

Bisphenol A

Position paper

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BPA is authorized in plastics for food contact (EU Regulation 10/2011), with the exception of baby bottles (EU Regulation N°321/2011). The safeguard measure of the EU Framework Regulation 1935/2004 allows some Member States to introduce national restrictions on BPA in food contact applications. Since January 2015, the French Decree no. 2012-1442 prohibits the use of BPA in all packaging intended to come into direct contact with food. This prohibition does not apply to packaging for cosmetic products. Regulation (EU) 2016/2235, amending Annex XVII to REACH regulation restricts the use of BPA in thermal paper. Thermal paper which contains BPA in a concentration equal to or more than 0.02% by weight will be not allowed to place on the EU market after January 2020. In January 2017 BPA was added to the Candidate List of SVHCs under REACH regulation.

According to the FDA, BPA is safe at the current levels occurring in food contact materials. Based on their ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging. However, the FDA no longer allows the use of BPA in baby bottles, sippy cups or coatings in packaging for infant formula, because its use has been abandoned by Industry.

In May of 2015, BPA was added to the substance list of California Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, because of potential female reproductive toxicity. On June 17, 2016, a Maximum Allowable Dose Level (MADL) of 3 µg/day for BPA was adopted for dermal exposure from solid materials.

We are well aware that the EU Regulation N° 1223/2009 on cosmetic products prohibits the use of Bisphenol A in the cosmetic formulation. However the text is not specific regarding the packaging. Due to the lack of clarity, it is commonly admitted that the legislative requirements of packaging for food contact are useful references for cosmetic packaging. The EU Commission Decision (N° 2013/674/EU) on Annex I to the cosmetics regulation states that reference to food contact legislation could be useful for characteristics of packaging materials. The FEBEA guidelines (2012) also indicate that *"food contact quality material can be used for packaging items in direct contact with the finished cosmetic product"*.

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Aptar Beauty + Home and Food + Beverage commits to using food grade plastics as far as possible. The use of such materials therefore means that the presence of traces in the cosmetic products cannot be excluded. The EU Regulation on cosmetics states, in article 17, that *“the non-intended presence of a small quantity of a prohibited substance, stemming from [...] migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is safe for human health”*. EFSA has evaluated the safety of BPA on several occasions (2006, 2008, 2009, 2010, 2011 and 2015), and has always concluded that existing exposures to BPA when used in food packaging do not pose a health or safety threat to the population as a whole, or to infants and children in particular.

To the best of our knowledge BPA is only used in the manufacture of epoxy, PVC, thermal paper, polycarbonate resins, and other polymers (e.g. polysulfones, polyamides, etc.). Aptar Beauty + Home and Food + Beverage only use polycarbonate for non-contact components. Epoxy coatings used on certain metallic components, such as mounting cups for deodorant sprays, may also contain BPA. The choice of such coatings is always in consultation with the customer.

Therefore, unless an Aptar product contains one of the aforementioned resins, the presence of BPA can reasonably be excluded.

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