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Short Communication

Better understanding of the EU regulatory frameworks for cosmetic products

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HIGHLIGHTS

- UV-filters in cosmetic products are "substances" and covered by CLP.
- Final cosmetic products intended for end-users are exempted from CLP.
- The REACH registration data set provides a publicly available summary data set for CLP.

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ABSTRACT

This letter to the editor corrects some misunderstandings regarding the EU regulations covering cosmetic products stated in a recent publication by A. Sobek et al. "In the shadow of the cosmetics directive — Inconsistencies in EU environmental hazard classification requirements for UV-filters" published in Science of the Total Environment 461–462 (2013) 706–711.

1. Introduction

In a recent publication "In the shadow of the cosmetics directive — Inconsistencies in EU environmental hazard classification requirements for UV-filters" (Science of the Total Environment 461–462 (2013) 706–711), A. Sobek et al. present the determination of the potential environmental hazard classification of UV-filters, used in sunscreen products, applying the aquatic environmental hazard criteria for mixtures.

In our opinion this article contains a series of misinterpretations of the legal frameworks for different uses of chemicals, which need to be cleared up.

Among others, we note the following interlinked issues:

1. The article seems to show an incomplete understanding of the regulatory coverage of substances used in cosmetic products and of cosmetic products.

2. In their article, A. Sobek et al. do not clearly distinguish between "substance" and "product". In a legal context, this is however important as they are different legal terms in the legislations discussed and the legal obligations and requirements are not the same.

Below we further explain the two issues and give examples.

2. Relevant regulatory framework

The relevant regulations are the following 3:

1. The REACH Regulation,[1]
2. The Classification, Labelling and Packaging Regulation (CLP)[2] and
3. The Cosmetic Products Regulation (CPR).[3]

[1] REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 2006, pp. 1–849.

[2] CLP Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 2008, pp. 1–1355.

[3] CPR Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. OJ L 342, 2009, pp.59–209.

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2.1. Definitions

These three regulations all define "substance" as a "chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition". Furthermore, REACH and CLP regulations define "mixture" as a "mixture or solution composed of two or more substances".

The CPR addresses "cosmetic products" which are defined as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours".

The UV-filter is a "substance" under all three legislations, and the CPR cosmetic product would be regarded as a "mixture" under the CLP and REACH regulations.

The information given here only addresses the case where the use of the substances is covered by CPR, CLP and/or REACH.

2.2. Overview of REACH and CLP regulatory coverage of substances used in cosmetic products

Article 6 (not cited) states a general obligation to register substances on their own or in mixtures. Article 2 of REACH does not list substances used in cosmetic products as exempted from REACH, only the cosmetic product "in the finished state intended for the final user" is exempted. Thus, substances used in cosmetic products have to be registered under REACH. The registration under REACH is based on total tonnage thresholds independently of use(s). The registration should contain the data pertaining to the relevant tonnage threshold (including all uses), as specified in the Annex VI to IX of REACH. The tonnage threshold for substance registration is per year and per producer or importer, and registration starts at 1 tonne.

For substances used in cosmetic products, REACH has specific exemptions that only concern the human health part and end use in cosmetic products regarding the chemical safety report (Article 14), authorisation (Article 56) and restriction (Article 67). As the exemptions for use in cosmetic products specifically regard the human health aspects, environmental effects need to be assessed, as relevant, under these articles.

For ease of reference the relevant text of the REACH articles are cited in Box 1.

The CLP Regulation requires (see Box 2) that substances registered under REACH must be classified (Article 1.1.b), as must substances not registered under REACH (Article 1.1.c). Substances used in cosmetic products are not listed as being exempt from these requirements and thus there is an obligation under the CLP regulation to classify substances used in cosmetic products as relevant, whether they reach the minimum REACH registration tonnage threshold or not.

The CLP regulation has a list of cases to which it shall not apply (Art. 1.5.c), and cosmetic products are one of the exemptions when "… in the finished state, intended for the final user". The substances used as ingredients in cosmetic products are not exempt and hence the CLP regulation is applicable to them as well as cosmetic products if not in the finished state intended for the final user. Hence, substances used as UV-filters in sunscreens are subject to CLP.

The REACH-frequently-asked-questions (http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/topic/clp;jsessionid=A4C6DE094BCCADC417E089AE457BE670.live1) has the following explanation on the relationship between the substances used in cosmetic products and mixtures and the obligations under CLP, see Box 3.

The CLP Regulation requires data pertaining to the physical hazards. In general, for the other end-points the classification is based on available information. If the substance is registered under REACH, a legally defined REACH dataset will be available which, depending on the tonnage threshold, provides information for a number of environmental and human health end-points increasing with increasing tonnage. Generation of this dataset is primarily based on harmonised OECD test methods. If the substance is not registered under REACH (e.g. below the tonnage threshold) then information on physical hazards must be provided according to CLP.

Industry is responsible for the classification (self-classification), except when a harmonised classification at EU level has been deemed necessary (see Annex VI of CLP). Before REACH came into force a harmonised classification would cover all endpoints, and now the harmonised classification covers certain human health endpoints, and, where relevant, other end-points may be harmonised. When a harmonised classification is available, it must be applied.

For the self-classification, more than one classification of a substance may be available from industry. Under REACH and CLP, the manufacturer(s), producer(s) and importer(s) are required to notify their classification of their substance(s) to the classification and labelling (C&L) inventory at ECHA (C&L Inventory Database)[4], which is available to

Box 1
REACH text specifically on cosmetic products.

Article 2
Application
…
6. The provisions of Title IV [*information in the supply chain*] shall not apply to the following preparations in the finished state, intended for the final user:
…
(b) cosmetic products as defined in Directive 76/768/EEC;
Article 14
Chemical safety report and duty to apply and recommend risk reduction measures
…
5. The chemical safety report need not include consideration of the risks to human health from the following end uses:
…
(b) in cosmetic products within the scope of Directive 76/768/EEC.
Article 56
General provisions
5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:
(a) uses in cosmetic products within the scope of Directive 76/768/EEC.
Article 67
General provisions
1. A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.
2. Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.

[4] http://echa.europa.eu/information-on-chemicals/cl-inventory-database.