Amendment No: 01 approved on 2013-04-30 to SLS 589 : 1982

SRI LANKA STANDARD SPECIFICATION FOR BABY COLOGNE

FOREWORD

Delete 4th paragraph and substitute the following.

"This specification is subject to the restrictions imposed under the cosmetics, Devices and Drugs Act No. 27 of 1980 and the Excise Act No. 13 of 1980 and the regulations framed thereunder."

Insert the following text as the 6th paragraph of Foreword.

"In the preparation of this specification the assistance obtained from the following publications is gratefully acknowledged :

British Pharmacopoeia 2009
IS 8482 : 1995 Indian Standard Cologne – Specification
GS 777 : 2004 Ghana Standard Specification for Colognes and perfumes"

2 REFERENCES

Delete 2nd line.

Insert the following at the end of the reference list.

"SLS 1221 Denatured Alcohol
SLS 1316 Code of good manufacturing practices for cosmetics industry"

3 REQUIREMENTS

3.1 General requirements

Delete entirely the paragraph under Clause **3.1** and substitute the following.

3.1.1 The material shall be a clear aqueous solution of denatured ethanol containing perfume material and emollients. It shall be free from impurities.

3.1.2 Baby cologne shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS 1316**."

3.2 Ingredients

Delete paragraph under Clause **3.2.4** and substitute the following.

" Ethanol denatured with bitrex or brucine shall be used for the preparation of baby cologne. Denatured ethanol shall comply with the requirements given in Table **1** of **SLS 1221 : 2001**."

Insert Clause **3.2.5** as follows.

"3.2.5 *Water*

Water for dilution shall be de-ionized or distilled water and the conductivity shall be maximum of 10 µS/cm when tested by the conductivitymeter.

NOTE : *Quality certificates on conductivity of source water and type of water used for dilution should be submitted with the consignment for imported products."*

Insert Clause **3.4** as follows.

"3.4 pH

The pH value of baby cologne shall be 5.5 - 7.5 when tested as per the method prescribed in Appendix **B**."

4 PACKAGING AND MARKING

4.2 Marking

Delete Clause **4.2.1** and substitute the following.

"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 so marked on the boxes.

a) Name of the product as 'Baby cologne" ;
b) Name and address of the manufacturer for products manufactured in Sri Lanka. Name and address of the manufacturer and the distributor in Sri Lanka/ Importer need to be marked on imported products including country of origin ;
c) Registered trade mark, if any ;
d) Brand name, if any ;
e) Net volume in milliliters ;
f) Batch or code or lot identification number; and
g) Date of manufacture and best before / shelf life.

6 METHODS OF TEST

Insert " and Appendix **B**" at the end of the sentence under Clause **6**.

APPENDIX A

DETERMINATION OF ETHANOL CONTENT IN COLONGNE

Delete the subtitle "**A.1 PROCEDURE**" and insert the following.

"A.1 METHOD 1 : SPECIFIC GRAVIMETRIC METHOD

A.1.1 Procedure"

Insert the following at the end of Table **2**.

" A.2 METHOD 2 : GAS CHROMATOGRAPHIC METHOD

A.2.1 Reagents

A.2.1.1 Solution 1, absolute ethanol of 5.0 % v/v and 5.0 % v/v of propan-1-ol

A.2.1.2 Solution 2

Dilute a volume of the preparation being examined with water to contain between 4.0 and 6.0 % v/v of ethanol.

A.2.1.3 Solution 3

Prepare solution 3 in the same manner as solution 2 but adding sufficient of the internal standard to produce a final concentration of 5.0 % v/v.

A.2.2 Procedure

Carry out the chromatographic procedure using the above solutions (**A.2.1.1, A.2.1.2, A.2.1.3**) and using a column (1.5 m × 4 mm) packed with porous polymer beads (100 to 120 mesh) (Porapak Q and Chromosorb 101 are suitable) and maintained at 150^0 with both the inlet port and the detector at $170^{0.}$

A.2.3 Calculation

Calculate the percentage content of ethanol from the areas of the peaks due to ethanol in the chromatogram obtained with solution."

Insert Appendix **B** at the end of Appendix **A** as follows.

"APPENDIX B
DETERMINATION OF pH

B.1 APARATUS

B.1.1 pH meter equipped with combined electrodes

B.1.2 100-ml glass beaker

B.2 REAGENTS

B.2.1 pH 7.0 buffer solutions

B.2.2 pH 4.0 and pH 9.0 buffer solutions

B.2.3 Deionised / distilled water

B.3 PROCEDURE

Dip the combined electrode of this pH meter into 50 ml of 7.0 buffer solutions. Ensure the reading is 7.0. Rinse the electrode with deionised water and dip it into 50 ml of pH 4.0 buffer solutions. Ensure the reading is 4.0. Repeat using pH 9.0 buffer solutions.

Determine pH of the sample solution using the calibrated pH meter."

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