

Stellungnahme Coty Inc. vom 27.1.2016

COTY was founded in Paris in 1904 by François Coty, a visionary in the perfume industry. Today, COTY is a leader in the global beauty industry and one of the world's largest fragrance

companies with approximately 10,000 employees and corporate offices in Paris, Geneva and New York. Our products are developed, manufactured and packaged in compliance with the strict guidelines and regulations that are relevant and applicable in every jurisdiction where they are sold. Any new legal requirements are incorporated during the development process.

I. Preamble

The Environment Directorate General of the European Commission ('DG Environment') defines 'endocrine disruptor' as an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations [emphasis added].

We note that endocrine disruptors include both natural and man-made chemicals:

- Natural chemicals, including toxins produced by components of plants (phytoestrogens) and certain fungi.
- Man-made chemicals, e.g. pesticides, like DDT, plasticizers like bisphenol A used in consumer goods, and a number of industrial chemicals, like polychlorinated biphenols and dioxins.

There has been much controversy over endocrine disruptors. For two decades, hormone active substances have been given considerable attention by the scientific community, public authorities, industry, and non-governmental organizations. However, it remains uncertain whether some endocrine disruptors currently on the market actually harm humans and wildlife at the doses to which these are exposed.

Whilst the IPCS/WHO definition of potential endocrine disruptor, which dates back to 2002, is still used widely, the Danish EPA noted in 2011 that the OECD had agreed on a new operational definition in terms of a possible endocrine disruptor as "A possible endocrine disruptor is a chemical that is able to alter the functioning of the endocrine system but for which information about possible adverse consequences of that alteration in an intact organism is uncertain." (emphasis added)

By the same token, the Danish EPA further pointed out that "In addition to definitions, a more operational set of "level of evidence rules" or criteria is needed for allowing industry and authorities to determine whether a substance should be considered an endocrine disruptor ("ED") or a potential endocrine disruptor." Such rules include the general accordance with the OECD Conceptual Framework for Testing and Assessment of ED, which details the scientific evidence required for a substance to be considered as either confirmed ED (category 1), suspected ED (category 2a) or indicated ED (category 2b). Finally, the Danish EPA recommended, among others, that identified potential endocrine disruptors, if meeting priority criteria, be selected for substance evaluation with the aim of obtaining sufficient data allowing for a conclusion on their endocrine disrupting properties.

II. Legal considerations

The European Cosmetic Products Regulation (EC) No 1223/2009 (the “CPR”) does not restrict substances on the basis of endocrine disrupting effects. However, it requires that cosmetic products contain no UV-filters other than those listed in CPR Annex VI.

Chemical substances are required to undergo a very specific programme of testing and assessment prior to being introduced into the Community market, to ensure that their use or release into the environment poses no danger to humans or to wildlife.

Annex XVII of the REACH Regulation (EC) No 1907/2006 of 18 December 2006 (the Restricted Substances List) contains the existing restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles, whilst substances that require authorization to be used, placed on the market or imported into the EU for being “Substances of Very High Concern” are listed in Annex XIV of REACH (the Authorisation List).

III. Comments on selected substances mentioned in your e-mail

III.1. Ethylhexyl methoxycinnamate (or octyl methoxycinnamate, “OMC”)

We note that ethylhexyl methoxycinnamate is listed in CPR Annex VI (12) and therefore permitted for use in cosmetic products, up to a maximum concentration of 10 %.

We also note that ethylhexyl methoxycinnamate has not been entered into the Authorisation List nor does it appear on the Candidate List of substances of very high concern for Authorisation.

The French National Agency for the Safety of Medicines and Health Products (MSNA, formerly Afssaps) evaluated the risks associated with OMC in 2012 and concluded that this organic UV-filter poses no risk to human health at the levels it is used in cosmetics: Concerning the potential endocrine disrupting effects (i.e. estrogenic, androgenic and antiandrogenic activity) of OMC, many in vitro and in vivo studies are available in the scientific literature. As shown by the results of the in vitro studies, the endocrine disrupting potential of OMC proved negative. Some studies indicated a weak estrogenic, androgenic and antiandrogenic activity, however at high concentrations of OMC.

OMC was evaluated based on the Danish criteria for identification of ED as category 2b related to human health. However, it is not on the EU list of potential endocrine disruptors that is currently available from the website of the Ministry of Environment and Food of Denmark.

OMC has also not been entered into the Candidate list of 553 substances established from a total of 564 chemicals suggested by various organizations or in published papers or reports as being suspected ED.

III.2. Benzophenone-3

We note that benzophenone-3 is listed in CPR Annex VI (4) and therefore permitted for use in cosmetic products, up to a maximum concentration of 10 %.

We also note that benzophenone-3 has not been entered into the Authorisation List nor does it appear on the Candidate List of substances of very high concern for Authorisation.

Benzophenone-3 has also not been entered into the Candidate list of 553 substances mentioned above.

To date, benzophenone-3, (also known as oxybenzone) is approved for use in specific concentrations for sunscreens sold in all major countries, including the United States, Canada, European Union countries, Japan, Australia, China, and South Korea.

III.3. Diethylphthalate (“DEP”)

DEP is the only phthalate with significant use in personal care products. It is currently permitted for use as denaturant in alcohol, and as diluent in perfumes, in Europe and in the U.S.

However, COTY decided to stop the use of DEP worldwide in 2012, starting with new fragrances and gradually removing it from all existing products in the course of a global harmonization of denaturants, and replace it by a mixture of t-butyl alcohol and denatonium benzoate.