

Annex A
Updates and Amendments to the ASEAN Cosmetic Directive (ACD) Ingredient Annexes

The updated ASEAN Cosmetic Directive (ACD) Ingredient Annexes incorporating the new and amended entries adopted during the 31st ASEAN Cosmetic Committee (ACC) Meeting and its related meetings are posted in the Food and Drug Administration (FDA) website. The tabulation below representing the new and modified entries of the ACD Ingredient Annexes are shown only for easy reference of the cosmetic industry.

A. ACD Annex II - List of Substances Which Must Not Form Part of the Composition of Cosmetic Products

ACD Annex II Ref. No. 221 (Revised Entry)

Substances	CAS Number	Ref. No.
Mercury and its compounds except those special cases included in Annex VI	7439-97-6	221
	54-64-8	
	62-38-4	
	94-43-9	
	102-98-7	
	1192-89-8	
	100-56-1	

B. ACD Annex VI - List of Preservatives Which Cosmetic Products May Contain

ACD Annex VI Ref. Nos. 16 and 17 (Deleted Entry)

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
16	Entry deleted Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	—Contains thiomersal

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
17	Entry deleted Phenylmercuric salts (including borate)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	— Contains phenylmercuric compounds

C. ACD Annex VI - List of Preservatives Which Cosmetic Products May Contain

ACD Annex VI Ref. No. 32 (Revised Entry)

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (±) ¹⁵ Climbazole CAS 38083-17-9	Hair lotions; 0.2% Face creams; 0.2% Foot care products; 0.2% Rinse-off shampoo; 0.5%		



SUMMARY REPORT
The Thirty First Meeting of the
ASEAN Consultative Committee for Standards and Quality (ACCSQ)
The ASEAN Cosmetic Committee (ACC)
The ASEAN Cosmetic Scientific Body (ACSB)
12-13 November 2019
Muntinlupa City, Philippines

INTRODUCTION

1. The Thirty First Meeting of the ASEAN Cosmetic Scientific Body (ACSB) was held on 12-13 November 2019 in Muntinlupa City, Philippines.
2. The Meeting was chaired by Engr. Ana Trinidad Rivera from the Food and Drug Administration, Philippines and the Alternate Chair Mrs. Viengxay Vansilalom, Food and Drug Department MOH, Lao PDR.
3. The Meeting was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam, representatives from the ASEAN Cosmetics Association, and the ASEAN Secretariat. The list of delegates appears as **APPENDIX 1.**

AGENDA ITEM 1: WELCOMING REMARKS

4. The Chair welcomed all delegates and observers to the Meeting and expressed her appreciation to the host country for organizing the Meeting.

AGENDA ITEM 2: ADOPTION OF AGENDA

5. The Meeting agreed to adopt the proposed agenda. The final agenda appears as **APPENDIX 2.**

AGENDA ITEM 3: BUSINESS ARRANGEMENTS

6. The Meeting was held in plenary.

AGENDA ITEM 4: CONTINUING DISCUSSIONS FROM 30th ACSB MEETING**4.1 Matrix of Follow-up Actions**

7. The Secretary presented the status of actions following from the 30th ACSB Meeting. This appears as **APPENDIX 3**.

4.2 1,4-DIOXANE

8. The Secretary updated the Meeting that ACTLC has secured several analytical methods for 1,4-Dioxane, including the method indicated in the ICCR document titled 'Technical Guidance Document on determining 1,4-Dioxane in cosmetics, Cosmetic Europe, March 2012'. This method will be validated by ACTLC, and they will advise ACSB accordingly. ACTLC Chair from Thailand also informed the ACSB that they are participating in the ISO discussions on the standard method for 1,4-Dioxane.

4.3 TAGETES

9. ACA presented the safety information on the three (3) species of *Tagetes* (*Tagetes minuta*, *Tagetes patula* and *Tagetes erecta*) indicating that the critical end point for this substance is phototoxicity. According to the published EU Regulation on *Tagetes patula* and *Tagetes minuta*, the levels of alpha-terthienyl (TTP) content should be restricted to less than or equal to 0.35% in the flower and oil extracts of these *Tagetes* species. This finding was the basis for the restrictions and limits set for *Tagetes minuta* and *Tagetes patula* in EU Annex III. Based on these data and the in-use data of *Tagetes erecta* available from Thailand, ACA presented that *Tagetes erecta* should not present any safety concern on the endpoint of phototoxicity if restricted the same way as *Tagetes minuta* and *Tagetes patula*. ACA presentation appears as **APPENDIX 4**.

10. Thailand informed the Meeting that there are currently 166 products containing *Tagetes erecta* in their local market and there has been no adverse event reported on these products. Further, *Tagetes erecta* flower extract (**LUTEIN**) has been granted approval as food additive in Thailand as colour and nutrient supplement. Due to this premise, Thailand expressed her intention to allow the current use of *Tagetes erecta* for cosmetics. Thailand presentation appears as **APPENDIX 5**.

11. The Meeting noted that the ASEAN Member States (AMS) do not have products containing *Tagetes erecta* except for Indonesia, Thailand, Malaysia and Philippines. Indonesia commented that it is important to understand the basis for the EU ban on *Tagetes erecta*, while allowing *Tagetes patula* and *Tagetes minuta* when the safety

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information and conclusion as presented can be applied across extracts. The Meeting then requested the Secretary to seek further clarification from EU on this.

Action by ACSB Secretary

12. The Chair also reiterated the SCCS Opinion that stated that the use of *Tagetes erecta* poses safety risk when use in cosmetic products. The SCCP opinion (2005) states that "As no safety limit of use in cosmetic products has been demonstrated, it is recommended that *Tagetes erecta*, *Tagetes minuta* and *Tagetes patula* extracts and oils should not form part of cosmetic products". Likewise in the EU Commission Regulation (EU 2018/78) item 4 states that "In the light of the opinion of the SCCP of 21 June 2005 there is a potential risk to human health arising from the use of *Tagetes erecta* flower extract and *Tagetes erecta* flower oil in cosmetic products. Those substances should therefore be prohibited in cosmetic products and added in the list of prohibited substances in Annex II to Regulation (EC) No. 1223/2009". Considering all information presented, the Meeting agreed that there is a need for further review of *Tagetes erecta* and requested ACA and Thailand to conduct this and present to the next ACSB Meeting.

Action by ACA and Thailand

13. The Secretary informed the Meeting that per ACTLC's advice, there is a current method to detect the presence of TTP, and a journal method to determine TTP content quantitatively that will undergo validation. Considering there is a timing for the implementation of the restriction on *Tagetes patula* and *Tagetes minuta* by December 2020, the ACTLC will take up in their Meeting whether the method validation can be pursued to meet the timing.

4.4 BIPHENYL-2-OL and its salts (EU 2018/1847)

14. Indonesia informed the Meeting that there are products containing Biphenyl-2-ol and its salts in her local market. She also commented that the salts of this substance which was the subject of the safety concern and ban in EU, transform back to its stable non-salt form when dissolved. Indonesia commented that there is a need to understand the EU ban on the salt forms of Biphenyl-2-ol. In this case, Indonesia will extend the grace period for these products until December 2021. Additionally, the Meeting requested the ACSB Secretary to seek clarification from EU on the ban.

Action by ACSB Secretary

4.5 SILVER NITRATE

15. ACA presented the safety information on Silver Nitrate, appearing as **APPENDIX 6**. It was highlighted that the effect of repeated exposure to silver in humans and experimental animal species is argyria, where the rate of absorption of silver exceeds the rate of biliary or urinary excretion resulting in blue-grey discoloration, but this is not associated with toxicity.

16. The Meeting noted that there are no products containing silver nitrate as hair dye or for other purposes in the ASEAN market except Thailand. The Meeting agreed to discuss further in the next ACSB Meeting.

4.6 MERCURY-CONTAINING PRESERVATIVES IN EYE AREA COSMETIC PRODUCTS

17. ACA reported that based on their industry survey with 68 respondents, there are no products containing Mercury as preservatives in the market. Similarly, AMS informed that there are no notified products in their local markets. Following this, the Meeting agreed to remove the entries for the Mercury-containing preservatives (Thiomersal and Phenylmercuric salts) in ACD Annex VI. In parallel, the entry for Mercury and its compounds in ACD Annex II will be revised to include the CAS #s (to be provided by ACA) for the above mentioned Mercury-containing preservatives from Annex VI.

Indonesia further informed that national regulation has already been issued to prohibit the use of these substances as preservatives in cosmetic products in her market.

Action by ACSB Secretary and ACA

AGENDA ITEM 5: NEW ISSUANCE OF EU REGULATIONS

5.1 AMENDMENT OF ANNEXES II, III and V (EU 2019/831)

18. The ACSB Secretary informed the Meeting that the previous EU rulings on CMR (Carcinogenic, Mutagenic, and Toxic to Reproduction) and the accompanying SCCS Opinions are the main basis for the issuance of EU Regulation 2019/831. In this regard, ACA was requested to present the information on EU Regulations on CMR (Carcinogenic, Mutagenic, and Toxic to Reproduction) and how it is incorporated into

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the EU Cosmetic Regulations. The presentation included a proposal for ACSB to review the safety of the substances that will be categorized as CMR by EU prior to decision/adoption in ASEAN. The presentation appears as **APPENDIX 7**.

19. The Meeting agreed to the ACA proposal, and recognizing that there is a long list of EU CMR substances, further agreed to prioritize those that are categorized as CMR Category 1. Member States can also propose CMR substances for ACSB review based on need and use in their respective local markets via the submission of ACSB proposal template.

20. The Secretary presented the proposal and summary of the revisions made on EU Annexes II, III and V per EU Regulation 2019/831, appearing **as APPENDICES 8 and 9** respectively. Reviewing the list, the Meeting agreed to prioritize the following substances – i. Formaldehyde (Category 1B); ii. Perboric Acid and Sodium Perborate compounds (Category 1B); iii. some Boron compounds listed in EU Annex III 1a and 1b and Dibutyltin hydrogen borate (Category 1B); and iv. Paraformaldehyde and Methylene Glycol. The Meeting requested ACA for the safety review of these substances for presentation to the next ACSB Meeting.

21. Indonesia commented that while Formaldehyde is categorized as CMR 1B and banned for use in EU, there are other substances in Annex III that are 'formaldehyde donors' that remain in Annex III with restriction on formaldehyde content. The Meeting then requested the ACSB to seek clarification on the label requirements for 'formaldehyde donors' while there is a complete ban on formaldehyde.

22. The ACSB Chair also requested ACA to inform the industry in advance that the EU CMR substances are undergoing ACSB review and to anticipate potential ban or restrictions.

Action by ACA, AMS and ACSB Secretary

AGENDA ITEM 6: NEW PROPOSALS FROM AMS

6.1 UV Filters Safety Assessment

23. ACA presented the safety assessment for Menthyl Anthranilate (Meradimate) and Avobenzone, appearing as **APPENDICES 10 and 11** respectively. The Meeting noted that the safety information for Avobenzone is sufficient, but not for Menthyl Anthranilate. At the same time, the AMS informed that there are products containing

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Avobenzone in their local markets. ACA and Singapore will provide updates on Menthyl Anthranilate in the next ACSB Meeting.

Action by ACA and Singapore

24. The ACSB Chair commented that the brewing concern for Avobenzone is on its effect to the environment. In this note, Indonesia suggested for the Meeting to consider an opinion statement for Avobenzone.

6.2 Animal Stem Cells (Derived Secretomes) as Cosmetic Ingredients

25. Singapore presented the proposal on Animal Stem Cells, specifically on Derived Secretomes. This appears as **APPENDIX 12**.

26. The Meeting agreed to assess any safety concerns or risks associated with the use of these materials for cosmetic products. On this note, the Meeting requested ACA and Singapore to study and gather data from companies using these ingredients and present the data/assessment in the next ACSB Meeting.

Action by ACA and Singapore

6.3 Persulfates of Ammonium, Potassium or Sodium (ACD Annex III, Entry A4)

27. The Philippines presented the proposal on the current entry on Persulfates of Ammonium, Potassium or Sodium, in particular to the restriction on the maximum concentration of 45% Persulphate before mixing. The presentation appears as **APPENDIX 13**.

28. ACA informed the Meeting that this pre-mix restriction is necessary for the powder form of the substance as this is a control during mixing to ensure that the final cosmetic preparation meets the 20% concentration limit. Indonesia also advised that their laboratory testing includes testing of the substance in the pre-mix material. Following this, the Meeting agreed for AMS and ACA to check the local practice/testing of these substances to ensure compliance with the 20% maximum concentration in the final mixture/product.

Action by AMS and ACA

6.4 CLIMBAZOLE (Annexes III and VI)

29. ACA presented the proposal and presentation on Climbazole, in particular to the list of product types (addition of hair conditioner) to its entries under Annexes III and VI, appearing as **APPENDICES 14 and 15** respectively.

30. The Meeting noted that the safety data as presented show that the addition of hair conditioner at 2% in the current list of product types result to a decrease of Margin of Safety of (MOS) for the aggregate use from 89 to 85. Indonesia recommended to review the need for the use of both hair shampoo and hair conditioner containing Climbazole and determine the efficacy and safety of Climbazole at different levels for hair conditioner.

31. In response, ACA presented the information on the efficacy on the combined use of both shampoo and conditioner with Climbazole, and the recalculations of MOS at different levels in hair conditioner in addition to the list of current product types - hair shampoo, face cream, with and without foot care. The presentation appears as **APPENDIX 16**.

32. Considering the varying opinions from AMS on the list of product types to reflect under the Climbazole entries, the Meeting agreed for the AMS to further review the information and defer the decision by the next ACSB Meeting.

Action by AMS

33. The Meeting also discussed the possible interpretation of the (+) in the entry of Climbazole in Annex VI that the substance may be used other than preservative beyond its restrictions and levels as reflected in its Annex III entry. In this case, the Meeting agreed to remove the (+) for Climbazole in Annex VI, while maintaining the footnote reference (*). Further, the Secretary will check similar cases as Climbazole in Annex VI and will reflect the same to standardize across entries.

Action by ACSB Secretary

6.5 WIG ADHESIVE

34. Thailand presented the proposal on wig adhesive that is currently under e-notification and sought guidance from the Meeting whether the product is under cosmetic classification. The Meeting noted that this product contains Toluene which is

only allowed in nail products, and Thailand advised that this ingredient will be replaced eventually. The proposal appears as **APPENDIX 17**.

35. Due to varying opinions from AMS whether this product is cosmetic or not, and whether the classification will be on the total product (wig + adhesive) or the adhesive only, the Meeting agreed to further review this matter and requested the ACSB Secretary to seek information from EU Commission on how adhesive glue product is classified in the EU region.

Action by ACSB Secretary

36. Related to the discussion, the Meeting recalled that the previous ACSB decisions classified nail adhesives and false eyelashes glue as cosmetic, while dental adhesives were classified as non-cosmetic. The Meeting agreed that there should be a standard classification across adhesives/glues in ASEAN and this will be further discussed in the next ACSB Meeting.

Action by AMS

6.6 LEAVE-ON PREBIOTIC INTIMATE HYGIENE SPRAY

37. Myanmar presented the proposal and the presentation on the Leave-On Prebiotic Intimate Hygiene Spray and sought guidance from the Meeting whether this product is under cosmetic classification. The Meeting noted that the product is undergoing notification in Myanmar and based on the evaluation of Myanmar on formulation, claims, and presentation, the product may fall under cosmetic classification. The proposal and presentation appear as **APPENDICES 18 and 19**.

38. The Meeting noted that several AMS have notified intimate hygiene sprays (leave-on) as cosmetic in their respective markets, however the products do not contain prebiotics. The Meeting also discussed the importance to determine the benefits and safety assessment for this product type as these come in contact with mucous membranes and are not rinsed off afterwards. The Meeting requested Myanmar, Philippines and ACA to further review the efficacy and safety data on these products from the notifying companies for continuing discussions in the next ACSB Meeting.

Action by Myanmar, Philippines and ACA

AGENDA ITEM 7: JOINT OPINION STATEMENTS (JOS)

39. The Task Forces presented the final draft of the JOS for Plastic Microbeads, Antimony and Parabens. The JOS documents appear as **APPENDICES 20, 21 and 22** respectively.

40. The Meeting discussed and finalized the JOS incorporating inputs and comments. The final JOS documents appear as **APPENDICES 23, 24 and 25** for Plastic Microbeads, Antimony and Parabens respectively. Singapore and Malaysia informed the Meeting that they would need internal consultation with their respective Environmental Agency and will accordingly inform the ACSB Secretary by February 13, 2020.

41. The Meeting agreed to standardize the title for the statements to be ACC Statements and this will apply across all Opinion Statements developed and issued by ACSB, including the previous Statement on Talc. The Meeting requested the ASEAN Secretariat to revise the title of the Opinion Statement on Talc accordingly.

42. Upon endorsement of ACC, the Meeting requested the ASEAN Secretariat to process the posting of the ACC Statements for Antimony and Parabens to the ASEAN website. The Opinion Statement for Plastic Microbeads, can be posted post receipt of the result of the internal consultations of Singapore and Malaysia.

AGENDA ITEM 8: KOREAN COSMETIC REGULATORY FRAMEWORK

43. On behalf of the Korean Ministry of Food and Drug Safety, Ms Minjung Kim, presented the Korean Cosmetic Regulatory Framework. The full presentation appears as **APPENDIX 26**.

44. The ACSB Chair and Alternate Chair, on behalf of ACSB, expressed appreciation to Korea MFDS for the presentation. The Chair highlighted the importance to create understanding on the Korean cosmetic regulations as there are many cosmetic products being imported from Korea to ASEAN and vice versa.

45. The Korean MFDS responded to several queries of the AMS related to the presentation, and created better understanding on the Korean Cosmetic Regulations and implementation.

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46. The Meeting agreed that there is a good opportunity to determine balance of cosmetic regulations between Korea and ASEAN, particularly on Functional Cosmetics which undergo registration in Korea while notification in ASEAN. The Meeting requested the ASEAN Secretariat to check on the possible technical cooperation with Korea to pursue this further.

Action by ASEAN Secretariat

AGENDA ITEM 9: OTHER MATTERS

47. The Philippines presented the cosmetic refilling concept, appearing as **APPENDIX 27**. The Meeting commented that this is a good initiative to reduce the plastic waste and the impact to the environment. However, it is important that this is properly set-up and regulated to ensure the quality and safety of the products under the refilling station. In this regard, the Meeting agreed to the creation of the Technical Working Group (TWG) composed of Philippines (lead), Malaysia and ACA to study the concept and determine the requirements/guidelines for the refilling set-up.

Action by Philippines, Malaysia and ACA

48. The Meeting also discussed whether the products in vials and ampoules will be classified as cosmetic products. The Meeting noted that there are products in vials/ampoules that have been notified in most AMS provided that they are not meant for injection and have clear directions for use and benefits as cosmetic. However, there are issues arising during Post Marketing Surveillance, where there are instances when some of these products are also being used as injectables.

49. ACA informed the Meeting that the use of vials/packaging in certain cosmetic products is intended for product hygiene (single use) and stability. There are cosmetic products proven to be more stable when packaged in glass vials or ampoules.

50. In consideration of these information, the Meeting agreed to create the Technical Working Group composed of Thailand, Indonesia, Malaysia and ACA, to further study these types of product and determine the product classification and requirements.

Action by Thailand, Indonesia, Malaysia and ACA

51. The Meeting requested the AMS to provide more information on personalized cosmetic products and products in tablet forms for discussion in the next ACSB Meeting.

Action by AMS

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52. Referencing to the previous ACSB discussions and decisions on Triclosan, the Meeting agreed to the Singapore proposal to revise the current entry 288 of ACD Annex III to include the phrase 'Singapore: Not Permitted for non-preservative use.'

Action by ACSB Secretary

AGENDA ITEM 10: DATE AND VENUE OF NEXT MEETING

53. The 32nd ACSB Meeting will be held in Singapore tentatively on 09-10 June 2020. Singapore will advise the details eventually.

AGENDA ITEM 12: ADOPTION OF THE REPORT

54. The Meeting agreed to adopt the Final Report of the 31st ACSB Meeting and to seek ACC Meeting endorsement.

55. Meeting Close

The Chair and Alternate Chair of ACSB thanked all Member States, delegates, ACA representatives and ASEAN Secretariat for their cooperation, support and valuable inputs during the meeting.

Acknowledgement

The delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand and Vietnam, representatives from the ASEAN Secretariat and representatives from the ASEAN Cosmetic Association expressed their appreciation to the Food and Drug Administration, Department of Health, Philippines for the warm hospitality extended to all delegates and for the excellent arrangements made for the meeting.

**The Meeting was held in the traditional spirit of
ASEAN cordiality and solidarity**

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