Classification of raw materials

	Part 1 Substances permitted subject to restrictions and permitted colourants, preservatives and UV filters
	Part 2 Prohibited substances
SLS 495	Sampling of cosmetics and toilet preparations
SLS 1587	Cosmetics – Packaging and labeling

3 REQUIREMENTS

3.1 General

3.1.1 Baby cologne shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS ISO 22716**.

3.1.2 The product shall be free from any impurities and foreign matter.

3.2 Raw Materials

3.2.1 The raw materials used shall comply with the provisions of **Part 1** and **Part 2** of **SLS 457**.

3.2.2 The fragrance used shall comply with the provisions of IFRA Standards.

3.2.3 Water for dilution shall be de-ionized or distilled water with the maximum conductivity of 10 µS/cm.

3.2.4 Ethanol used for baby cologne shall be denatured with either Denatonium benzoate (Bitrex), Brucine or Diethyl phthalate. Methanol and isopropyl alcohol shall not be used.

3.3 Other requirements

3.3.1 Baby cologne shall also comply with the requirements given in Table **1** when tested in accordance with the methods prescribed in Column **4** of the table.

TABLE 1 – Requirements for baby cologne

Sl No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of test** (4)
i)	Cloudiness	To pass the test	Appendix B
ii)	pH (neat)	5.0 – 7.0	Appendix C
iii)	Ethanol content, per cent (V/V), max.	55	Appendix D

3.3.2 Microbiological limits

Baby cologne shall comply with the microbiological limits given in Table **2** when tested in accordance with the relevant method given in Column **4** of the table.

TABLE 2 - Microbiological limits

Sl. No. (1)	Test (2)	Limit (3)	Method of test (4)
i)	Total aerobic mesophilic microorganisms (bacteria, yeast and mould count), ml, max.	100	SLS 1349 SLS 1445
ii)	*Pseudomonas aeruginosa*	Absent in 1 ml	SLS 1350
iii)	*Staphylococcus aureus*	Absent in 1 ml	SLS 1351
iv)	*E.coli*	Absent in 1 ml	SLS 1489
v)	*Candida albicans*	Absent in 1 ml	SLS 1488

3.3.3 Heavy metal limits

Baby cologne shall also comply with the heavy metals limits given in Table **3** when tested in accordance with **SLS ISO /TR 17276.**

TABLE 3 – Heavy metal limits

Sl. No. (1)	Test (2)	Limit (3)
i)	Lead (as Pb), mg/kg, max.	10
ii)	Arsenic (as As), mg/kg, max.	1.5
iii)	Cadmium (as Cd), mg/kg, max.	3
iv)	Mercury (as Hg), mg/kg, max.	1

4 PACKAGING AND MARKING

4.1 Packaging

4.1.1 The baby cologne shall be packaged in suitable, well-closed containers which shall not cause any deterioration to the quality of the product and shall made of material non reacting with baby cologne compounds and not releasing any toxic or carcinogenic material.

4.1.2 Baby cologne shall not be packaged in spray cans.

NOTE
Number of containers or boxes may be packed together to form a package.

4.2 Marking

4.2.1 The following information shall be legibly and indelibly marked on the containers. Where containers are enclosed in boxes, the information shall be marked on the boxes.

a) Name of the product;
b) Name and address of the manufacturer including country of origin (see Note **1***);*
c) Registered trade mark, if any;
d) Brand name, if any;
e) Net volume, in millilitres;
f) Batch identification number;
g) Date of manufacture and best before / shelf life / Date of expiry (see Note 2);
h) List of ingredients present in greater than 1 per cent in descending order of weight, followed by those in concentration of less than or equal to 1 per cent, in any order;
j) A declaration, if product containing less than 1 per cent of ethanol;
k) Warning statement as "Not recommended for infants"; and
l) Directions for use, if any.

NOTES :

1. *Name and address of the manufacturer and the distributor need to be marked on imported products.*

2. *The date of expiry / best before / shelf life of the finished product shall be determined on results of the stability test.*

4.2.2 The marking and labeling shall also be in accordance with **SLS 1587.**

5 SAMPLING

Representative samples of baby cologne for carrying out tests shall be drawn as specified in Appendix **A.**

6 METHODS OF TEST

6.1 Tests shall be carried out as prescribed in Appendices **B** to **D.**

6.2 During the analysis, unless otherwise stated, use only reagents of recognized analytical grade and only distilled water or water of equivalent purity.

APPENDIX A
COMPLIANCE OF A LOT

The sampling scheme given in this Appendix shall apply where compliance of a lot to the requirements of this standard has to be assessed based on statistical sampling and inspection.

Where compliance with this Specification, appropriate schemes of sampling and inspection shall be adopted based on manufacturer's control systems coupled with Type Tests and Testing Procedures.

A.1 LOT

In any consignment containers of one batch with the same type and capacity shall be grouped as a lot.

A.2 SCALE OF SAMPLING

A.2.1 Samples of the baby cologne shall be drawn from the lot for testing. The number of samples to be selected at random from the lot shall depend upon the size of the lot and shall be in accordance with Table **4**.

TABLE 4 – Scale of sampling

No. of cartons in a lot (1)	**No. of cartons to be selected** (2)	**No. of containers to be selected from each carton** (3)
Up to 20	3	3
21- 50	4	2
51-100	5	2
101-200	7	1
201-300	7	1
301 and above	8	1

A.3 NUMBER OF TESTS

A.3.1 Each container selected as in **A.2.1** shall be examined for packaging and marking requirements.

A.3.2 Tests for the requirements specified in **3.3** of this Specification shall be carried out on the composite sample prepared as in **6.4.1** of **SLS 495**.

A.4 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this Specification, if the following conditions are satisfied:

A.4.1 Each container examined as in **A.3.1** satisfies the relevant requirements; and

A.4.2 The composite samples tested as in **A.3.2** satisfies the relevant requirements.

APPENDIX B
DETERMINATION OF CLOUDINESS

B.1 PROCEDURE

Pour 20 mL of baby cologne into a wide cylinder and close it with a plug. Insert a thermometer having scale up to -20 °C. Immerse the thermometer into the liquid in such a manner that its bulb is placed at the same distance from the bottom and walls. Immerse the cylinder containing the liquid into a cooling mixture containing ice and salt. After cooling the sample to 5 °C, take out the cylinder, shake it and scan it in transmitted daylight, or in the light of a 40-W electric lamp.

B.2 RESULT

The product shall be taken to have passed the test if no turbidity appears at a temperature of 5 °C. The baby cologne shall be transparent.

APPENDIX C
DETERMINATION OF pH

C.1 APPARATUS

C.1.1 pH meter equipped with glass electrode

C.1.2 Beaker of 100 mL capacity

C.2 REAGENTS

C.2.1 pH 7.0 buffer solution

C.2.2 pH 4.0 and pH 9.0 / 10.0 buffer solutions

C.2.3 Deionized water

C.3 PROCEDURE

C.3.1 Dip the pH meter into about 50 ml of pH 7.0 buffer solution. Ensure that the reading is 7.0.

C.3.2 Rinse the meter with deionized water, and dip it into about 50 mL of pH 4.0 buffer solution. Ensure that the reading is 4.0. Repeat using pH 9.0 or 10.0 buffer solution.

C.3.3 Determine the pH of baby cologne at 27±2 °C temperature using the calibrated pH meter.

APPENDIX D
DETERMINATION OF ETHANOL CONTENT

D.1 APPARATUS

D.1.1 Volumetric flasks-10 mL, A-grade

D.1.2 Micro pipette-1000 µL, 100 µL

D.1.3 Centrifuge

D.1.4 Gas Chromatograph, recorder and integrator with an injector for capillary columns facility, suitable detector and a temperature programmer

Column shall be made of an inert material such as glass, stainless steel, silica or fused silica and the internal diameter shall be 0.2 mm-0.5 mm and length shall be 15 m-100 m.
Suitable stationary phase such as polyethylene glycol or equivalent shall be used.

D.2 REAGENTS

D.2.1 Absolute ethanol, AR grade, purity > 99% or known purity

D.2.2 Internal standard, (n-propanol or isopropanol) AR grade, purity > 99% or known purity

D.2.3 Distilled Water

D.2.4 Carrier gas - Nitrogen, Helium or Hydrogen according to the type of detector, purity $\geq$ 99.995%

D.2.5 Auxiliary gases, any gases suitable for the detector used. For a flame ionization detector hydrogen and dry air of suitable purity

D.2.6 Solution 1, Reference solution (a)

Prepare a solution containing 5.0 % V/V of Ethanol and 5.0 % V/V of internal standard in distilled water.

D.2.7 Solution 2, Test solution **(**a)

Pipette 0.5 mL of internal standard and 1.0 mL of preparation being examined (baby cologne) into volumetric flask and dilute to 10.0 mL with distilled water. (or add in preferred volumes to have 5.0 % V/V final concentration of internal standard in the final solution)

D.2.8 Solution 3, Reference solution (b)

Prepare a solution containing 100 µL/L of ethanol and 100 µL/L of internal standard in distilled water.

D.2.9 Solution 4 ,Test solution (b)

Add 1 µL of internal standard and 8.0 mL of preparation being examined (baby cologne) into volumetric flask and dilute to 10.0 mL with distilled water (or add in preferred dilutions to have 100 µL/L concentration of internal standard in the final solution)

D.3 PROCEDURE

D.3.1 Ethanol content in alcohol based baby cologne

Gently shake the container of the preparation before open. Prepare Solution 1 and Solution 2 as given in **D.2.6** and **D.2.7**. Inject sufficient amount of clear sample to Gas Chromatograph. (If necessary centrifuge to obtain a clear sample.)

D.3.2 Ethanol content in non-alcoholic baby cologne

Gently shake the container of the preparation before open. Prepare Solutions 3 and 4 as in **D.2.8** and **D.2.9**. Inject sufficient amount of clear sample to Gas Chromatograph. (If necessary centrifuge to obtain a clear sample)

D.3.3 Chromatographic Analysis

Carry out the chromatographic procedure at suitable conditions, maintain inlet and detector end at 220 ^{o}C (or suitable temperature condition) and maintain oven temperature at 50 ^{o}C or suitable isothermal temperature.

D.4 CALCULATION

D.4.1 Determination of Response Factor (R_F)

Determine the R_F value as follows using the chromatograms of solution 1 or 3 (**D**.**2.6** or **D.2.8)**.

Calculate the mean value of duplicate values and record as R_F value.

$$R_F = \frac{A_I \times Ve}{Ae \times V_I}$$

where,

A_I is the Peak area of internal standard in reference standard solution;
Ae is the Peak area of ethanol in reference standard solution;
Ve is the Volume, in milliliters, of ethanol in reference standard solution; and
V_I is the Volume, in milliliters, of internal standard in reference standard solution.

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AMD 526

Amendment No: 01 approved on 2019-10-22 to SLS 589: 2018

AMENDMENT NO: 01 TO SLS 589: 2018
SRI LANKA STANDARD SPECIFICATION FOR BABY COLOGNE (*First Revision*)

SRI LANKA STANDARDS INSTITUTION

AMD 526

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AMENDMENT NO: 01 TO SLS 589: 2018
SRI LANKA STANDARD SPECIFICATION FOR BABY COLOGNE

3 REQUIREMENTS

3.3.2 Microbiological limits

Delete the text in **3.3.2** and substitute with the following**:**

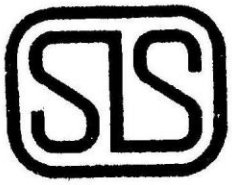
"Baby cologne containing alcohol content less than 20 per cent shall comply with the microbiological limits given in Table **2** when tested in accordance with the relevant method given in Column **4** of the table."

…….

SLS CERTIFICATION MARK

The Sri Lanka Standards Institution is the owner of the registered certification mark shown below. Beneath the mark, the number of the Sri Lanka Standard relevant to the product is indicated. This mark may be used only by those who have obtained permits under the SLS certification marks scheme. The presence of this mark on or in relation to a product conveys the assurance that they have been produced to comply with the requirements of the relevant Sri Lanka Standard under a well designed system of quality control inspection and testing operated by the manufacturer and supervised by the SLSI *which includes surveillance inspection of the factory, testing of both factory and market samples.*

Further particulars of the terms and conditions of the permit may be obtained from the Sri *Lanka Standards Institution, 17, Victoria Place, Elvitigala Mawatha, Colombo 08.*



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SRI LANKA STANDARDS INSTITUTION

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All members of the Technical and Sectoral Committees render their services in an honorary capacity. In this process the Institution endeavours to ensure adequate representation of all view points.

In the International field the Institution represents Sri Lanka in the International Organization for Standardization (ISO), and participates in such fields of standardization as are of special interest to Sri Lanka.

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