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In the shadow of the Cosmetic Directive — Inconsistencies in EU environmental hazard classification requirements for UV-filters

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HIGHLIGHTS

- UV-filters are used in both cosmetic and industrial products/applications
- UV-filters in cosmetic products are excluded from CLP
- We assessed CLP environmental hazard classifications of UV-filters and sunscreens
- UV-filters in cosmetics meet CLP criteria as hazardous to the aquatic environment
- This study has revealed inconsistencies in current EU regulations of UV filters

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ABSTRACT

UV-filters are chemicals with potentially environmental hazardous properties. In the European Union (EU), UV-filters contained in sunscreen products are currently regulated by the Cosmetic Directive (from July 2013 by the Cosmetic Products Regulation). Environmental hazard classifications according to the regulation on classification, labelling and packaging of substances and mixtures (CLP) must be determined for UV-filters contained in industrial chemical products, whereas UV-filters contained in sunscreens are exempted from CLP. In this study we determined the potential environmental hazard classifications of UV-filters and sunscreen products if the CLP regulation was to be required for cosmetic products. Two sunscreen products were evaluated in accordance with the aquatic environmental hazard criteria for mixtures. The results highlight that the inconsistencies in the current EU regulation of UV filters hamper the risk management of environmental hazards of UV filters used in cosmetic products. Almost 50% of the investigated UV-filters approved for use in cosmetic products on the European market according to the current Cosmetic Directive were identified to meet the CLP classification as being hazardous to the aquatic environment. Assuming a worst-case scenario, the two examined sunscreens could both be classified as hazardous to the aquatic environment with long-lasting effects according to CLP classification criteria. Hence, if the CLP regulation was applicable to sunscreen products, both brands could potentially be labelled with the environmental hazard pictogram and associated hazard and precautionary statements. Including cosmetic products, and thereby sunscreens, in the CLP regulation would contribute to a more harmonized and transparent regulation of potentially hazardous substances on the EU market.

1. Introduction

Chemicals that absorb or reflect ultraviolet (UV) radiation in sunlight are used in sunscreen products to protect the skin from UV-induced damage. These chemicals are commonly referred to as UV-filters. In the European Union (EU) sunscreen products for human use are defined as cosmetic products and are regulated by the Cosmetic Directive (CD, EEC 76/768; European Economic Community, 1976), to be replaced by the Cosmetic Products Regulation (CPR, EC/1223/2009) in July 2013 (European Community, 2009). Both the current directive and the new regulation list UV-filters approved for use in sunscreen products on the EU market (26 UV-filters in the directive and 28 in the regulation). These, as well as other UV-filters, may also be used in industrial applications, such as in house paints. The marketing approval of UV-filters in cosmetic products is based on a human safety assessment. The Cosmetic Directive does not include any requirements on conducting environmental risk assessments (ERAs). The list of UV-filters approved by the Cosmetic Directive may therefore include substances with environmentally hazardous properties. The new regulation states that environmental concerns should be regulated under the Registration, Evaluation, Authorization and restriction of Chemicals

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regulation (REACH; EC (European Community), 2006) in a "cross-sectoral manner" (Recital 5 CPR). However the UV-filters approved by the Cosmetic Directive are also approved by the new regulation, and thus the implementation of the new regulation will at least not initially result in extended risk assessments of potentially environmentally hazardous UV-filers used in sunscreen products.

UV-filters are released to the environment directly via wash-off from the skin or via sewage treatment plants (STPs). Accordingly, UV-filters approved for use on the European market have been detected in surface water, sediment and biota (Balmer et al., 2005; Remberger et al., 2011; Zhang et al., 2011), drinking water (Rodil et al., 2012), sludge and effluent water from STPs (Balmer et al., 2005; Plagellat et al., 2006; Zhang et al., 2011) and even in breast milk and urine (Kunisue et al., 2012; Schlumpf et al., 2010). These findings demonstrate the apparent likelihood that chemicals contained in cosmetic products may be emitted to the aquatic environment. A previous monitoring study performed in Sweden demonstrated that UV-filters are ubiquitously present in the Swedish aquatic environment, and that STPs and usage of sunscreens at beaches are the main pathways into the environment (Remberger et al., 2011).

The EU regulation on classification, labelling and packaging of substances and mixtures (CLP; EC/1272/2008) prescribes that substances and mixtures distributed within the EU should be classified when meeting the physical, health or environmental hazard criteria set out in that regulation, and be labelled accordingly (Art. 4 CLP). CLP is the European corresponding development of the United Nations Globally Harmonized System on classification and labelling of chemicals (GHS), which promotes the use of one globally harmonized classification system. The aim of the CLP regulation is to provide hazard and safety information to both professional buyers and consumers. However, some substances and mixtures are excluded from the CLP requirements, including cosmetic products, and thus UV-filters when they are used in sunscreen products. Other exemptions include pharmaceuticals, veterinary medical products and food additives (ECHA, 2011). The implication of this system is that UV-filters do not require CLP hazard classification and warning labelling when used in cosmetic products, in contrast to if the same UV-filters are used in other product types, such as house paints.

In this study we determine the potential environmental hazard classifications of UV-filters and sunscreen products approved for use in Europe by the Cosmetic Directive if the CLP regulation was to be required also for cosmetic applications. Available data on biodegradability, bioaccumulation and aquatic toxicity for the 26 UV-filters currently approved in sunscreens according to the EU Cosmetic Directive were compiled and compared with the aquatic environmental hazard criteria in the CLP regulation. Two sunscreen products were also evaluated on a worst-case scenario basis in accordance with the aquatic environmental hazard criteria for mixtures. Further we assessed existing CLP classifications for the 26 approved individual UV-filter substances made by different risk assessors under the REACH and CLP legislation in order to investigate if and how these classifications are diverging in relation to one another and to the classifications made based on the open scientific literature gathered for the present study, respectively. The overall aim of this effort is to contribute with knowledge that can help further development towards a more consistent and transparent chemicals legislation within the EU.

2. Background

2.1. The Cosmetic Directive

A cosmetic or personal care product is defined as any substance or mixture that is intended to be placed externally on the body or in the oral cavity, with an intension of perfuming, cleaning, protecting, keeping it in good condition and/or changing its appearance (European Community, 1976). This applies to sunscreens and many other commonly used products such as make up, skin lotions, toothpaste and shampoo. The Cosmetic Directive includes (negative) lists of substances prohibited in cosmetic products and (positive) lists that comprise substances that are approved for a specific purpose in cosmetic products. The substances on the positive lists are often associated with restrictions, such as a maximum concentration percentage of the final product amount. All of the 26 UV-filters approved for use in sunscreens on the European market intended for human use are prescribed with restrictions on maximum percentage of the final product. For instance 3-benzylidene camphor is not allowed to exceed 2%, while titanium dioxide (TiO_2) is allowed to constitute of up to 25% of the final product (CD, Annex VII).

2.2. CLP

One of the main purposes of the CLP regulation is to protect humans and the environment from harmful, both physical and chemical, exposures (CLP; EC/1272/2008). Therefore substances and mixtures are classified irrespective of produced or imported volume. The emphasis is on self-classification by industry (CLP, Title II). Environmental hazard classifications are based on data on biodegradation, bioaccumulation and toxicity of the substances. Available information on hazardous properties is used, including animal experimental and epidemiological data. Data from quantitative structure activity relationships (QSARs) may be used for predicting biodegradability and log K_{ow} as part of expert judgement and Weight of Evidence practices (ECHA, 2011, Annex 1). The data used for classification purposes should preferably be obtained from standardized tests (or equivalently well described and performed tests). However, if only data from non-standard tests are available these may be considered. The CLP regulation sets out criteria for five different classification categories for substances and mixtures with regard to environmental hazard (Table 1). Substances and mixtures classified as acute category 1 and/or chronic category 1 or 2 must be labelled with the GHS09 pictogram (Fig. S1). Classifications also include hazard statements (Table 1) and in some cases precautionary statements (European Community, 2008). Species-specific limits on LC_{50}- and EC_{50}-values determine the toxicity categories (Table 1). A chemical considered as not rapidly degradable and/or to be bioaccumulative is classified in one of the chronic categories. Chronic category 4 is an additional category for substances that do not meet the requirements in the other categories but that still possess properties that might pose a threat to the environment.

Table 1
CLP aquatic hazard classifications with associated hazard statements and category levels based on ecotoxicity, biodegradability and bioaccumulation properties. The toxicity limits are based on tests with fish (96 h LC_{50}), crustaceans and/or algae or aquatic plants (48 h; EC_{50}). BCF is the bioconcentration factor and K_{ow} is the octanol–water partition coefficient.

CLP classification	Hazard statement (CLP)	LC_{50} or EC_{50} mg L^{-1}	Additional requirements
Aquatic acute 1	H400: Very toxic to aquatic life	≤1	None
Aquatic chronic 1	H400, H410: Very toxic to aquatic life with long lasting effects	≤1	Not rapidly degraded or BCF ≥500 (log K_{ow} ≥4)
Aquatic chronic 2	H411: Toxic to aquatic life with long lasting effects	>1 to ≤10	Not rapidly degraded or BCF ≥500 (log K_{ow} ≥4)
Aquatic chronic 3	H412: Harmful to aquatic life with long lasting effects	>10 to ≤100	Not rapidly degraded or BCF ≥500 (log K_{ow} ≥4)
Aquatic chronic 4	H413: May cause long lasting harmful effects to aquatic life	No acute toxicity	Data indicating possible aquatic environmental endangering properties

2.3. REACH

The overall objective of REACH is to improve how industrial chemicals produced in or imported into the EU are risk managed with regard to human health and the environment (European Community, 2006). REACH requires all manufacturers of substances produced at or above 1 tonne per year to collect information on chemical properties and usage before putting the substances on the market. In contrast to the CLP regulation, the REACH requirements are volume-dependent; the higher the produced or imported volume of the substance, the more information about the substance is required. The required information is communicated to the European Chemicals Agency (ECHA) via registration dossiers. General requirements for all substances to be registered include providing e.g. potential classification and labelling of the substance according to the CLP hazard criteria, information on the use of the substance and on its intrinsic properties (European Community, 2006).

For substances produced or imported at or above 10 tonnes per year registration entails including a Chemical Safety Assessment (CSA). For substances not classified as hazardous according to the CLP criteria or identified as a persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB; according to criteria set out in Art. 14 (4) REACH (EC (European Community) (2006))) the CSA is limited to a hazard assessment. For substances identified as hazardous or PBT/vPvB the CSA should also contain an assessment of the risks based on the use of the substances and measures for how these risks should be adequately controlled. A core process of this risk characterization is to generate exposure scenarios. An exposure scenario consists of a description of how the substance is manufactured or used during its full life cycle as well as how the manufacturer controls, or recommends downstream users to control, exposures of humans and the environment. These recommended control measures are stipulated as risk management measures (RMMs) (REACH, Annex I).

2.4. The Cosmetic Products Regulation

The Cosmetic Directive will during 2013 be replaced by the Cosmetic Products Regulation No. 1223/2009 (European Community, 2009). The new regulation will have a stronger enforcement and contain more detailed specifications to avoid different implementations by the EU member states. It is stated that environmental concerns that substances used in cosmetic products may raise are to be considered through the application of REACH. Hence the new regulation may open up for future amendments concerning ERA of cosmetic products. Nevertheless, it is not clear if or how any RMMs aiming at controlling environmental effects of UV filters and sunscreens within REACH will harmonize with measures in the Cosmetic Products Regulation.

3. Methods

3.1. Databases

Data on properties and classifications of UV-filters approved for use in cosmetic products by the EU Cosmetic Directive were collected from the scientific literature (web-of-science), the databases Classification and Labelling Inventory; ECOTOX; ESIS; HSDB; N-CLASS; Prevent; the Registered Substance Database; and The Swedish Commodity Guide. The databases were searched in January and February 2012.

3.2. Classification of UV-filters and mixtures

The classification of individual UV-filters was done according to instructions in Guidance to Regulation (EC) No. 1272/2008 (ECHA, 2011). In cases of non-conclusive data, the classifications were made on a worst-case-scenario basis, as recommended by the CLP instructions. Two sunscreens common on the Swedish market were assessed for mixture classification of UV filters; Brand 1 and Brand 2 (see Table S1). The summation method was applied for assessing mixture toxicity (ECHA, 2011, part 4). According to this method, first substances classified as acute category 1 are assigned a multiplying factor (M-factor) to give additional weight to very toxic ingredients. If the sum of the concentration of the individually classified UV-filters multiplied with their M-factor equals or exceeds 25%, the mixture will be classified as acute category 1 (Eq. (1)). In addition, the summed toxicity of substances classified as chronic categories 1–4 can be calculated the same way, where M-factors are applied for substances classified as chronic 1. As in the case for Brand 1 and Brand 2 the summed toxicity and percentage of substances classified as chronic 1 are multiplied with a factor of 10 when summed with other substances classified as chronic 2 (Eq. (2); ECHA, 2011).

$$\sum(\mathrm{Conc}_{\mathrm{acute}\ 1} \times \mathrm{M-factor}) \geq 25\% = \text{acute category 1} \quad (1)$$

$$\sum(\mathrm{Conc}_{\mathrm{chronic}\ 1} \times \mathrm{M-factor} \times 10) + \sum(\mathrm{Conc}_{\mathrm{chronic}\ 2}) \geq 25\% \quad (2)$$

The concentration of each individual substance in a cosmetic product is not specified on the product. The classification of the sunscreens, i.e. with regard to the UV-filter mixtures, was therefore done based on a worst-case scenario using the highest concentration quantity allowed according to the Cosmetic Directive for each UV-filter. However, since the order of the ingredients specified on a cosmetic product denotes its relative content (i.e. the ingredient specified first in the list has the highest content by weight, and so on), this information was also included in the calculation/classification. For example, if the first UV-filter on the list was allowed at a concentration of 5%, the second UV-filter was assumed to be present at the same or a lower concentration, regardless if the maximum allowed concentration according to the Cosmetic Directive was higher than 5%. Further, in the case where multiple classifications for single UV-filters exist as for e.g. octocrylene, a worst-case scenario was assumed and thus the highest classification was selected irrespective of whether the classification was a result of this study or done by industry. This procedure is in accordance with recommendations in CLP instructions.

4. Results and discussion

4.1. Classification of individual UV-filters

In total 12 of the 26 (46%) individual UV-filters approved for use in cosmetic products on the European market according to the current Cosmetic Directive were identified to meet the CLP classification as hazardous to the aquatic environment (9 classified as part of this study and 3 by industry; Table 2). Of these 12 chemicals, 4 were classified according to the highest toxicity category 1. For 12 of the 26 UV-filters (Table S3) not enough information was found to be available in the open scientific literature for classification according to the CLP data requirements and there were no classifications made by industry available. Many UV-filters are currently only pre-registered under REACH (ECHA, 2012) meaning that information on properties may be limited. Yet, some of these UV-filters have been detected in the environment (Balmer et al., 2005; Kunisue et al., 2012; Remberger et al., 2011) and are known to have hazardous properties, such as being endocrine disruptors (Table S2). For 2 of the 26 UV-filters information on properties was available but did not (fully) meet the environmental hazard classification criteria (i.e. for benzophenone-4/benzophenone-5 and 3-benzylidene camphor; Table 2).

4.2. Classification of mixtures of UV filters in sunscreens

The two examined sunscreens (Brand 1 and Brand 2) could both be classified to the category chronic 2, according to the CLP classification

Table 2
UV-filters approved in cosmetic products in the EU and for which there was available information sufficient for CLP classification in this study or a classification was available by industry. Data (ecotoxicity, degradability and bioconcentration) used for the hazard classifications in this study is listed in Table S2.

Substance name (CAS#)	Chemical classification (this study)	(No. of) classifications made by industry
Benzophenone-3 (131577)	*Acute 1 and chronic 1* Toxicity < 1 mg L^{-1} Not rapidly degradable	(2) Acute 1 and chronic 1 (180) Chronic 2 (1) Chronic 4
Benzophenone-4/benzophenone-5 (4065456/6628371)	Not toxic	
3-Benzylidene camphor (15087248)	Not hazardous enough for classification categories 1–3 according to standardized test data; indications of hazardous properties could result in a classification as chronic 4	
Butyl methoxy dibenzoyl methane (70356091)	*Chronic 2* Toxicity > 1 mg L^{-1} to ≤10 mg L^{-1} Not rapidly degradable	(23) Acute 1 and chronic 1 (>900) Chronic 4 (29) Chronic 2 (19) Chronic 3
Diethylamino hydroxy benzoyl hexyl benzoate (302776687)	No data available for this study	(8) Chronic 4
Ethyl hexyl methoxy cinnamate (5466773)	*Acute 1 and chronic 1* Toxicity < 1 mg L^{-1} BCF > 500	(37) Chronic 4
Ethyl hexyl salicylate (118605)	*Chronic 2* Toxicity > 1 to ≤10 mg L^{-1} BCF > 500	(1) Chronic 2
Ethyl hexyl triazone (88122990)	*Chronic 4*	(1) Chronic 4
Isoamyl *p*-methoxy cinnamate (71617102)	*Acute 1* Toxicity < 1 mg L^{-1}	(53) Acute 1
4-Methyl benzylidene camphor (36861479, 38102624)	*Acute 1 and chronic 1* Toxicity < 1 mg L^{-1} BCF > 500	(205) Acute 1 and chronic 1
Methylene bis-benzo triazolyl tetramethyl butyl phenol (103597451)	No data available for this study	(112) Chronic 4
Octocrylene (6197304)	*Chronic 4* Not rapidly degradable Bioaccumulative	(10) Chronic 1 (20) Chronic 3 (267) Chronic 4
Polysilicone-15 (207574741)	No data available for this study	(19) Chronic 4
Titanium dioxide (13463677)	*Chronic 2* If nano-sized; toxicity > 1 mg L^{-1} < 10 mg L^{-1} Not rapidly degradable	(16) Chronic 4

criteria, assuming a worst-case scenario. The classification as chronic category 2 of Brand 1 was calculated according to Eq. (2) as:

$$\begin{aligned}&\text{Octocrylene } 10\%(\text{chronic category } 1;\text{M}-\text{factor } 1)\times 10\times 1\\&\quad+\text{titanium dioxide } 10\%(\text{chroniccategory 2 assuming nano}-\text{sized})\\&\quad+\text{butyl methoxy dibenzoyl methane } 5\%(\text{chronic category } 1;\text{M}-\text{factor } 1)\\&\quad\times 10\times 1=160.\end{aligned}$$

The classification of Brand 2 was calculated according to Eq. (2) as:

$$\begin{aligned}&\text{Octocrylene } 10\%(\text{chronic category } 1;\text{M}-\text{factor } 1)\times 10\times 1\\&\quad+\text{ethylhexyl salicylate } 10\%(\text{chronic category } 2)\\&\quad+\text{butyl methoxy dibenzoyl methane } 5\%(\text{chronic category } 1;\text{M}-\text{factor } 1)\\&\quad\times 10\times 1=160.\end{aligned}$$

None of the brands could be classified as acute category 1. These results imply that if the CLP was applicable to sunscreen products, both brands could potentially be subject for labelling with the hazard statement H411 stating “toxic to aquatic life with long-lasting effects” (Table 1). In addition to this hazard statement, both brands could potentially also be required to be labelled with the environmental hazard pictogram (GHS09; Fig. S1). It should be noted that the assessment of mixtures of UV-filters in sunscreens was based on the assumption that the maximum allowed concentration of UV-filters were in fact included in the product. Further, in case of where the individual UV-filters contained in the sunscreen product had several category classifications, as for octocrylene, the highest classification was consequently used for the classification of the mixture. Still, these results demonstrate how the lack of ERA in the Cosmetic Directive and the omission of cosmetic products from the CLP requirements allow chemicals that may be hazardous to aquatic organisms to be used without being assessed for environmental effects, classifications or labelling. The increasing use of cosmetic products, including sunscreens, constitutes a significant pathway of potentially environmentally hazardous chemicals to the environment.

4.3. Regulation of UV-filters in the EU

The CLP classification of a substance or mixture is an indication of a risk and the results of this study suggest that sunscreens on the European market may meet the criteria for environmental hazard labelling according to CLP. It is not possible to extrapolate and conclude from the human safety assessment required in the Cosmetic Directive what possible effects the UV-filters or sunscreen products may have on aquatic ecosystems. For other products containing UV-filters, such as house paints, the classification of each chemical component is used to provide a classification for the whole mixture. This in turn provides information to customers on how the product should be used to minimize or avoid harm to human health and the environment. This flow captures one of the major aims of the EU chemical legislation REACH; that the responsibilities shall be on the producing industry to ensure that the chemicals and products they put on the market are safe to use, which in this case is aimed to be fulfilled by providing the user with adequate information for a safe handling.

Fig. 1 illustrates an overview of the present EU regulation of UV-filters depending on product application. This flow chart demonstrates the inconsistency of the regulation of UV-filters contained in industrial chemical applications versus cosmetic products. Making an informed decision (Recital 117 REACH) on sunscreen products based on potential risk to the environment requires great efforts as it implies reading the list of ingredients and making sure there are no environmentally hazardous UV-filters in the product. Obviously this is a difficult task for private consumers as well as for manufacturers and other supply-chain actors. Previous studies have shown that some sunscreens contain zinc oxide which functions as a UV-filter, although it is prohibited in the EU (MPA, 2010; SSNC, 2008). Including cosmetic products and thereby sunscreens in the CLP-regulation would contribute to a better awareness of potentially negative environmental impact caused by

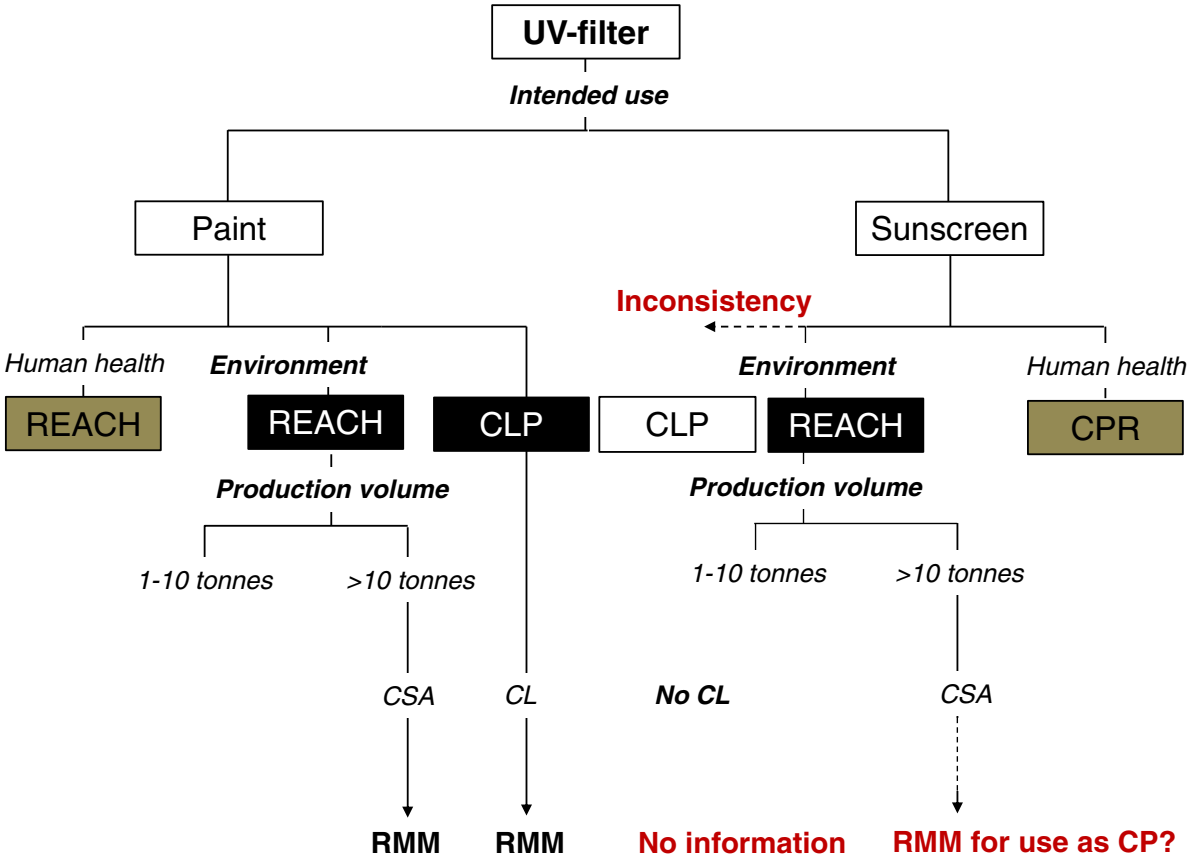

Fig. 1. Regulatory flow of UV-filters in the EU, illustrating inconsistencies depending on whether the UV-filter is used in industrial chemical applications, e.g. in house paints, or in cosmetic products, e.g. sunscreen products.

these products. Similarly, labelling of sunscreen products highlighting the fact that the products contain synthetic nanoparticles has been shown to increase the risk perception of the consumer, although the label did not contain any information of risk or hazard of the product (Siegrist and Keller, 2011). Furthermore, the CLP labelling of hazardous chemicals not only contributes to an increased awareness of the risk of a certain product, it also contributes to a reduced usage of the chemical (in tonnes per year as well as the number of products in which the chemical is present), as recently demonstrated by an evaluation of the effect of CLP labelling on the usage of hazardous chemicals in Sweden (Pilenvik and Falck, 2012).

In general, for substances manufactured or imported at or above 10 tonnes per year and that are classified as hazardous or considered as PBT or vPvB, industry will need to build exposure scenarios for all uses as part of the CSA (REACH, Art. 14 (1–4)). However, for substances used in cosmetic products, including UV-filters, only environmental concerns need to be taken into account in building exposure scenarios and characterizing the risks (REACH, Art. 14(5)). Also, the authorization (Annex XIV) and restriction (Annex XVII) procedures are limited to environmental concerns with regard to chemicals in cosmetic products (REACH, Art. 57). Although the requirements concerning information in the supply chain (Title IV) do not apply to cosmetic products irrespective of whether the chemical is classified as hazardous to human health or the environment, the CLP is applicable through the entire route from the producer to all downstream users until the very moment of the final formulation and packaging as a cosmetic product. Still, it is an open question if this means that the maximum concentration in ready-for-use preparations (specified in the Cosmetic Products Regulation No. 1223/2009 Annex VI) will be revised given that risk characterization activities under REACH would indicate that emissions from sunscreens must be lowered to minimize the risk to the environment. Given that 46% of the approved UV-filters in fact have properties that make them hazardous to the environment, it is critical that the outcome of the environmental risk assessment performed under REACH effectively informs the processes of approving and setting concentration limits of UV-filters in cosmetic products under the new regulation. In our view, this would help ensure that all environmental exposures of UV-filters are taken into account, and subsequently reduce potential risks to aquatic ecosystems caused by cosmetic products.

4.4. Divergence in industry-made classifications

In total 12 of the 26 UV-filters had been classified by the producers as being hazardous to the aquatic environment according to the CLP criteria (Table 2). These classifications were made under REACH because these UV-filters have other applications falling within the scope of industrial chemicals. For 3 of these UV filters (oxybenzone; butyl methoxy dibenzoyl methane; octocrylene) classifications made by industry span over 4 or 5 of the in total 5 toxicity classes (Table 2). No information on the date of the industry-made classifications is available, neither is the data used by industry as basis for the classifications. Variability in chemicals' risk assessment has previously been demonstrated to depend on several factors including the selection of data (i.e. possible

bias), the way the data are interpreted, different assessments of statistics and variability in how the toxicological relevance of the data are assessed (Rudén, 2001a,b). The divergence in the CLP classifications of the same UV-filter is serious since it specifically may undermine the credibility of the CLP system. For 2 UV-filters (butyl methoxy dibenzoyl methane and octocrylene) the great majority of industry-made classifications (>90% in each case) apply to the category Chronic 4. This classification implies that there is no evidence of acute toxicity, but that the data indicate possible aquatic environmental hazardous properties (Table 1). Hence, it seems that there either is a general lack of data to make a proper environmental hazard assessment and/or that the existing data is inconclusive.

5. Conclusions

This study has revealed inconsistencies in current EU regulations of UV-filters. UV-filters contained in industrial chemical applications are classified and labelled according to CLP and risk assessed under REACH. In contrast, the same UV-filters contained in sunscreen products are exempted from CLP and it is unclear how or if environmental RMMs will be undertaken as part of REACH when the new Cosmetic Products Regulation is implemented in July 2013. Still this investigation demonstrates that almost 50% of the investigated UV-filters approved for use in cosmetic products on the European market according to the current Cosmetic Directive were identified to meet the CLP classification as hazardous to the aquatic environment. Including cosmetic products and thereby sunscreens in the CLP-regulation would contribute to a more harmonized and transparent regulation of potentially hazardous substances on the EU market.

Appendix A. Supplementary material

Supplementary information to this article can be found online at http://www.sciencedirect.com http://dx.doi.org/10.1016/j.scitotenv.2013.05.074.

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