

**AMENDMENT NO: 01 TO SLS 1657: 2020**

**SPECIFICATION FOR HAND SANITIZERS (ALCOHOL BASED)**

**EXPLANATORY NOTE**

The Sri Lanka Standard for hand sanitizers SLS 1657 was developed by following the accelerated procedure for formulation of National standards during the emergency period prevailed in the country. As such this Standard was not opened-up for “public comments stage” of 60 days. Therefore the comments received during the past 60 days have been considered by the relevant working group and the sectoral committee.

This amendment is issued accordingly.



**Amendment No: 01 approved on 2020-07-22 to SLS 1657: 2020**

## **SPECIFICATION FOR HAND SANITIZERS (ALCOHOL BASED)**

### **FOREWORD**

Delete the text given in second paragraph and substitute the following:

This Standard is published in response to the COVID-19 pandemic and the increased risk, this disease presents to the health, safety and wellbeing of people. Due to the availability of limited scientific data on virucidal effects against emerging strains of SARS-CoV-2 viral pathogen, manufacturers are encouraged to follow the two WHO- recommended hand rub formulations which are validated to this effect.

Delete the following text given in the 9<sup>th</sup> paragraph.

Since there is a need to implement this Sri Lanka Standard immediately, steps have been taken to publish it with the currently available information but this Standard remains subject to amendments based on further comments in accordance with the good practices of Standardization.

### **1 SCOPE**

Delete the text given in **1.1** and substitute the following:

**1.1** “This Standard prescribes the requirements and methods of test for alcohol based liquid hand sanitizers formulated align with the recommendations of World Health Organization (WHO), in response to viral pathogen SARS-CoV-2”.

### **2 REFERENCES**

Delete the ASTM E 2315 and substitute the following:

“ASTM E 2783 Standard test method for assessment of antimicrobial activity for water miscible compounds using a time-kill procedure”

Delete the SLS 1348 and insert the followings at the end of references.

SLS ISO 22716 Guidelines on good manufacturing practices for cosmetics

“Guide to Local Production: WHO-recommended hand rub formulations (2010)”

### 3 DEFINITIONS

Delete the two words “gel or” given in Clause 3.1

#### 4.1 General requirements

Delete the two words “gel or” given in Clause 4.1.2

Delete the text given in 4.1.3 and substitute the following:

**4.1.3** “The raw materials used shall comply with the provisions of **Part 1** and **Part 2** of **SLS 457** and Guide to Local Production: WHO-recommended hand rub formulations (2010)”.

**NOTE:** In the case of any additions, other than those specified in WHO-recommended hand rub formulations full justification shall be provided together with recognized documentary evidence for safety of the additive, its compatibility with the other ingredients, and all relevant details shall be given on the product label.

Delete the “**SLS 1348**” and substitute the “**SLS ISO 22716**” at the end of the text given in Clause 4.1.4”

#### 4.2 Other requirements

#### TABLE 1 : Requirements for hand sanitizers

Delete the S. No. i) given in Table 1 and substitute the following:

i)	Alcohol content, % (V/V)		
	(a) Ethanol	75-85	Appendix B
	(b) Isopropanol	70-80	

In Sl. No. ii) Column (3),  
Delete ‘6 - 8’ and substitute ‘5.0 - 7.5.’

In Sl. No. iii) Column (4),  
Delete ‘ASTM E 2315’ and substitute ‘ASTM E 2783.’

Delete the NOTE given underneath the Table 1 and substitute the following:

**NOTE:** Minimum of two types (gram positive and gram negative bacteria) of reference strains shall be used for this test. Plates shall be incubated at  $37 \pm 1$  °C for  $48 \pm 2$  hrs.

Delete the Clause **4.2.3**

**5.1 Packaging**

Delete the word ‘well-closed’ given in clause 5.1.1 and substitute the “air tight sealed”

**5.2 Marking**

Delete the S. No. a) of Clause 5.2.1 and substitute the following:

- a) Name of the product as “alcohol based liquid hand sanitizer”

Insert the followings as S. No. n) and S. No. o)

- n) Statement “WHO-recommended hand rub formulation”
- o) Statement “Keep the container tightly closed after each use”.

**7 METHODS OF TEST**

Delete the text given in **7.1** and substitute the following:

**7.1** Tests shall be carried out as prescribed in ASTM E 2783 and Appendix B to D of this Standard.

**APPENDIX A**

Delete the table given underneath **A.3.2** and substitute the following:

**TABLE 2 – Scale of sampling**

<b>No. of containers in a lot</b>	<b>No. of containers to be Selected</b>
(1)	(2)
Up to 500	8
501 - 3 200	13
3 201 - 35 000	20
35 001 - 500 000	32
500 001 and above	50

**A.5 NUMBER OF TESTS**

Delete the two words “and **4.2.3**” given in Clause **A.5.2**

**APPENDIX B**

Change the Title of Appendix **B** as “**DETERMINATION OF ALCOHOL CONTENT (ETHANOL OR ISOPROPANOL)**”

Delete the sub titles **B.5.2.1** and **B.5.2.2** and the text underneath **B.5.2.2**

**APPENDIX E**

Delete the Appendix E

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