**ADDENDA TO THE AGENDA OF THE 37th Meeting of Cosmetics Sectional Committee PCD 19**

**Time & Date: 02 June 2023, 11:00 h**

**Venue: BIS Western Regional Laboratory, Mumbai**

**ITEM 2 CONFIRMATION OF MINUTES**

**2.1** The Minutes of the 36th meeting of Cosmetics Sectional Committee, PCD 19 held on 26 April 2022 virtually, was circulated through the portal. Comments were received from HUL, ELCA and Loreal India Pvt. Ltd. about **Item 5.12 Document No. PCD/19/15096: Sunscreen Cosmetic Products Specification**.

They suggested the Average ITA to be 28-55° instead of 28-41°, as recorded in the Minutes of the 36th Meeting of PCD 19.

However, the comment was discussed during the second meeting of PCD 19 : 3 Skin Care Products Sub-Committee, held on 20 October 2022, and the sub-committee REQUESTED Ms. Arushi Chaudhary from ELCA Cosmetics to submit a Study Report on the Indian Population Distribution based on Skin tone and RECOMMENDED to keep the average ITA as 28-55° in Clause 5.1.2 of Document No PCD/19/20109 Cosmetics Sun Protection Test Methods-In Vivo Determination Of Sun Protection Factor SPF.

Ms. Arushi Chaudhary has submitted a study report vide mail dated 13 February 2023.

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From the report, it is evident that **only 159 subjects were considered for the panel** and out of the 159 subjects for the panel **only 2 percent** of the subjects belong to **ITA > 55°**, **13 percent** of the subjects belong to the ITA range between **41-55°**. It may be NOTED that **75 percent** of the subjects belong to the ITA range between **(-30)° to 41°**, which covers **majority of the Indian Population**.



Also, as per the validation data of ISO, as mentioned above, data on **9931 individuals** were received from **12 laboratories located on 5 continents** to determine MEDu values in prospective sunscreen testing studies. The locations included **3 laboratories in Asia (Singapore, China, and Japan)**, 2 laboratories in North America, 2 laboratories in South America, 1 laboratory in Australia, and 4 laboratories in West and East Europe. No other information was provided beyond the subject's ITA° and their MEDu in J/m2 eff. **However, it may be NOTED that one Western European Laboratory provided over 6500 data points.** In order to not grossly influence the relationship between ITA° and MEDu by the preponderance of the data from this one laboratory, the ITA° relationship versus MEDu was calculated by **determining a polynomial regression for each laboratory individually**. Using each laboratory's individual regression, an average value for each ITA° value from 28° to 70° was determined. A polynomial regression was then performed on these averages for an overall prediction of MEDu value for any given ITA°. A distribution of subjects with a given ITA° in each laboratory was also calculated to show **the regional differences in subject skin color.**

To summarize, **5 out of the 12 laboratories** have the Maximum ITA Distribution in the range **51-55°**, **3 out of the 12 laboratories** have the Maximum ITA Distribution in the range **46-50°**, **2 out of the 12 laboratories** have the Maximum ITA Distribution in the range **41-45°**, and the remaining **2 laboratories** have the Maximum ITA Distribution in the range **36-40°.**

*Only* ***2 out of the 12 laboratories (One in South East Asia and another in South America)*** *have the Maximum ITA Distribution in the range* ***36-40°****, which resembles with the Maximum ITA Distribution found in India.*

Thus, in view of the ITA Distribution in Indian Population, the Committee may **CONSIDER** retaining the Average ITA as **28-41°**, and conduct a Validation Study on over 1000 subjects across India.

The Committee may **CONSIDER** finalization of the minutes of the 36th meeting.

**ITEM 3 THE PRESENT TITLE, SCOPE AND COMPOSITION OF PCD 19**

**3.1 a)** The present Scope of Cosmetics Sectional Committee is “*to formulate Indian Standards for terminology, methods of sampling and test, codes of practice and specifications for raw materials for cosmetics and toilet goods (excluding washing and bathing soaps) and for finished products.*”

**b)** Liaison with ISO/TC/217 Cosmetics

**3.2** The Composition of PCD 19 is given at **ANNEX I.**



**3.3 Review of Composition for Cosmetics Sectional Committee**

The attendance of the organizations representing the Committee, in the last three meetings is given as **ANNEX II** and the Committee may **REVIEW**.



As per BIS Guidelines, the composition of committees shall be reviewed by the appointing authority at least once in every three years, with a view to making such changes as may be considered necessary in order to make the committee more effective and fully representative of the interests concerned. It has been observed that the Committee has 39 percent of representation from Industry/ Industry Associations, which is violating the prescribed limit of 33 percent, as per the BIS Guidelines. Therefore, to ensure that the committees provide a fair representation of the range of interests affected by the standard, particularly of the users/consumers, as well as to achieve a fair balance of interests, the Committee may **REVIEW** the Composition and **RECONSTITUTE** the Committee.

**ITEM 5 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS**

The Agenda Items which come directly under preview of PCD 19 are put up below for consideration by the Committee.

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| **Sl No** | **Title of Work** | **Decision of Last Meetings** | **Present Status** |
| **Cosmetics Sectional Committee, PCD 19** | | | |
| **5.1** | **An indigenous standard on Labelling and Claims for the natural and organic cosmetics (Part 3 in this series)** | The Committee NOTED that the panel meeting has not been conducted yet. The Committee REQUESTED the Panel to meet at the earliest. | A Panel meeting was conducted on 10 May 2022, for the Working Draft of IS 17316 (Part 3).  It was decided to classify the Cosmetic Products based on the percentage of the Organic Content in the product. The Panel also DECIDED that the Working Draft would be prepared by Dr. Benedict M. Mascarenhas, and thereafter it would be circulated as P-Draft for comments. The Draft is awaited from Dr. Benedict M. Mascarenhas.  Dr. Benedict vide his mail dated 23/05/23, informed that Clarity from the Regulators as well as other Stakeholders is required on the list of specific claims for Natural and Organic Cosmetics, so that the suitable guidelines can be prepared accordingly.  He also shared the following Indian and International Definitions on Organic & Natural (100% organic/natural, organic/natural, made from organic/natural ingredients etc.), to provide a more clear understanding on the various definitions of Organic and Natural Cosmetics.    The Committee may **DELIBERATE**. |

**6.5 Document No. PCD 19 19461 WC ORAL RINSES — SPECIFICATION**

The Draft Indian Standard, PCD 19(19461) WC was issued into Wide Circulation, eliciting comments. End date for comments was 26-06-2022.

The comments received on the draft were discussed during the second and third meetings of PCD 19:4, Decorative and Miscellaneous Cosmetics Products Subcommittee held on, 03 January 2023 and 27 march 2023 respectively, and the following recommendations had been made by the sub-committee.

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| **Sl.**  **No.** | **Clause/Subclause/**  **para/table/fig. no. commented** | **Commentator/**  **Organization/**  **Abbreviation** | **Type of Comments**  **(General/Editorial/**  **Technical)** | **Justification** | **Proposed**  **change** | **Sub-committee’s Recommendation** |
| 1 | Annexure B  Sub Clause B-1.1 and B-1.2 | Dabur India Limited | Technical | Clause contradicts to clause 7.4.1 of ISO 16408, where there is a difference in shelf life period over same exposure period under same conditions of samples. | 3 months defined time is too less to extrapolating to 3 years shelf life. Most FMCG products are with 2 years shelf life. Also this may be first time that BIS will directly advocating shelf-life of formulation which are different. It will be blanket approval for all formulas passing 3 months.  A longer duration of study is required to define shelf life of formulation. | AGREED with modifications to further align with ISO 16408, as mentioned below.  **B-1.1 Accelerated Test**  Store the oral rinse at (40 ± 2) °C for 3 months at (75 ± 5) percent relative humidity or under such conditions of time and temperature as will stimulate storage at room temperature for **30 months.**  **B-1.2 Real Time Test**  Store the oral rinse at (27 ± 2)°C at (65 ± 5) percent relative humidity for **30 months** or for the period indicated by the expiry date listed on the product label. |
| 2 | Table 1, Point 2 | Dabur India Ltd. | Technical | pH range mentioned as 3 -10.5, which contradicts to one mentioned in IS 6356\_2021 for toothpaste. | Should be in a range of 5.5 -10.5 as per IS 6356\_2021, which ensure the safety of tooth enamel irrespective the usage behaviour of consumer. | NOT AGREED. |
| Dabur India ltd. had proposed to reassess the comment for changing the pH range from 5.5-10.5 as our saliva is neutral, and pH 3 would be too acidic for our mouth. The comments has been discussed during the third meeting of PCD 19:4 Sub-Committee held on 27 March 2023. The Sub-Committee RECOMMENDED to change the pH in Table 1 (*Clause* 5.5), *Sl. No.* ii) from 3.0 - 10.5 to 5.5 - 10.5, with the footnote as mentioned below.  *NOTE — The oral rinses are acceptable with pH range 3.0 to 5.5, but the product shall pass the screening test as specified in ISO 28888, and the pH range must be mentioned on the label of such products. Also, the normal pH range of 5.5 to 10.5 will not be applicable for these products.*  The Minutes of the Third Meeting of PCD 19:4 Sub-Committee is given below.    Dr Dilip Tripathi from Johnson and Johnson vide his mail dated 25 May 2023,  has sent an additional proposal to categorise the Oral rinses into four types as given below:    The Committee may **DELIBERATE and** **CONSIDER** for a R&D Project to assess the **Effect of Low pH (3 to 5.5) on the Enamel of the Teeth.** | | | | | | |
| 3 | Table 1, Point vii, a) | Dabur India Ltd. | General | Total bacterial count limit contradicts to IS 6356\_2021 which states limit to be 1000cfu/g. | Such drastic reduction in limit may limit the manufacturing to companies having high budget and facility. This 100 cfu/gm limits look stringent. Limit reduction to 300cfu/g is proposed. | AGREED with modifications as mentioned below.  The maximum limit for Total Microbial Count would be **1000 CFU/g.**  The Sub-Committee further RECOMMENDED to add the foot note as mentioned below:  ‘The limit is not applicable to the oral rinses where the probiotic is added as one of the active ingredients.’ |
| 4 | Clause A-1.1.1.1 | Dabur India Ltd. | Technical | GC Conditions for β – DEX 225 Chiral Column | Column used should not be brand specific. | AGREED.  The Sub-Committee further RECOMMENDED to modify the column dimension as mentioned below.  Column Dimension:  30 m length × (0.25 to 0.53 mm) ID |
| 5 | Clause A-1.1.1.1 | Dabur India Ltd. | Technical | |  | | --- | | Hydrogen gas flow mentioned is 300ml/min | | |  | | --- | | Hydrogen gas flow mentioned cannot be 300 ml/min, Zero Air flow is missing. | | AGREED with modifications as mentioned below.  Zero Air flow : 300 mL/ min  Hydrogen gas flow : 30 mL/ min |

The Committee may **ENDORSE** the recommendations of the sub-committee and **FINALIZE** the draft for printing.