Extended producer responsibility of Cosmetic ingredients in wastewater

Report

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Prepared for L'Oreal

The expert in **WATER ENVIRONMENTS**

Extended producer responsibility of Cosmetic ingredients in wastewater

Assessment of the background for identification of the Cosmetic sector as a candidate for an EPR under the recast UWWTD

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1 Executive summary

The recast Urban Wastewater Treatment Directive identifies cosmetics and pharmaceuticals as major contributors to micropollutant pollution in wastewater, which conventional treatment methods cannot effectively eliminate. The Directive introduces a quaternary treatment step in large and medium sized wastewater treatment facilities and an Extended Producer Responsibility scheme to provide the funding based on the "polluter pays" principle. This approach mandates that producers of pharmaceuticals and cosmetics contribute at least 80% of the costs associated with quaternary treatment for micropollutant removal.

This current report aims to identify the uncertainties of the reasoning that connects the identification of hazardous micropollutants in raw wastewater to the allocation to industrial sectors, ultimately concluding that the cosmetic sector is a key contributor to these pollutants.

The basis for the work is the database by Pistocchi et al. (2022) containing 1337 substances commonly found in raw wastewater representing 'Total Pollution Proxy Substances' (the JRC database). The entries and concentrations in this database were compared with available Danish wastewater data, revealing that the composition and concentrations align with what is typically found in municipal raw wastewater.

The European Commission's DG Environment commissioned a feasibility study by Bio Innovation Service, which assigned substances from the JRC database to sectors using usage data from multiple sources. The feasibility study found that 17% of the toxicity, based on chronic toxicity data, comes from cosmetic products. DHI recalculated the data and can confirm the estimate if the substances are used only in cosmetic products.

However, a more detailed evaluation shows:

- **Definitional inconsistencies**: The databases used to classify cosmetic substances employ varying criteria for identifying cosmetic products. This leads to ambiguous results when identifying cosmetic products as the source of substances sin wastewater.
- **Cross-sectoral usage**: Most substances linked to cosmetics have dual or multiple applications in other industries, with the dominant toxicity contributions arising from multi-use chemicals. Consequently, the toxicity contribution from cosmetic products is overestimated.
- **Questionable attribution**: The 9 most toxic substances flagged as cosmetic-derived in the feasibility study account for 97.5% of the chronic toxicity, yet these chemicals are not exclusive to cosmetics. Notably, Permethrin—the most toxic substance identified—is likely not used in cosmetic products. The observation suggests that the feasibility study's calculations are incorrect and overestimate the toxicity contribution from cosmetics.

We conclude that these discrepancies introduce significant uncertainty in attributing toxicity impacts to the cosmetics sector, as proposed in the feasibility study.

This study offers an alternative assessment by combining anonymized sales data of cosmetics with manufacturer-reported compositions, estimating that 1.1% of wastewater toxicity comes from cosmetic substances. This is over 15 times lower than the 17% suggested by the Bio Innovation Service feasibility study.

In addition to assessing the toxicity contribution from cosmetics, the present study evaluated the removal efficiency of cosmetic substances in wastewater treatment plants using JRC database data. The results indicate that substances from cosmetic products are generally removed more efficiently than other substances during wastewater treatment.

Consequently, the feasibility study grossly overestimates the role of substances used in cosmetic products and the conclusion of the present study is that the contribution from the cosmetic sector in terms of environmentally hazardous substances in raw municipal wastewater is very low.

The main conclusions of this study are:

- The JRC database accurately **reflects typical contents and concentrations** of micropollutants in raw wastewater.
- The feasibility study overestimates the role of cosmetics in wastewater toxicity; actual data suggest cosmetics contribute with about **1.1%** to the overall toxicity, or over 15 times less than the 17% claimed in the feasibility study.
- Cosmetic substances are generally **removed more efficiently** than other micropollutants during wastewater treatment.

2 Introduction

The recast Urban Wastewater Treatment Directive (UWWTD) identifies cosmetics and pharmaceuticals as major contributors to micropollutant pollution in wastewater, which conventional treatment methods cannot effectively eliminate. To combat this issue, the directive introduces quaternary treatment as a mandatory fourth step for large wastewater treatment plants and potentially for medium-sized facilities. The implementation of quaternary treatment in EU wastewater facilities will require significant financial investments. To address this, the European Commission has introduced an Extended Producer Responsibility (EPR) scheme based on the "polluter pays" principle. This approach mandates that producers of pharmaceuticals and cosmetics contribute at least 80% of the costs associated with quaternary treatment for micropollutant removal.

The aim of this report

The assumption that the cosmetics sector is responsible for main parts of the micropollutants found in wastewater is based on selected monitoring data, toxicity data and on the allocation of the identified substance to one of several possible sectors. This report aims to identify the uncertainties of the chain of arguments from the identification of micropollutants in wastewater and their toxicity via the allocation of substances to industrial sectors, and ending with the conclusion that the cosmetic sector is one of two sectors that are the main responsible for the presence of hazardous micropollutants in wastewater.

Key questions include:

1. Do the substances in the applied database represent untreated municipal wastewater across the EU?
2. Is the allocation of the identified substances in the wastewater to specific sectors accurate and true.
3. Why is the cosmetics sector identified as one of two sectors subject to the suggested EPR scheme intended to fund a 4^{th} treatment step across Europe.

3 Identification of micropollutants in urban wastewater

A database compiled by Pistocchi et al. (3) provides the basis for a discussion of micropollutants in wastewater in the Commission's Impact Assessment and Feasibility Study. It is, however, well documented that quantities of micropollutants vary widely and that pollutant load depends on many factors. Consequently, creating a uniform wastewater matrix that accurately represents the entire European region is challenging and may not be feasible.

Substances in municipal wastewater vary widely and depends on the composition of the wastewater and the sources to hazardous substances including industrial activities, population density, rainwater collection, traffic load and drainage from polluted sites. The purpose of wastewater monitoring in the sewer is to assess the impact on the sewer system and to the wastewater treatment plant, e.g. pH, hydraulic load, and COD, as well as to monitor toxic substances. Chemical pollutants in municipal wastewater treatment facilities, called micropollutants[1], are monitored to assess their removal and possible impact to the receiving water body. The European surface waters are regulated via the national implementation of the EU Water Framework Directive (WFD), and the national monitoring programmes reflects the substances prioritised under the WFD as well as specific national standards for chemical substances. In the recent years the available scientific literature on micropollutants in municipal wastewater and surface water has focussed on new groups of pollutants including pharmaceuticals and PFAS. These substances are not degraded easily, not removed efficiently by traditional wastewater treatment techniques and regarded as threats to the water environment due to their toxicity.

Consequently, monitoring programmes today often include pharmaceutical substances and PFAS because of the concern of these 'new' substance groups. Further, the development of analytical methodologies influences the parameters contained in monitoring programmes. For example, PFOS and PFOA were until recently the only PFAS included in the Danish monitoring programmes. More recent developments allowed a sum of four PFAS and later sum 22 PFAS to be included, which is the standard used in Denmark today. Today the environmental labs offer an analytical package covering 40 groups of PFAS.

Thus, wastewater monitoring programmes tend to reflect new substances of concern in addition to mandatory monitoring requirements in the WFD, including national prioritised substances.

[1] Micropollutant, as defined in the recast Urban Wastewater Directive (EU) 2024/3019 of 27 November 2024, Art 2 (17)

In the Impact Assessment of the recast UWWTD (1) Ramboll concluded (2):

> Citation from Ramboll (2023)
>
> *In general, data on the quantities of micropollutants vary widely. It is in line with Ramboll's understanding that the pollutant load depends on many factors, such as location population density, population habits, industrial, agricultural, or commercial use, traffic or weather conditions. A uniform wastewater matrix for the whole Europe as assumed in the impact assessment is therefore not realistic*.

Pistocchi et al. (2022) (3) compiled a database containing 1337 substances commonly found in raw wastewater representing 'Total Pollution Proxy Substances' commonly found in wastewater (hereafter called the JRC database). The authors state that: *micropollutant concentrations in raw wastewater may vary significantly across the EU depending on chemical use patterns, the contribution of industrial emissions to wastewater, the combination of stormwater with wastewater, and several other factors. Despite this, we assume for each substance a representative, uniform concentration in the raw sewage entering the WWTP.*

Data used for compiling the JRC database

The database is built on data from 4 European reported measurements campaigns or databases:

- 4th Joint Danube Survey (https://www.danubesurvey.org/jds4/about)
- The Dutch WATSON database (https://www.emissieregistratie.nl/data)
- The data compilation by Finckh et al (2022) (4)
- The European Commission, DG JRC data collection: Saouter et al. 2020. (5)

The first three references present monitoring results from wastewater effluents while the data compilation by Saouter et al. provides data for use in Life Cycle Impact Assessment on the endpoints freshwater ecotoxicity, human cancer and non-cancer toxicity.

The data collection seems to cover well the identified substances in wastewater effluents with the limitations addressed by Pistocchi et al.: *Our knowledge of mixtures is confined to those chemicals that have been detected and measured. Other compounds may go undetected or unmeasured in spite of their presence, due to limitations in analytical techniques.* (Citation from the Supporting Information, Note 1).

As a simple check of the database (3) it was compared with measured inflow concentrations of substances in Danish municipal wastewater treatment plants, representing a north-European situation. The data were analysed and Figure 1Figure 1 shows that the substance groups and number of substances included in the JRC database are very similar to the Danish observations.

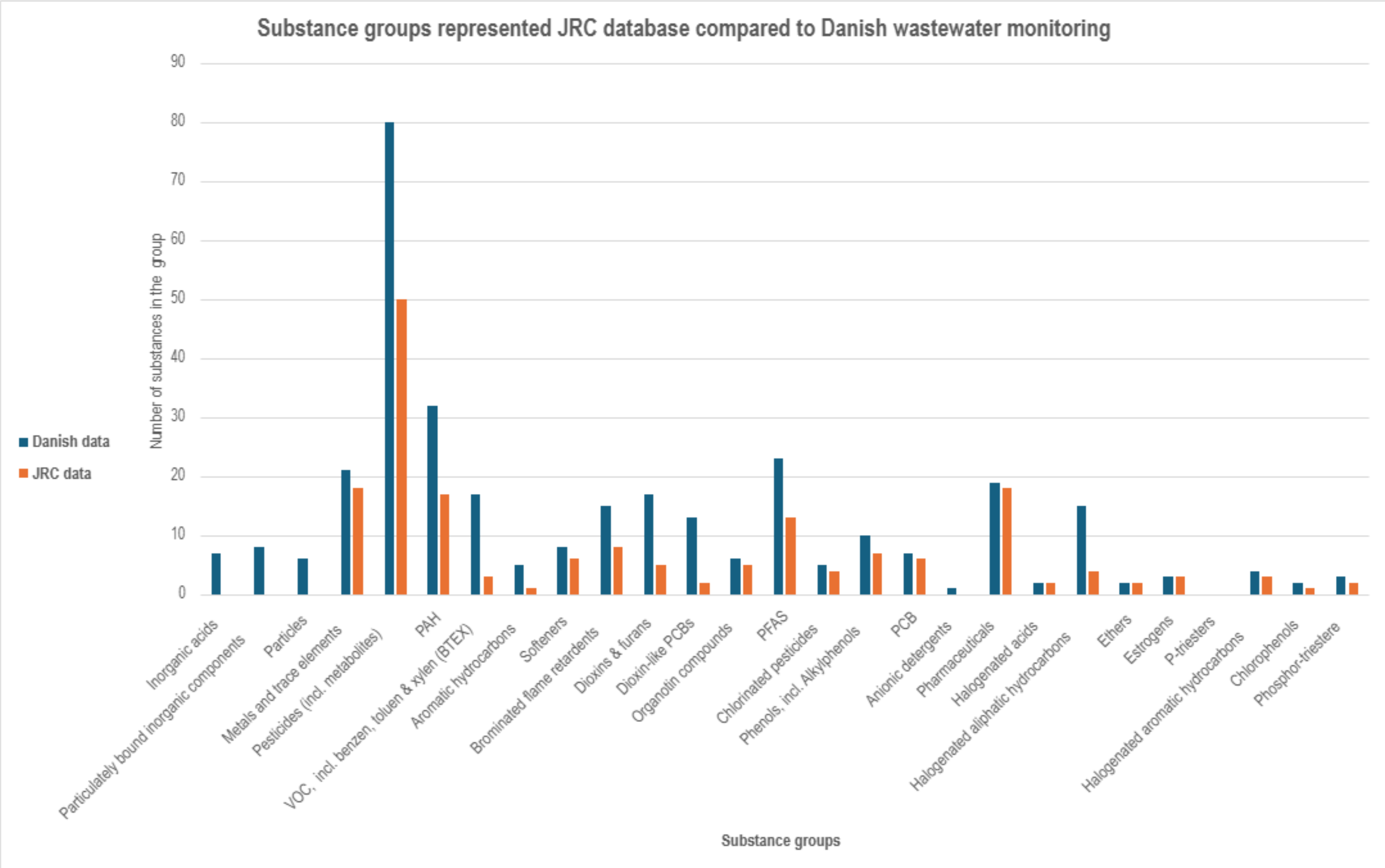

Figure 1 Data from the JRC database (Pistocchi et al 2022 (3)) compared to Danish wastewater monitoring data

The substances and concentrations in the JRC database are representative for European municipal wastewater

Furthermore, the substance concentrations in the JRC database were compared to Danish observations. The 50th and 95th percentile of the concentration in the inflow from Danish municipal wastewater treatment plants for 2011-2019 were compared with the JRC substance list. Figure 2. indicates that the inflow concentrations from Danish wastewater treatment plants are well distributed around the concentrations of the JRC database, with no clear pattern of deviations. The conclusion is that the concentrations reported by Pistocchi et al. (3) seem realistic for a European WWTP.

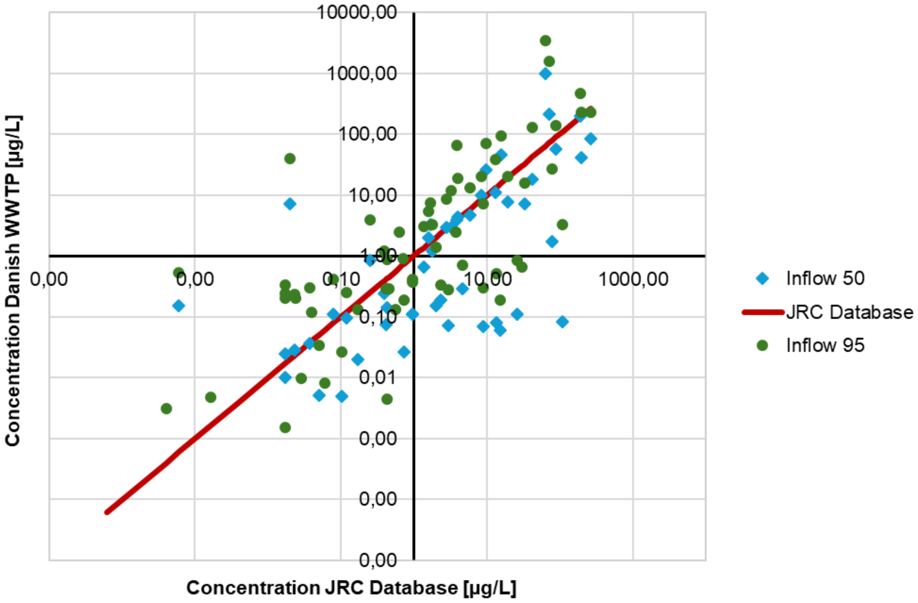

Figure 2: **Inflow concentrations of micropollutants (50th and 95th percentile) in Danish WWTPs in the period 2011-2019 compared to the inflow concentrations in the JRC Database.**

4 Allocation of substances to sectors

In the Feasibility Study for an Extended Producer Responsibility (EPR) system (6), substances from the JRC database were assigned to specific industrial sectors using data from multiple databases. In this section we discuss whether the report establishes a clear connection between micropollutants found in wastewater and the responsible industrial sector. Furthermore, it is debated whether this relationship can be accurately quantified.

The allocation of substances to sectors was in the feasibility study by Bio Innovation Service (6) done using a step-vice approach. In the process, the substances were allocated to the sector referenced as their main usage domain. For active pharmaceutical ingredients (API) this allocation is easy because the substances are used almost exclusively in pharmaceutical products.

Substances used in cosmetics often have multiple uses

In contrast, substances used in cosmetics often have multiple uses in addition to cosmetics, e.g., in preservatives and biocides. The term ‘main usage domain’ applied in the feasibility study is not transparent and well defined. Further, there is no access to the underlying documentation.

The authors of the feasibility study address the allocation to individual sectors in section ‘3.1.4. Uncertainties and limitations’ and write that an observed micropollutant in wastewater in most cases cannot be the responsibility of one sector alone (6).

> *As expected, the database development process represents several uncertainties. The chemicals were attributed to different sectors, but some chemicals were present in multiple areas of the chemical landscape. Thus, they occur more than once in the database to account for their prevalence. Moreover, most of the time in the database, the chemicals were put in the sector that was referenced as their main usage domain. Hence, the main sector they belong to cannot account for the full amount of that chemical put on the market.*
>
> Citation from Bio Innovation Service 2022 (6), Section 3.1.4.

4.1 Method applied for allocation of substances to the cosmetic products

The definition of a cosmetic product in the EU regulation on cosmetic products[2] is:

> *'cosmetic product' means 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.*
>
> Regulation (EC) 1223/2009 of 30 November 2009 on cosmetic products

The identification of substances used in cosmetic products should as far as possibly apply this definition when referring to European conditions.

The feasibility study by Bio Innovation Service (6) used the following main references for the allocation of substance to the cosmetic sector:

- The NORMANN databases (7)
- ECHA (13)
- PUBCHEM (12)
- The CosIng database (11)
- The ChemExpo/ Comptox databases (8)

The databases used for allocation of cosmetic substances apply different definitions of 'cosmetic products'. This introduces errors in the calculation.

The databases use different approaches to identify substances as being used in cosmetic products:

- The Norman databases combine different other databases but refer to the COSING, PUBCHEM and COMPTOX database.
- The registered uses of the substances in the ECHA database are the registrant own information. An indication of a use of the substance in cosmetics therefore depends on the registrants own understanding of what is a cosmetic product.
- PUBCHEM refers to the California Safe Cosmetics Act of 2005. The definition in the legal text of a cosmetic product is as follows: *"Cosmetic product" means an article for retail sale or professional use intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance*
- The ChemExpo/ Comptox databases include broad product groups in its approach to substances in cosmetic products: body paint, glitter and makeup related products.

The conclusion therefore is that the main data sources used in the Feasibility Study (6) apply different definitions or approaches to identifying a substance being used in cosmetic products, and that this may introduce errors. This could

[2] Regulation (EC) 1223/2009 of 30 November 2009 on cosmetic products

for example be the allocation of substances to cosmetics that are used in Personal Care Products, which is a much broader group of products. Appendix A includes further information.

4.2 Evaluation of uncertainties and errors of the allocation of substances to cosmetic products in the feasibility study.

To examine the consequences of allocating substances used in cosmetics exclusively to the cosmetic sector, DHI used the following databases to redo the allocation to sectors and evaluate the possible error resulting from the methodology employed in the feasibility study:

- Norman substance database (7).
- Chemexpo database (8).
- SPIN database. Substances in Preparations in Nordic Countries (SPIN) (10).
- CosIng database (11)

The JRC database includes 525 substances that have been evaluated for their toxicity to the environment. From the information on uses of substances in the Norman and ChemExpo databases we identified 70 that are used in cosmetics. This includes also substances in the JRC database used in cosmetics according to CosIng and the SPIN database. Appendix B presents the SPIN product categories and product uses that were allocated to the group of cosmetic products.

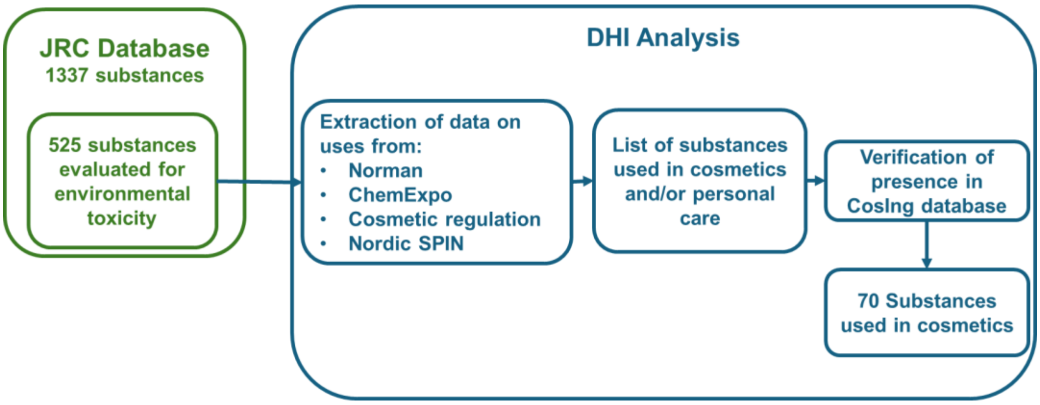

Figure 3 Overview of approach

Most substances in cosmetics are also used in other sectors

The identification of the 70 substances used cosmetics is presented in Figure 3. However, the substances are according to the Norman and the ChemExpo databases used in other products as well. The information on uses was extracted and used as basis for further analysis. Figure 4 shows that 8 substances are used in cosmetic products only, but the majority, 62 substances, are used at least in one other product type as well.

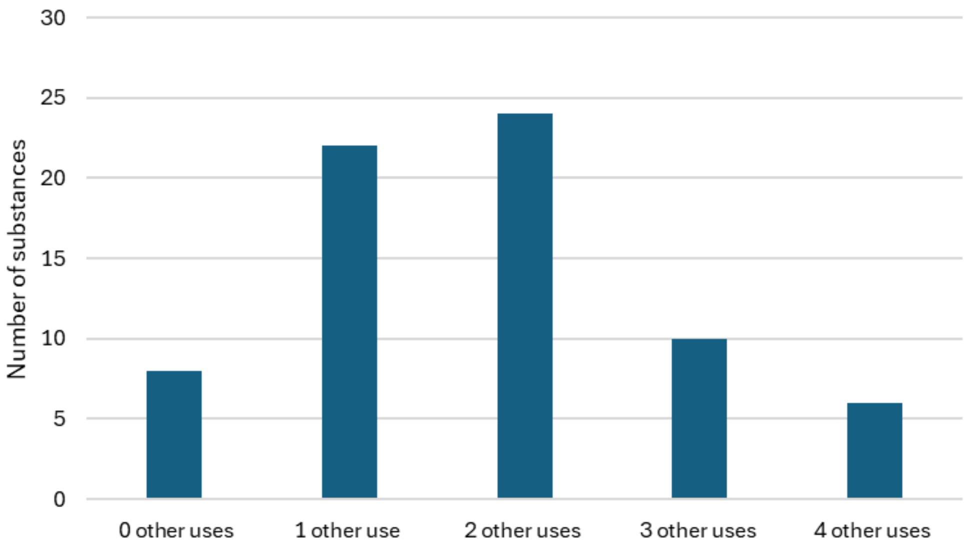

Figure 4 **Distribution of the number of uses of substances used in cosmetics according to the Norman and ChemExpo databases.**

The conclusion is that most substances that are used in cosmetic products are also used in products from other sectors.

In total 8 of the 70 substances have been identified as present in the CosIng database, but with no other uses in the Norman and Chemexpo database. Their identities are presented in Table 1.

Table 1 **Substances identified in the CosIng database with no other identified uses in the Norman and ChemExpo databases.**

CAS	Name	Remarks
27176-93-8	Nonylphenol diethoxylate	Used in cosmetics and cleaning/household care (12).
47221-31-8	Dodecylbenzene sulphonic acid	Listed under CAS: 27176-87-0 and 85536-14-7 in CosIng.
100-88-9	Cyclamate	Listed in CosIng as Calcium cyclamate (CAS: 139-06-0). It is used as an artificial sweetener and for masking in cosmetics (12).
33665-90-6	Acesulfame	Listed in CosIng as Potassium Acesulfame (CAS: 55589-62-3). It is used as an artificial sweetener and for hair styling (12).
47324-98-1	Denatonium	Listed in CosIng as Denatonium Benzoate (CAS: 3734-33-6) and Denatonium Saccharide (CAS: 90823-38-4). Among other used for cleaning, bitterant, denaturant and flavouring agents (12).
626-93-7	2-hexanol	
142-54-1	Lauramide MIPA	
142-98-3	Decyl hydrogen sulfate	Listed in CosIng under Sodium Decyl Sulfate (CAS: 142-87-0).

The main concern of the release of micropollutants to the water environment from municipal treatment plants is the hazard of the substances and the risk of effects in the water environment. The assessment of the future EPR therefore focuses on the toxicity of the micropollutants in the wastewater.

The contribution to wastewater toxicity of cosmetic substances cannot be attributed to cosmetic products only.

The toxicity of the substances used in cosmetic products varies considerably. Figure 5 Figure 5 shows the distribution based on toxicity (Toxic Units, TU) across sectors for the same 70 substances presented in Figure 4. The figure indicates that the main toxicity contribution comes from substances used in other sectors than cosmetics. The dominating toxicity contribution is due to the substance Permethrin (see Table 2.)

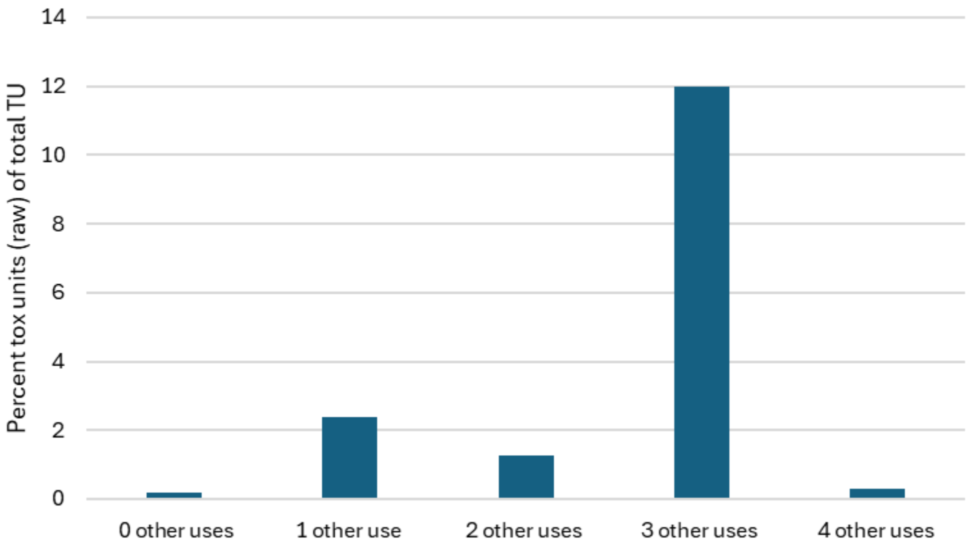

Figure 5 **Distribution of the toxicity contribution of the substances used in cosmetics according to the Norman and ChemExpo databases.**

The main toxicity contribution comes from substances that are used in other products in addition to cosmetic products

The conclusion is that the highest toxicity contribution comes from substances that are used in other products in addition to their use in cosmetic products.

The feasibility study concludes that 17% of the total toxicity based on the chronic toxicity in raw wastewater comes from substances used in the cosmetic products. The present study found similarly that 16% of the toxicity based on the chronic toxicity can be attributed to the 70 substances that are used in cosmetics products alone, or as one of several uses.

9 substances used in cosmetics and other sectors are responsible for 97.5% of the estimated toxicity

Table 2 Figure 6shows that only 9 of these substances represent 97.5% of the chronic toxicity contribution. In the feasibility study by Bio Innovation Service (6) this toxicity was allocated 100% to the cosmetic sector.

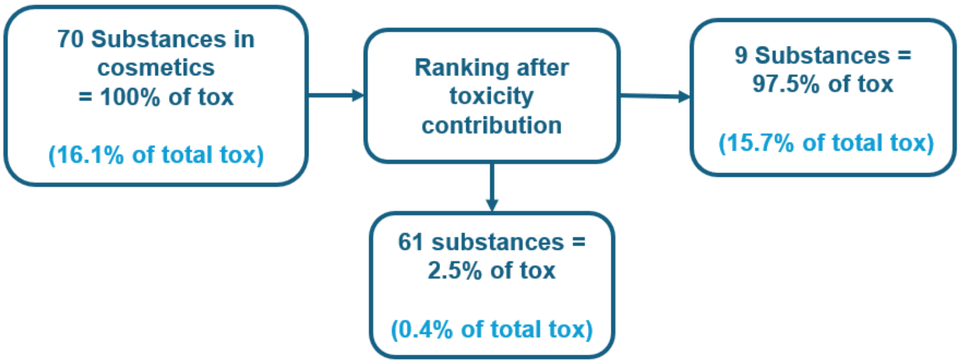

Figure 6 **Approach for ranking of substances according to toxicity. 9 substances used in cosmetics and other products are responsible for 97.5% of the toxicity**

Table 2 shows for each of these 9 substances the toxicity contribution in percent of the total calculated chronic toxicity of the raw wastewater, according to Pistocchi et al (3). The column to the right shows the cumulative chronic toxicity of the substances in percent of the total toxicity contribution from substances used in cosmetics, assuming this is their only use.

Table 2 Substances with the highest toxicity contribution among the substances identified as used in cosmetics

Substance name	Cas No.	Toxicity contribution (% of total)	Cumulative toxicity contribution (% of cosmetics and other products)
Permethrin	52645-53-1	9.6	59.6
Oleanolic acid	112-80-1	2.2	73.6
Hexadecanoic acid	57-10-3	1.4	82.2
Tetradecanoic acid	544-63-8	1.0	88.4
N,N-Dimethyldodecylamine	112-18-5	0.5	91.8
Caffeine	58-08-2	0.4	94.5
Triclosan	3380-34-5	0.2	96.0
Nonylphenol diethoxylat	27176-93-8	0.1	96.8
2-Ethylhexyl-4-methoxycinnamate	5466-77-3	0.1	97.5

Figure 7 presents more detailed picture of the uses of the 9 substances that are responsible for 97.5% of the chronic toxicity contribution and were allocated fully to cosmetic products in the feasibility study (6). The figure shows the application in different types of products of the 8 substances (Based on information from the Norman database (7)).

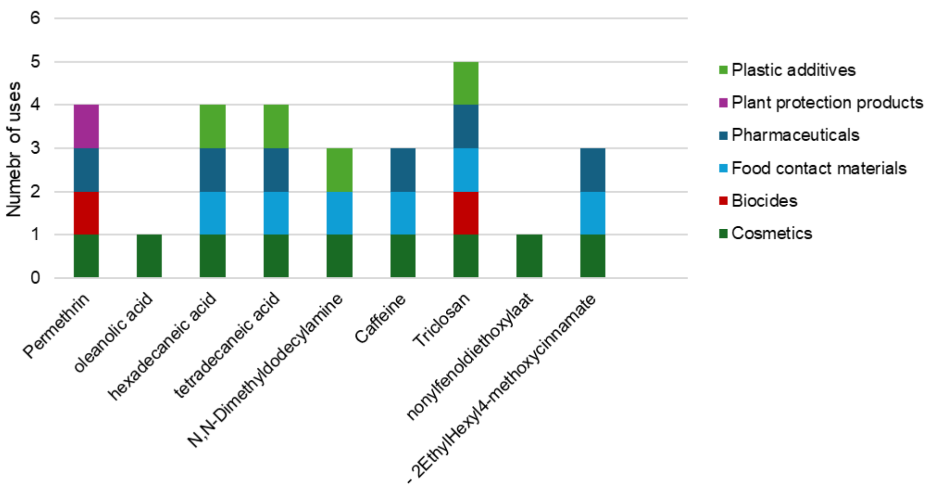

Figure 7 Uses of the substances with the highest toxicity contribution that are allocated to be used in cosmetic products. Based on data from the Norman database.

Comments to the Figure 8:

- Oleanolic acid is only used in cosmetics. It is, however, identified in the ChemExpo database as being used also in 'Cleaning and household care' products.
- N,N-Dimethyldodecylamine is not identified in the Norman and ChemExpo databases as being used in other sectors than cosmetics. However, according to the Nordic SPIN database the substance is used also in cleaning and washing agents.

The most toxic substances are used also in other products than cosmetics

It is concluded that the feasibility study (6) allocates the 9 substances that are responsible for most of the chronic toxicity contribution in raw wastewater to the cosmetic sector only. The data clearly shows that these substances are used broadly in other sectors as well and that the highest contribution comes from permethrin. Permethrin is used in biocides, plant protection products and in pharmaceuticals.

4.3 Distribution to sectors based on SPIN database

The discussion above concludes that substances identified in cosmetic products are also used also in other product types. This is done without considering the volumes of the substances used in different sectors and product types.

The Nordic SPIN database is a publicly available database containing information on substance volumes being marketed in different product types in the Nordic countries (Denmark, Sweden, Norway and Finland). The information is based on a legally binding reporting requirement on products placed on the market by manufacturers and importers. The database includes anonymized information on the concentration of substances in group of products, their function as well as the marketed volumes.

The SPIN database can be used to quantify the substance volumes on the European market

The market data in SPIN are unique and other EU member states does not have similar information due to missing legal requirement on product information. Although the markets in the EU are different the same products and brands are often found across the European countries. Assuming similarity between the markets the Nordic SPIN database is therefore often used to evaluate the composition of products on the EU market in general. For the same reason the feasibility study by Bio Innovation Service (6) also applies Danish data on pharmaceutical products sales and extrapolate these data to cover the European market.

The information from the publicly available part of the SPIN database was in the present study used to quantify the use of the 9 most toxic substances discussed above across sectors, based on the reported substance use categories (in SPIN "PSD"). The list of categories included as cosmetics is found in Appendix B.

Table 3 Amount used in cosmetic products of the 9 highest ranking substances in terms of chronic toxicity. According to the Nordic SPIN database.

Substance name	Percent of total market volume[1] used in cosmetics (SPIN PSD) (%)	Ton/ year contained in cosmetic products	Main category of use (SPIN PSD)
Permethrin	0	0	Insecticides, acaricides and biocidal products (PT18)
Oleanolic acid	2.9	10.9	Lubricant additives, others
Hexadecanoic acid	0.3	13.3	Other raw materials
Tetradecanoic acid	23.5	56.0	Other raw materials
N,N-Dimethyldodecylamine	0	0	Other cleaning/washing agents
Caffeine	0	0	Intermediates (pharmaceuticals)
Triclosan	59.2	1.8	Cosmetics
Nonylphenol diethoxylat	Not in SPIN database		
2 EthylHexyl 4-methoxycinnamate	100	17.4	Cosmetics

[1] Market volume as reported for the Nordic Countries

Specific comments to

Table 3 are:

- Nonylphenol diethoxylat, is not registered in the SPIN database. However, the Norman or ChemExpo databases indicate its use is cosmetics and personal care products only. It is therefore assumed to be used in cosmetics. The substance is an endocrine disruptor and classified as hazardous to the environment.
- Hexadecanoic acid is according to the SPIN database used mainly as an intermediate in chemicals industry and for chemical products. It is also registered for production of rubber and plastic products and pharmaceuticals, but in much smaller volumes. The Norman database indicates use in food contact materials, pharmaceuticals, plastic additives, as well as in personal care products.
- Tetradecanoic acid is in the SPIN database registered as used in organic chemical industry but also in perfumes and toiletries and preparations thereof. According to the Norman database it is used in food contact materials, pharmaceuticals, plastic additives, as well as in personal care products.
- Permethrin, N,N-Dimethyldodecylamine and Caffeineare not reported used in cosmetics in the SPIN database, although they are included in CosIng.
- Triclosan is subject to regulation under the Cosmetics Directive and in REACH under assessment for ED and PBT properties.

The highest toxicity contribution according to the feasibility study is probably due to use in other sectors

It is concluded that the substance that contribute the most to toxicity from cosmetic products according to the feasibility study by Bio Innovation Service (6) is not contained in cosmetic products according to the Nordic SPIN database.

4.4 Comparison of the sector allocation with the feasibility study

As mentioned, the feasibility study concludes that 17% of the total chronic toxic load to WWTP comes from the cosmetic sector. The present study found that 16% of the chronic toxicity contribution can be attributed to the 70 substances that have been identified as used in cosmetics as one of several uses.

Use of Permethrin in cosmetics is not significant

Permethrin is an insecticide and contained in biocidal products (PT18), e.g., lice shampoo or in creams against scabies (7). Other uses reported in the Norman and ChemExpo databases are in pharmaceuticals and plant protection products. Based on this information and supported by the observation that according to the SPIN database Permethrin most likely not used in cosmetics in the Nordic countries.

Based on this information we suspect that the use of Permethrin in cosmetics is insignificant on a European scale, and that the toxicity contribution from Permethrin at about 10% can be neglected. If this is correct the toxicity contribution from cosmetic products as calculated by Bio Innovation Service (6) can be reduced from 17% to 7% of the total chronic toxicity if raw wastewater. This is a very conservative estimate as it assumes that all other substances are used only in cosmetic products.

The stepwise process of this calculation is illustrated in Figure 7. In the first step the contribution from the toxicity contribution from permethrin is subtracted from the combined toxicity contribution from the 8 substances resulting in a toxicity contribution at 6.1% of the total toxicity. The remaining toxicity contribution from other substances is 0.4% resulting in 6.5% of the toxicity contribution coming from substances used in cosmetic products.

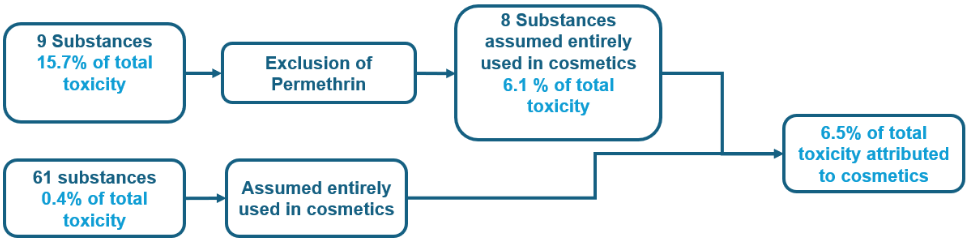

Figure 8 **Stepwise approach for conservative calculation of the toxicity contribution from cosmetics.**

A more realistic estimate can be made by using the information from the SPIN database. The toxicity contribution from the 9 substances with the highest toxicity contribution (i.e. Table 2 the column: *Toxicity contribution (% of total)*) is multiplied with the percent of the marketed volume in the Nordic countries according to the SPIN database (

Table 3). This gives a realistic estimate indicating that only 1.1% of the overall toxicity contribution can be allocated to substances used in cosmetics.

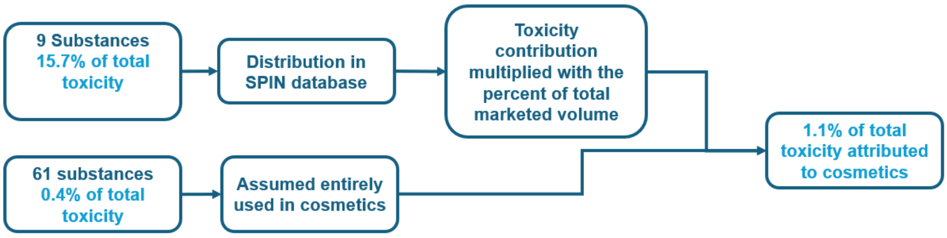

Figure 9: Stepwise approach for a realistic estimate of the toxicity contribution from cosmetics.

A realistic estimate is that 1.1% of the toxicity in wastewater comes from cosmetic products.

The conclusion is that the toxicity contribution from substances identified as being used also in cosmetic products can only be responsible for 1.1% - 6.5% of the total toxicity of the raw wastewater. The lower end of this range (1.1%) is based on actual market data and provides a realistic estimate of the toxicity that can be attributed cosmetic products. This is a factor of more than 15 times lower than reported in the feasibility study by Bio Innovation Service (6).

5 Removal of cosmetics in existing treatment steps

The main justification for a 4th treatment step as required by the recast UWWTD is that some hazardous micropollutants, e.g., pharmaceuticals, are not removed efficiently in the three treatment steps that are normally applied in larger European municipal wastewater treatment plants.

The feasibility study on EPR claims that cosmetic substances are not removed in wastewater treatment plants

It is a key point in the discussion of the feasibility of the EPR system (6) that the cosmetic sector is responsible for release of substances that are not removed in municipal wastewater treatment plants and that the sector therefore needs contribute to the establishment of a 4th treatment step in wastewater treatment plants across Europe.

The basis for the impact assessment of the recast UWWTD and the feasibility study of an EPR system is report by Pistocchi et al (3). The report evaluates the removal efficiency of substances in the individual treatment steps based on estimated removal efficiencies.

To investigate the removal of cosmetic substances in the first 3 treatment steps and in a future 4th treatment step, we applied the removal efficiencies used by Pistocchi et al. The results are presented in Table 4.

The average removal was calculated for all 525 substances that have been evaluated for toxicity. 428 substances are not used in cosmetics. 70 substances are identified as being used in cosmetics as the only use, or one of several uses.

The removal efficiency was calculated for substances used in cosmetic products compared to all other substances. The data clearly show that cosmetic-related substances in average are removed more effectively by conventional treatment steps than the non-cosmetic substances.

Table 4 shows the average removal of cosmetic substances compared to non-cosmetic substances, and all substances in average. The third treatment step is compared to the untreated wastewater (first row). The second row shows the estimated removal in the 4th treatment step.

In the report by Pistocchi et al. (3) the removal efficiency of the 4th treatment step is very similar for all substances. This is likely due to limited evidence of the treatment efficiency on the substances in the JRC database.

Table 4 Average removal between treatment steps, for all substances, non-cosmetic substances and cosmetic-related substances.

	All substances	Non-cosmetic substances	Cosmetic substances
Removal after 3rd step compared to input.	35,1 %	30,8%	54,2 %
Removal between 3rd and 4th treatment step	71,4 %	71,5%	71,1%

Data from the JRC database show Cosmetic substances are removed more efficiently in conventional 3-step treatment plants than other substances

The conclusion is that the substances used in cosmetics as the only use, or one of several uses, are removed more effectively in a three-step conventional wastewater treatment plant than other substances in average.

The reason is most likely that many substances used in cosmetics are large molecules with a low water solubility that are efficiently adsorbed to sludge particles and removed efficiently in a wastewater treatment plant. Moreover, many substances in cosmetic products are based on fatty acids, which generally are readily biodegradable.

The conclusion is that there is no documentation supporting the view that the cosmetic sector is responsible for substances that are not removed by a conventional 3-step municipal treatment plant.

6 Identification of the Cometic sector as a candidate to EPR

The feasibility study used the following criteria for the identification of sectors suitable for a future EPR scheme (6):

> Citation from the feasibility study, p 13.
>
> 1. *Micropollutants measured above a defined threshold using a standardised testing protocol in urban wastewater along with their physico-chemical properties and concentrations (see JRC work on chemicals) and products containing these substances;*
> 2. *Substances which can be treated by fourth (or quaternary) treatment;*
> 3. *Substances for which an environmentally less harmful alternative is available (i.e., change in product composition and/or ease of substitution) but not used;*
> 4. *Products sold in large quantities (market data); and*
> 5. *Substances which we can map back to pharmaceuticals and other sectors.*

In section 2.3 of the feasibility study (6) different possible sectors including biocides and pesticides are discussed as candidates for an EPR system. It is concluded that cosmetic products seem to be the strongest candidate for the following reasons:

> Citation from the feasibility study, Section 2.3, p 16.
>
> - *They (i.e. cosmetic products) have several substances in common with the pharmaceutical sector, so we could target more sources for the same set of substances.*
> - *A significant amount of recently published research tackles pharmaceuticals and cosmetic products together from a wastewater treatment perspective. This sector is also highlighted by the recent report by UN Environment and Stockholm Environment Institute*
> - *They have a high level of persistence.*
> - *They are sold in large volumes.*
> - *This sector could be useful from the EPR perspective on cost-sharing as targeting similar substances.*
> - *As the sector has already started to think about alternative formulations, it will probably be more open to the idea of EPR.*

We have the following comments to this:

- Pharmaceutical API's are normally not found in cosmetic products, and the assumed overlap in terms of micropollutants from the two sectors is not documented.
- The feasibility study section 2.3 refers to recently published research that treat pharmaceuticals and cosmetic products together from a wastewater treatment perspective and use this to support the view that the cosmetic sector is one of two sectors responsible for hazardous micropollutants in wastewater. The studies referred to do not discuss cosmetics but personal care products, which covers a broader range of product types. This is also true for the study by UNEP and Stockholm Environment Institute.
- The statement that the cosmetic substances are persistent is not documented in the feasibility study. On contrary, a indicated in the section above, cosmetic substances are more efficiently reduced in traditional 3-step treatment plants than other substances in general.
- The suitability of the cosmetic sector in an EPR scheme due to 'similar substances', undocumented and unclear.
- It is correct that the cosmetic sector is progressively substituting hazardous substances in their products, as are other sectors in the EU.

6.1 Quantifying substances in cosmetic products

Section 3.2.3 of the feasibility study (6) contains three approaches to quantify the substances reaching wastewater. The purpose is a possible allocation scheme for a future EPR system.

The first approach is based on national data on the sale of cosmetic products:

> Approach 1, (p. 43, in (6))
>
> *Mass of cosmetic product substance used per year = (Mass of cosmetic product 1 sold in EU x Percentage content of substance in cosmetic product 1) + (Mass of cosmetic product 2 sold in EU x Percentage content of substance in cosmetic product 2) + …*

.

The approach requires data on the marketed volumes of groups of cosmetic products and the concentration of individual substance in these products. These data are, however, unlikely to be available and probably confidential.

The second approach is based on published data on the frequency of daily use of personal care and cosmetic products (7) and population statistics in the EU:

> Approach 2, (p. 44, in (6))
>
> *Mass of cosmetic product substance used per year = Population x Daily 'doses' of cosmetic product x Mass per dose x Percentage active ingredient content*

The second approach also requires data on the percentage of the substances contained in the products in addition to the daily dose. As for the approach discussed above the data on substances in specific groups of cosmetic products are not available and most likely confidential.

The third approach is based on the database compiled by Pistocchi et al (3), which can be combined with Member State wastewater monitoring data to estimate the actual emission loads at a national level. In contrast to the other approaches, it is possible to estimate the actual loads to wastewater by extrapolating from measurement in the in- or outflow from wastewater treatment plants. As discussed above, however, no clear link can be established between the observed micropollutants in the wastewater and the responsible sector. Most substances in wastewater have several possible uses and an EPR system, which is based on measured levels in wastewater of substances that are (also) used in cosmetics will likely overestimate the contribution from the cosmetic sector.

7 Conclusion

The recast Urban Wastewater Directive introduces a quaternary treatment step in large and medium sized wastewater treatment facilities and an Extended Producer Responsibility scheme to provide the funding based on the "polluter pays" principle. A review of micropollutants in municipal wastewater identified 1337 substances commonly found in raw wastewater representing ‘Total Pollution Proxy Substances’ (3). Based on these data a feasibility study by Bio Innovation Service found that 17% of the toxicity, based on chronic toxicity data, comes from cosmetic products (6).

DHI recalculated the data and can confirm the estimate if the substances are used only in cosmetic products. However, a more detailed evaluation shows:

- **Definitional inconsistencies**: The databases used to classify cosmetic substances employ varying criteria for identifying cosmetic products. This leads to ambiguous results when identifying cosmetic products as the source of substances sin wastewater.
- **Cross-sectoral usage**: Most substances linked to cosmetics have dual or multiple applications in other industries, with the dominant toxicity contributions arising from multi-use chemicals. Consequently, the toxicity contribution from cosmetic products is overestimated.
- **Questionable attribution**: The 9 most toxic substances flagged as cosmetic-derived in the feasibility study account for 97.5% of the chronic toxicity, yet these chemicals are not exclusive to cosmetics. Notably, Permethrin—the most toxic substance identified—is likely not used in cosmetic products. The observation suggests that the feasibility study's calculations are incorrect and overestimate the toxicity contribution from cosmetics.

We conclude that these discrepancies introduce significant uncertainty in attributing toxicity impacts to the cosmetics sector, as proposed in the feasibility study.

The present study offers an alternative assessment using actual market data on cosmetic product and manufacturer-reported compositions. We estimate that only 1.1% of the wastewater toxicity comes from substances used in cosmetic products. This is over 15 times lower than the 17% suggested by the Bio Innovation Service feasibility study.

Moreover, the present study evaluated the removal efficiency of cosmetic substances in wastewater treatment plants using data by Pistocchi et al. (3). The results indicate that substances from cosmetic products are generally removed more efficiently than other substances during wastewater treatment.

Consequently, the feasibility study grossly overestimates the role of substances used in cosmetic products and the conclusion of the present study is that the contribution from the cosmetic sector in terms of environmentally hazardous substances in raw municipal wastewater is very low.

8 References

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10. SPIN database. Substances in Preparations in Nordic Countries (SPIN). SPIN | Substances in Preparations in Nordic Countries
11. EU Regulation No 1223/2009 on cosmetic products, and the CosIng database. CosIng - Cosmetics - European Commission.
12. PUBCHEM. US National Institute of Health. PUBCHEM is an open chemistry database at the National Institutes of Health (NIH). Link: PubChem
13. ECHA. European Chemicals Agency. Database on registered chemical substances. Search for chemicals - ECHA

Appendix A Databases and their definition of cosmetic products

Norman database S13:

The Norman database combines different other databases but refer to the COSING, PUBCHEM and COMPTOX database. Other references remain unclear (i.e. the "Merged Cosmetics CSV (4/05/2017)

- *Combined Inventory of Ingredients Employed in Cosmetic Products (2000) and Revised Inventory (2006)*
- *Merged Cosmetics CSV (4/05/2017)*
- *CompTox EU Cosmetics List*
- *Merged Cosmetics InChIKeys (4/05/2017)*
- *The scientific committee on cosmetic products and non-food products Intended for consumers - SCCNFP/0389/00 Final and Commission Decision 2006/257/EC amending the Decision 96/335/EC. Provided by Peter von der Ohe, UBA, curated by Reza Aalizadeh, University of Athens.*
- *Update 12 May 2020: Added the source data from both reports (INCI-2000 and Decision 96/335/EC), including the function information and undefined structures. Update 28 May 2020: removed incomplete structural information from Decision 96/335/EC files. Update 24/7/2020: corrected one synonym reported by PubChem*

PUBCHEM

The database is referring to the California Safe Cosmetics Act of 2005.

The definition in the legal text of a cosmetic product is as follows.

(1) "Cosmetic product" means an article for retail sale or professional use intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

COSING

The definition of a cosmetic product in COSING is linked to the Regulation (EC) No. 1223/2009

CosIng is an information-only database that provides a distinction between ingredients and substances. By convention in CosIng:

- *Ingredients are considered all entries included in the CosIng inventory[1] for labelling purposes and are displayed in capital letters (e.g. ETHANOL) and with the symbol "I". The inclusion of an ingredient in the CosIng inventory is not an indication of authorisation, only the Cosmetics Regulation (EC) No. 1223/2009 has legal value in this respect.*
- *Substances are considered only those chemical elements and compounds that are regulated by the Cosmetics Regulation (i.e. listed in the Annexes to this Regulation). They are included in the CosIng inventory for information purposes (only the Cosmetics Regulation has legal value) and displayed in small letters (e.g. Formaldehyde) and with the symbol "S".*

The current data in the database can be found under the default status as "active", whereas historical data have the status "not active".

Chemexpo/Comptox:

The definition of cosmetics is a sub-group under Personal Care products. The following 6 product categories containing the word 'cosmetic' is contained in the PUC Directory of the ChemExpo database (updated 16 December 2020).

No clear definition of 'cosmetic products' is found.

cosmetic

Reset Filters

Kind	Gen Cat	Prod Fam	Prod Type	Definition	Product Count	View ..
Formulation	Arts and crafts/office supplies	body paint		products placed on the skin for decorative purposes (body paints, markers, play cosmetics, Halloween cosmetics, and products such as henna)	10	
Formulation	Personal care	glitter		products containing reflective particles applied to the face or body for cosmetic purposes	61	
Formulation	Personal care	makeup and related		makeup or cosmetic products which do not fit into a more refined category	979	
Formulation	Personal care	makeup and related	cosmetic tool cleaner	products for cleaning brushes and other devices used to apply makeup	2	
Formulation	Personal care	makeup and related	eye makeup	miscellaneous cosmetic eye products including lash adhesives and tints (excludes eye shadow, mascara, eye primer, and eye liner)	105	
Formulation	Personal care	makeup and related	eyebrow makeup	Brow gels, pencils, fillers, and other eyebrow cosmetic products	512	

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Appendix B The Nordic SPIN database

Table 5 shows the list of categories included to extract information on cosmetic products

Table 5 PSD Use categories included as cosmetics

Cosmetics
Deodorants
Hair care products (see also Cosmetics)
Hair cleansing products (shampoos, powders etc.)
Hair shampoo
Human hygiene (PT1)
Intermediates (cosmetics, hygienic articles
Moisturizers
Odour agents
Raw materials for production of cosmetics etc
Skin care products (see also Cosmetics)
Skin cleaners (Rinse creams, rinse fluids, skin tonics)
Skin cleaners (Soap, shower gel, hand cleansing cream)
Skin protection materials
Toilet soaps, deodorant soaps, bath foams, shower gels

[a] Assumed to be only cosmetics related, since *Odor agents (not cosmetic products)* is also available.

The following SPIN Product category "PC" were included in the extract of Cosmetic Products.

Table 6 Extract of product categories (PC)

Substance name	Percent used in cosmetics (SPIN PC) (%)	Main category of use (SPIN PC)
Permethrin	0	Non-agricultural pesticides and preservatives
Oleanolic acid	0,79	Cleaning/washing agents
hexadecaneic acid	0,002	Others
tetradecaneic acid	1,67	Others
N,N-Dimethyldodecylamine	0	Others
Caffeine	0	Others
Triclosan	16,31	Non-agricultural pesticides and preservatives
Nonylfenoldiethoxylat	Not in SPIN database	
2-Ethylhexyl4-methoxycinnamate	0	Others
Pb	0	Others