**ADDENDA TO THE AGENDA OF THE 35th MEETING OF PCD 19 COMMITTEE IN JOINT SESSION WITH PCD 19:1, PCD 19:2, PCD 19:3, AND PCD 19:4 SUB-COMMITTEES**

**DATE : 24 February 2022, Thursday**

**TIME : 11:30 h**

**VENUE : Virtual**

**Item 4 ACTIVITIES OF PCD 19**

**4.2** The list of Indian Standards published, since its last meeting held on 17.3.2021, is given below.

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| **Sl No.** | **No., Year & Title of the Indian Standards Established** | **Date of Establishment** | **Date of Gazette** |
| 11. | IS 5383 : 2021 Tooth Powder ─ Specification (*Third Revision*) | 22 Nov 2021 | 29 Nov 2021 |

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

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| **Sl No** | **Title of Work** | **Decision of Last Meetings** | **Present Status** |
| **5.4** | **IS 4011 : 2018 Methods of Test for Safety Evaluation of Cosmetics (*Third Revision*)** | During the 31st meeting of the committee on 30.4.2019, while deliberating on the comments received, members agreed that the comments are majorly typographical /editorial errors and need to be carried out through amendment. Regarding proposal of ITC to incorporate the paragraph ‘*All cosmetic products should be formulated conforming to the restrictions imposed by IS 4707 (Parts 1 and 2)……………... documents shall require safety testing using the guidelines Provided in this standard.*’ which was given in previous version of IS 4011:1997, it was OPINED that the para helps the cosmetic manufacturers to understand when the cosmetic products/ingredients need to be evaluated for their safety as per IS 4011. Therefore, the Committee DECIDED to issue an amendment to IS 4011 for correction of typographical error at 4.3.1.4(a) and to incorporate the para 3, foreword of IS 4011:1997 in the foreword of IS 4011 : 2018 (latest version) directly for publication as it is non-controversial in nature.Further, during deliberations, Dr Ankita Pandey, PETA India informed the Committee that some more OECD alternative test procedures have been published which need to be incorporated in the Annex B ‘Alternate Methods for Safety Testing**’** *(Source Reference — OECD Guidelines, EURL ECVAM Recommendations)*. In addition, earlier at Finalized Draft stage, PETA had submitted comments on the standard which also need to be addressed. In this regard, the Member Secretary said that in the 28th meeting, the Committee while finalizing the Draft Revision of IS 4011 for printing (published as IS 4011:2018) decided to simultaneously take up revision of Annex B of standard based on the comments received from PETA and technological advancements taking place in the world.The committee after detailed deliberations, once again REQUESTED the Working Group to revise the Annex B of IS 4011 and to provide the same to BIS Sectt. within 3 months’ time for issue of Amendment To IS 4011 into Wide Circulation for 60 days.**Composition of the Working Group for revision of IS 4011:**i) Shri Benedict M. Mascarenhas (Convener)ii) Representative from CDSCO, New Delhiiii) Representative from Johnson & Johnson Ltd.iv) Mr. Kern Petra, Procter & Gamble, Mumbaiv) Dr. Vijay Iyer, HUL, Mumbaivi) Representative from KET’s Scientific Research Centre, Mumbaivii) Dr. James Bhaskar, ITC R&D Centre, Bangaloreviii) Dr. R. S. Ray, IITR, Lucknowix) Representative from PETAThe Committee during its 34th Meeting on 17.3.2021, NOTED that the draft revision of Annex B of IS 4011 is awaited from Shri Benedict M. Mascarenhas (Convener of Working Group for revision of IS 4011) and requested the Working group to expedite submission of the draft for revision. Shri Benedict M. Mascarenhas informed the committee that since comments are still being received for inclusion in the revision, 31st March 2021 will be taken as the last date for receipt of comments and the final draft for revision will be prepared and submitted thereafter. The Meetings of the Working Group were held on 27th October, 2021, and 15th December, 2021. | The final comments regarding Annexure B that has been reviewed and agreed by the Working Group, have been received from Shri Benedict M. Mascarenhas (Convener of Working Group) on 18.02.22.The list of resolved comments is placed below.Strong need was expressed by the Members of the Working Group for an additional Annexure C to cover in-silico models, TTC Approach and other Safety Assessment Workflow Methodologies.An example of one such approach is shared by HUL, which is placed below.The Committee may **CONSIDER**. |
| **5.7** | **New Work Item Proposals (NWIPs) for Face Wash (Detergent & Soap Base), Shower Gel, Calamine Containing Products etc.** | During the 33rd Meeting of PCD 19, the committee decided to prepare individual product standards wherever possible and also simultaneously prepare horizontal standards for products for which individual standards are not prepared and are less common. Some members felt that the development of horizontal standard would address safety and some of the physio-chemical tests, tests for toxic metals and the microbiological requirements. The Sub-Committee PCD 19:3, during its meeting held on 18th December, 2020, after prolonged discussions, **REQUESTED** the Panel under the convenorship of Dr. R.A.Singh, RDTL ,Chandigarh constituted to consider development of horizontal standards to hold further meetings to deliberate and submit comprehensive proposal for horizontal standards and to submit revised working drafts on the subject.The Subcommittee also **REQUESTED** Shri. T.Kumar and Shri Vinay Kumar of Cavinkare to provide working draft on **New Work Item Proposals** of Facewash and Shower gel draft within 3 weeks to BIS Sectt. | The Draft Documents of Face Wash (Detergent & Soap Base),  Shower Gel/Body wash (Detergent & Soap Base), Face Scrub and Body Scrub standards, have been received from Dr. T. Kumar, Cavinkare on 22.02.22. The Drafts are placed below.The Committee may **CONSIDER**. |

**ITEM 6 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION**

**6.2 Doc No.: PCD 19 (17248) C Henna (Mehendi) Powder – Specification (*Second revision* of IS 11142)**

The document no. PCD 19 (17248) C was issued into Wide Circulation vide letter no.PCD 19 (17248) C dated 22/04/2021eliciting comments. End date for comments was 21/06/2021. The following comments have been received on the draft:

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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** |
| 3. | F — 4.3 & G-6 under ANNEX — F & G respectively | Henna Agriculture & Trade Association | Technical | It has been observed that the standard henna leaves are not easily available and hence many times the analysts use non-standard henna powder sample prepared from unauthenthic henna leaves available in the market for the analysis. Because of this use of non standard henna powder being taken for reference, sometimes the test sample of Henna powder shows a variation in the TLC pattern vis-à-vis the non-standard Henna Powder used as reference and gets wrongly reported as `Does not pass the Test'. The quality of henna leaves is based on agroclimatic conditions and varies from location to location. Hence it is recommended to use authentic henna leaves preferably taken from the original plant source and location or respective manufacturer to avoid the sample being erroneously reported as 'Does not pass the Test' due to use of improper reference standard. | Disperse about 3g of Henna powder prepared from authentic Henna leaves (taken from original plant source and location so as to account for the inherent variabilities in plant materials of natural origin) in about 7mL water and make a smooth paste, allow to stand for 4h. Mix 1g of this paste with chloroform into the 10mL flask and make up volume to about 10mL with chloroform then centrifuge at 4000 rpm for about 10 min and use the supernatant liquid (Filter it if suspended particles are observed) for spotting and apply one drop of the extract on the base line of the plate. |

The Committee may **CONSIDER** finalization of the draft.

**ITEM 8 COMMENTS ON STANDARDS**

**8.1 IS 6356 : 2021 – Toothpaste Specification (*fourth revision*)**

The following comments have been received from Dr Hemalatha Purushothaman Panicker, from CFTRI and Colgate-Palmolive (India) Ltd.

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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** |
| 2. | 5.3 StabilityThe toothpaste shall not show any physical sign of deterioration during normal conditions of storage and use. When subjected to a temperature of45±2 °C for a period of 28 days the toothpaste shall meet the requirements of the standard. When cooled to a temperature of 5 °C for 1hour, after taking out and pressing tube, the paste shall be found extrudable from the tube and meet the requirement of this standard. It is not advisable to keep the toothpaste tube without the cap. If left open for a long duration, the toothpaste might lose moisture on account of evaporation and harden. | Colgate-Palmolive (India) Ltd. | Editorial | Extrudability of toothpaste is covered in “Clause 5.2 Dispensing” of this standard as follows: “The paste shall extrude from the collapsible tube or any other suitable container in which it is packed, at 27±2 °C in the form of continuous mass with the application of normal force, without the application of excessive force which would cause injury to the tube or the container. It shall be possible to extrude bulk of thecontents from the container or the tube starting from the crimped end of the tube by rolling the tube gradually.”However, extrudability is again referred to in clause 5.3 which pertains to stability.This is likely to cause confusion and lead to unclarity as to which clause needs to be referred to for extrudability. Hence, this editorial change is being proposed for the purpose of clarity. | 5.3 StabilityThe toothpaste shall not show any physical sign of deterioration during normal conditions of storage and use. When subjected to a temperature of 45±2 °C for a period of 28 days the toothpaste shall meet the requirements of the standard. When cooled to a temperature of 5 °C for 1 hour, after taking out and pressing tube the paste shall be found extrudable from the tube as per clause 5.2 and meet the requirement of this standard. It is not advisable to keep the toothpaste tube without the cap. If left open for a long duration, the toothpaste might lose moisture on account of evaporation and harden. |

**8.2 IS 17318 : 2020 — Henna (MEHENDI) Paste in Shape of Cone & other Allied Packaging – Specificaiton**

The following comments have been received from Henna Agriculture & Trade Association.

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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** |
| **1** | E— 4.4 under ANNEX — E | Henna Agriculture & Trade Association | Technical | It has been observed that the standard henna leaves are not easily available and hence many times the analysts use non-standard henna powder sample prepared from unauthenthic henna leaves available in the market for the analysis. Because of this use of non standard henna powder being taken for reference, sometimes the test sample of Henna powder shows a variation in the TLC pattern vis-a-vis the non-standard Henna Powder used as reference and gets wrongly reported as `Does not pass the Test'. The quality of henna leaves is based on agroclimatic conditions and varies from location to location. Hence it is recommended to use authentic henna leaves preferably taken from the original plant source and location or respective manufacturer to avoid the sample being erroneously reported as 'Does not pass the Test' due to use of improper reference standard. | Disperse about 3g of Henna powder prepared from authentic Henna leaves (taken from original plant source and location so as to account for the inherent variabilities in plant materials of natural origin) in about 7mL water and make a smooth paste, allow to stand for 4h. Mix 1g of this paste with chloroform into the 10mL flask and make up volume to about 10mL with chloroform then centrifuge at 4000 rpm for about 10 min and use the supernatant liquid (Filter it if suspended particles are observed) for spotting and apply one drop of the extract on the base line of the plate. |
| **2** | **Section E.6.2,** under Annex E | Henna Agriculture & Trade Association | Technical | 1.During test procedure, reference solution of preservatives being used inthe henna paste is prepared and applied on the chromatograms which give the spots on it. But since it is not clearly mentioned in section E.6.2, there is possibility that the spot due to preservative on the chromatogram may be considered (misunderstood) as possible extraneous dye and chances of sample being erroneously failed in the said test.**Additional Related Points to be covered under E.3.10:**1. Additionally, in existing section E.6.2, binding agent is mentioned, however

during the procedure, preparation of reference solution for binding agent is not given. Hence it is recommended to provide the following information in the procedure for the preparation of binding agent in this test as follows;**E.3.10 Binding agents** — Sodium CMC, Xanthan Gum, Guar gum or any other binding agents declared on the label matter by the manufacturer. | Any other dye spots on the chromatogram other than lawsone, chlorophyll, binding agents, essential oils and other preservatives indicates presence of possible extraneous dyes. In case, unknown spots from suspected chemical dyes are observed, further testing is done by applying the standards of suspected synthetic dyes and check for matching Rf values and spot characteristics. |
| **3** | **F-6 under ANNEX — F** | Henna Agriculture & Trade Association | Technical | Aligning of the procedure for the preparation of Henna powder reference sample with the procedure given in section G-6 under Annex G of IS standard 11142 : 2019 of Henna powder.Because dry Henna powder when mixed with Chloroform does not give lawsone spot on the TLC Plate, whereas when it is soaked in water for 4 hrs and then mixed with chloroform, it gives distinct spot of lawsone (an inherent component of henna leaves) on the TLC Plates.Hence it is requested to please align the said procedure with that of section G-6 under Annex G of IS standard 11142: 2019 of Henna powder. | Disperse about 3g of Henna powder prepared from authentic Henna leaves (taken from original plant source and location so as to account for the inherent variabilities in plant materials of natural origin) in about 7mL water and make a smooth paste, allow to stand for 4h. Mix 1g of this paste with chloroform into the 10mL flask and make up volume to about 10mL with chloroform then centrifuge at 4000 rpm for about 10 min and use the supernatant liquid (Filter it if suspended particles are observed) for spotting and apply 5 p1 to 10 pl of the extract on the base line of the plate. |

The Committee may **CONSIDER.**

**8.3 Withdrawal of IS 10301:1982 Specification for Isopropyl Alcohol for Cosmetic Industry**

Two Indian Standards are available for the specifications of Isopropyl Alcohol : IS 10301 : 1982 Specification for Isopropyl Alcohol for Cosmetic Industry and IS 2631 : 2020 Isopropyl Alcohol - Specification. The table of requirements for Isopropyl Alcohol is more detailed in IS 2631 : 2020 in comparison to to IS 10301 : 1982. The scope of IS 2631 : 2020 also covers the use of Isopropyl Alcohol in Indian Cosmetic Industry, and all the requirements of IS 10301 : 1982, so that IS 10301 : 1982 stands irrelevant in today's scenario. In this regard, it is proposed to withdraw IS 10301 : 1982 Isopropyl Alcohol - Specification.

The Committee may **CONSIDER**.

**ITEM 9 REVIEW/REAFFIRMATION OF INDIAN STANDARDS**

**9.2 Revision of Indian Standards**

However comments were received only from IBHA for IS 10284 : 1982 Specification for lipsalve and no drafts for revision of standards have been submitted by the working group yet. The ARP Report for IS 10284 :1982 Specification for lipsalve is placed below.



The Committee may **CONSIDER**.