Specific Environmental Release Categories (SPERCs) for the formulation of cosmetic products (ERC 2)

Background Document

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Glossary: List of acronyms and abbreviations

AISE	International Association for Soaps, Detergents and Maintenance Products
AOX	Absorbable organic halogenated compounds
BOD	Biochemical oxygen demand
CE	Cosmetics Europe
COD	Chemical oxygen demand
ECHA	European Chemicals Agency
ERC	Environmental release category
LCA	Life cycleaAssessments
M_{SPERC}	Indicative worst-case value for the substance use rate per site
REACH	Registration, evaluation, authorization and restriction of chemicals
RF	Release factor
RMM	Risk management measure
RRM	Risk reduction measure
SPERC	Specific environmental release category
TGD	Technical guidance document
VOC	Volatile organic compound
WWT(P)	Wastewater treatment (plant)

General disclaimer

SPERCs are **SP**ecific **E**nvironmental **R**elease **C**ategories and are meant to specify broad emission scenario information (Environmental Release Categories (ERCs)). Although specific, SPERCs reflect emissions of a broad application area of a substance within an industry sector. For their purpose, SPERCs are conservative for use in lower tier REACH safety assessments and, therefore, their emission estimates are not intended to reflect all regulatory requirements which may relate to environmental emission thresholds. These SPERCs might be further refined providing site-specific data.

1. Statement of purpose

To carry out an environmental exposure assessment, the quantification of the rates of substances released to the environment is key. While ECHA's Guidance R.16 (ECHA, 2016) provides a generic set of release factors, they are less meaningful for several industry sectors, including Cosmetics Europe (CE). Sector organisations have refined the generic Environmental Release Categories (ERCs) by detailed analysis of the sector's specific typical operational conditions in order to build 'SPecific Environmental Release Categories' (SPERCs).

The CE SPERCs refine and specify emission scenario information for the use of substances in cosmetic products throughout their life cycle (Reihlen et al., 2016). The SPERCs described in this document are specific to the formulation of cosmetic consumer products. They apply for processes which are operated according to common efficient industry practices. Formulation of raw materials (compounding) is not explicitly covered, although not excluded if belonging to the formulation steps of a cosmetic product at a specific site. This document provides the background information to the corresponding SPERC factsheets, referring to ERC 2.
The SPERC Factsheets covered in this document are:

Table 1: Overview on CE SPERCs in scope

CE SPERC Code	Ingredients	Domain	Production Scale (tonnes of product / year)
CE SPERC 2.1.a	All substances (i.e. solid, liquid and volatile substances)	Formulation of liquid products, low viscosity	>10,000 t/a
CE SPERC 2.1.b			1,000 - 10,000 t/a
CE SPERC 2.1.c			<1,000 t/a
CE SPERC 2.1.d		Formulation of liquid alcohol-borne products (cleaning with water)	any
CE SPERC 2.1.f		Formulation of cosmetic products, high viscosity	1,000 - 10,000 t/a
CE SPERC 2.1.g			<1,000 t/a
CE SPERC 2.1.h		Formulation of non-liquid creams	>10,000 t /a
CE SPERC 2.1.i			1,000 - 10,000 t/a
CE SPERC 2.1.j			<1,000 t/a
CE SPERC 2.2		Formulation of cosmetic products involving cleaning with organic solvents	any
CE/AISE SPERC 2.3.a		Formulation of solid cosmetic (and home care) products*	>10,000 t/a
CE/AISE SPERC 2.3.b			1000 - 10,000 t/a
CE/AISE SPERC 2.3.c			<1000 t/a

*As this is a joint SPERC with AISE, home care products are covered but not being considered as cosmetic products

Specific information is given as regards to the operational conditions of use relevant to exposure in formulation (chapter 2 and 3), the risk reduction measures (chapter 4), as well as the derivation method and justification of release factors plus indicative use rates (chapter 5). External references are provided in chapter 8.

2 Scope

Cosmetic products are formulated for consumers and personal service providers. Whereas many products meet consumers' needs for hygiene, protection, care and healthiness, they may as well support comfort and well-being and serve for the expression of individual style.

For the formulation stage of the products' life cycle, release rates depend on aspects such as:
- Water-solubility or water-miscibility of finished products;
- Viscosity;
- Granularity;
- Production capacity.

2.1 Product types and their main ingredients

According to the European regulation on cosmetic products (Reg. 1223/2009/EC), 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. With regard to their application, cosmetic products are categorised as either wash-off products or wipe-off (leave-on) products.

Related to environmental safety aspects for cosmetic products, the REACH regulation (Reg. 1907/2006/EC) governs registration, evaluation, authorisation and restriction of chemicals in the European Union. The provisions of REACH apply to substances and preparations used in cosmetic products.

Each cosmetic product consists of a variety of ingredients brought together in a formulation. Substances are mainly liquid or solid, some are volatile (organic solvents, fragrances, propellants). Frame formulations are displayed in annex 2.

Cosmetic products can be clustered into:

Liquid products, low viscosity
(See chapter 3.1.2 for further explanations on viscosity.)

<u>a) Surfactant-based products (e.g. shampoos)</u>
Cleaners are based on water and surfactants (anionic, cationic and/or amphoteric) and contain only minor amounts of other ingredients like oils, glycerine, perfumes, colorants, sodium chloride, and pH adjusters. As an aqueous product, they are typically treated with a preservative for higher shelf

lives (unless containing high concentrations of certain surfactants). Products are capable of absorbing oil, fat and grease from skin and/or make-up.

Table 2: Exemplification of product types

CE SPERC Code	Domain	Product Characteristics	Product Examples
CE SPERC 2.1.a.b.c	Liquid products, low viscosity	Cleaning products (surfactant-based, water-soluble, low viscosity)	Shampoo, foam bath, shower gel, washing lotion, make-up remover, foot bath
		Liquid care and styling products for skin, hair, face, hands or feet (oil-in-water or water-in-oil emulsions or gels, water-soluble or water-miscible, low viscosity range from lotion, milk to gel)	Skin lotion/milk, cleaning emulsion, shower emulsion/oil, two-phase bath, after-shave balm, hair conditioner, sunscreen lotion/gel, after-sun, self-tanning lotion, hair styling lotion/gel
CE SPERC 2.1.d	Liquid alcohol-borne products (cleaning with water)	Alcohol-borne solutions (water-soluble, low viscosity)	Fragrances, perfumes, toner, pre-shave, after-shave, shaving lotion, shaving gel, hair tonic, deep hair conditioner, setting lotion, anti-transpirant/deo gel
CE SPERC 2.1.f.g	Cosmetic products, high viscosity	Liquid care and styling products (oil-in-water or water-in-oil emulsions or gels, water-soluble or water-miscible, high viscosity range from gel to cream)	Liquid soap formulation, liquid tooth-paste, emulsion make-up, eyeliner, shaving gel, hair colour, hair-styling cream, anti-transpirant stick
CE SPERC 2.1.h.i.j	Non-liquid creams	Creams (emulsions or emulsifier containing)	Tooth paste, face cream, make-up foundation, eye foundation cream, lip salve, mascara, skin cream, sunscreen cream, self-tanning cream, nail care cream, hair wax, hair gel, hair gum, depilation cream, foot balm
CE SPERC 2.2	Cosmetic products involving cleaning with organic solvents	Products based on oils, grease, wax and other non-water-soluble substances	Oil bath, skin care oil, sunscreen oil, sunscreen stick, cream make-up, hard skin remover, fragrances, perfumes (if not cleaned with water), epilation wax, hair wax (pomade), kajal, eyebrow stick, lip stick, lip gloss, lacquer, varnish remover, water-proof decorative cosmetics, foot balm, foot deo
CE/AISE SPERC 2.3. a.b.c	Solid cosmetic (and home care) products*	Soaps (water-soluble sodium or potassium salts of fatty acids) and syndets (synthetical detergents)	All kinds of soap including solid form shampoos, shaving soap
		Powders (dispersible in water)	Powder make-up, rouge, eye shadow, foot powder, bath salt, dental powder, dental prosthesis cleaner, henna

*As this is a joint SPERC with AISE, home care products are covered but not being considered as cosmetic products

b) Emulsions or gels (e.g. skin lotions/milks)

As surfactant-based products may extract too much fat from skin, many care products contain oils, moisturing agents, conditioners, perfumes and other care compounds such as plant extracts, essential oils, vitamin derivatives, vitalizing, cooling or calming agents. Special products also contain active ingredients like UV absorbers or self-tanning compounds. All of these compounds are emulsified which may require the addition of emulsifiers or chelating agents. Depending on the kind of oils, antioxidants or other stabilizers may be added. In addition, certain cleaning products may contain small particles for a peeling effect. Products containing water and no relevant content of organic solvents are typically equipped with a preservative.

Liquid alcohol-borne products (cleaning with water) (e.g. after-shave)
Products are based on water and water-soluble alcohols. Further ingredients such as perfumes, oils, care compounds, and colorants are typically water-soluble as most products are filtered before packing. Depending on solvent content, products do not require other preservatives. Special products may contain UV absorbers or anti-transpirant agents. Viscosity of solutions may be increased (products be transformed into gels) by adding gellants.

Cosmetic products, high viscosity (e.g. emulsion make-up)
Ingredients are similar to the ones used in less viscous products. Make-up formulations contain pigments which need to be dispersed in polyethylene glycol using wetting agents.

Non-liquid creams (e.g. mascara)
In addition to oils, non-liquid creams may be based to a higher content of fat, grease, or wax. Tooth paste is mostly surfactant-based with a high level of gellants. In addition, it contains polishing powders, pigments, multiple active agents, wetting agents, and flavours.

Products involving cleaning with organic solvent (based on non-water-soluble compounds)
Products mostly consist of oils, fats, grease, polymer solutions or non-alcohol organic solvents. Non-liquid compounds need to be molten for processing. Pigments and dyes are typically dispersed in castor oil before mixing into the lipophile phase. Emulsifiers are added if products are designed for being dissolved in water (e.g. oil bath).

Solid cosmetic products

a) Soaps
Solid cosmetic soaps are water-soluble sodium or potassium salts of fatty acids. They are made from fats and oils from both animal and vegetable sources that react with sodium hydroxide. Pigments and perfumes are often added during that process (CCSPA, 2020).

b) Powders, dispersible in water (e.g. rouge, henna)
Products consist of milled pigments and extenders. For certain applications, a part of the pigments is dispersed in oils.

2.2 Production scale

The cosmetics industry in Europe produced at a relatively constant volume range of 4.2 to 4.4 million tonnes per year in the period of 2014 to 2019 (Euromonitor, 2020). Almost 6,000 companies are contributing which means that average production scale is below 1,000 tonnes per year. Most of the companies are small and medium size enterprises. Even at sites of large multinational companies, most production lines are designed for capacities in the range of 1,000 to 10,000 tonnes per year. Only few lines exceed the threshold of 10,000 tonnes per year production volume (e.g. for production of liquid cleaners, conditioners, shampoos, and shower gels).

The release factors of the environmental emissions from small, medium and large size plants, were predominantly extrapolated from data referred to in the Royal Haskoning report (Royal Haskoning, 2009). This report contains estimates of the environmental emission scenarios for fragrance materials during compounding of perfume oils (i.e. raw materials for cosmetic products) and formulation of consumer products. It displays empirical release rates for large and medium production volumes.

In the cases of liquid alcohol-borne products, cosmetic products with high viscosity (covering non-liquid creams), soaps and solid cosmetic products, and products involving cleaning with organic solvents, tonnage bands of the Royal Haskoning report match well with production scales as used in CE SPERCs. Figures for small production lines are extrapolated where appropriate.

In the case of liquid products with low viscosity, the Royal Haskoning report describes total production volumes for liquid cleaners, conditioners, shampoos, and shower gels above 100,000 tonnes per year as ‘large’ and for total production volumes above 10,000 tonnes per year as ‘medium’. In this segment, a large plant typically consists of multiple production lines for multiple products. For the purpose of this SPERC document, the reported release ratios for large plants (> 100,000 tonnes per year) are considered to be valid for large production lines (> 10,000 tonnes per year), reported release ratios for medium plants (> 10,000 tonnes per year) are considered to be valid for medium production lines (1,000 - 10,000 tonnes per year).

For all cosmetic product domains, a uniform distinction is made for the production scale per location. Three size classes were defined: small (< 1,000 tonnes finished product (fp)/year); medium (1,000 -10,000 tonnes fp/year); large (> 10,000 tonnes fp/year). It is assumed that higher production scales are usually associated with a higher degree of automatisation and efficiency. Hence, environmental release factors decrease with increasing production scales.

2.3 Measurement of chemical emissions

For a correct and consistent derivation of the release factors defined in the SPERCs, it is important to understand the underlying modelling framework for manufacturing sites, as described in ECHA REACH Technical Guidance Document R.16 (ECHA, 2016). The release of a substance and subsequent exposure of the environment are in principle assessed on two spatial scales: locally in the vicinity of a representative source of the release to the environment, and regionally for a larger area which includes all release sources in that area. At the local scale, two release scenarios are distinguished to assess the release to the environment, i.e; for uses taking place at industrial sites and for uses taking place in a widespread manner. The life cycle stage of formulation is assumed to take place at an industrial site. As illustrated in Fig. 1 below (i.e. Fig. 16-9 of ECHA guidance R.16), the emissions from the plant are assumed to pass a biological sewage treatment plant (STP) prior release to the environment. This STP is a standard municipal STP (10,000 inhabitants connected, discharge 2,000 m^3/day) by default in the model but can also be an on-site biological treatment plant in case there is no external STP.

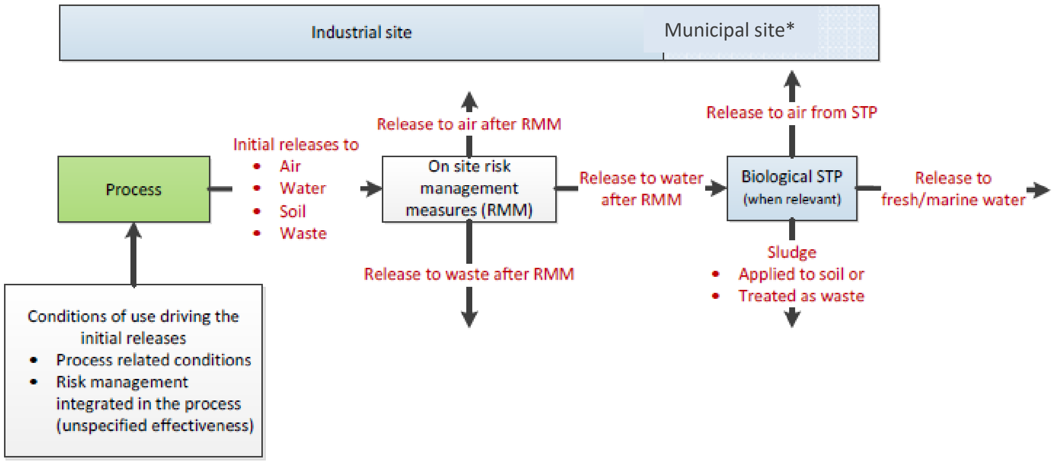

Figure R.16-9: Relationship between the different releases

Fig. 1: Relationship between different releases (taken from ECHA guidance R.16 (ECHA, 2016))
*) Explanation "Municipal site" inserted to improve clarity with regard to CE SPERCs

Fig. 1 further illustrates the modelling framework relevant to the SPERCs. The release factors are intended to reflect the process losses, including on-site risk management measures (RMMs) and according to the described operational conditions (OC), at the point of leaving the site, but prior final treatment in a biological STP. For many substances, the processes occurring in the municipal STP provide for efficient removal from the wastewater. Nonetheless, the municipal STPs are considered to be a default risk management measure, after local emission, in the SPERCs framework but they are not under the control of the downstream user.

To the best of our knowledge, there is no standard or uniform way to describe material losses (release factors) from formulation to the environment in the chemical and/or consumer goods industry. Analytical measurements may also differ with the compartment of interest (e.g. air, water, waste). In general, SPERCS define the mass of chemicals lost in a process per mass of chemicals entering the site. Since these are both mass units, it is possible to express this ratio as a release fraction (%). A local daily release rate can also be derived from this information. In this context it should be mentioned that any release during formulation is an economical loss and is therefore typically already reduced to a minimum.

Measurements and assessments are rarely conducted at formulation sites unless required for a permit or as part of process efficiency monitoring. Consequently, little specific information is available from formulating operations. Instead, operating permits and environmental reporting duties may require tracking of chemical group parameters, e.g. volatile organic compounds (VOCs) to air, chemical oxygen demand (COD) or absorbable organic halogenated compounds (AOX) to water. Solid waste is often split in different material fractions. Therefore, in this SPERC exercise, proxy data, such as COD, often had to be interpreted and translated to average chemical loss fractions.

Other factors that may complicate this type of estimation are:

1) Many factories produce a diversity of products on separate productions lines. Rarely, waste waters from production lines are monitored separately.

2) Measurements of waste-water at the point of release from a production site often also include the organic load of grey (kitchen) and black water (toilets).

Hence, there is some heterogeneity in the underlying data collected, and the proposed emission factors are the best available approximations.

2.4 Formulation technologies

Formulation of cosmetic products consists of a broad range of processing and packaging operations (Umbach, 2004). Products are manufactured either in a batch process or in a continuous process. The batch process is more straightforward since the different constituents are brought in an agitated tank, and further mixing can be provided via a recirculation loop. They are frequently used for specialised products and/or small-scale operations. In comparison, continuous processes are more complex and more adapted to large-scale production. In a continuous process both, dry and liquid ingredients, are added and then mixed via in-line mixers. Continuous processes require less cleaning. While actual production processes vary across manufacturers, there are steps which are common to all products of a similar form. Large companies may frequently work with masterbatches. These cover a core formulation that is individually completed by adding different ingredients to achieve products of the same category but different nuances.

Specific aspects of the production process relevant in the context of the SPERC description:

Liquid products, low viscosity
(See chapter 3.1.2 for further explanations about viscosity.)

<u>a) Surfactant-based products</u>
Liquid surfactant-based products are water-borne mixtures manufactured by mixing and pumping the ingredients into mixing tanks. The exact process used depends on the formulator and the form of the final product. Viscous ingredients are added towards the end of the process. The process occurs at ambient temperature.

<u>b) Emulsions or gels</u>
In addition to the process described for surfactant-based products, a couple of side processes may be required such us melting of waxes, dissolving of colorants, or dispersing of solid compounds in water. Depending on mixed compounds, the creation of a stable emulsion may require a specific sequence of manufacturing steps with different levels of agitation. The process occurs at ambient or slightly elevated (tepid) temperature. Volatilisation of perfumes is negligible. Products are manufactured either in a batch process or a continuous process.

Liquid alcohol-borne products (cleaning with water)
In addition to the process described for low viscosity products, a cooling step to ca. 4°C is typical in order to verify that the solution stays clear under any condition. Agglomerates and impurities are filtered. In case of gelation, gellants are dispersed by propeller mixers at the beginning. Subsequently, mixers need to be changed for the homogenization of the resulting highly viscous product.

Cosmetic products, high viscosity

The process description for this group of products has elements of liquid products with low viscosity and of non-liquid creams, staying closer to the non-liquid products.

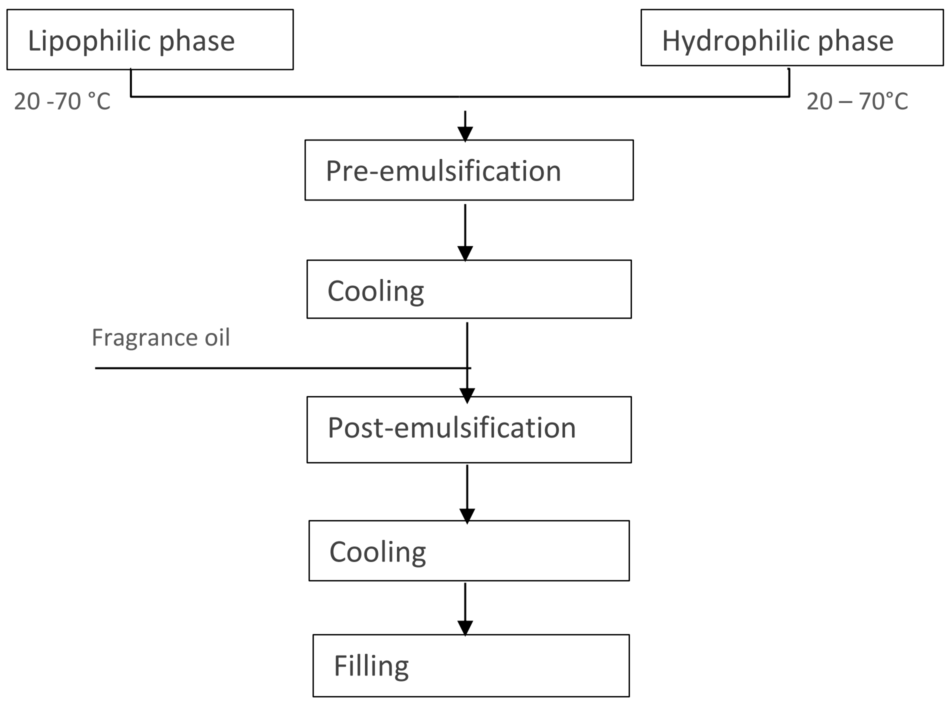

Fig. 2: Diagram of the emulsifying process (adapted from Umbach (Abbildung 17.1-3), translated (Umbach, 2004))

Non-liquid creams

Many creams contain fats which have to be molten at about 80°C before they are emulsified in products with an aqueous phase. Also, the water phase which may contain dispersed pigments and other compounds needs to be heated up to this temperature in order to allow the formation of a stable emulsion. Depending on the mixed compounds, the creation of a stable emulsion may require a specific sequence of manufacturing steps with different levels of agitation. Mixers need to be appropriate for highly viscous products. Manufacturing of certain products may require a milling step with colloid mills (e.g. mascara). Emulsifiers and other additives are typically added at temperatures around 60°C, perfumes at lower temperatures between 40°C and 60°C. Consequently, volatilisation of perfumes has to be considered. The process is mostly a batch process. Final cleaning can be done with water, but may need warm water and/or additional emulsifiers.

Products involving cleaning with organic solvent (based on non water-soluble compounds)

Non-liquid products like lip sticks or pomade are manufactured at elevated temperature (around 80°C) in order to melt grease, fat, or wax. Also, other compounds, e.g. colorants dissolved in castor oil, are heated up in order to allow a homogeneous blending and subsequent milling at colloid mills. Perfumes are added towards the end of the process at temperatures around 60°C. Packaging requires still temperatures above 45°C. If packaging takes place at a different area, vessels may need to be heated up a second time.

Liquid products such as nail polish are manufactured at ambient temperature due to the use of organic solvents (non-alcohols). They may be manufactured in a two-stage process with a master batch for a lacquer base (nitrocellulose wetted in isopropanol and dissolved in butyl acetated, completed by further generic ingredients) in combination with pigment pastes or colour concentrates which are added at a subsequent stage. In any case, vessels, mixers, and tubes are cleaned by using organic solvents, as water would not be suitable.

Solid cosmetic products

a) Soaps (process description taken from AISE SPERC Background Document (AISE, 2021))
The manufacturing of bar soap consists in four basic steps (EIPPCB, 2017):
Step 1 – Saponification: A mixture of tallow (animal fat) and coconut oil is mixed with sodium hydroxide and heated. The detergent produced is the salt of a long chain carboxylic acid.
Step 2 – Glycerine removal: Glycerine is more valuable than soap, so most of it is removed. Some is left in the soap to help make it soft and smooth.
Step 3 – Soap purification: Any remaining sodium hydroxide is neutralized with a weak acid such as citric acid and two thirds of the remaining water removed.
Step 4 – Finishing Additives such as preservatives, colour and perfume are added and mixed in with the soap/detergent and it is packed for sale".
In addition to the described process, solid detergents like soap bars usually incorporate a variety of other ingredients that act as water softeners, free-flowing agents, etc. The below process flow diagram indicates the general flow of plant processes and equipment involved in the formulation/production of solid cosmetic products like bar soap (Fig. 3).
As soaps are water-soluble, cleaning may be achieved by using water.

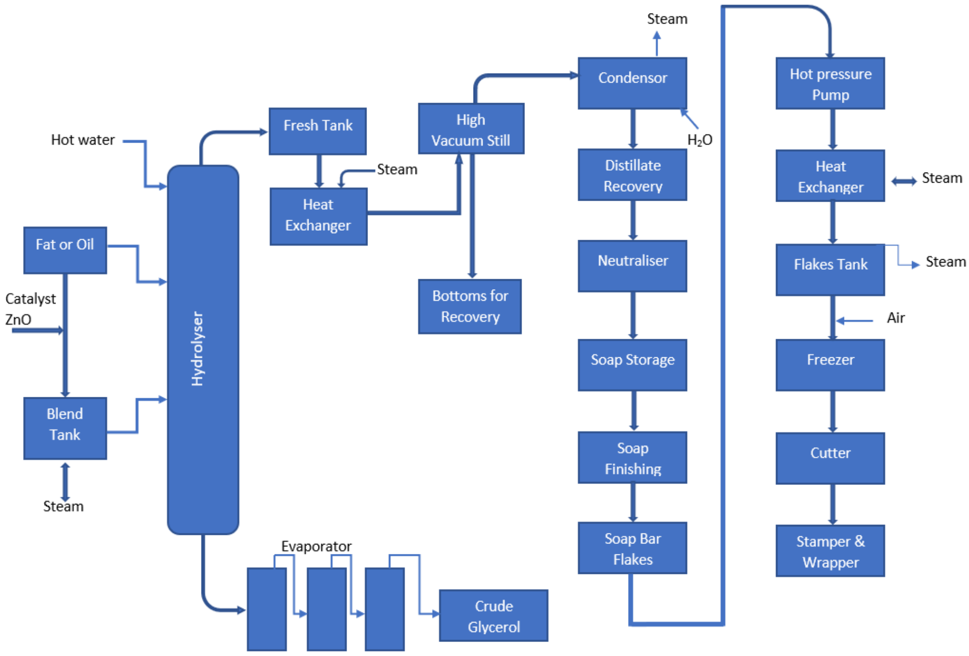

Fig. 3: Continuous process of fatty acids and soaps production (reworked from US EPA, 1993)

b) Powders, dispersible in water
Solid ingredients are mixed and milled in a powder mixer. Depending on the product, a small amount of oil may be sprayed into the mixer towards the end of the process. The finished product is then either tableted or pressed into small pans. The process occurs at ambient temperature, preferably as batch production. To a certain extent, mills and vessels can be cleaned by vacuum cleaners without water.

Powders contribute far less than 0.5 % to the overall production volume of cosmetics, production lines are typically in the small range. Therefore, no separate CE SPERC has been derived for this product group. Release factors which have been derived for solid cosmetic products in general are deemed to be sufficiently conservative. For powders which are subsequently used for the formulation of high viscosity products or non-liquid creams, release factors for these products are applicable.

3 Emission relevance of operational conditions

The OECD exposure scenario document on fragrance oils (OECD, 2010) entails a comprehensive description of the complete formulation process and provides a good qualitative and quantitative base for the understanding and identification of potential sources and pathways of substance releases into the environment. In that document, the formulation of cosmetic products is subsumed into common process steps; these include transfer of substances from containers into storage or mixing vessels, container cleaning or disposal of empty containers, the formulation/mixing step, product quality sampling, the packaging or filling of the product and finally the equipment cleaning and disposal of material which cannot be recycled or reused. Emissions occurring during these operational processes can be differentiated into material loading emissions, evaporation, filling losses and all kinds of miscellaneous cleaning operations. The OECD process flow description represents a refinement and further development of an underlying US EPA document (US EPA, 1993; OECD, 2010). For the purpose of this CE SPERC background document, the occupational exposure aspects are beyond scope.

From the perspective of the formulators of cosmetic products inside the European Union, there is a clear focus on releases to water from sampling and equipment cleaning, because

- Transport containers are cleaned off-site by third parties when refilled or reused,
- Emptied containers which are not reconditioned are collected and recycled,
- Combustible substance residues from container cleaning, equipment cleaning, or on-site waste-water treatment are incinerated, non-combustible residues are disposed according applicable legislation without release to soil,
- Emission of dust is irrelevant as production of cosmetics does not entail spray-drying,
- Emission of volatile organic compounds to air is not substantial due to applicable legislation on industrial emissions where appropriate (especially for liquid alcohol-borne products and products involving cleaning with organic solvent).

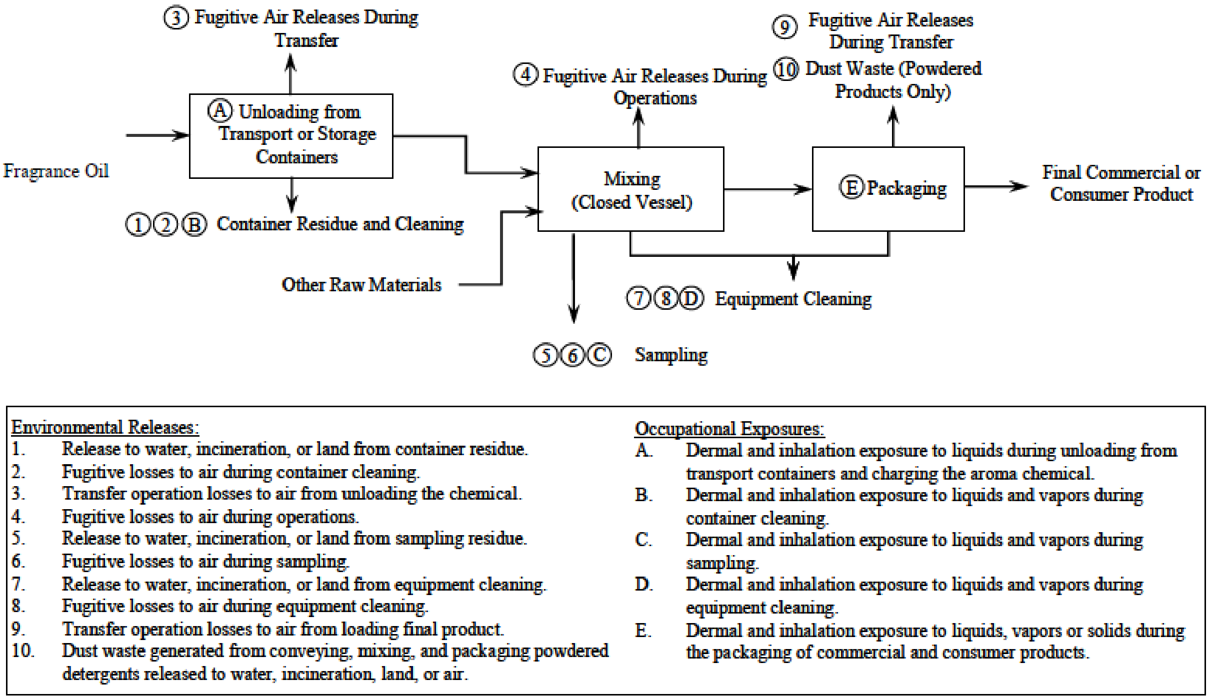

Fig. 4: Process flow diagram – Fine and functional fragrance oil (taken from (OECD, 2010))

3.1 Relevant aspects of operational conditions

As already mentioned in chapter 2, release rates in the formulation stage depend on i.a.:

- Water-solubility or water-miscibility of finished products;
- Viscosity;
- Production capacity.

3.1.1 Water-solubility (low water solubility may require application of specific CE SPERC 2.2)

Due to the properties of manufactured products, equipment may need to be cleaned with organic solvents. Cleaning solvents are collected and recycled or incinerated (reused energetically or disposed off as hazardous waste by third parties).

3.1.2 Viscosity (CE SPERC 2.1.a.b.c vs. CE SPERC 2.1f.g vs. CE SPERC 2.1.h.i.j)

Besides the differentiation among product types, to obtain adequate emission estimates, a distinction in viscosity should be made for liquid products. This is because products of higher viscosity typically leave higher amounts of residues in production vessels and lead to a higher environmental release fraction. The viscosity of liquid cosmetic products may vary from product to product, with low or medium viscosity liquids being respectively like water or syrup. A high viscosity liquid is more like creamy emulsions or a paste. There is no quantitative viscosity cut-off between both product categories. However, high viscosity fluid is operationally defined here as an ingredient in a formulation that will not readily flow out of its container when it is tilted at room temperature. Consequently, high viscosity liquid products will adhere more strongly to the walls of mixing vessels, tubing, production and packaging lines. High viscosity and non-liquid products may require a multi-stage mixing process with different mixing techniques. They may require different handling during cleaning of production equipment. This affects the environmental emissions of such materials, as opposed to free-flowing liquid formulations.

3.1.3 Production capacity (with impact on intrinsic emission control)

Several separate and distinctive processes are taking place during cosmetic products formulation which may require emission reduction measures. It is assumed that the below techniques are known and applied by industry, where appropriate, as 'good industry practice'. Hence, the emission reduction by these techniques either solitarily, in combination or in its entity, is incorporated in the reported emissions by the given release factors, respectively. Releases to water are minimized by using risk reduction measures. Applicability may depend on plant size and production volume. CE considers the following measures as typical with regard to production volume.

Large scale production (CE SPERC 2.1.a and 2.1.h)
Environmental release of substances is controlled through production processes that are optimised for highly efficient use of raw materials. Typical improvement measures for large production sites may include the adoption of practices such as:

- Closed automated process and/or closed transfer system and/or centralised process control and/or re-use of process grey water for cleaning;
- Optimised and/or automated systems for the transport and handling of raw materials, that minimise overall exposure levels and incidental spills;
- Reduced number of transfer and cleaning operations through e.g. manufacturing of different products from one premix (masterbatch), to which certain ingredients are added to yield the final products;
- Dedicated storage tanks for raw materials, premixes and final products;
- Recovery of materials.

The operation that is most common to the formulation of all product types, and that may lead to the most significant product losses, is the equipment cleaning. Related environmental releases are kept under control by the implementation of general good practices in the cosmetics industry. Within this context, typically implemented measures for reducing emissions to wastewater may include:

- Dry cleaning of equipment (use of absorbent materials and vacuum cleaning);
- Cleaning involving so-called pigs;
- Cleaning involving so-called 'cleaning in place' (CIP System);
- Steam cleaning and/or manual removal of residual products adhering to equipment (e.g. by manual scrabbing, vacuum cleaning, etc.);
- Use of two-liner systems (i.e. single use disposable reactor cover);
- Re-use of grey water.

Most of these waste reduction measures are supported by comprehensive worker environmental and safety training programs. Trained staff can implement spill protection procedures.

Medium scale production (CE SPERC 2.1.b, 2.1.f and.2.1.i)

- Closed batch systems and/or semi-closed transfer system and/or batch production of final product;
- Reduced number of transfer and cleaning operations through e.g. dedicated storage tanks for raw materials, premixes and final products;
- Manual removal of residual products adhering to equipment (e.g. by manual scrabbing, vacuum

cleaning, etc.);
- Use of two-liner systems (i.e. single use disposable reactor cover).

Small scale production (CE SPERC 2.1.c, 2.1.g and 2.1.j)
- Closed batch systems.

Production of liquid alcohol-borne products (CE SPERC 2.1.d)
Whereas fragrance products and perfumes are liquid products of low viscosity, the assigned release factor is quite different. The reason behind this is because fragrance products and perfumes are typically produced at low volumes per batch which results in a high frequency of cleaning operations (on a daily base rather than on a weekly base as assumed for other liquid products). Pumps and tubes may retain considerable amounts of residues (Royal Haskoning, 2009).

All chemical processes and some of the other operations involved in the making of cosmetic products, unless operated in completely closed systems, have odors as a common air pollution problem. The final elimination of odors from the manufacture of cosmetic products can be accomplished by scrubbers, such as water ejectors of barometric condensers. The odor-containing gases vented from this scrubber are in very low volumes. The residual odors are diluted in the atmosphere well below their perception threshold levels in traveling through the atmosphere for only a short distance from the scrubber exhaust (OECD, 2010).

No direct exposure of ingredients to soil is to be expected during normal manufacturing operations (Royal Haskoning, 2009). In total, only a very small fraction of the substances ends up in the waste stage. Any disposal leading to emissions is covered in the exposure assessment and is accounted for in the emission factor.

4 Application of risk reduction measures (RRM)

The focus of this background document is on risk reduction measures through process optimisation and material flow management in order to minimize releases. A key aspect of chemical RRM is wastewater treatment (WWT) which can occur at some productions sites or at municipal wastewater treatment plants (WWTP) (see Figure 1). However, the focus of the SPERCs is on the releases prior to wastewater treatment and thus WWT is not in scope. Nevertheless, municipal WWT is generally applied after emission and is assumed to be included as a subsequent risk management measure (RMM) in a risk assessment. Any additional WWT removal that may be included in a separate step of the exposure assessment in a chemical risk assessment remains the responsibility of the risk assessor.

RRM limiting release to air are site-specific according to requirements of Industrial emissions directive, national transposition of this directive and site-specific permit conditions. Preferably process integrated measures for minimization of releases.

5 SPERC information sources and justification

The derivation of release factors is based on literature and data collected from industry associations. To a certain extent, data collection by the detergents industry is taken into account as there is an overlap in the product portfolio (especially liquid products of low viscosity and soaps), and as a couple of reports cover both, detergents and cosmetic products. However, the overall production volumes of detergents are about three times higher than production volumes of cosmetic products. That detergent industry has far less production sites and therefore typically higher production volumes per site compared to the cosmetic industry.

First relevant figures originate from life cycle assessments (LCA) which were performed in cooperation with the European detergents industry in order to compare regular and compact, liquid and granular detergents over their complete life cycle. A peer reviewed LCA was conducted and published by Franke et al. (Franke et al., 1995). Reviewers included Öko-Institut Freiburg on behalf of Umweltbundesamt (German environmental protection agency). The reference cases of the LCA were production of 1,000 kg of product or washing of 1,000 kg of tissue. This study was the basis for the European Chemicals Bureau technical guidance document on risk assessment (ECB, 2003) for the assessment of soaps, fabric washing, dish cleaning and surface cleaning substances.

It may thus be considered as relevant for liquid cosmetic products with low viscosity (surfactant-based as well as emulsions), especially for releases to air and waste. For releases to water, there are uncertainties with regard to the volume scale of production sites, the inclusion or non-inclusion of waste water treatment and the reliability of COD assignments at production plants. Franke et al. are explicitly expressing this concern on COD assignments in their publication.

A further LCA study on the same subject was performed and published by Saouter et al. (Saouter et al., 2002). It allows for better interpretation regarding releases to water. Whereas it is focused on granular detergents, certain conclusions may be adapted for liquid cleaning products. The report displays figures for COD and biochemical oxygen demand (BOD) i.a. for the life cycle stages manufacturing and disposal (i.e. release from consumer use) per 1,000 wash cycles. Knowing the detergent consumption per wash cycle for respective products allows to compare COD freights for these two stages and to determine a relation (1.8 g resp. 3 g COD release from formulation vs. 1 kg COD release from consumption). This may lead to the derivation of a release rate. As all LCA data are related to 1 kg of product or to 1,000 wash cycles, no information is provided with regard to volume scale of the production plant.

Further studies are more specific for cosmetic products as they refer to fragrance materials during compounding of perfume oils and formulation of consumer products (Royal Haskoning, 2009) respectively to blending of fragrance oils into commercial and consumer products (OECD, 2010). The OECD emission scenario document is referring to the Royal Haskoning study on behalf of the Research Institute for Fragrance Materials (RIFM), reassessed it und endorsed their conclusions. Both documents provide information on emissions to water, to air, to soil and to waste for cosmetic products. There are a few gaps on small scale production plants.

Table 3: Overview on release factors presented in reports

Domain	Volume Scale	Release Fractions to Water				
		Saouter	ECB	Royal	OECD	Amec
Liquid products of low viscosity	Large	0.18-0.3%		**0.1%**	**0.1%**	**0.1%**
	Medium		0.09%	**0.2%**	**0.2%**	**0.2%**
	Small					**0.4%**
Liquid alcohol-borne products (cleaning with water)	All			**1.5%**	**1.5%**	
Cosmetic products of high viscosity	Medium			0.2%[1]	0.2%[1]	2%
	Small					
Non-liquid creams	Large			**1%[2]**	**1%[2]**	
	Medium			1%[2]	1%[2]	
	Small					
Products involving cleaning with organic solvents	All			0%		
Solid cosmetic (and home care) products*	Large			**0.05%**	**0.05%**	
	Medium			**0.1%**	**0.1%**	
	Small					

Saouter: (Saouter et.al., 2002); ECB: (ECB, 2003); Royal: (Royal Haskoning, 2009); OECD: (OECD, 2010); Amec: (Amec, 2017)

1) Reports refer to cleaners, conditioners, shampoos, and shower gels without any consideration of viscosity
2) Reports refer to liquid creams and lotions which may match better with liquid products of high viscosity
Bold figures: considered as reference values for release fractions to water by CE SPERCs (see Table 4)
*As this is a joint SPERC with AISE, home care products are covered but not being considered as cosmetic products

A more recent study was performed by Amec Foster Wheeler about releases of intentionally added microplastics in products (Amec, 2017). Despite its focus, the Amec Foster Wheeler study provides general information on release rates and endorses the approach that only the aquatic route is deemed to be relevant.

All referenced information is displayed in Table 3 above.

5.1 Justification of use rates

As already mentioned, the cosmetics industry in Europe (Western plus Eastern Europe) produced relatively constant volumes of 4.2 to 4.4 million tonnes per year in the period of 2014 to 2019 (Euromonitor, 2020). These products are allocated to use categories as follows:

- 30% Bath and shower (mainly liquid products, low viscosity; soaps)
- 26% Hair care (predominantly liquid products, low viscosity)
- 11% Oral care (predominantly non-liquid creams)
- 10% Baby and child-specific products (liquid products, low viscosity; non-liquid creams)
- 9% Skin care (cosmetic products, high visc.; non-liquid creams)
- 7% Men's grooming (cosmetic prod., high visc.; alcohol-borne prod.)
- 5% Deodorants (predominantly cosmetic products, high visc.)
- <1% Sun care (liquid products, low viscosity; non-liquid creams)
- <1% Fragrances (liquid alcohol-borne products)
- <1% Colour cosmetics (non-liquid creams; prod. inv. clean. w. solvents)
- <1% Depilatories (non-liquid creams; prod. inv. clean. w. solvents)

Taking into account the large diversity of cosmetic products, this clustering provides a further indication that only few product types are produced at large scale whereas small and medium size enterprises are typical for this segment.

Information on the typical composition of cosmetic products can be found at Umbach (Umbach, 2004). Based on these compositions, indicative substance use rates can be estimated for typical large, medium and small scale formulation sites.

M_{SPERC} (in Kg/day) represents an indicative worst-case value for the substance use rate per site. M_{SPERC}'s can be used by a registrant when starting the environmental assessment. The derivation of the M_{SPERC}'s is explained in Annex 1 of this document while high-end substance use rates in formulation of cosmetic products can be found in Annex 2. The production volumes are indicative and can be used as a worst case estimate for emission estimations, i.e. where exact data are lacking. As concentrations of substances in finished products may vary over a broad range due to the complexity of the cosmetics industry, C_{SP} values in annex 2 represent the upper limit as derived from frame formulations published by Umbach (Umbach, 2004). Therefore, also M_{SPERC} figures represent an upper estimate and are very conservative.

In practical terms, the operational scales roughly circumscribe the degree of automatism and technical standards applied in an operation. As this is not expected to have significantly changed, the scales as implemented for the early SPERCs have been maintained in the update of the SPERCs.

5.2 Justification of days emitting

The justification of the emission days is a reasonable worst-case value for large and medium industrial sites, operating at > 300 days a year. Many large plants operate non-stop. The 300 days per year allows a buffer to account for eventual plant closure during holidays, and days for maintenance where operations are forced to be stopped or limited. For small sites, the ECHA guidance for environmental exposure assessment assumes 100 days a year as default for formulators. The number of emitting days is corresponding to this guidance (ECHA, 2016), except for CE/AISE SPERC 2.3.c, where 150 days were found more appropriate for small scale production (based on the B-tables for chemical formulation processes outlined in the Technical Guidance Document on Risk Assessment (Part II: Environmental Risk Assessment) (ECB, 2003)).

5.3 Justification of release factors

The general approach that has been followed is to define the Release Factors (RF) as the observed emissions amounts to air/water/soil/waste in relation to the volume of produced finished product (i.e. mass/mass), and converted to percent, for the overall process or production line.

For ERC 2 (formulation, inclusion into a mixture), ECHA's guidance R.16 for environmental exposure assessment (ECHA, 2016) considers the following release fractions as default worst-case:

- 2.5% to air;
- 2% to water (before WWTP);
- 0.1% to soil.

As suggested by Reihlen et al. (Reihlen et al., 2016), different approaches and information sources were consulted in this background document, sometimes in a weight of evidence approach, to derive the most appropriate and representative release factors. These approaches include 1) extraction of release factors from literature, 2) data collected of cross-checks done in the sector, and 3) qualitative argumentation based on thorough process and plant operations management understanding.

The derivation of release factors to water, waste and soil by CE starts from figures as shared by Royal Haskoning and OECD (Royal Haskoning, 2009; OECD, 2010). Release fractions for liquid products of low viscosity (large and medium volume band), liquid alcohol-borne products, products involving cleaning with organic solvents, and solid cosmetic products (large and medium volume band) were taken over without adjustment.

The presented figure for liquid creams by Royal Haskoning and OECD (without link to a volume band) (Royal Haskoning, 2009; OECD, 2010) was adapted for liquid products of high viscosity (medium volume band) and non-liquid creams (high volume band). This entails a high degree of conservatism as the option to connect release factors for liquid products of high viscosity to those of low viscosity was not chosen.

All other release factors were derived by extrapolation. A factor of 2 was applied once (or twice for non-liquid creams) for the lower volume bands, where appropriate. This approach was established by Royal Haskoning and OECD for large and medium production scales in case of soaps (i.e. solid cosmetic products), liquid products of low viscosity (and granular detergents) (Royal Haskoning, 2009; OECD, 2010). CE expanded this approach to cosmetic products of high viscosity and non-liquid creams and re-applied to small scale production. For cosmetic products of high viscosity and non-liquid creams, it needs to be mentioned that a release factor to water of 2% represents the default value in ECHA guidance R.16 (ECHA, 2016).

Table 4 provides an overview of the release fractions recommended by CE for use in its SPERCs.

Table 4: Summary of release factors in the CE SPERCs for formulation

CE SPERC Code	Domain	Production Scale (volume/line)	Release Fractions			
			to Air	to Water	to Soil	to Waste
CE SPERC 2.1.a	Liquid products of low viscosity	>10,000 t/a	0%	0.1%	0%	0-6%
CE SPERC 2.1.b		1,000 - 10,000 t/a	0%	0.2%	0%	0-6%
CE SPERC 2.1.c		<1,000 t/a	0%	0.4%	0%	0-6%
CE SPERC 2.1.d	Liquid alcohol-borne products (cleaning with water)	All	0*	1.5%	0%	0-6%
CE SPERC 2.1.f	Cometic products of high viscosity	1,000 - 10,000 t/a	0%	1%	0%	0-6%
CE SPERC 2.1.g		<1,000 t/a	0%	2%	0%	0-6%
CE SPERC 2.1.h	Non-liquid creams	>10,000 t/a	0%	1%	0%	0-6%
CE SPERC 2.1.i		1,000 - 10,000 t/a	0%	2%	0%	0-6%
CE SPERC 2.1.j		<1,000 t/a	0%	4%	0%	0-6%
CE SPERC 2.2	Products involving cleaning with organic solvents	All	0%**	0%	0%	0-6%
CE/AISE SPERC 2.3.a	Solid cosmetic (and home care) products***	>10,000 t/a	0.006%	0.05 %	0%	0-6%
CE/AISE SPERC 2.3.b		1000 - 10,000 t/a	0.006%	0.1%	0%	0-6%
CE/AISE SPERC 2.3.c		<1000 t/a	0.006%	0.2%	0%	0-6%

* Minor emissions to air may occur at specific sites, depending on applicable restrictions based on the Industrial emissions directive and its national transpositions

** No release of cosmetic product ingredients; emissions may be linked to use of cleaning solvents

*** Data on release to air (scented candles) shared by Candle Makers Association with AISE SPERC Task Force
As this is a joint SPERC with AISE, home care products are covered but not being considered as cosmetic products

5.4 Justification of risk management measures

RMM and emission control technologies for the cosmetic products manufacturing operations are generally following 'good industry practice'. They are described in general terms in chapter 3. Chapter 4 further defines elements of the practice, while no additional mandatory RMM is deemed necessary for the purpose of the SPERCs. Therefore, the use of data on efficiencies of individual RMM or equipment performance is not considered in this approach.

6 Conservatism

As outlined in the European Chemical Industry Council (CEFIC) guidance (CEFIC, 2010), SPERCs are intended to provide realistic but conservative emission estimates (Reihlen et al., 2016). Normally, an (average) realistic worst-case value is taken from the whole of the data pool collected.

CE SPERCs are overly conservative because

- Substance concentrations in finished products are always taken from the upper end of reported formulations,
- Production volumes represent the upper end of tonnage bands,
- Release factors for cosmetic products with high viscosity are derived from figures assigned to non-liquid creams.

In addition, the use of historical emission information for the RF derivation may contribute to conservatism because those emissions are likely higher than current emissions as a result of ongoing innovation and regulation, thus increasing process efficiency and emission reductions over time (Reihlen et al., 2016).

To continuously lower emissions is also driven by economic considerations and materials efficiency, to ensure that cleaning residues and spills are reused to a maximum extent by re-blending them into the process.

7 Applicability of SPERCs

7.1 Tiered assessment

We consider SPERCs presented in this document to be suitable for use in standardised, lower tier REACH assessments for most formulation processes and the associated chemical ingredients. These SPERCs are conceived to allow risk assessors to discriminate substances with minor impact and emission situations from more challenging ones based on standardised emission estimates. Based on this distinction, efforts can be focused on further (higher tier) assessments and refinement of problematic issues.

7.2 Regional assessment

In view that there is only limited variation in today’s formulation processes of cosmetic products across Europe, these SPERCs may be seen as broadly applicable.

8 References

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(Umbach, 2004) Umbach, W. (ed.). *Kosmetik und Hygiene (von Kopf bis Fuß)*. Wiley VCH, Weinheim (DE)

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9 Annexes

9.1 Annex 1: Derivation of the M_{SPERC}'s

M_{SPERC} (in Kg/day) represents an indicative worst-case value for the substance use rate per site M_{SPERC} can be used by the registrant when starting the environmental assessment. M_{SPERC} is calculated according to:

$$M_{SPERC} = M_{Finished} \times C_{SP} \times T_{Emission,SPERC}^{-1}$$

Where:

C_{SP} = maximum concentration of substance in finished product (Umbach, 2004)

$M_{Finished}$ = the maximum amount of finished product manufactured (per year), per tonnage band

$T_{Emission,SPERC}$ = number of days emitting (ECHA, 2016).

Typical parameter values are given in Annex 2. The $M_{Finished}$ ranges are provided to help formulators find out which SPERC is relevant for their operation. For M_{SPERC} distinct values founded on expert estimation are provided, since these are recommended as starting values for environmental exposure assessments, provided no better information is available.

9.2 Annex 2: Derivation of indicative M_{SPERC}'s values

Derivation of the default substance use rate M_{SPERC} for industrial use in formulation of cosmetic products. The derivation is based on figures of production volumes at the upper end of applicable tonnage bands and typical values of the operational conditions for the various applications covered by these SPERCs.

Table 5: Cosmetic product frame formulations with indicative use values (M_{SPERC}) for specified production scales

Product domain	Substance's function	Indicative C_{SP} values*	$M_{Finished}$ (tonnes/year)**			$T_{emission}$ (days)			M_{SPERC} (tonnes/day)*		
			Small production	Medium production	Large production	Small production	Medium production	Large production	Small production	Medium production	Large production
Liquid cosmetic products of low viscosity	Abrasives	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Additives	20	<1 000	10 000	50 000	100	300	300	<2	6.7	33.3
	Alkalinity sources	12	<1 000	10 000	50 000	100	300	300	<1.2	4	20
	Colourants	0.5	<1 000	10 000	50 000	100	300	300	<0.05	0.17	0.83
	Fatty acids	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Fragrances	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Glycerine	12	<1 000	10 000	50 000	100	300	300	<1.2	4	20
	Mineral oils	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Natural oils	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Oxidising Agents	12	<1 000	10 000	50 000	100	300	300	<1.2	4	20
	Polymers	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Preservatives	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Salt	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Solvents	3	<1 000	10 000	50 000	100	300	300	<1.2	2	5
	Surfactants	40	<1 000	10 000	50 000	100	300	300	<4	13.3	66.7
Liquid alcohol-borne products (cleaning with water)	Additives	20	<1 000	10 000	50 000	100	300	300	<2	6.7	33.3
	Alcohol, low boiling	98	<1 000	10 000	50 000	100	300	300	<9.8	32.7	163
	Alkalinity sources	1	<1 000	10 000	50 000	100	300	300	<0.1	0.33	1.67
	Fragrances	30	<1 000	10 000	50 000	100	300	300	<3	10	50
	Glycerine	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Natural oils	1	<1 000	10 000	50 000	100	300	300	<0.1	0.33	1.67
	Polymers	12	<1 000	10 000	50 000	100	300	300	<1.2	4	20
	Surfactants	1	<1 000	10 000	50 000	100	300	300	<0.1	0.33	1.67
Cosmeticproducts of high viscosity	Abrasives	20	<1 000	10 000	50 000	100	300	300	<2	6.7	n.a.
	Additives	6	<1 000	10 000	50 000	100	300	300	<0.6	2	n.a.
	Alkalinity sources	6	<1 000	10 000	50 000	100	300	300	<0.6	2	n.a.
	Colourants	0.5	<1 000	10 000	50 000	100	300	300	<1	1.7	n.a.
	Fatty acids	12	<1 000	10 000	50 000	100	300	300	<1.2	4	n.a.
	Fragrances	3	<1 000	10 000	50 000	100	300	300	<0.3	1	n.a.
	Glycerine	12	<1 000	10 000	50 000	100	300	300	<1.2	4	n.a.
	Mineral oils	15	<1 000	10 000	50 000	100	300	300	<1.5	5	n.a.
	Natural oils	3	<1 000	10 000	50 000	100	300	300	<0.3	1	n.a.

Product Domain	Substance's Function	Indicative C_{SP} values*	$M_{Finished}$ (tonnes/year)**			$T_{emission}$ (days)			M_{SPERC} (tonnes/day)*		
			small production	medium production	large production	small production	medium production	large production	small production	medium production	large production
Cosmeticproducts of high viscosity (continued)	Pigments	15	<1 000	10 000	50 000	100	300	300	<1.5	5	n.a.
	Polymers	12	<1 000	10 000	50 000	100	300	300	<1.2	4	n.a.
	Preservatives	0.5	<1 000	10 000	50 000	100	300	300	<1	1.7	n.a.
	Salt	3	<1 000	10 000	50 000	100	300	300	<0.3	1	n.a.
	Solvents	6	<1 000	10 000	50 000	100	300	300	<0.6	2	n.a.
	Surfactants	40	<1 000	10 000	50 000	100	300	300	<4	13.3	n.a.
	Waxes & Paraffines	15	<1 000	10 000	50 000	100	300	300	<1.5	5	n.a
Non-liquid creams	Abrasives	30	<1 000	10 000	50 000	100	300	300	<3	10	50
	Additives	9	<1 000	10 000	50 000	100	300	300	<0.9	3	15
	Colourants	0.5	<1 000	10 000	50 000	100	300	300	<0.05	0.17	0.83
	Emulsifiers	12	<1 000	10 000	50 000	100	300	300	<1.2	4	20
	Fatty acids	3	<1 000	10 000	50 000	100	300	300	<0.3	1	5
	Fragrances	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Glycerine	25	<1 000	10 000	50 000	100	300	300	<2.5	8.3	41.7
	Pigments	15	<1 000	10 000	50 000	100	300	300	<1.5	5	25
	Polymers	1	<1 000	10 000	50 000	100	300	300	<0.1	0.33	1.67
	Preservatives	0.5	<1 000	10 000	50 000	100	300	300	<0.05	0.17	0.83
	Silica	9	<1 000	10 000	50 000	100	300	300	<0.9	3	15
	Solvents	1	<1 000	10 000	50 000	100	300	300	<0.1	0.33	1.67
	Surfactants	6	<1 000	10 000	50 000	100	300	300	<0.6	2	10
	Waxes & Paraffines	90	<1 000	10 000	50 000	100	300	300	<9	30	150
Solid cosmetic products	Abrasives	6	<1 000	10 000	50 000	150***	300	300	<0.4	2	10
	Additives	1	<1 000	10 000	50 000	150***	300	300	<0.07	0.33	1.67
	Alkalinity sources	30	<1 000	10 000	50 000	150***	300	300	<2	10	50
	Fatty acids	60	<1 000	10 000	50 000	150***	300	300	<4	20	100
	Fragrances	3	<1 000	10 000	50 000	150***	300	300	<0.2	1	5
	Glycerine	12	<1 000	10 000	50 000	150***	300	300	<0.8	4	20
	Natural oil	9	<1 000	10 000	50 000	150***	300	300	<0.6	3	15
	Salt	1	<1 000	10 000	50 000	150***	300	300	<0.07	0.33	1.67

* As concentrations of substances in finished products may vary over a broad range due to the complexity of the cosmetics industry, C_{SP} values in this table represent the upper limit as derived from frame formulations published by Umbach (Umbach, 2004). Therefore, also M_{SPERC} figures represent an upper estimate and are very conservative.
** For methodological reasons, the calculation requires of a maximum value for $M_{Finished}$. The figure for the large production volume is considered as maximum.
*** Referenced by the European Chemicals Bureau (ECB) in the B-tables for chemical formulation processes found in the Technical Guidance Document on Risk Assessment (Part II: Environmental Risk Assessment) (ECB, 2003).