

AMD 406

AMENDMENT NO: 03 TO SLS 275 : 2006
SRI LANKA STANDARD SPECIFICATION FOR TOOTHPASTE

SRI LANKA STANDARDS INSTITUTION

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EXPLANATORY NOTE

This Amendment has been issued to include following changes :

- to exclude medicated toothpaste, toothpaste in pressurized packs and any therapeutic or prophylactic functions of the toothpaste from the Scope of the standard.
- to refer to **SLS 1316** to adhere the manufacturing process of toothpaste to Good Manufacturing Practise.
- to replace “information of content” with “list of ingredients” under marking requirements to avoid misinterpretation.
- to specify marking requirements for each toothpaste tube.
- to modify the calculation for the determination of “Available Fluoride Ion” to consider fluorides come from any source of ingredients of fluoridated toothpaste.
- to change the requirement for “Ease of extrusion” as “Extrusive content” and to express the limit as a per centage of net mass declared in the package.
- to introduce a requirement for net mass.

Amendment No: 03 approved on 2010-09-03 to SLS 275 : 2006

SRI LANKA STANDARD SPECIFICATION FOR TOOTHPASTE

1. SCOPE

Insert the following.

“Medicated toothpaste, toothpaste in pressurized packs and any therapeutic or prophylactic functions of the toothpaste are not covered by this specification.”

2 REFERENCES

Insert the following before the last line.

“SLS 1316 Code of good manufacturing practices for cosmetics industry”

5 REQUIREMENTS

Insert the following :

“The toothpaste shall be manufactured by a process adhering to Good Manufacturing Practices (GMP) complying with **SLS 1316.**”

5.4 Ease of extrusion

Delete **5.4** and substitute the following.

“5.4 Extrusive content

When tested in accordance with Appendix C.1 it shall be possible to extrude toothpaste not less than 91 per cent of net mass declared from the tube or sachet in a continuous mass without application of excessive force which would cause damage to the tube.”

Include Clause **5.13** as follows.

“5.13 Net mass

The net mass of toothpaste packed shall not be less than the net mass declared on the package when tested in accordance with Appendix **C.1.**”

7 MARKING

Delete entirely Clause **7** and substitute the following :

“7.1 Each container and sachet shall be marked legibly and indelibly with the following information :

- a) Name of the product as “Toothpaste” ;
- b) Type of the product, and fluoride content in ppm for Type 1 toothpaste ;
- c) In fluoridated toothpaste to have either the words “use a pea sized amount for children under 6 years” or in the pictorial form ;
- d) Name and address of the manufacturer including country of origin (See Note) ;
- e) Brand name / trade name or registered trade mark, if any ;
- f) Date of production ;
- g) Date of expiry / best before ;
- h) Batch or code number ;
- j) Net mass of the product in gram ; and
- k) List of ingredients.

NOTE: *Name and address of the manufacturer and the distributors need to be marked on imported products.*

7.2 Each tube shall be marked legibly and indelibly with the following information :

- a) Name of the product as “Toothpaste” ;
- b) Type of the product, and fluoride content in ppm for Type **1** toothpaste ;
- c) Name and address of the manufacturer including country of origin (See Note) ;
- d) Brand name / trade name or registered trade mark, if any ;
- e) Batch or code number ; and
- f) Net mass of the product in gram.

NOTE: *Name and address of the manufacturer and the distributors need to be marked on imported products.”*

APPENDIX A**COMPLIANCE OF A LOT****A.3 NUMBER OF TESTS**

Delete **A.3.5** and substitute the following.

“**A.3.5** A sub sample of size as given in Column (3) of the Table 3 shall be selected from the sample and tested for the requirement given in 5.4 and 5.13.”

APPENDIX C

Delete Appendix C and substitute the following.

**“APPENDIX C
DETERMINATION OF NET MASS, EXTRUDABLE CONTENT AND CONSISTANCY**

C.1 DETERMINATION OF NET MASS AND EXTRUDABLE CONTENT**C.1.1 Procedure**

Weigh the gross mass of the tube or sachet (m_1). After opening the tube or sachet, extrude the bulk of the contents of the tube by the application of light pressure with the fingers. Starting from the crimp end, roll the tube up to the shoulder over a cylindrical surface of diameter 7.5 mm to 8.0 mm approximately. Weigh the remaining of toothpaste with the tube or sachet (m_2). Cut the tube or sachet and remove the remaining toothpaste, wash, dry and weigh the empty tube or sachet (m_3).

C.1.2 Calculation

Net mass packed, g = $m_1 - m_3$

Extrusive content, per cent by mass of declared net mass = $\frac{(m_1 - m_2)}{M} \times 100$

where,

m_1 is the gross mass of toothpaste, in g;

m_2 is the mass of the remaining of toothpaste with the tube or sachet, in g;

m_3 is the mass of empty tube or sachet, in g ; and

M is the net mass declared on the tube or sachet.

C.2 DETERMINATION OF CONSISTANCY

Examine the toothpaste extruded as in C.1.2 for lumps or particles.”

APPENDIX K

DETERMINATION OF FLUORIDE

K.4.4 Determination of fluoride

Insert the following under K.4.4.

“NOTE : *If only free fluoride (eg. NaF) is added as declared by the manufacturer, determination of monofluorophosphate should not be required.*”

K.4.5 Calculation

Delete the paragraph of K.4.5 and substitute the following :

“ Read from the calibration curve the logarithm of fluoride concentration corresponding to E mV. Take its antilog to find the fluoride concentration in the solution measured. Let this be C_1 mg/l for solution B and C_2 mg/l for solution C. Fluoride content in solution A = $5 C_1$ and $5 C_2$ respectively.

K.4.5.1

If only free fluoride is added :

Available fluoride content in toothpaste = $500 C_1/W$ mg/kg (ppm)

If free fluoride and monofluorophosphate are added, or if only monofluorophosphate is added :

Available fluoride content in toothpaste = $500 C_2/W$ mg/kg (ppm)”

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