

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 33<sup>d</sup> 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 (highlighted in yellow) 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. Nos. 1642, 1643 and 1644 (New Entries)**

***Grace Period: 28 May 2022 (12 months)***

| Substances   | CAS Number  | Ref. No. |
|--|-------------|----------|
| 1,2,4-Trihydroxybenzene when used as a substance in hair and eyelash dye products<br>Except Singapore                        | 533-73-3    | 1642     |
| 4-Amino-3-hydroxytoluene when used as a substance in hair and eyelash dye products<br>Except Singapore                       | 2835-98-5   | 1643     |
| 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid when used as a substance in hair and eyelash dye products<br>Except Singapore | 117907-43-4 | 1644     |

**B. ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down**

**ACD Annex III Ref. Nos. 328 and 329 (New Entries)**

**Grace Period: 28 November 2022 (18 months)**

| Ref No<br>ACD #<br><br>(EU #) | Substance/CAS No <sup>(19)</sup>   | Restrictions                       |   |   | Conditions of use and warning<br>which must be printed on the<br>labels |
|-------------------------------|--|------------------------------------|---|---|---|
|                               |  | Field of application and/or<br>use | Maximum authorised<br>concentration in the<br>ready for use preparation | Other limitations and<br>requirements                           |   |
| A                             | B  | C                                  | D   | E   | F   |
| 328<br><br>(313)              | 2-Hydroxyethyl Methacrylate<br><br>HEMA<br><br>868-77-9  | Nail Products                      |   | Professional use only<br><br>Except Singapore – under<br>review | For professional use only<br><br>Can cause an allergic reaction         |
| 329<br><br>(314)              | 11,14-Dioxo-2,9- diazaheptadec-16-<br>enoic Acid, 4,4,6,16- tetramethyl-<br>10,15- dioxo, 2-[(2-methyl- 1-oxo-2-<br>propenyl) oxy]ethyl ester<br><br>DI-HEMA TRIMETHYLHEXYL<br>DICARBAMATE<br><br>41137-60-4/ 72869-86-4 | Nail Products                      |   | Professional use only<br><br>Except Singapore – under<br>review | For professional use only<br><br>Can cause an allergic reaction         |

**C. ACD Annex III - List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down**

**ACD Annex IV Ref. No. 322 (Revised Entry)**

| Colour Index Number or Denomination | Colour | Field of application |   |   |   | Other limitations and requirements  |
|-------------------------------------|--------|----------------------|---|---|---|---|
|                                     |        | 1                    | 2 | 3 | 4 |   |
| 77266                               | Black  | x                    |   |   |   | Purity >97% with the following impurity profile: Ash content ≤ 0.15%, total Sulphur ≤ 0.65%, total PAH ≤ 500 ppb, and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, <b>total Hg ≤ 1 ppm</b>   |
| 77266 (nano)                        | Black  | x                    |   |   |   | 10% max. concentration in the finished product<br><br>Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.<br><br>Only nanomaterials having the following characteristics are allowed:<br>• Purity >97% with the following impurity profile: Ash content ≤ 0.15%, total Sulphur ≤ 0.65%, total PAH ≤ 500 ppb, and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, <b>total Hg ≤ 1 ppm</b><br>• Primary particle size ≥ 20 nm |

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

**Inclusion of 5<sup>th</sup> Statement in the PREAMBLE**

5. All finished products containing formaldehyde or substances in this ANNEX and which release formaldehyde (**Entries 20,21,27,30,31,33,46,49,51,55**) must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.

**ACD Annex VI Ref. No. 7 (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   |
| 3                | Salicylic acid and its salts (++) <sup>(1)</sup>              | 0.5% (acid)  | Not to be used in preparations for children under three years of age, except for shampoos           | Not to be used for children under three years of age <sup>(2)</sup> |
| 7                | Biphenyl-2-ol CAS 90-43-7                                     | Rinse-off products; 0.2% (as phenol)<br>Leave-on products; 0.15% (as phenol) | Indonesia: Under Review   | Avoid contact with eyes.  |
| 9                | Inorganic sulphites and hydrogensulphites (++) <sup>(4)</sup> | 0.2% expressed as free SO <sub>2</sub>                                       |   |   |
| 23               | Triclocarban (INN) (++) <sup>(5)</sup>                        | 0.2%   | Purity criteria: 3,3',4,4'-Tetrachloroazobenzene < 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene < 1 ppm |   |

|    |  |   |   |  |
|----|--|---|---|--|
| 34 | Benzyl alcohol (±) <sup>(8)</sup>  | 1%  |   |  |
| 43 | 1-Phenoxypropan-2-ol (±) <sup>(10)</sup>   | 1.0%  | Only for rinse-off products   |  |
| 54 | Benzalkonium chloride, bromide and saccharinate ■ <sup>(13)</sup>  | 0.1% calculated as Benzalkonium chloride            |   | Avoid contact with the eyes                            |
| 58 | Ethyl Lauroyl Arginate HCl (INCI) (±) <sup>(6)</sup> Ethyl-N α -dodecanoyl- L-arginate hydrochloride CAS No 60372-77-2 | (a) mouthwashes: 0.15%<br>(b) other products: 0.4 % | (a) Not to be used in preparations for children under 10 years of age.<br>(b) Not to be used in lip products, oral products and spray products. | (a) Not to be used for children under 10 years of age. |