Ministry of Environment and Gender Equality
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Survey and risk assessment of bath products for children

Survey of chemical substances in consumer products No. 200

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Declaration of consultant reports drafted for public authorities

The title of the report:
Survey and risk assessment of bath products for children

Purpose of the report:
The purpose of the project has been to build knowledge about which ingredients are used in different bath products targeted at children. Including which fragrance ingredients and colourants, as well as other potentially problematic substances these products may contain. In addition, the aim of the project was to investigate whether this type of product could constitute a risk to children.

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FORCE Technology with DHI as a subcontractor

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Preface

Survey and risk assessment of bath products for children

In this project, various bath products targeted at children have been examined. The focus has been on chemical bath products, such as bath bombs, bath beads, bathwater colours, bath slime and foam bath. All products are sold specifically for children and for use in bathtubs. The results of the survey, chemical analyses, and risk assessment of the selected chemical substances are presented in this report.

The project was carried out by FORCE Technology with DHI as a subcontractor. DHI was responsible for the description of exposure scenarios, selection of chemical substances for analyses, hazard assessment and subsequent risk assessment. FORCE Technology was responsible for mapping, product procurement, all chemical analyses and project management of the project.

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The project was funded by the Danish EPA.

The project was carried out between April 2023 and November 2023.

Summary

Bath products for children are added to the bathwater to make bathing fun and/or to clean the child due to the chemical ingredients added to the product. The bath products can foam, contain different colours, or transform the bathwater into slime or jelly. Many products contain fragrance ingredients that smell like strawberries, watermelon, etc. The products may be covered by the rules for either toys or cosmetic products (or both) depending on the purpose of the individual product.

The types of bath products that have been studied in this project are the products below, which are a mixture of dry and wet ingredients moulded into a specific shape and then dried. They all dissolve directly in the bathwater and may release colour and/or fragrance:

- Bath balls/bath bombs – larger balls, some of which contain a toy (a figure) inside that appears when the bath bomb has dissolved.
- Bath beads/bath crystals – smaller beads.
- Crackle powder/bath salts – powder or small balls/pieces that make the water crackle/sizzle.
- Bathwater volcano – powder that crackles and bubbles like a volcano (through a small opening in the packaging) when it comes into contact with the water.
- Bathwater colours – small tablets or balls in different colours to colour the bathwater as desired.

In addition, the following other types of bath products have been investigated in this project, which differ from the above products listed:

- Foam bath – liquid soap that produces a lot of foam in the bathwater. May also contain colour and fragrance.
- Modelling soap/coloured soap – different types of soap, such as solid soap that becomes mouldable in contact with hot water and spray foam soap in different colours that can be sprayed in different patterns.
- Bath slime/bath gel – powder that turns the bathwater into either coloured slime or coloured jelly lumps.

Purpose

The purpose of the project has been to build knowledge about which ingredients are used in different bath products targeted at children. Including which fragrance ingredients and colourants, as well as other potentially problematic substances these products may contain. In addition, the aim of the project was to investigate whether this type of product could constitute a risk to children.

Survey

The survey showed that there are several different types of bath products for children and that many of the products contain ingredients that are typical for cosmetic products. An overview of approx. 90 different bath products for children was compiled, where the ingredients were analysed if these were available online in the webshop.

Ingredients such as sodium bicarbonate and citric acid are typical for products such as bath balls, crackle powder, bathwater colours and bathwater volcanoes, whereas common salt (sodium chloride) is typically used in bath crystals and bath salts. Products like bath gel and bath slime are significantly different as they typically consist of a polyacrylate (bath gel) and polyacrylamide or polycarboxylate (bath slime) as the primary ingredients to form the jelly-like or slimy consistency. In addition, the majority of products contain various fragrance ingredients and colourants. It is mainly aqueous products such as foam baths that contain preservatives.

The literature study conducted in the survey showed that the main health concern regarding bath products for children is that the majority of the products contain allergenic fragrances and that some of the products may contain carcinogenic azo dyes. This picture was confirmed by a review of the ingredient list of 45 selected products.

For these 45 bath products with ingredient lists, the following was observed:
- 82% of the products contain perfume and/or essential oils (37 out of 45 products).
- 73% of the products are coloured and contain one or more colourants (33 out of 45 products), although the colourants were not necessarily specifically declared on the products.

Several of the perfumed products (10 products) contained fragrances subject to mandatory labelling. The majority of the products that did not contain colourants were bubble bath products (9 out of 11).

Prioritising substances and purchasing products for analysis
The 45 products contained a total of approximately 180 different ingredients, all of which were ingredients typical of cosmetic products (with the exception of the main ingredient in bath slime and bath gel). From this list of ingredients, the substances were prioritised based on the classification of the ingredients. Products with ingredients with health classifications of concern were prioritised when purchasing 42 products for the chemical analyses. The 42 products were selected from a total of approximately 90 identified bath products for children.

However, products were also purchased so that all of the above product types were represented, and that half of the products were purchased from Danish websites, a quarter from websites in the EU and the remaining quarter from websites outside the EU.

Screening analyses
Based on the ingredient lists of the 42 products purchased for analysis, a prioritisation of ingredients was made based on the classification of the substances, the presence on the EU list of suspected endocrine disruptors or whether or not being in scope of the special mandatory labelling of allergenic fragrances in cosmetic products. The prioritisation also consisted of which screening analyses to focus on initially for the chemical analyses.

pH measurements were performed on concentrated solutions of all 42 purchased bath products, as many of the ingredients are classified as skin and/or eye irritants and some ingredients are classified with Eye Dam. 1, whereby they can cause serious eye damage in high concentrations. In addition, GC-MS screening of the 23 products containing fragrances (but without a declared content of fragrance ingredients subject to mandatory labelling) was performed to analyse for content of some of the substances subject to mandatory labelling today or that will be subject to mandatory labelling in the future.

The results of the GC-MS screening showed that all products contain a wide range of different volatile organic substances in small amounts. Up to about 120 different substances (or isomers of substances) were seen in a single product. This is an indication that the plant extracts used in some of the products contain a wide range of different chemical substances. As this was a screening analysis, the focus was on at least the five largest peaks in the GC-MS chromatograms, as well as the fragrances subject to mandatory labelling and BHT (antioxidant suspected of being an endocrine disruptor).

The GC-MS screening identified 150 different substances in the analysed products combined. Half (12) of the 24 fragrance ingredients subject to mandatory labelling were identified in several of the 23 selected products, and eight of the fragrance ingredients that will be subject to

mandatory labelling in the future, were identified in some of the analysed products. BHT was identified in seven products.

Selection of substances and products for quantitative analyses
Based on the results of the screening analyses, the hazardousness of the substances, the availability of toxicological data and the availability of the substances as reference substances, the following five substances were focused on in the subsequent quantitative analyses:

- Colourant CI 15510 as the substance is an azo dye and classified for organ toxicity (STOT RE 1, H372).
- Colourant CI 18050, as the substance is an azo dye and is classified as allergenic.
- BHT, as the substance is suspected of being an endocrine disruptor.
- HHCB, as the substance is suspected of being an endocrine disruptor and is also one of the fragrance ingredients that will be subject to mandatory labelling in the future.
- *Endo*-borneol as the substance is classified for organ toxicity (STOT SE 2, H371).

Fifteen products were selected for quantitative analyses for these five prioritised substances. Of these, seven products were selected for analysis of BHT, HHCB and *endo*-borneol, five products were selected for analysis of CI 15510 and CI 18050, and three products were selected for analysis of all five prioritised substances.

The results of the quantitative analyses were as follows:

- The colourant CI 15510 was identified in two of eight products at concentrations of 1 and 47 mg/kg respectively.
- The colourant CI 18050 was identified in two of eight products at concentrations of 16 and 29 mg/kg, respectively.
- BHT was identified in eight out of ten products at concentrations between 0.01 and 50 mg/kg.
- HHCB was identified in all ten products at concentrations between 0.01 and 1862 mg/kg.
- *Endo*-borneol was identified in six out of ten products at concentrations between 0.03 and 76 mg/kg.

Exposure and hazard assessment
The Danish Environmental Protection Agency and the Danish Safety Technology Authority carried out an assessment of the 15 products to determine whether the products should be considered a toy, a cosmetic product or both. The assessment was based on the available information, including, among other things, the design of the product, the information on the packaging and the intended use of the product.

For toys, the risk assessment guidelines in the REACH guidelines are used, whereas cosmetic products must be assessed based on the so-called Notes of Guidance from the SCCS (Scientific Committee on Consumer Safety) (SCCS, 2023). For the few products that were assessed to be both a toy and a cosmetic product, the REACH risk assessment method was used, as modelling showed that this method was the most restrictive.

When reviewing the data for the five prioritised substances, it was assessed that there was a well-founded toxicological data basis for the hazard and risk assessment of the substances. On this basis, the uncertainties associated with the assessments of the substances are considered to be limited.

Risk assessment and conclusion
The risk assessment of the five priority substances in the 15 products analysed shows that for the vast majority of the products, there is no health risk associated with exposure to these substances in the products. However, for one product NEU 41 - KBS (crackling powder/bath salts purchased and produced outside the EU), the content of the fragrance ingredient HHCB is so

high (0.18%) that the substance, which is a skin sensitiser and suspected endocrine disruptor, is assessed to constitute a risk to children during repeated use of the bath salt product.

Of the 15 products selected for the quantitative analyses, over half (eight) of them were purchased outside the EU. Considering that 50% of the products were purchased from Danish shops/web shops and 25% each from EU and non-EU, it is striking that one or more of the five prioritised substances were identified in twice as many non-EU products as in EU and DK products combined. As products purchased outside the EU often do not contain an ingredient list, the results of this project show that there is reason to be aware of purchasing these types of products outside the EU.

It must be emphasised that the risk assessment has only been carried out with regard to the content of the five prioritised substances, and that the assessment does not include other known/unknown substances. However, the content of a number of skin sensitising substances (typically in the form of fragrance ingredients) in over 80% of the purchased bath products is considered highly undesirable, especially when it comes to relatively intensive skin exposure to this type of product to young children.

1. Introduction

Many bath products for children are sold with the aim of making the time the children spend in the bath a fun experience. The bath products can foam, contain glitter and different colours, or transform the bathwater into slime or jelly. Some products contain fragrance ingredients that smell like strawberries, coconut, orange, watermelon, etc. The products are covered by the Cosmetics Regulation[1] and/or the Toy Safety Order[2] depending on the purpose of the individual product.

In 2020, the Danish Consumer Council Tænk Kemi investigated bath bombs and bath slime and found that all nine products investigated contained either perfume and/or azo dyes, which can be allergenic. For this reason, the Danish EPA has initiated this project to further investigate bath products targeted at children.

1.1 Purpose

The purpose of the project is to gain knowledge about which ingredients are used in different bath products targeted at children. This includes which fragrance ingredients, colourants and preservatives, as well as other potentially problematic substances, these products contain. In addition, the purpose of the project is to investigate whether this type of product can constitute a risk to children.

1.2 What are bath products for children?

For the purpose of this project, bath products for children are defined as chemical products that are added to the bathwater in the bathtub to make bathing fun and/or clean the child due to the added ingredients in the product. A bath product may be a bath foam in the form of foam soap or a bath bomb, which is a compressed mixture of wet and dry ingredients that is moulded into a shape and then dried[3]. The bath bomb is placed in the bathtub (bathwater), where it dissolves. Bath products may also contain colours to colour the bathwater, even though the product may not contain cleaning ingredients.

Therefore, for the purpose of this project, bath products for children do *not* include 'toys for use in a bathtub'. That is, bath ducks, other bath toys or products such as crayons to draw on the inside of the bathtub are outside the project's scope of bath products for children. However, the bath products investigated in this project can also be toys.

Some bath products for children are purely cosmetic products, such as some foam bath products. On the other hand, if a propellant (e.g., a gas), stabiliser or colourant is added so that the soap can be sprayed or shaped into different forms, it is also a product that can be played with. Many bath products for children can therefore be perceived as both a cosmetic product[4]

[1] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

[2] Statutory Order on Toys no. 815 of 07/06/2022

[3] https://en.wikipedia.org/wiki/Bath_bomb

[4] The definition of cosmetic products is set out in Article 2(1)(a) of the Cosmetics Regulation (EU Regulation 1223/2009). See section 2.1.1 of this report for the exact definition.

(cleans the child, nurtures the skin, etc.) and a toy[5] (the product can be played with or comes with a toy). For example, some bath bombs contain toy figures that emerge when the entire bath bomb is dissolved in the bathwater. Other bath bombs can be shaped like an animal or a rocket, so this type of bath product has both a cosmetic and a playful purpose.

Other bath products may be purely for play and are not necessarily a cosmetic product, i.e., they are not intended to clean the child, make the skin smell clean, etc. These types of products can include bathwater colours (which simply colour the bathwater to make it more interesting) or products such as bath slime and bath gel.

The different types of bath products identified and investigated in this project are described in more detail in TABLE 1 below. The description of the products is based on the products identified in the survey of this project. It will always be the overall impression of the individual product, i.e., an assessment of claims, images, product ingredients, design, form of use, presentation, etc., that will determine whether the product is assessed as a cosmetic product and/or a toy.

TABLE 1. Different types of bath products

Bath product type	Description	Designation of product type used in this project
Bath balls Bath bombs	Compressed mixture of wet and dry ingredients that are moulded into a shape and then dried. Dissolves in the bathwater and may give off colour to the water.	Bath balls/bath bombs
Bath beads Bath crystals	Are powder shaped like small beads or crystals that dissolve in the bathwater. May add colour and fragrance to the bathwater.	Bath beads/crystals
Crackle powder Bath salts	Powder moulded into small balls/pieces. Makes the water crackle and sizzle. Can add colour and fragrance to the water.	Crackle powder/bath salts
Foam bath	Soap that creates extra foam. The foam may be coloured.	Foam bath (also coloured)
Bathwater volcano	Powder that crackles and bubbles like a volcano when it comes into contact with the bathwater. Is a form of powder, similar to crackle powder or bath bombs, that is emitted from a small opening in a pouch and produces a volcano-like effect.	Bathwater volcano
Bathwater colours	Powder or small hard balls/'buttons' that are added to the bathwater to give it colour.	Bathwater colours
DIY bath product kits	Contains ingredients to make your own bath bombs, for example	DIY kit
Modelling soap	A solid soap that becomes mouldable when heated in warm water.	Modelling soap/coloured soap
Soap in spray form	Soap that can be foamed, sprayed and used to draw different shapes and patterns. In different colours.	
Coloured soap	These are soaps that come in different colours so the child can see how much of their body is covered in soap.	

[5] The definition of toys can be found in Annex 1 of the Danish Toy Order (Statutory Order no. 815, 2022). See section 2.2.1 of this report for the exact definition.

Bath product type	Description	Designation of product type used in this project
Collection of several different types of the above-mentioned bathing products.	This simply involves the sale of packages containing various types of bathing products for children, allowing them to try out different varieties.	Collection of multiple types
Bath slime	Powder that turns the bathwater into a coloured slime.	Bath slime/gel
Bath gel	Powder that transforms the bathwater into coloured jelly lumps. After playing, add powder again so that the gel becomes liquid and can be flushed down the drain.	

1.3 Scoping and prioritisation

Thus, children's bath products which have been included in this project are a chemical product that is added to the bathwater in the bathtub for either one or both of the following purposes:

- Playful purpose: Making the bath a game
- Cosmetic purpose: e.g., to clean the child due to the ingredients in the product, to make the child emit fragrance due to the added perfume in the product, etc.

This means that products such as finger paints or markers intended for use in the bathtub and drawing on the bathtub walls are not included in this project. These are not products that need to be added to the bathwater like other products.

In co-operation with the Danish EPA, it was decided to limit this project to focus exclusively on products specifically targeted at children. This includes products such as:

- sold on websites with products only for children
- sold in toy stores (physical or online)
- contain images or figures/drawings that appeal to children
- contains images on the website stating that the product can be used by children
- contains words like "children" or "kids" or similar in the product name or product description

Products that contain warnings such as "keep out of reach of children", even if the products are sold in stores that may appeal to children, are not included in the study.

Do-it-yourself products are not included in the project unless they are self-mixing kits that contain all the ingredients needed to make the finished product. By agreement with the Danish EPA, kits for self-mixing were included in the survey, but not for analyses.

The project is also limited to focusing solely on chemical bath products and not on toy figures that may be included with the bath product or emerge when, for example, a bath ball has dissolved.

1.4 Naming of chemical substances in the report

In this report, we have chosen to use the so-called INCI names for the naming of chemical substances when it comes to ingredients in cosmetic products. INCI names are International Nomenclature Cosmetic Ingredients. In the case of non-cosmetic ingredients, the naming has been used as stated by ECHA in their database "Information on chemicals"[6].

[6] https://echa.europa.eu/da/information-on-chemicals

2. Legislation

It will depend on the specific bath product whether the product will be classified exclusively as a cosmetic product, exclusively as a toy or both a toy and a cosmetic product. The legislation for cosmetic products and toys is described below. The focus is on the aspects of the legislation that are relevant to this project. Furthermore, the Danish legislation and EU legislation regarding microplastics are described as some bath products may contain microplastics (e.g., in the form of glitter).

2.1 Legislation for cosmetic products

The legislation for cosmetic products is described in the Cosmetics Regulation (EU Regulation 1223/2009). As it is a regulation, the rules apply directly in all EU countries, including Denmark. The Cosmetics Regulation regulates, among other things, which substances are allowed to be used in cosmetic products.

The Cosmetics Regulation contains several provisions regarding, among other things, safety, labelling of products (e.g., ingredient list requirements) and the content of chemical substances in cosmetic products. The Cosmetics Regulation contains several restrictions on various chemical substances described in the annex of the regulation. For example, only certain colourants (Annex IV), preservatives (Annex V) and UV filters (Annex VI) are allowed. In addition, several chemical substances are directly prohibited for use in cosmetic products (Annex II) and finally, several chemical substances are only authorised for use in cosmetic products in accordance with established restrictions (Annex III).

Below, selected aspects of the Cosmetics Regulation relevant to this project are described in detail.

2.1.1 Which bath products are cosmetic products?

Cosmetic products are defined according to Article 2(1)(a) of the Cosmetics Regulation as *"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours"*.

This means that all bath products for children whose main purpose is to clean the skin will be subject to the Cosmetics Regulation. Many of the products also contain fragrance ingredients, where the main purpose is considered to be to perfume the skin (correcting body odours). Examples include that the bath products "leave your child's skin pleasantly scented" and similar claims. Finally, some of the products contain various oils that are intended to "nourish" or "perfume" the skin.

Among the examined bath products for children in this project, the majority of the products would fall under the category of cosmetic products as they are intended to cleanse and/or nurture children's skin, and/or correct body odour (perfume). However, product types such as bath slime/gel and bathwater colours may not necessarily fall within the definition of cosmetic products. Bath slime/gel does not contain cleansing ingredients, and these products are primarily

sold with a play purpose rather than a cleansing purpose. If the products contain fragrance ingredients, it could be argued that the purpose is to mask the chemical odour of the products rather than to leave the child pleasantly scented, which has also been seen in previous surveys, for example by the Danish EPA regarding modelling clay (Poulsen et al., 2016). This will depend on the individual products. For bathwater colours, it will depend on the ingredients in the product, including whether they contain cleaning, conditioning and/or perfuming ingredients, and whether they are also intended to clean and correct body odour rather than just colour the water in the bathtub.

2.1.2 Safety assessment

According to Article 3 of the Cosmetics Regulation, a cosmetic product made available on the EU market must be safe for human health when used under normal or reasonably foreseeable conditions. In order to demonstrate that a cosmetic product is safe for human health, cosmetic products must undergo a safety assessment (Article 10) before being placed on the market.

2.1.3 Ingredient list

According to Article 19(1)(g) of the Cosmetics Regulation, cosmetic products must be labelled with a list of ingredients, which is defined as ”*any substance or mixture intentionally used in the cosmetic product during the process of manufacturing*”. Impurities in raw materials are not considered to be ingredients. The list begins with the term "ingredients".

Therefore, it is possible to examine the product packaging to determine which ingredients have been used in the cosmetic products. In the ingredient list, the ingredients must be indicated by their INCI name, i.e., the International Nomenclature Cosmetic Ingredients. An INCI name can cover several different chemical substances.

In the ingredient list, ingredients must be listed in order of decreasing weight/content. However, ingredients in a concentration below 1% can be listed in any order after the ingredients with concentrations higher than 1%. There are special considerations for the labelling of colourants and fragrance ingredients:

- Fragrance ingredients should be listed collectively as "perfume" or "aroma". Therefore, it is not clear from the ingredient list exactly which fragrance is used. However, 24 specific fragrance ingredients must be listed on the ingredient list by their INCI name if their concentration exceeds 0.001% in leave-on products or 0.01% in rinse-off products (according to Annex III).
- Colourants that are not intended for hair colouring purposes can be listed in any order after the other ingredients. For decorative cosmetics marketed in a range of colour shades, the colourants used can be listed on the ingredient list with the words "may contain" or the symbol "+/-". The CI (Colour Index) nomenclature should be used where applicable.

2.1.4 Colourants

According to Article 14(1)(c) of the Cosmetics Regulation, cosmetic products may only contain colourants listed in Annex IV "List of colourants allowed for use in cosmetic products" and used under the specified conditions (such as limited to certain product types, specific body parts, or within a maximum permitted concentration).

2.1.5 Preservatives

According to Article 14(1)(d) of the Cosmetics Regulation, cosmetic products may only contain preservatives listed in Annex V "List of preservatives allowed for use in cosmetic products" and used under the specified conditions (such as limited to certain product types, specific body parts, or within a maximum permitted concentration).

2.1.6 CMR substances

According to Article 15 of the Cosmetics Regulation, substances classified as carcinogenic (Carc.), mutagenic (Muta.) or toxic to reproduction (Repr.) (referred to as CMR substances) with category 1A, 1B or 2 are not allowed to be used in cosmetic products. However, there may be exceptions where such substances may be authorised under certain conditions, including when the SCCS[7] (Scientific Committee on Consumer Safety) has evaluated the substances and found them safe for such use. Different requirements apply for category 1 and category 2 substances for such an exemption.

For substances where a harmonised classification is adopted, a ban on that substance will automatically take effect on the date the CMR classification applies.

2.1.7 Fragrance ingredients

A specific mandatory labelling requirement applies to 24 fragrance ingredients. These 24 fragrance ingredients are listed separately in Annex III of the Cosmetics Regulation and, as described above, must be listed separately by their INCI name in the ingredient list if their concentration exceeds 0.001% in leave-on products or 0.01% in rinse-off products. All types of bath products in this project were rinse-off products.

During this project, an amendment to the Cosmetics Regulation regarding an expansion of the number of fragrance ingredients subject to mandatory labelling to a total of 81 fragrances, was decided (EU Regulation 2023/1545). This proposal was published in the Official Journal of the European Union, July 27, 2023, and became effective 20 days after this date. However, a transition period of three years for placing of products on the market and five years for making cosmetic products available on the market, from the date of entry into force, has been established.

By the term “fragrances subject to mandatory labelling” used in this report, is meant the 24 fragrances subject to mandatory labelling today (2023). Otherwise, the terms “the future” or “the new fragrances subject to mandatory labelling” are used for the extra fragrances that in the future must be labelled (up to the total of 81 fragrances).

2.2 The legislation for toys

The Danish Statutory Order on toys from 2022[8] (Statutory Order no. 815, 2022) implements the EU Toy Safety Directive (EU Directive 2009/48) and subsequent amendments such as amendments to Annex II of the Toy Safety Directive regarding the restriction of allergenic fragrances in toys (EU Directive 2020/2089) and regarding the labelling of allergenic fragrances (EU Directive 2020/2088). The EU's basic chemicals legislation, the REACH Regulation (1907/2006), contains some restrictions on chemical substances that are also relevant for toys.

Below, selected aspects of the Danish Order on Toys and the REACH Regulation relevant to this project are described in more detail.

2.2.1 Definition of toys

The Danish order on toys, cf. section 1(1), applies to “*products which are exclusively or partly designed or intended for use in play by children under 14 years of age*”. However, certain types of toys are exempted, such as playground equipment intended for public use, slingshots,

[7] In English: EU Scientific Committee on Consumer Safety (SCCS)

[8] Statutory Order on Toys, no. 815 of 07/06/2022

toy steam engines, as well as scooters, sports equipment, etc., as listed in Appendix 1 of the order (Statutory Order no. 815, 2022).

2.2.2 Safety requirements for toys

According to the Danish order on toys, toys may only be placed on the market if they fulfil the safety requirements listed in section 26 and Annex 2 of the order. According to section 26, a toy product, including the chemicals it contains, must not endanger the health and safety of users or other persons when used in a way that children are likely to use the product. When assessing whether a toy product poses a risk, "the ability of the users, and where appropriate, their supervisors ability to handle the toy product shall be taken into account. This applies in particular to toy products intended for children under 36 months or other specific age groups".

Appendix 2 describes safety requirements for physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity.

2.2.3 Chemical properties

According to Annex 2 on 'Safety requirements' Part III 'Chemical properties' of the Danish Order on Toys, toy products must "*be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain, when the toys are used as specified in section 26*", i.e., used in a way that children are expected to use the product.

Toy products that are themselves a substance or a mixture (like the children's bath products included in this project) must also comply with the CLP Regulation (EU Regulation 1272/2008).

The Danish Order on Toys sets the following requirements (restrictions) for the content of chemical substances in toys:

- Restriction of the use of CMR substances (Annex 2, Part III, items 3-7)
- Restriction of the use of N-nitrosamines and nitrosable substances (Annex 2, Part III, item 8)
- Restriction of the use of allergenic fragrances (Annex 2, Part III, item 11)
- Restriction of migration of certain elements (Annex 2, Part III, item 13)

N-nitrosamines, nitrosable substances and migration of elements are not the focus of this project and are therefore not discussed further.

Additionally, in Appendix C of the Toy Safety Order, specific limit values are set for chemical substances (such as preservatives), but these limits apply only to toys intended for use by children under 36 months or for other toys intended to be placed in the mouth. These limitations, therefore, only apply to the few products purchased in this project that were also recommended for children under the age of three.

2.2.4 Restricting the use of CMR substances

According to Annex 2 of the Danish Order on Toys (Part III on "Chemical properties", sections 3, 4 and 5), substances classified as CMR category 1A, 1B or 2 cannot be used in toys, in toy components or in micro-structurally distinct toy parts.

CMR substances can be used in concentrations below the general classification limits set out in the CLP Regulation on classification, labelling and packaging of substances and mixtures. If specific classification limits are set for individual substances, the specific classification limits will apply. In addition, CMR substances may be used if these substances and mixtures are inaccessible to children (including by inhalation) when the toy is used in a manner that can be

reasonably expected for children to use it. If specific classification limits have not been established for individual substances, the general classification limits apply, which are as follows:

- Carc. and Muta. category 1A and 1B: 0.1% (1000 ppm)
- Repr. category 1A and 1B: 0.3% (3000 ppm)
- Carc. and Mut. Category 2: 1.0% (10,000 ppm)
- Repr. category 2: 3.0% (30,000 ppm)

However, CMR substances can be exempted if the substance is not restricted under REACH and if they have been assessed as safe to use by the relevant Scientific Committee authorised by the Commission and are listed in Appendix A of the Order. Furthermore, CMR 1A and 1B substances can only be exempted if no alternatives are available. As of May 2023, Appendix A only contains the substance nickel, which has a classification as Carc. 2.

2.2.5 Restricting the use of allergenic fragrances

According to the Danish Order on Toys, Annex 2, Part III, item 11, toy products cannot contain 58 specific allergenic fragrances in concentrations above 100 mg/kg, provided that their presence is technically unavoidable through good manufacturing practice. In addition, 71 other fragrances must be indicated on the toy product, on a label on the packaging itself or in an accompanying leaflet if they are used in toy products at concentrations exceeding 100 mg/kg in the toy product or its components.

Fragrances (as they are called in the Danish Toy Order) are generally referred to as fragrance ingredients in this report.

2.2.6 Limitations in Appendix C

Appendix C of Annex 2 of the Danish Order on Toys contains specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be put in the mouth. These limit values will therefore only be applicable to the few bath products purchased in this project that are also recommended for use by children under three years old.

Appendix C contains limit values for a number of preservatives that are also restricted in the legislation for cosmetic products, including isothiazolinones. Benzisothiazolinone (BIT) may be used in toys, but not in cosmetic products. The remaining substances listed in Appendix C, such as some flame retardants, bisphenol A, formaldehyde, formamide and phenol, are not expected to be used in this type of product (and are not allowed to be used in cosmetic products as they are listed in Annex II of the Cosmetics Regulation).

2.3 Legislation on microplastics

In 2022, the EU drafted a proposal for legislation on microplastics (EU Commission, 2022). The proposal on microplastics was drafted as a restriction to be included in Annex XVII of the REACH regulation. The proposal was submitted to the REACH Committee on 30 August 2022, and was adopted on 25 September 2023 (EU Regulation 2055/2023). The proposal concerns a broad restriction against microplastics that will apply to microplastics in general and in mixtures that include them (including cosmetic products). However, a transition period exists, meaning that the restriction of microplastics in rinse-off cosmetic products, will not apply before 17 October 2027.

Microplastics are currently permitted in products in the EU today (spring 2023) and thus permitted in the bath products for children that have been studied in this project. However, Danish legislation regarding microplastics in cosmetic products exists (Statutory Order no. 655, 2020). This is described in more detail below.

2.3.1 Danish legislation regarding microplastics in cosmetic products

The Microplastics Order (Statutory Order no. 655, 2020) defines microplastics in section 1, no. 4) as "*plastic in solid state, which is less than or equal to 5 mm in all dimensions and insoluble in water*". Plastic is defined in section 1(3) as "a synthetic polymeric substance that can be moulded, extruded or physically manipulated into various solid forms, and retains its final manufactured form when used in its intended applications".

According to the Microplastics Order, it is prohibited to import and sell cosmetic products that contain microplastics in a concentration of 0.01% (100 ppm) or more in rinse-off products. The ban only applies to microplastics that are not biodegradable. Biodegradable microplastics are microplastics that fulfil the criteria for biodegradability according to the test methods listed in Annex 1 to the order. The Microplastics Order came into force on 1 July 2020.

Microplastics are thus banned in bath products for children in Denmark if these products are cosmetic products and if they contain microplastics that are not biodegradable. The use of microplastics in the form of glitter will most likely be covered by this ban, depending on its biodegradability.

3. Survey

The market for bath products marketed to children was investigated. The survey was carried out using the following sub-elements:

- Searching the internet for different types of bath products for children, including identification of products with a description of the ingredient list (ingredients)
- Searching for bath products for children in selected Danish stores
- Searching for previous studies and tests on bath products for children
- Contacting selected distributors/internet shops that sell various bath products for children
- Contacting the Danish Consumer Council Tænk Kemi, including extracts from their database Kemiluppen
- Purchasing products

The survey was carried out over a period of approximately one month due to the project's timeline. For this reason, neither the cosmetics industry nor the toy industry was contacted. Information about the ingredients in the products was solely collected via the products' ingredient lists – either from the websites where the products were sold or from purchased products.

3.1 Previous studies on bath products for children

A search was conducted for previous studies and tests of bath products for children. The following tests were identified and are described in more detail in the individual sections below.

3.1.1 Testfakta, Swedish test, 2016

In 2016, the Swedish test and research organisation "Testfakta" examined a total of 16 different bath products for children, consisting of body wash and foam bath (Testfakta, 2016). Seven of the products were foam baths.

The test was a declaration test, i.e., the products were judged solely on the ingredients listed in the ingredient list. The classification of ingredients was reviewed, and it was noted whether the products contained possible allergenic or endocrine disrupting substances.

Of the seven foam bath products, only one product did not contain any substances of concern. This product was eco-labelled (Nordic Swan Ecolabel). Five of the seven foam bath products contained fragrance (indicated by the ingredient "perfume"), which can be allergenic. Of these, one of the five fragrance-containing products contained one ingredient subject to mandatory labelling (limonene). Three foam bath products contained the preservative phenoxyethanol, which has a harmonised classification as Acute Tox. 4, H302 "Harmful if swallowed". Testfakta considered this to be problematic in products intended for young children who may be at risk of ingesting some of the bathwater.

3.1.2 Consumer Council Tænk Kemi, 2020

In 2020, the Danish Consumer Council Tænk Kemi carried out a so-called declaration test of nine chemical bath products for children (Consumer Council Tænk Kemi, 2020), i.e., based on the information available via the ingredient list on the product. The nine bath products were three bath slimes and six bath bombs. Of the six bath bombs, four contained perfume, two of which also contained allergenic plant extracts. Five of the bath bombs contained azo dyes. The product without azo dyes contained perfume.

The Danish Consumer Council Tænk Kemi states that it is the combination of baking soda (sodium bicarbonate; INCI name: sodium bicarbonate) and citric acid (INCI name: citric acid) that gives the sizzling and bubbling effect when the bath bomb is added to the bathwater.

All three bath slime products contained fragrance, but none of them contained any of the 24 fragrance ingredients that are subject to mandatory labelling. However, all three bath slime products contained azo dyes, which can be allergenic. Furthermore, the Danish Consumer Council Tænk Kemi states that some azo dyes are suspected to increase the risk of cancer and have harmful effects on children. The Danish Consumer Council Tænk Kemi states that bath slime contains polyacrylamide or polycarboxylate. It is these substances that give the bathwater its slimy consistency.

Two of the products (a bath bomb and a bath slime product) were so-called glitter products and contained microplastics in the form of polyethylene. However, Denmark implemented a national ban on the use of microplastics in cosmetic leave-on products, which came into effect on July 1, 2020 (Statutory Order no. 655, 2020). This occurred a few months after the February 2020 test. As a result, these two products were subsequently withdrawn from the market, which can explain why no glitter products were identified in the Danish market in connection with the current project.

Based on the ingredients, the Danish Consumer Council Tænk Kemi could not recommend any of the bath slimes or bath bombs tested.

3.1.3 VKI, Austrian test, 2020

Four of the 15 bath products tested in this 2020 Austrian test by VKI (Verein für Konsumentinformation) were also included in the Danish test of bath bombs and bath slimes, as described above. As in the Danish test, the test examined bath bombs and bath slime, but also crackle powder, bath pearls, foam bath and bathwater colours.

Of the 15 bath products analysed, 13 contained fragrances, five of which contained allergenic fragrances subject to mandatory labelling. Out of the 15 products, five had contents including azo dyes, which are considered problematic.

Four of the products contained a PEG compound (PEG-400), which according to VKI can weaken the skin barrier and thus facilitate the absorption of other substances.

A slime bath product with glitter contained polyacrylamide as the ingredient making the water slimy. The test states that the presence of the carcinogenic substance acrylamide in free form cannot be ruled out.

3.1.4 Ökotest, German test, 2022

In October 2021, the German magazine Ökotest purchased 21 bath products for children. The test was published in February 2022. One of the 21 products was a regular body wash product that did not contain problematic substances. The remaining 20 bath products consisted of 15 foam bath products, four bath bombs and one bath pearl product. The bath pearl product and one of the foam bath products also contained colourants that colour the bathtub water.

Öekotest tested for fragrances, problematic preservatives (such as formaldehyde releasers), PEG compounds and halogenated organic compounds.

All of the 20 bath products for children contained fragrances and/or essential oils; of these, four products contained fragrance ingredients subject to mandatory labelling. Two products were foam baths and two were bath bombs.

Seven of the 20 bath products contained PEG compounds, which, according to Öekotest, weaken the skin barrier and thus facilitate the absorption of other problematic substances. Eight of the 20 bath products contained halogenated organic compounds. This group covers many thousands of substances. Öekotest performed chemical analyses for content such as chlorine and bromine. However, Öekotest includes criticism from the manufacturers' side regarding the test: A positive result may be due to the presence of trace amounts of chloroacetic acid from cocamidopropyl betaine, which are technically unavoidable and not problematic.

3.1.5 Summarising the previous studies on bath products

The previous studies on bath products for children have thus focused on the substances below, which the test institutes believe are problematic in bath products for children:

- Fragrance ingredients that may be allergenic
- Plant extracts that may be allergenic
- Azo dyes, which are carcinogenic and can harm the environment.
- The preservative phenoxyethanol, which is classified as hazardous when ingested in concentrated form (possible risk when children swallow the bathwater)
- PEG compounds, which can weaken the skin barrier and thus facilitate the absorption of other problematic substances
- Acrylamide (derived from polyacrylamide used in bath slime), which is carcinogenic

3.2 Contact the Danish Consumer Council Tænk Kemi

The Danish Consumer Council Tænk Kemi is responsible for the app Kemiluppen, where it is possible to get a rating (A, B or C) of a cosmetic product based on Tænk Kemi's assessment of the ingredients declared on the product. The database behind Kemiluppen contains information about all the ingredients declared in the approx. 15,000 products from the Danish market that Kemiluppen contains (according to the Danish Consumer Council Tænk Kemi's website as of December 2022[9]).

The Danish Consumer Council Tænk Kemi rates the products with an A, B or C rating depending on the ingredients:

- Products with an A rating are free of a number of substances that are problematic in relation to both the environment and health.
- Products with a B rating are free from a number of problematic substances, but contain, for example, fragrances that may be allergenic or substances that are harmful to the environment.
- Products with a C rating contain problematic ingredients such as substances suspected of being endocrine disruptors. The substances are legal to use, and the product does not constitute a risk in itself.

In the spring of 2023, the Kemiluppen contained a few bath products for children in the form of foam baths, bath bombs, bath salts and the like. None of the other types of bath products for children identified in this project are included in the Kemiluppen. The Danish Consumer Council Tænk Kemi was contacted to obtain an extract of the bath products for children included in Kemiluppen and to gain knowledge about the ingredients these types of bath products contain.

An extract was received from Kemiluppen consisting of a total of 36 different bath products that, according to the Danish Consumer Council Tænk Kemi, are marketed for children. However, a large number of these products (21 in total) have been discontinued, meaning they are no longer on the market. When products are listed as discontinued in Kemiluppen, it is either because the manufacturers have actively informed the Danish Consumer Council Tænk Kemi

[9] https://taenk.dk/kemi/plejeprodukter-og-kosmetik/kemiluppen-tjek-din-personlige-pleje-uoensket-kemi

that the products are no longer being produced and marketed or because the Danish Consumer Council Tænk Kemi has investigated the market for the specific product without finding it.

In this report, only ingredients from the 15 so-called "current" products are reported, i.e., products that the Danish Consumer Council Tænk Kemi has not identified as discontinued from the market. Therefore, there is a presumption that these products are still available on the market in Denmark. In addition, only the typical ingredients from the group of bath bombs and foam baths (12 products in total) are reported, where more than one product of each product type is present.

The types of ingredients in bath bombs and foam baths for children from Kemiluppen are presented in TABLE 2 below. It should be noted that TABLE 2 only lists the function or type of ingredient used in these two types of bath products for children. If there are ingredients that are common to the majority of the listed products of this type, these are listed specifically. Only the ingredients from bath bombs and foam baths are listed in TABLE 2 below, as more than one of these product types are included in Kemiluppen.

TABLE 2. The ingredients in 15 bath products for children in Kemiluppen. The numbers in brackets indicate the number of products of that type or substance. The ingredients are listed by their INCI (International Nomenclature of Cosmetic Ingredients) names.

Product type (number)	Ingredient type	Comments
Bath bomb (7)	Foaming effect (7)	The following ingredients are used in almost all bath bombs: Sodium bicarbonate (7), sodium sulphate (6), citric acid (7)
	Fragrance (5) and essential oils (1)	Five of the bath bombs contain fragrance, and one of these contains some of the fragrance ingredients that are subject to mandatory labelling.
	Moisturising oils[10] (2)	Various vegetable oils are used
	Absorbents / binding agents / emulsifiers (3)	
	Surfactants (1)	These are types of cleansing ingredients that enhance moisturization ability and adsorb onto oil and fat droplets.[11]
	Colourants (7)	All bath bombs contain one or more colourants
	Salt (1)	Common table salt (sodium chloride)
	Water (2)	Two bath bombs also contain water, despite being solid dry products.
Foam bath (5)	Water (5)	All foam bath products contain water as the primary ingredient. This is a liquid product.
	Surfactants (5)	All foam bath products contain cocamidopropyl betaine, which has some kind of cleansing effect.
	Moisturising (5)	All foam bath products contain moisturising ingredients, including glycerine.
	pH stabiliser	Three of the five products contain citric acid.

[10] Specified with the "skin conditioning" function according to CosIng

[11] https://denstoredanske.lex.dk/vaskemidler

Product type (number)	Ingredient type	Comments
	Fragrance (3) and essential oils (1)	Three out of five bubble bath products contain fragrance and/or essential oils.
	Preservatives (5)	All five foam bath products contain water as the main ingredient, and all five products therefore contain preservatives. The most commonly used preservatives are: Sodium benzoate (3), phenoxyethanol (2), and potassium sorbate (2).
	Colourants (1)	Only one of the five foam bath products contains colourants.

TABLE 2 This indicates that different bath bombs contain essentially the same basic ingredients, such as sodium bicarbonate, sodium sulphate, and citric acid. They all contain colourants, and the majority of them also contain fragrance. Some of them may be supplemented with surfactants or moisturizing oils. Foam baths consist primarily of water, surfactants, moisturising oils and preservatives. Some of them may contain fragrance, but not all of them are supplemented with colourants.

3.3 Market survey – insights from search and procurement

The survey of children's bathing products available on the market was conducted solely through internet search and visits to selected stores in Denmark (in the Copenhagen area). In addition, contact was made with individual distributors of bath products for children in order to get an overview of which product types are most commonly sold on the Danish market.

The market survey in this project also included products that can be purchased outside of Denmark and shipped to Denmark via various online shops. The goal of the project was to purchase and analyse approx. 50% of the products in Denmark (DK), approx. 25% within the European Union (EU) and approx. 25% outside the EU (non-EU). The non-EU products are defined in this project as products purchased from a website outside the EU.

When searching for bath products for children, examples of different bath products were listed in a spreadsheet, where various relevant information was listed, such as product type, manufacturer, price, website, ingredients, region (DK, EU or non-EU), etc. The goal was to purchase approximately 45 different products in total, which is why a list of approximately 90 different children's bath products was compiled, distributed across different product types and regions (DK, EU, or non-EU).

In TABLE 3 below you will find an overview of the distribution of the different children's bath product types identified in the different countries; DK, EU and non-EU.

TABLE 3. Distribution of the number of types of children's bath products identified in DK, EU and non-EU

Product type	DK	EU	Non-EU	Total
Bath balls/bath bombs	12	6	9	27
Bath beads/crystals	4	0	0	4
Bathwater colours	4	3	4	11
Bathwater volcano	1	1	1	3
DIY kit	1	2	0	3
Crackle powder/bath salts	3	2	2	7

Product type	DK	EU	Non-EU	Total
Modelling soap/coloured soap	3	1	2	6
Foam bath (also coloured)	10	6	3	19
Bath slime/gel	2	2	3	7
Collection of multiple types	2	0	0	2
Total	**42**	**23**	**24**	**89**

3.3.1 Online and in-store search experiences

The general impression when searching the internet for bath products for children was that bath bombs were the most popular and the product type with the highest number of different products (in April 2023, when the search was conducted). In addition, bath foam (bubble bath products) and bathwater colours were also product types that came in many variations and from several different manufacturers. There were not a significant number of other types of bath products for children identified, such as bath pearls/crystals, crackling powder/bath salts, bathwater volcanoes, modelling soap/coloured soap, or bath slime/gel. Especially for bath slime/gel, it seemed as if there were primarily two manufacturers on the market, i.e., the same products were identified on non-EU, EU and Danish websites. During the internet search, only a few examples of kits for homemade bath bombs and collections of multiple types of bathing products were identified. It was not possible to identify all types of bath products in all three regions (DK, EU and non-EU).

The general impression is that it is possible to find and purchase various types of bath products targeted at children. However, it is much easier to find these types of products online compared to physical stores. During the survey, 17 different stores were visited, including supermarkets (four different ones), toy stores (two different ones), various health stores (four different ones), baby equipment stores (two different ones), hobby stores (two different ones) and various mixed product stores (three different ones). Bath bombs and foam baths were only found in physical stores in Denmark, and only in a few of the stores visited (four out of 17). In some of the stores, there were bath bombs with labels stating that they should be kept out of children's reach. These products are therefore not targeted directly at children, but are perceived as products for adults only.

The general picture from the survey was that the majority of the products were cosmetic products. Primarily, bath slime/gel, bathwater colours, and bath volcanoes are not considered cosmetic products as they do not have a cosmetic purpose but solely serve as toys for play purposes. Many of the cosmetic products could also be categorised as toys – either because they contain a toy (e.g., inside a bath bomb) or because they are sold on toy websites and presented with a playful purpose. However, whether the products are both a toy and a cosmetic product depends on the specific product.

3.3.2 Contacting selected distributors

A total of five different distributors of children's bath products were contacted to find out which product types they sell the most of. Contact was made with the Danish web shops that had several different children's bath products for sale on their websites. Of the five distributors contacted in April 2023, all responded to our questions about their sales:

- One distributor sold such a small number of children's bath products that they believed their sales or the distribution between different product types would not be representative enough to make a statement about which product types were the most popular.
- One distributor stated that bath bombs, bath foam, and bathwater colours were the most sold items, and these were also the product types they had the most of on their website. They also sold some crackle baths, but fewer than the other three product types.

- One distributor reported that bath foam was the bestselling product on their website among the product types they sell (bath bombs, bath foam and bath crystals).
- One distributor stated that there was a specific brand they sold the most of, and often several different product types were sold at the same time, such as sets including bath bombs, bath colours, bath foam, etc.
- One distributor stated that they sold the most of a specific brand, but roughly equal numbers of the different product types. Therefore, they could not say which of the bath products (bath bombs, bath volcano, bath pearls, bath crystals, bathwater colours or bath foam) were the most popular.

The impression from contacts with selected distributors is that bath bombs and bath foam are the most sold product types, but that bathwater colours are also a popular product type.

3.3.3 Ingredients

In the survey, an overview of approx. 90 different bath products for children was compiled, divided into the different types of bath products, as well as products identified in the three regions DK, EU and non-EU. Ingredient lists were identified for about half of the listed products, which is why only three products were purchased during the survey with the aim of gaining knowledge about ingredients in this type of product. The few products purchased at the beginning of the survey were bought because only one or none of this type of product had an ingredient list available through website searches. Product purchases were made to gain knowledge about the ingredients in these types of products.

TABLE 4 contains an overview of the types of ingredients identified in the survey of bath products for children. The overview covers the 45 products for which an ingredient list was identified on the website during the search (of which three products were purchased to read the ingredient list). Ingredient lists were primarily identified for the types of bath products that are classified as cosmetic products. The product types of bath slime/gel, which appear to have no cosmetic function, had an ingredient list identified in only one case (and to a limited extent).

In TABLE 4 below, specific ingredients are only listed if they are found in the majority of the product type. In total, approximately 180 different ingredients were identified in the 45 bath products with ingredient lists. For products that are cosmetic products (i.e., all product types except, for example, bath slime/gel, bathwater colours and bathwater volcano), all of the approximately 180 ingredients are identified in the EU CosIng database[12] as "active" ingredients, i.e., current ingredients that are either listed in the Cosmetics Regulation (EU Regulation 1223/2009), in the EU glossary of common ingredient names (EU Decision 2019/701) or have been assessed in an SCCS[13] opinion.

Appendix 1 "Ingredients in bath products for children" contains a list of the approximately 180 different ingredients identified in the 45 bath products for children with a list of ingredients.

[12] https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-ingredient-database_en

[13] Scientific Committee for Consumer Safety

TABLE 4. Ingredients in 45 bath products for children identified in the survey. The numbers in brackets indicate the number of products of that type or substance. The ingredients are listed by their INCI names. Ingredients indicated by bold in the table are ingredients that occur in multiple products of this type.

Product type (number)	Ingredient type	Comments
Bath bomb (15)	Foaming effect (15)	The following ingredients are used in almost all bath bombs: **Sodium bicarbonate** (15), **sodium sulphate** (8) or **magnesium sulphate (**3**), citric acid (**15**)**
	Fragrance (10) and essential oils (7)	13 of the bath bombs contain fragrance and/or essential oils. Four of these contain some of the fragrance ingredients that are subject to mandatory labelling.
	Moisturising oils[14] (9)	Various vegetable oils are used.
	Surfactants (6)	Some of the bath bombs contain some kind of cleansing ingredients that increase moisturisation and adsorb onto oil and fat droplets[15].
	Colourants (15)	All bath bombs contain one or more colourants.
	Salt (4)	Common table salt **(sodium chloride** (4))
	Preservatives (1)	One of the products contains a preservative. The preservative used is **sodium benzoate**.
	Water (5)	Five bath bombs also contain water despite being solid dry products.
Bath beads/crystals (2)	Salt (1)	Common table salt **(sodium chloride**).
	Surfactants (2)	Both products contain some form of cleansing ingredients.
	Moisturising oils (2)	Various vegetable oils.
	Fragrance (2) and essential oils (2)	Both products contain fragrance and essential oils.
	Colourants (2)	Both products contain one or more colourants.
Crackle powder/bath salts (5)	Salt (4)	The majority of the products contain common salt, with three of them having it as the primary ingredient.
	Foaming effect (3)	Several products have the same ingredients as bath bombs that provide the foaming effect, i.e.: **Sodium bicarbonate** (3), sodium **sulphate** (3) or **magnesium sulphate** (1), **citric acid** (2). However, two products also contain **carbon dioxide**.
	Moisturising oils (5)	All products contain some form of moisturising ingredients.
	Surfactants (2)	Two of the five products contain some form of cleansing ingredients.
	Fragrance (2) and essential oils (4)	A total of four products contain fragrance and/or essential oils.
	Colourants (3)	Three of five products contain one or more colourants.
Bathwater Volcano (2)	Foaming effect (2)	Both products have the same ingredients as bath bombs that provide the foaming effect, i.e.: **Sodium bicarbonate** (2), **sodium carbonate** (1) and **citric acid** (2).

[14] Specified with the "skin conditioning" function according to CosIng

[15] https://denstoredanske.lex.dk/vaskemidler

Product type (number)	Ingredient type	Comments
	Moisturising oils (1)	One of the products contains some form of moisturising ingredients.
	Surfactants (1)	Only one of the products contains some kind of cleansing ingredients.
	Fragrance (2) and essential oils (2)	Both products contain fragrance and/or essential oils. One of the products contains several fragrance ingredients that are subject to mandatory labelling.
	Colourants (1)	One of the two bathwater volcanoes contains colourants.
Bathwater colours (5)	Foaming effect (4)	Several of the products have the same ingredients as bath bombs that provide the foaming effect, i.e.: **Sodium bicarbonate** (4), **sodium sulphate** (2) and **citric acid** (4).
	Moisturising oils (4)	Several of the products contain some form of moisturising ingredients.
	Fragrance (3) and essential oils (1)	A total of three products contain fragrance and/or essential oils.
	Surfactants (1)	Only one of the products contains some kind of cleansing ingredients.
	Colourants (5)	All products contain one or more colourants.
	Water (1)	One of the products contains water, even though they are solid products.
Modelling soap, solid (2)	Moisturising (2)	Both modelling soaps contain moisturising ingredients, including **glycerine** (2).
	Surfactants (2)	Both products contain some form of cleansing ingredients.
	Fragrance (2)	Both products contain perfume.
	Colourants (2)	Both products contain colourants.
	Water (1)	One of the products contains water, even though they are solid products.
	Preservatives (1)	One of the products contains a preservative (as the product also contains water). The preservative used is **phenoxyethanol** (1).
	pH stabiliser (1)	One of the products contains **citric acid**.
Foam bath (11) (however, only 10 of them, which are liquid, are included here)	Water (10)	All but one of the bubble bath products contain water as the primary ingredient. These are liquid products. The last product is a powder, although it is called a foam bath and may belong more to the group of powdered bath bombs according to the ingredients.
	Surfactants (7)	All foam bath products contain some form of cleansing ingredients. Most products contain **cocamidopropyl betaine** (7).
	Moisturising (10)	All foam bath products contain moisturising ingredients, such as **glycerine** or oils.
	pH stabiliser (10)	All 10 products contain **citric acid**.
	Fragrance (8) and essential oils (4)	Eight out of ten foam bath products contain fragrance and/or essential oils. Three of the products contain fragrance ingredients that are subject to mandatory labelling.

Product type (number)	Ingredient type	Comments
	Preservatives (10)	All ten foam bath products contain water as the main ingredient, and all products therefore contain preservatives. The most commonly used preservatives are: **Sodium benzoate** (8), **potassium sorbate** (5) and **phenoxyethanol** (2).
	Colourants (2)	Only two of the ten foam bath products contain colourants.
Bath slime (1)	Polymer (1)	This slime product contains sodium polyacrylate as the polymer to provide the slimy, cohesive consistency. The Danish Consumer Council Tænk Kemi has in its study stated that polyacrylamide and polycarboxylate can also be used.
	Fragrance (1)	
	Salt (1)	
	Colourant (1)	All identified bath slime products are coloured in some way.
Bath gel (0)	*No ingredients identified for bath gel products*[16]	
DIY	*The ingredients depend on the type of product being manufactured*	
Collection of multiple types	*The ingredients depend on the type of product being manufactured*	

TABLE 4 indicates that many of the same types of ingredients are found across different bath products for children. Here are the key points that can be highlighted:

- The more solid bath products, such as bath bombs, crackle powder, bathwater volcano and bathwater colours predominantly consist of a combination of sodium bicarbonate, a sulphate (e.g. sodium or magnesium sulphate) and an acid (typically citric acid). These ingredients contribute to the foaming effect (generation of carbon dioxide) when the product comes into contact with water.
- Far more than half (37 out of 45) of the products contain fragrance, even though they are products for children. Of the remaining 40 or so bath products on the list (which do not contain an ingredient list), 14 have website descriptions indicating that the product contains fragrance (products smell like watermelon, popcorn or something else).
- More than half (33 out of 45) of the products contain one or more colourants. Based on the images of the bath products, virtually all of the 90 or so products listed contain some kind of colour (with the possible exception of foam bath).
- It is mainly foam bath products (which typically contain a large amount of water) that contain preservatives. The most commonly used preservatives are sodium benzoate, potassium sorbate and phenoxyethanol. None of the 45 bath products with an ingredient list contain parabens, isothiazolinones or formaldehyde-releasing preservatives.

3.3.4 Target group

Of the approximately 90 bath products identified, the vast majority (51 of 85, 60%) are indicated for use by children over three years of age. For approximately one-third of the products (27 products), there is no information regarding the target group, either through product images or website text. Three products should only be used by children from 7 or 8 years of age. These three products are all DIY (do-it-yourself) kits for making your own bath products (bath bombs).

[16] Two bath gel products purchased for the chemical analysis later in the project, show that this product type contains sodium polyacrylate, fragrances and colourants.

Only four products are labelled for use by children under the age of three. These four products consist of the following product types:

- Bathwater colour (available on a Danish website), that states its use is suitable for children aged two years and older. The colour tablets are labelled with instructions to place them inside bath toys, which are sold on the same website.
- Bathwater colour (from non-EU website) where the age indication is from 12 months and upwards.
- Bath balls/bath bombs (from non-EU website), where there is no age indication, but there are pictures of very young babies in the bath on the website. The bath bomb includes a small toy.
- Crackle powder/bath salts (from non-EU website) where the age indication is from six months and upwards.

For the products in the category "for children over 3 years old", the age indication on the product varies greatly. Many products are simply labelled "from 3 years", "+3" or similar, whereas other products are labelled "3-7 years", "3-15 years" or similar. Some of the products (7 products) in this category do not have a specific age indication, but there were images of children older than three years in bathtubs on the websites.

The target group for the individual types of bath products is also listed in TABLE 5.

3.3.5 Usage information

Relevant information regarding how the products should be used has been noted for the approximately 90 products. In general, there is very little information on how often (frequency) and for how long (duration) the products can be used. Most of the information identified relates to the quantity to be used. A form of usage instructions has been observed for a total of 37 products. This information is listed in TABLE 5 below and is broken down by bath product type.

TABLE 5. Usage information for products identified through internet search

Product type	Target audience (age)	Frequency of use	Bath duration	Quantity used
Bath bombs/bath balls	Primarily from three years and up One particular product can also be used by babies, based on the images provided.	Two products state "every day"	Two products state "10-20 minutes"	Values between 80 and 160 g for a bath (depending on the size of the bath bomb) 75 g for 200 litres
Bath pearls/bath crystals	From three years and up	No information	One product states "10-20 minutes"	40 g for a bath
Bath slime/gel	From three years and up	No information	No information	300 g for a bath 300 g for 30-40 litres
Bathwater colours	Primarily from three years and up Two products specify an age recommendation of 12 months and 2 years, respectively.	No information	Two products state "10-20 minutes"	30 g or 40 g for a bath A couple of tablets 1-2 tablets One pack (183 g) for a bath
Bathwater volcano	From three years and up	No information	One product states "10-20 minutes"	One bag per bath (70 litres)

Product type	Target audience (age)	Frequency of use	Bath duration	Quantity used
DIY kit	From seven years and up	No information	No information	Use a half or full bath bomb for a bath
Crackle powder/bath salts	Primarily from three years and up One product states from six months	No information	No information	Entire bag contents (5 g) for one bath
Modelling soap/coloured soap	From three years and up	No information	No information	No information
Collection of multiple types of bath products	From three years and up	No information	No information	No information
Foam bath	From three years and up	No information	Three products state “10-20 minutes"	Values between 10 and 40 g per bath Values between 30 and 40 ml per bath 2-3 capfuls per bath

4. Exposure scenarios

This section describes and discusses exposure scenarios considered to be relevant for children's exposure related to the use of the bath products, as well as methods and parameters that will be used for estimation of the exposure.

As the survey has shown that the products are primarily marketed as cosmetic products, the exposure assessment is based on the guidance from the Scientific Committee on Consumer Safety (SCCS): "The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation - 12th revision" (hereinafter referred to as "Notes of Guidance") (SCCS 2023).

If one or more of the products are marketed as toys, the exposure assessment of the chemical substances is based on the guidance for consumer exposure under the REACH regulation: "Guidance on Information Requirements and Chemical Safety Assessment Chapter R.15: Consumer exposure assessment" (ECHA 2016).

If there are products that by the Danish EPA are considered to be both cosmetic products and toys, the risk assessment for toys is used (i.e., as described in the REACH guidance), as this is the most conservative risk assessment (see Appendix 4).

4.1 Exposure routes

When using chemical products, including toys and cosmetic products, an important part of the safety assessment is to evaluate the extent of exposure via the different possible routes of exposure:

- *Skin contact*
- *Eye contact*
- *Oral ingestion*
- *Inhalation*

Below, using the SCCS Notes of Guidance (SCCS 2023), relevant parameters in an exposure scenario for a bath product are discussed. This means that the starting point is for cosmetic products.

4.1.1 Skin contact

Specifically for bath products, skin contact is considered to be the primary route of exposure during use. Children may have direct skin contact with the concentrated product before mixing it in the water (typically with their hands) and with the diluted product after mixing it in the bathwater (whole body).

In connection with a risk assessment, it must be assessed whether the child can absorb the substances through the skin to an extent that may cause damage to internal organs and/or whether local contact with skin may cause local skin effects or allergies.

In a risk assessment for harmful effects on internal organs after possible absorption of the chemical substances through the skin, the dermal exposure is calculated in "mg substance/kg body weight/day".

In the Notes of Guidance, SCCS (2023) uses the following equation for the daily dermal exposure (E dermal (mg/day)) of a substance in a given product:

$$E\ dermal\ (mg/day) = C\ (mg/g) \times Q\ (g/day)\ X\ F_{ret}$$

Where

C (mg/g): concentration of the substance in the product
Q (g/day): amount of product used per day
F_{ret}: the retention factor on the skin, i.e., the proportion of the product that is considered available for skin absorption/is in direct contact with the skin. For bath gels, SCCS (2023) states a retention value of 0.01, which means that 1% of the amount used is considered to be available for skin uptake in the body.

As can be seen from the equation, the size of the retention factor is very crucial to the exposure assessment. For general use of bath gel and shampoo (including in the shower), the SCCS (2023) recommends a retention factor of 0.01, i.e., 1% of the amount used is considered to be available for dermal uptake into the body during use of these products.

For children's play in the bath, where exposure occurs partly through exposure of the hands to concentrated bath product for a short time (minutes) and partly through exposure of the whole body to the bath product dissolved in the bathwater for up to 1 hour, it will be necessary to increase the retention factor compared to shampoo and bath gel, where the product is rinsed off after short-term contact (approx. 1 minute) with the body. No further guidance for such a scenario is given by SCCS (2023), but since a number of parameters (playing with the product, bathing time and softening of the skin by prolonged contact with warm water) indicate a significantly higher exposure compared to the general use of bath gel and shampoo, it is considered relevant to increase the retention factor.

Considering the above-mentioned factors, a significantly higher retention factor for bath products is considered relevant. Therefore, a retention factor of 0.1 is used in this project, corresponding to 10% of the amount of the chemical substances in the product being assessed to be available for absorption in the body during the use of the product in the bath for up to 1 hour and in connection with any residues remaining on the skin after the bath.

The child's exposure as "mg/kg bw/day" (bw = body weight) can then be calculated by dividing by the child's body weight.

Bath products are typically marketed for children aged 3 years and above. The website sundhed.dk states that Danish boys and girls who have just turned 3 years old weigh an average of 14 kg and 14.5 kg respectively. Based on this, a body weight of 14 kg for a 3-year-old child is used as a starting point in the risk assessment. In the event that the product is marketed to other age groups, the specific exposure assessment is based on the average weight for that age group.

Since the weight of a 3-year-old child is set at 14.0 kg, the skin exposure to a cosmetic product according to SCCS (2023) can be calculated by:

$$E\ dermal\ (mg/kg\ bw/day) = C\ (mg/g) \times Q\ (g/day) \times 0.1 / 14\ kg$$

However, if the bath product is considered to be covered by the toy legislation, the exposure assessment follows the guidelines of the REACH regulation. Here, knowledge of the surface area of the skin that is exposed is taken into account, and for aqueous products, it is estimated that the substances are available for absorption in a liquid layer of 0.01 cm against the skin.

The formula for calculating dermal exposure using this method are given in section 11.1.2 and in Appendix 4, as this method calculates both hand exposure to the concentrated product and whole-body exposure to the dissolved product in the bathwater.

In Appendix 4, a hypothetical example is given for calculating skin exposure to a bath product with the two different methods and with the given assumptions, a relatively similar exposure is obtained regardless of the method. However, exposure calculations based on the REACH guidelines will typically give slightly higher values.

For risk assessment of local effects on the skin, exposure to the concentrated product on hands (and eyes and other mucous membranes) is considered most critical, while contact with the diluted/dissolved product is considered less critical. In these cases, the substance concentration in the product is used as the basis for assessment, i.e., the percentage or mg/g of substance in the product that comes into contact with the skin either before or after mixing with the bathwater.

Finally, the pH of the concentrated product will be an important parameter for assessing the risk of skin irritation.

4.1.2 Eye contact

Eye contact is also considered to be a relevant route of exposure when assessing the risk of eye irritation. Eye contact can be made by rubbing the child's eye with a finger containing residues of the concentrated product and/or getting water in the eyes from the mixed bathwater. The greatest exposure is estimated to occur when the child plays with the concentrated product. When assessing local effects on the skin, the substance concentration in the product and the pH value of the product are taken as a starting point.

4.1.3 Oral exposure

As a starting point for assessing the possible swallowing of bathwater, one can imagine that the child, during play, fills their mouth completely with bathwater to squirt it out again, but accidentally swallowing it. In such a scenario, an amount of 50 ml (i.e., ½ dl) is estimated to be a realistic worst-case amount swallowed during the time the child is bathing. The SCCS (2023) does not describe estimates for such a scenario, so in the absence of concrete estimates, the total amount of 50 ml water swallowed during the bathing time has been determined based on an overall assessment by the project's monitoring group.

Oral exposure to a substance is calculated in mg/kg body weight for the child. Based on this calculation it is assessed whether the exposure constitutes a risk.

4.1.4 Inhalation

When inhaling chemicals, it will mainly be volatile chemical substances, which can be in vapor form, that will be relevant to assess. To risk assess this type of exposure, it is important to know the concentration in the air the child breathes (i.e., mg substance/m^3 air).

In order to calculate a realistic inhalation exposure in connection with the evaporation of volatile substances, this would require that measurements of the degassing of volatile substances from the product are also carried out, i.e., measurements in a climate chamber where the concentration of the substances is measured in the air at a given ventilation.

Only very low levels of volatile substances are expected in the soap products, so exposure through inhalation must be considered to be much lower than exposure through skin contact. As the volatile substances that typically occur in soap products are fragrances, and as their critical effect is predominantly allergenic effects on skin contact, this project has chosen not to

use resources on emission measurements, which is why the calculation of exposure by inhalation is not included in the project.

This decision is supported by a study by Zhou et al. (2017), who measured the concentrations of seven different fragrances at a height of 7.6 cm to 30.5 cm above the water surface in a vessel containing 6 litres of 37 °C water with 15 ml of a bath product added. For each of the seven substances, 14 measurements were taken in different sections of the tub. The vast majority of measurements (>90%) showed concentrations of each of the fragrance ingredients below 1 µg/m^3. A single concentration of 5 µg/m^3 was measured for dimethyl heptenal. These are considered to be exposure levels significantly below health significance.

4.2 Bath and product parameters

Important parameters for exposure when using bath products in a bath are listed below.

The bath duration
The US EPA (2009) states in their "Child Specific Exposure Factors Handbook" that bathing time for children aged 3-6 years is 24 minutes on average, with a 95-percentile value of 60 minutes.

As the bath products in this project also appeal to play, it is considered realistic that children can stay in the bathtub for up to 60 minutes. However, some of the bath products purchased have a recommended bathing time that is significantly less than 60 minutes.

Frequency
It is not considered realistic for the same bath product to be used daily for extended periods of time. On the other hand, it is considered realistic for a bath product to be used daily over a shorter period of time or, for example, once a week.

Water volume
A search on Danish websites revealed photos of bathtubs where a child of approx. 3 years old is sitting in approx. 10 cm of water in a bathtub measuring 40 x 80 cm. The volume of bathwater here is estimated to be around 30 litres. This means that the bath products are estimated to be dissolved and diluted in 30 litres of bathwater. However, for a few of the bath products purchased, specific dosage instructions are given in relation to the amount of bathwater.

Product volume
The volume of content in each bath product is generally used as the product volume used for the 30 litres of bathwater, unless a specific usage volume is stated on the packaging.

Substance concentration
The substance concentration obtained from the chemical analyses is used to calculate the substance exposure.

pH
As indicated for skin and eye contact, the pH value is considered to be an important parameter for assessing the risk of local irritation effects on skin and eyes.

Washing off
It is not assumed that the skin is necessarily rinsed with clean water after a bath with these products, but that the child gets out of the bath and is dried with a towel. This will leave product residues (soap, perfume colourants, etc.) on the skin until the child is washed again.

5. Initial screening of ingredients

In total, around 180 ingredients were found on the product ingredient lists (see Appendix 1) for the 45 products where an ingredient list could be identified through searches on various web shops (both Danish and international).

5.1 Screening method for declared ingredients

When assessing the safety of products, the substances of greatest health concern are identified from this list. These substances are identified based on the following criteria:

- Classification of substances, where substances are prioritised if they have an EU harmonised classification or are classified in their REACH dossier according to Regulation (EC) No 1272/2008 with the following classifications considered the most severe classifications:
  - CMR category 1A, 1B or 2
  - STOT SE 1 or SE 2
  - STOT RE 1 or RE 2
  - Skin sens. 1, 1A or 1B
  - Skin Corr. 1, 1A, 1B or 1C
  - Eye Dam. 1
  - Acute Tox. 1, 2 or 3
- Whether the substances are fragrance ingredients that are regulated in the Cosmetics Regulation or the Toy Safety Order or are in the process of being regulated (extension of the number of fragrance ingredients subject to mandatory labelling) (European Regulation 1545, 2023).
- Whether the substances are suspected endocrine disruptors, cf. EU lists (Endocrine Disruptor List (edlists.org)).

In TABLE 6 on the following pages, all the ingredients covered by this screening are listed, along with the corresponding classifications or appearances on the mentioned lists.

Of the approximately 180 substances listed in Appendix 1, around 115 substances do not have either harmonized classification or REACH classification. It is estimated that several of these substances, according to their REACH registration, do not require hazard classification (approximately 40 substances). Furthermore, several substances are not subject to a REACH registration but can be considered harmless. Examples of such substances include lactose, glucose, sucrose, sodium citrate, lanolin, lecithin, and others. These substances are natural food ingredients or natural fats. Finally, there are several substances that are likely not registered under REACH due to their annual tonnage being below 1 ton. For these substances, there is typically insufficient data available to assess their classification. This means that these substances are not actually included in the screening but are excluded due to lack of data. However, all of these substances are used or have been used in cosmetic products as they are listed in the CosIng database.

TABLE 6. Screening and prioritisation of declared ingredients based on their effects and regulation. Classifications in **bold** are among the prioritised classifications.

Name of substance	CAS no.	Classification	Regulation of fragrance ingredient	Suspected endocrine disruptor	In number of products (out of 45)	Comments and possible further prioritisation
Tetrasodium EDTA	64-02-8	Acute Tox. 4 **Eye Dam. 1**	-	-	1	pH value is measured
Disodium EDTA	139-33-3	Acute Tox. 4 **STOT RE 2**	-	-	1	Yes, because of STOT RE 2 classification
Succinic acid	110-15-6	**Eye Dam. 1**	-	-	1	pH value is measured
Phenoxyethanol	122-99-6	Acute Tox. 4 **Eye Dam. 1** STOT SE 3	-	-	3	pH value is measured
Tartaric acid	133-37-9	**Eye Dam. 1**	-	-	4	pH value is measured
Methyl ethyl ketone; MEK	78-93-3	Eye Irrit. 2 STOT SE 3	-	**List II**	1	Yes, due to possible endocrine disrupting effect
Sodium lauroyl sarcosinate	137-16-6	Skin Irrit. 2 **Eye Dam. 1** **Acute Tox. 2**	-	-	2	Yes, due to classification with Acute Tox. 2
Cocamidopropylamine oxide	68155-09-9	Acute Tox. 4 Skin Irrit. 2 **Eye Dam. 1** **STOT RE 2**	-	-	1	Yes, due to STOT RE 2
Sodium hydroxide	1310-73-2	**Skin Corr. 1A**	-	-	2	No, used as a pH-regulating agent
Sodium C14-16 olefin sulfonate	68439-57-6	Skin Irrit. 2 **Eye Dam. 1**	-	-	3	pH value is measured
Caprylyl/caprylic glucoside	68515-73-1	**Eye Dam. 1**	-	-	1	pH value is measured
Denatonium benzoate	3734-33-6	Acute Tox. 4 **Eye Dam. 1** Acute Tox. 4	-	-	2	pH value is measured
Ethylhexylglycerin	70445-33-9	**Eye Dam. 1**	-	-	2	pH value is measured
Cocamidopropyl betaine	97862-59-4	**Eye Dam. 1**	-	-	8	Perhaps due to frequent use of the substance

Name of substance	CAS no.	Classification	Regulation of fragrance ingredient	Suspected endocrine disruptor	In number of products (out of 45)	Comments and possible further prioritisation
Lauryl glucoside	110615-47-9	Skin Irrit. 2 **Eye Dam. 1**	-	-	2	pH value is measured
BHT (butylated hydroxytoluene)	128-37-0			**List II**	1	Yes, due to possible endocrine disrupting effect
Colourants						
CI 15510 Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzenesulphonate	633-96-5	**STOT RE 1**	-	-	1	Yes, azo dye and due to STOT RE 1
CI 73015 Indigotindisulfonate sodium	860-22-0	**Skin Sens. 1**	-	-	3	Yes, not azo dye, but allergenic
CI 18050 Disodium 5-acetylamino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate	3734-67-6	**Skin Sens. 1B**	-	-	2	Yes, azo dye and allergenic
CI 77891 Titanium dioxide	13463-67-7	**Carc. 2**	-	-	3	No, classification related to inhalation only
CI 45380 Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxoxanthen-9-yl)benzoate	17372-87-1	**Skin Sens. 1** Eye Irrit. 2	-	-	1	Yes, not azo dye, but allergenic
Fragrance ingredients						
Linalool	78-70-6	**Skin Sens. 1B**	**A1** **B2**	**-**	1	Yes, allergenic
Butylphenyl methylpropional; Lilial	80-54-6	**Repr. 1B**	**A** **B2**	**List II**	1	Immediately yes due to classification and possible endocrine disrupting effect; but no because the substance is now banned under the Cosmetics Regulation

Name of substance	CAS no.	Classification	Regulation of fragrance ingredient	Suspected endocrine disruptor	In number of products (out of 45)	Comments and possible further prioritisation
Coumarin	91-64-5	Acute Tox. 4 **Skin Sens. 1**	**A1** **B1**	-	2	Yes, allergenic
Eugenol	97-53-0	**Skin Sens. 1B** Eye Irrit. 2	**A** **B1**	-	1	Yes, allergenic
Benzyl alcohol	100-51-6	**Skin Sens. 1B**	**A1** **B1**	-	1	Yes, allergenic
Citronellol	106-22-9	Skin Irrit. 2 **Skin Sens. 1B** Eye Irrit. 2	**A1** **B2**	-	2	Yes, allergenic
Geraniol	106-24-1	**Skin Sens. 1**	**A1** **B1**	-	4	Yes, allergenic
Hydroxycitronellal	107-75-5	**Skin Sens. 1B** Eye Irrit. 2	**A1** **B1**	-	1	Yes, allergenic
Benzyl salicylate	118-58-1	**Skin Sens. 1B** Eye Irrit. 2	**A1** **B1**	**List II**	1	Yes, due to possible endocrine disrupting effects and allergenic
Benzyl benzoate	120-51-4	Acute Tox. 4	**A1** **B2**	-	1	Yes, allergenic
Limonene	138-86-3	Skin Irrit. 2 **Skin Sens. 1**	**A1** **B2**	-	7	Yes, allergenic
Citral	5392-40-5	Skin Irrit. 2 **Skin Sens. 1**	**A1** **B1**	-	1	Yes, allergenic
Citrus aurantium dulcis flower extract	8028-48-6	Asp. Tox. 1 Skin Irrit. 2 **Skin Sens. 1**	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Chamomilla recutita flower extract	84082-60-0	Asp. Tox. 1 Skin Irrit. 2 **Skin Sens. 1B** Eye Irrit. 2	- -	-	3	No, due to technical analysis issues - is a UVCB substance*

Name of substance	CAS no.	Classification	Regulation of fragrance ingredient	Suspected endocrine disruptor	In number of products (out of 45)	Comments and possible further prioritisation
Rosmarinus officinalis leaf extract	84604-14-8	Asp. Tox. 1 Skin Irrit. 2 **Skin Sens. 1B** Eye Irrit. 2 **STOT SE 2**	- -	-	1	No, due to technical analysis issues - is a UVCB substance*
Lavandula angustifolia oil	90063-37-9	Asp. Tox. 1 **Skin Sens. 1B** Eye Irrit. 2	**A2**	-	3	No, due to technical analysis issues - is a UVCB substance*
Mentha piperita oil	8006-90-4	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Citrus aurantium bergamia fruit oil	8007-75-8	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Citrus aurantium dulcis peel oil	8008-57-9	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Jasminum officinale oil	8022-96-6	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Citrus aurantium amara peel oil	68916-04-1	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Cananga Odorata flower oil	83863-30-3	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*
Rosa Centifolia flower oil	84604-12-6	-	**A2**	-	1	No, due to technical analysis issues - is a UVCB substance*

-: not included; UVCB stands for unknown or variable composition, complex reaction products or of biological materials

A1: Mandatory labelling for cosmetics, see Annex 3, EU Directive 1223/2009.

A2: Substances with future mandatory labelling for cosmetics.

B1: Prohibited for use in toys at conc. > 100 mg/kg, see Annex 2, EU Directive 2009/48.

B2: Must be labelled at conc. > 100 mg/kg in toys according to Annex 2, EU Directive 2009/48/EC.

List II: Substances under EU evaluation for endocrine disrupting effects according to the EU Endocrine Disruptor List (EDLists.org) (List II) (EDLists.org, 2023).

5.2 Results and prioritisation of declared ingredients

Based on the screening criteria, a total of 45 ingredients were found, of which 23 of the substances are allergenic fragrance ingredients subject to regulation in cosmetics or toy legislation. Two of these ingredients (butylphenyl methylpropional and benzyl salicylate) are suspected endocrine disruptors. In addition, BHT and methyl ethyl ketone are also included on the list due to suspected endocrine disrupting effects.

Out of 22 colourants named with their CI number in Appendix 1, classifications were found for eight of the substances. The classification of five of these substances prompted their inclusion in the table. Among these, two are azo dyes.

It should be noted that only substances classified as allergenic were found in the group of colourants and fragrance ingredients.

As indicated in TABLE 6, there are 11 allergenic perfume oils or extracts listed. However, these were excluded from further prioritisation due to the highly demanding analytical requirements for their analysis. Oils and extracts consist of numerous chemically diverse and not clearly defined substances (referred to as UVCB substances). For some of these extracts, quantification will be possible (they can be purchased as reference substances), but quantification will be uncertain and potentially very extensive.

For the substances included in the table based solely on Eye Damage 1 classification, no basis for further prioritisation is given, as several of the other priority substances also have this classification. Furthermore, when it comes to assessing the risk of eye irritation, it is considered equally important to evaluate this risk based on measuring the pH value of the product.

Based on the above screening, the following individual substances were proposed for inclusion in the subsequent chemical analyses:

- The package of fragrance ingredients subject to mandatory labelling (the 24 substances that are subject to mandatory labelling today)
- Screening for suspected endocrine disruptors, i.e. BHT; methyl ethyl ketone; benzyl salicylate
- Other substances designated based on classification:
    - EDTA
    - Sodium lauroyl sarcosinate
    - Cocamidopropylamine oxide
    - Colourants CI 15510; CI 73015; CI 18050; CI 45380

Additionally, measurement of the products' pH value was suggested.

6. Products purchased for analysis

As described earlier, a gross list of approx. 90 different bath products for children was compiled, divided into different types of bath products (bath bombs, foam bath, bath slime/gel, etc.) and different regions (DK, EU and non-EU). Based on this gross list, a total of 45 products were selected for purchase for chemical analysis. A few extra products were deliberately purchased from non-EU countries in case some products did not arrive before the chemical analyses were to be initiated.

The products selected for purchase for the chemical analyses were chosen based on the following criteria:

1. The distribution key for the distribution of products from non-EU, EU and DK was agreed to be 25%, 25% and 50% respectively. However, some additional non-EU products were deliberately purchased, as the experience has shown that not all products arrive during the month allocated for product procurement in the schedule.
2. The distribution between the different product types was predominantly bath bombs, foam bath and bathwater colours, which were the most commonly identified products in the survey. The product types were divided into non-EU, EU and Danish products according to the above distribution key. However, the following product types were excluded when purchasing for analyses:
   - DIY kits, as they often consist of a collection of ingredients for different types of bath products.
   - The product type called "collection of multiple types", which consists of several different types of bath products (e.g. bath bombs, bathwater colours, crackle powder, etc.)
   - More common types of foam baths, as they often consist of just a soap without colourings and possibly without fragrance ingredients. For this project, only more specialised types of foam baths were deliberately purchased, such as extra thick foam, where the products may also have a play purpose.
3. Products containing one or more of the prioritised substances were deliberately purchased based on the ingredient list from the products identified in the survey. In other words, there was a focus on purchasing products containing fragrances (and any fragrances subject to mandatory labelling), products with suspected endocrine disruptors, and the prioritised colourants.
4. Bath products were purchased, some of which are considered exclusively as toys, some exclusively as cosmetic products, and some as both toys and cosmetic products.
5. Products were sourced so that different manufacturers were covered in the study. However, the survey revealed that there were a few manufacturers who had a whole range of different bath products specifically targeted at children. For this reason, there are some cases where several of the products purchased for the project are from the same manufacturer.

Within the allotted time for purchasing bath products, 42 products arrived, i.e. these 42 products were chemically analysed. The products that were purchased for the chemical analyses and were received prior to the start of the chemical analyses are distributed as indicated in TABLE 7 below.

TABLE 7. Distribution of the number of types of children's bath products purchased for the chemical analyses from each country. DK, EU and non-EU

Product type	DK	EU	Non-EU	Total
Bath balls/bath bombs	7	3	3	13
Bath beads/crystals	2	0	0	2
Bathwater colours	3	2	3	8
Bathwater volcano	1	1	1	3
Crackle powder/bath salts	1	2	2	5
Modelling soap/coloured soap	2	1	1	4
Foam bath (also coloured)	2	1	1	4
Bath slime/gel	1	1	1	3
Total	**19**	**11**	**12**	**42**

Of the 42 products purchased and received, 40 products had some form of ingredient list. "Some form of ingredient list" means that the main ingredients are listed, but colourings and fragrances are not necessarily specified. The two products without an ingredient list were a non-EU product (bath ball) and an EU product (crackle powder/bath salts). The list of ingredients was also listed for the product group bath slime/gel, although it was not complete (specific colouring agents used were not listed, but simply indicated as "content of colouring agents").

The majority of products contain fragrance (35 out of 42 products) and colourants (37 out of 42 products).

TABLE 8 below shows the distribution of products containing fragrance ingredients and colourants for products purchased in DK, EU and non-EU respectively. The table also shows information about the products' ingredient list. It should be noted that even though for some products there has not been an ingredient list on either the product or the website, a yes or no is indicated next to colourants and fragrances, respectively, if, for example, there are pictures showing that the product is coloured or there is a description showing that the product is fragranced.

TABLE 8. Distribution of the number of children's bath products containing fragrance ingredients and colourants, and the list of ingredients from DK, EU and non-EU respectively. In brackets under fragrance is the number of products that contain fragrance but do not contain any of the fragrance ingredients subject to mandatory labelling.

Purchased in	Contains perfume*	Contains colourants	Ingredient list	Comments
DK	Yes: 16 (9) out of 19 No: 3 out of 19	Yes: 19 out of 19 No: 0 out of 19	Yes: 19 out of 19	All products contain a detailed ingredient list
EU	Yes: 10 (4) out of 11 No: 1 out of 11	Yes: 9 out of 11 No: 1 out of 11 No info: 1	Yes: 10 out of 11 No: 1 out of 11	A product without information. Two products without an ingredient list on the product, but on the website.
Non-EU	Yes: 9 (9) out of 12 No: 2 out of 12 No info: 1	Yes: 9 out of 12 No: 3 out of 12	Yes: 11 out of 12 No: 1 out of 12	A product without information.

Purchased in	Contains perfume*	Contains colour-ants	Ingredient list	Comments
				Two products without an ingredient list on the product, but on the website. Three products, where the colourants are not specified.
Total	**Yes: 35 (22) out of 42** **No: 6 out of 42** **No info: 1**	**Yes: 37 out of 42** **No: 4 out of 42** **No info: 1**	**Yes: 40 out of 42** **No: 2 out of 42**	Two products without information. Four products without an ingredient list on the product, but on the website. Three products, where the colourants are not specified.

* In brackets under "yes" is the number of products that contain fragrance but do not contain any of the fragrance ingredients subject to mandatory labelling.

6.1 Prioritisation of ingredients and screening analyses

Based on the screening of the declared ingredients, it was decided in collaboration with the Danish EPA that the screening analyses were distributed as follows:

- GC-MS screening is performed on a total of 23 products:
  - The two products that did not have an ingredient list, either on the website or on the purchased product, were selected. This means that generally it has been chosen to rely on the list of ingredients stated on the product's website, even if there was no list of ingredients on the product itself (especially for non-EU products). However, for one of these two products, the product was known to contain perfume as it was sold in different fragrance variants.
  - The remaining 21 products were selected for GC-MS screening because, according to the ingredient list, they contain perfume (indicated as "perfume" or "flavouring") but with no fragrance ingredients subject to mandatory labelling[17]. This could potentially make it possible to identify which fragrance ingredients will be present in the products. Any other relevant substances, such as BHT, which can be used as an antioxidant in fragrance blends, will also be identified by this GC-MS screening.
- Colourants are identified via FT-IR for seven products where the specific colourants used are not listed in the ingredient list.
- pH measurements are made for all 42 products. To get an idea of worst-case exposure, pH is measured in a relatively concentrated solution to simulate a child holding a bath ball in their hand as it dissolves.

[17] With the above-mentioned product without an ingredient list, but with knowledge of fragrance content, there were thus a total of 22 products with fragrance content, but without knowledge of the content of the 24 fragrance substances subject to mandatory labelling.

7. Screening analyses

The following screening analyses were performed on the purchased products:

- pH measurements on a solution of all 42 purchased products.
- FT-IR on seven coloured products that did not specifically state which colourants they contain in the ingredient list.
- GC-MS screening on a total of 23 products – for products either without an ingredient list or for products containing fragrance but without fragrance ingredients subject to mandatory labelling.

The methodology and results of the screening analyses are described in the text below.

7.1 pH value measurements

In co-operation with the Danish EPA, it was decided that the pH value should be measured for all 42 purchased products. Furthermore, it was decided that a known quantity of the product should be weighed in as little tap water as possible, where ideally a complete dissolution of the product had occurred, and there was enough liquid to conduct a correct pH measurement.

The pH values were measured potentiometrically using a calibrated pH electrode. The chosen ratio of product to water was 1 g of product to 15 ml of water. However, for the three bath slime/gel products, it was not possible to use this ratio for the pH measurement, as the mixture in this ratio was a solid mass of slime or gel. Instead, a much stronger dilution of 0.1 g product and 50 ml water was used. Plain tap water was used for the solutions. The tap water used from the laboratory in Brøndby had a pH value of 8.02. According to HOFOR, the measured pH value for Brøndby municipality, where the laboratory is located, was between 7.7 and 8.0 in 2022[18]. The last approved pH measurement of the tap water in Brøndby municipality was on 6 March 2023, when the pH was measured at 8[19].

For products consisting of several individual pieces with different colours, a specific colour was chosen on which the pH measurement is performed. Some of the products were multi-coloured, where the colours could not be separated from each other. The colour on which the pH measurements were made is indicated in TABLE 9 below. Note that pH measurement may have been performed on a different colour than the FT-IR or GC-MS screening.

The results of the pH measurements are listed in TABLE 9 below. The results are grouped by product type.

TABLE 9. Results of pH measurements for 1 g of product dissolved in 15 ml tap water.

Product (LAB no.)	Measured pH	Colour of product selected for measurement	Solution colour	Comment
DK 1 - BK	9.85	Orange-red	Red	

[18] https://www.hofor.dk/privat/vand/bliv-klog-paa-drikkevandet/se-vandkvaliteten-din-kommune/vandkvalitet-broendby-kommune/

[19] https://data.geus.dk/JupiterWWW/vandanalyse.jsp?anlaegid=107030&proeveid=2095193

Product (LAB no.)	Measured pH	Colour of product selected for measurement	Solution colour	Comment
DK 2 - BK	9.61	Pink	Orange	
DK 3 - BK	10.22	Greenish (yellow and blue)	Yellow	
DK 4 - BK	10.15	Blue	Blue	
DK 5 - BK	8.48	Blue	Blue	
DK 6 - BK	8.69	Green and pink	Purple	
DK 7 - BK	9.05	Pink	Pink	
EU 21 - BK	9.13	Pink	Pink	
EU 22 - BK	9.03	Blue	Blue	Turns into foam
EU 23 - BK	8.53	Pink and white	Pink	
NEU 33 - BK	8.82	Orange/yellow	Orange	
NEU 34 - BK	7.49	Pink	Pink	
NEU 35 - BK	7.35	Purple	Purple	
DK 8 - PK	9.22	Orange	Red	
DK 9 - PK	8.85	Orange	Red	
DK 10 - FA	8.27	Purple	Dark purple (black)	
DK 11 - FA	6.96	Orange	Yellow/orange	Foam at the surface
DK 12 - FA	9.16	Pink/red	Red	
EU 24 - FA	10.11	Blue	Blue	
EU 25 - FA	7.48	Blue	Blue	
NEU 36 - FA	6.85	Red	Red	
NEU 37 - FA	7.26	Purple	Purple	
NEU 38 - FA	8.64	Orange	Orange	
DK 13 - VU	6.10	Red	Red	
EU 26 - VU	8.87	Blue	Blue	Solution foams
NEU 39 - VU	7.88	Green and blue	Green	
DK 14 - KBS	5.24	Reddish	Pink	
EU 27 - KBS	7.17	Yellow	Yellow	
EU 28 - KBS	6.94	White, red, green, blue	Light blue	
NEU 40 - KBS	7.83	White	White	
NEU 41 - KBS	8.18	White	White	
DK 15 - MS	8.76	Green	Green	
DK 16 - MS	8.85	Blue	Blue	
EU 29 - MS	6.88	Orange	Orange	
NEU 42 - MS	9.51	Blue	Purple	
DK 17 - SK	8.80	Red	Red	
DK 18 - SK	9.02	Blue foam	Blue	
EU 30 - SK	2.46	Pink, blue crystals	Brown/purple	Solution foams
NEU 43 - SK	7.38	White	White	
DK 19 - GE	7.58	Orange	None	Diluted 0.1 g in 50 ml of water. Otherwise, thick jelly.

Product (LAB no.)	Measured pH	Colour of product selected for measurement	Solution colour	Comment
EU 31 - GE	7.67	Pink with silver coloured glitter	Pale pink	Diluted 0.1 g in 50 ml of water. Otherwise, thick jelly.
NEU 44 - SL	8.54	Green	Green	Diluted 0.1 g in 50 ml of water. Otherwise, thick slime.

BK = bath ball, PK = bath beads/crystals, FA = bath colours, VU = bath volcano, KBS = crackle powder/bath salt, MS = modelling soap, SK = foam bath, GE = bath gel, SL = bath slime.

The measured pH values range between 2.46 and 10.22. There are two individual products with acidic pH values of 2.46 (foam bath) and 5.24 (crackle powder/bath salts). The remaining products have pH values between 6.10 and 10.22. According to Hye Won Kin et al. (2020), the pH of many cosmetic products such as creams, lotions, perfumes, oils and lip products is between 5 and 7, but can be 10-11 for rinse-off products such as shampoo and body wash.

7.2 FT-IR on colourants

A total of seven products were selected for screening analysis of colourants. These seven products were all coloured products that did not specifically state which colourants they contain in the ingredient list. The seven products selected for this screening analysis are all listed in TABLE 10 below.

The samples were suspended in ethanol, and TLC (thin layer chromatography) was used to determine whether the samples contained one or more colourants. It was expected beforehand that identification via FT-IR would only be possible if the colourants were separated or present individually in the sample.

For samples that initially contained only one colourant, the ethanol phase was evaporated and examined with FT-IR. For samples containing multiple colourants distributed at different locations on the sample, a portion of the sample, primarily containing one colourant, was removed and suspended in ethanol. It was then examined by TLC whether both or only one of the colourants was present before the ethanol phase was evaporated and examined by FT-IR.

A single sample contained two colourants, equally distributed in the sample. Here, the sample was dissolved in two different solvents: acetone, where only one colourant was extracted from the sample, and ethanol, where both colourants were extracted from the sample. The two solutions were then concentrated for FT-IR analysis.

TABLE 10 below shows the results of the TLC tests. It shows how many colourants are present in the seven samples tested and whether the samples contain the same colourant.

TABLE 10. Results of the TLC tests. Listing the types of colourants in the seven samples tested.

Sample (lab no.)	Yellow a	Yellow b	Yellow c	Yellow d	Red a	Red b	Pink	Orange a	Blue
DK 11 - FA	x								
DK 19 - GE		x			x				
EU 27 - KBS				x					
EU 31 - GE							x		

Sample (lab no.)	Yellow a	Yellow b	Yellow c	Yellow d	Red a	Red b	Pink	Orange a	Blue
NEU 33 - BK			x					x	
NEU 35 - BK						x			x
NEU 36 - FA					x				

BK = bath ball, PK = bath beads/crystals, FA = bath colours, VU = bath volcano, KBS = crackle powder/bath salt, MS = modelling soap, SK = foam bath, GE = bath gel, SL = bath slime.

The results of the TLC test show that DK 19 - GE contains a red colourant and a yellow colourant that gives the product its orange colour. At first glance, it appears that four different yellow colourants are used in the four products containing yellow colourant. Based on the TLC study, NEU 36 - FA and DK 19 - GE contain the same red colourant.

Unfortunately, the analyses of the separated colourants on FT-IR did not allow for an identification of the colourants. This is because it was not possible to extract the colourants from the bath products as pure colourants. The colourants were mixed with several other substances from the bath products, making identification impossible. Despite attempts with several extraction agents, it was not possible to extract the colourants in sufficient purity for identification by FT-IR.

As a test, an FT-IR analysis was performed on EU 29, which contained only a single colourant CI 15510 (Acid Orange 7) according to the ingredient list. For this product as well, it was not possible to extract the colourant sufficiently pure (without too many other ingredients from the bathing product). Four different extraction agents were tried without success. The resulting FT-IR spectrum was compared with the known FT-IR spectrum of CI 15510 from the literature. Thus, identification of colourants is not possible by FT-IR when the colourants cannot be isolated from the other bath product ingredients in a sufficiently pure form.

7.3 GC-MS screening analyses

GC-MS screening analyses were performed on a total of 23 products, some of which did not have an ingredient list. The 23 products consisted primarily of products with a perfume content, but without a content of fragrance ingredients subject to mandatory labelling. The 23 products selected for GC-MS analysis are listed in TABLE 11 below.

However, it should be noted that in addition, DK 5 - BK and EU 24 - FA were also analysed by GC-MS. They were included in the screening analyses as reference products, as they contain some of the fragrance ingredients subject to mandatory labelling that were declared on the products. In doing so, these products were used as a check that the fragrance ingredients could be identified. The results for these two additional products are therefore also shown in the results below. For this reason, this section on GC-MS analysis refers to "23 (25) products".

TABLE 11. The 23 products selected for GC-MS analysis

Product type	Lab no.	Comments
Bath balls (BK)	DK 2 - BK	
	DK 3 - BK	
	DK 4 - BK	
	NEU 33 - BK	No ingredient list
	NEU 34 - BK	
	NEU 35 - BK	

Product type	Lab no.	Comments
Bath beads/crystals (PK)	DK 8 - PK	
Bathwater colours (FA)	EU 25 - FA	
	NEU 36 - FA	Does not contain perfume
Bath volcano (VU)	NEU 39 - VU	
Crackle powder/bath salts (KBS)	DK 14 - KBS	
	EU 27 - KBS	No list of ingredients
	NEU 40 - KBS	
	NEU 41 - KBS	
Modelling soap (MS)	DK 15 - MS	
	DK 16 - MS	
	EU 29 - MS	
	NEU 42 - MS	
Foam bath (SK)	DK 18 - SK	
	NEU 43 - SK	
Bath gel (GE) and bath slime (SL)	DK 19 - GE	
	EU 31 - GE	
	NEU 44 - SL	

7.3.1 Method of analysis

The sample was purified by retaining the oils and water and extracting the analytes. 0.1 g of sample was weighed and mixed with sodium sulphate and Florisil. Extraction was then performed with ethyl acetate and turbid samples were filtered through a 0.45 µm PTFE syringe filter before analysis on GC-MS with a wax column. For the three gel-like/slime products that swell on contact with water, the sample preparation was modified compared to the other products. In these cases, three different sample preparations were performed with and without the addition of salt (sodium chloride) and the use of ethanol to dissolve the sample and avoid swelling before adding sodium sulphate and Florisil, as for the remaining samples. According to the manufacturer, adding salt is recommended before rinsing these gel-like products out of the bathtub. No significant differences were observed in the content of the tests as a function of the difference in test preparation.

Single determinations were performed as the method was solely a screening method for the identification of primary fragrance ingredients. The analysis was performed as a screening, i.e. no exact value for the amount of content is given. The substances were identified by their mass spectra using the National Institute of Standards (NIST) database and retention time. The fragrance ingredients subject to mandatory labelling and 13 other fragrances were identified by reference substances, and the area of any substances found in the samples was compared to the area of the reference standard (where the concentration corresponded to approx. 600 ppm when weighing a sample of 0.1 g). For substances where no reference substance was used, the content in the sample was compared to the average content of the declarable and 13 other fragrance ingredients in the reference standards. The substances are indicated by one to three pluses corresponding to a content less than one tenth of the standard area (+), between one tenth and the standard area (++) or greater than the standard area (+++). It is therefore not possible to say anything about the approximate amount of the substances in the products other than that an indication with "+++" means a significantly higher concentration of the substance in question than an indication with "+".

The samples were run on a wax column, which is especially suitable for analysing fragrance ingredients. However, it is possible to identify content of e.g. both fragrances and BHT (which can be used as an antioxidant for perfume blends), as well as other volatile substances on the wax column, although it is not the optimal column for non-polar substances. The reporting of the substances identified in the different samples analysed is divided into two sections for fragrance ingredients and other volatile substances to provide a better overview of the different substance groups.

The samples were analysed at low dilution and on a 60 m wax column to ensure both high sensitivity (especially to fragrances) and good separation of the signals in the chromatograms. Due to the chosen analysis method, 50-100 substances could be identified in the blind sample alone. The samples therefore typically contained more than 100 signals in the chromatograms. For the fragrance ingredients subject to mandatory labelling and the 13 other fragrances, all samples were analysed for their content. In addition, only the largest signals (at least the 5 most intense) were identified in each sample. The identified substances reported from one sample may thus be present in other samples without being reported, but for the sake of the amount of data, the focus is on the largest signals in the individual samples.

7.3.2 Analysis results - general

The general picture of the analysis results from the GC-MS screening is that all 23 (25) products show a large number of small peaks, which indicates that the products contain a large number of volatile substances in small amounts. For example, up to about 120 different peaks have been seen in one of the chromatograms. These multiple peaks (each peak represents one substance, or an isomer of a substance) indicate that the plant extracts used in the products contain a wide range of different chemical substances. An example of a chromatogram is provided in FIGURE 1 below.

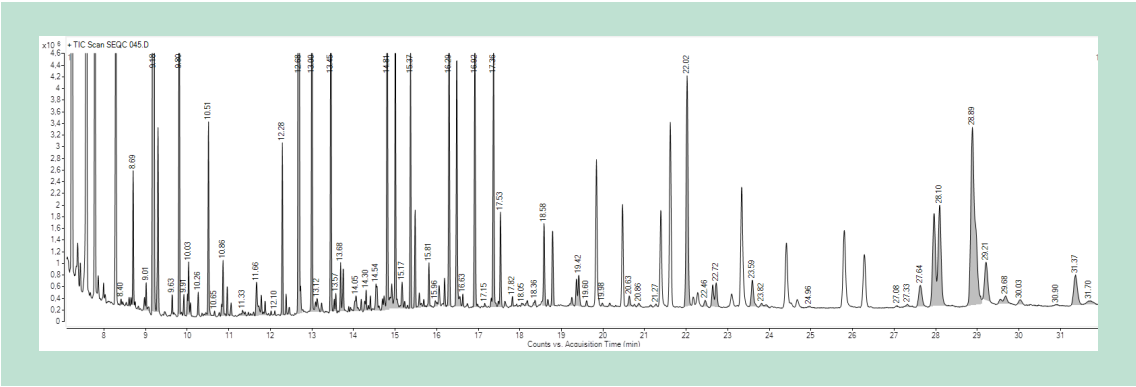


FIGURE 1. Example of a chromatogram for one of the screened bath products

During the screening, it has not been possible to identify all the different chemical substances. The focus is on certain fragrance ingredients (found as single substances), BHT and at least the five largest peaks in each chromatogram. Some substances are identified with high certainty due to comparison with reference substances that were analysed using the same analytical method. Other substances are identified solely by comparison with mass spectra from the NIST database, retention time and analytical specialists' knowledge of the properties of the identified compounds. However, this identification is less certain than identification using reference substances.

This approach has identified more than 150 different substances in the 23 (25) selected products combined.

7.3.3 Analysis results – fragrance ingredients

The results of the screening analyses regarding content of fragrance ingredients in the 23 (25) selected products are listed in TABLE 12 below. The 24 fragrance ingredients subject to mandatory labelling have been identified using reference substances, i.e. the substances have been identified with a high degree of certainty. In addition, a total of 13 other fragrance ingredients have been identified using reference substances. These 13 substances are not among the new fragrance ingredients that have been adopted in the EU in 2023 to become subject to mandatory labelling in cosmetic products. These 13 substances are flavourings that FORCE Technology has seen used in e-liquids for e-cigarettes in previous analyses of this type of product, and they are also substances that are listed in the CosIng database with the function "perfuming" or "fragrance". Finally, other fragrance ingredients are identified by comparing mass spectra with data from the NIST database, i.e. the substances are most likely present in the products, but their identification is more uncertain (compared to using reference substances).

It should be noted that TABLE 12 only lists the identified substances, i.e. the largest peaks in each individual product. TABLE 12 shows the identified fragrance ingredients and which of the 23 (25) products they are identified in. Fragrance ingredients that were looked for (compared with reference substances) but could not identify are listed in Appendix 2. Therefore, these substances are likely not present in products in quantities that have been possible to identify/find in the 23 (25) samples. The fragrance ingredients not detected include seven of the 24 fragrance ingredients subject to mandatory labelling.

Neither eugenol, isoeugenol nor benzyl salicylate (three of the fragrance ingredients subject to mandatory labelling) are identified in the samples. For eugenol and isoeugenol, this is probably because the detection limit has been too high, whereas for benzyl salicylate it is because the analysis time on GC may have been too short to analyse this substance (as the substance has a high retention time).

It should be noted that due to the amount of identified fragrance ingredients, only substances with the prioritised classifications from section 5.1 are listed in TABLE 12 unless they are substances that recur in several of the analysed products and in large quantities (indicated as +++). Other identified fragrance ingredients with non-relevant classifications in relation to the prioritisation of the substances for hazard assessment and risk assessment in this project are listed in Appendix 3 together with other identified volatile substances with non-prioritised classifications.

TABLE 12. Identified fragrance ingredients in the 23 (25) selected bath products. Subject to mandatory labelling following (24) and (81) respectively, indicate that the fragrance is one of the 24 fragrances in cosmetic products that are currently subject to mandatory labelling or one of the 81 fragrances that will be subject to mandatory labelling in the future. The number of pluses (+, ++, +++) after the product number indicates a relative quantity in which the substance is identified.

Fragrance ingredient	**CAS no.**	**Identified in** (+'s equal the quantity)	**Identification via**	**Comments**
Citral	5392-40-5	EU 29 - MS +. NEU 33 - BK (+)	Reference substance	Subject to mandatory labelling (24)
Lilial (butylphenyl methylpropional)	80-54-6	NEU 35 - BK +	Reference substance	Prohibited in cosmetic products (Annex II)

Fragrance ingredient	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
Amyl cinnamal	122-40-7	EU 25 - FA ++.	Reference substance	Subject to mandatory labelling (24)
Hexyl cinnamal	101-86-0	NEU 35 - BK +	Reference substance	Subject to mandatory labelling (24)
Linalool	78-70-6	DK 5 - BK + DK 15 - MS ++. DK 16 - MS + DK 19 - GE (+) EU 24 - FA ++ EU 29 - MS +. NEU 33 - BK + NEU 35 - BK + NEU 39 - VU + NEU 40 - KBS ++ NEU 41 - KBS + NEU 43 - SK ++	Reference substance	Subject to mandatory labelling (24)
Citronellol	106-22-9	DK 5 - BK + EU 29 - MS ++ NEU 33 - BK ++ NEU 39 - VU + NEU 43 - SK +	Reference substance	Subject to mandatory labelling (24)
Geraniol	106-24-1	DK 5 - BK + NEU 33 - BK + NEU 35 - BK + NEU 41 - KBS + NEU 43 - SK +	Reference substance	Subject to mandatory labelling (24)
Benzyl alcohol	100-51-6	DK 3 - BK + DK 8 - PK + DK 18 - SK +. DK 19 - GE NEU 33 - BK ++ NEU 35 - BK + NEU 39 - VU +	Reference substance	Subject to mandatory labelling (24)
Cinnamyl alcohol	104-54-1	DK 19 - GE	Reference substance	Subject to mandatory labelling (24)
d-limonene	5989-27-5	DK 5 - BK + DK 15 - MS + EU 24 - FA +++ EU 29 - MS ++ NEU 33 - BK + NEU 40 - KBS ++ NEU 41 - KBS + NEU 42 - MS + NEU 43 - SK +++	Reference substance	Subject to mandatory labelling (24)
Eucalyptol (Cineole)	470-82-6	NEU 40 - KBS + EU 24 - FA ++	Reference substance	Other fragrance ingredients Not. classification: Skin Sens 1B

Fragrance ingredient	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
Camphor	76-22-2	NEU 40 - KBS ++	Reference substance	Subject to mandatory labelling (81)
Allylanisole (estragol)	140-67-0	EU 24 - FA +	Reference substance	Other fragrance ingredients Not. classification: Skin Sens 1 Acute Tox. 4, H302
Alpha-isomethyl ionone	127-51-5	EU 24 - FA ++	Reference substance	Subject to mandatory labelling (24)
Coumarin	91-64-5	EU 24 - FA ++ NEU 35 - BK + NEU 40 - KBS +	Reference substance	Subject to mandatory labelling (24)
Benzyl benzoate	120-51-4	NEU 33 - BK +++ NEU 34 - BK + NEU 35 - BK +	Reference substance	Subject to mandatory labelling (24)
A-terpinyl acetate	80-26-2	DK 8 - PK + DK 19 - GE EU 24 - FA + NEU 33 - BK ++ NEU 40 - KBS + NEU 41 - KBS ++ NEU 43 - SK +++	Reference substance	Other fragrance ingredients Not. classification: Aquatic Chronic 2
Beta-ionone	14901-07-6	DK 2 - BK ++ DK 4 - BK ++ DK 5 - BK + DK 8 - PK + DK 14 - KBS + DK 15 - MS ++. DK 16 - MS ++. DK 19 - GE NEU 33 - BK + NEU 35 - BK + NEU 39 - VU + NEU 42 - MS + NEU 43 - SK +++	Reference substance	Other fragrance ingredients Not. classification: Aquatic Chronic 2
Gamma-undecalactone	104-67-6	DK 5 - BK ++ DK 8 - PK ++ DK 15 - MS ++. DK 19 - GE EU 24 - FA + EU 25 - FA ++. EU 29 - MS +++ NEU 39 - VU + NEU 42 - MS + NEU 43 - SK ++	Reference substance	Other fragrance ingredients Not. classification: Aquatic Chronic 3

Fragrance ingredient	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
Alpha-terpineol	98-55-5	DK 16 - MS ++. EU 24 - FA + EU 25 - FA + EU 29 - MS ++ NEU 35 - BK + NEU 43 - SK ++	Reference substance	Subject to mandatory labelling (81)
Anethole	104-46-1	EU 24 - FA ++	The NIST database	Subject to mandatory labelling (81)
Ethylene brassylate	105-95-3	DK 2 - BK + DK 4 - BK+ DK 8 - PK ++ DK 15 - MS +++ EU 24 - FA ++ EU 25 - FA +++ EU 29 - MS +++ NEU 41 - KBS +++	The NIST database	Other fragrance ingredients Not. classification: Aquatic Chronic 3
Cis-3-Hexenyl benzoate,	25152-85-6	DK 5 - BK +	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B
Dihydroactinidiolid	17092-92-1	DK 2 - BK + DK 5 - BK +	The NIST database	Other fragrance ingredients Not. classification: Acute Tox. 2, H300
4-tert-Butylcyclohexyl acetate	32210-23-4	DK 8 - PK + NEU41 - KBS ++	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B
Phenylpropanol	122-97-4	DK 15 - MS +++ DK 16 - MS +++ EU 24 - FA ++	The NIST database	Other fragrance ingredients Not. classification: Eye Dam. 1 Skin Corr. 1B
Tetrahydrolinalool	78-69-3	DK 8 - PK + DK 16 - MS +++ EU 29 - MS ++	NIST- the database	Other fragrance ingredients Not. classification: Skin Sens 1B
Methylcinnamic aldehyde	101-39-3	EU 24 - FA ++	NIST- the database	Other fragrance ingredients Not. classification: Skin Sens 1
Methyl cinnamate	103-26-4	EU 24 - FA ++	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B
1-trimethyl-2-cyclohex-enyl-1-penten-3-one	7779-30-8	EU 24 - FA + NEU 39 - VU +	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1

Fragrance ingredient	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
Pinene	80-56-8	EU 29 - MS ++	The NIST database	Subject to mandatory labelling (81)
Acetoin	513-86-0	EU 29 - MS +.	The NIST database	Other fragrance ingredients Not. classification: Eye Dam. 1
3-Carene	13466-78-9	NEU 33 - BK +	The NIST database	Other fragrance ingredients On Annex III/121 Not. classification: Asp. Tox 1 H304, Skin Sens 1B
Allyl cyclohexylpropionate	2705-87-5	NEU 33 - BK ++	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B
Hexamethylindanopyran 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran ("HHCB")	1222-05-5	NEU 33 - BK + NEU 34 - BK + NEU 35 - BK ++ NEU 41 - KBS +++	The NIST database	Subject to mandatory labelling (81) EDlists.org: List II Not. classification: Aquatic Acute 1, Aquatic Chronic 1
Phenylisohexanol	55066-48-3	NEU 35 - BK +	The NIST database	Other fragrance ingredients Not. classification: STOT RE 2 H373
Borneol (*endo*-Borneol)	507-70-0	NEU 35 - BK + NEU 40 - KBS ++ EU 29 - MS (+) NEU 39 - VU (+)	The NIST database	Other fragrance ingredients Not. classification: STOT SE 2 H371, Eye Dam. 1
Cedryl acetate	77-54-3	NEU 35 - BK +	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B
Heliotropine (piperonal)	120-57-0	NEU 39 - VU +	The NIST database	Other fragrance ingredients Not. classification: Skin Sens 1B Repr. 2
Geranyl acetate	105-87-3	NEU 40 - KBS ++ NEU 41 - KBS +	The NIST database	Subject to mandatory labelling (81) Not. classification: Skin Sens 1
(E)-3,7-dimethylocta-1,3,6-triene	3779-61-1	NEU 40 - KBS + NEU 41 - KBS +	The NIST database	Not. classification: STOT SE 3 H373
4-Terpinenol	562-74-3	NEU 40 - KBS +	The NIST database	Not. classification: Skin Sens. 1

Fragrance ingredient	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
Linalyl acetate	115-95-7	NEU 41 - KBS ++ NEU 43 - SK +	The NIST database	Subject to mandatory labelling (81) Not. classification: Skin Sens 1B
Carvone	6485-40-1	NEU 43 - SK +	The NIST database	Harmonised classification: Skin Sens. 1

BK = bath ball, PK = bath beads/crystals, FA = bath colours, VU = bath volcano, KBS = crackle powder/bath salt, MS = modelling soap, SK = foam bath, GE = bath gel, SL = bath slime.

+ = less than one tenth of the standard area, ++ = between one tenth and the standard area, +++ = greater than the standard area, (+) = identification is uncertain.

Not. Classification = notified classification according to ECHA's C&L database.

It should be noted that the screening results show that NEU 35 - BK appears to contain lilial which is on Annex II of the Cosmetics Regulation, i.e. it is not authorised for use in cosmetic products.

In addition, the screening for fragrances shows that 12 of the 24 fragrance ingredients subject to mandatory labelling are identified in several of the 23 (25) products, even though this has not been stated in the list of ingredients. According to the Cosmetics Regulation, the fragrance ingredients subject to mandatory labelling must be listed in the list of ingredients of cosmetic products if they are present in a concentration above 100 ppm (rinse-off products). The identified substances are all present in small quantities, and the concentration of 100 ppm is therefore unlikely to have been exceeded. However, this can only be confirmed with quantitative analyses.

The screening for fragrances also shows that eight of the upcoming 81 fragrance ingredients subject to mandatory labelling are included in several of the 23 (25) analysed products.

Finally, the screening shows that many other fragrance ingredients are identified in one or more of the 23 (25) analysed bath products for children. This is because many of the analysed products contain one or more different plant extracts, which can easily contain, for example, 50-75 different individual substances (fragrance ingredients).

7.3.4 Analysis results – other volatile substances

The results of the screening analyses regarding the content of other volatile substances in the 23 (25) selected products are listed in TABLE 13 below. What these other volatile substances have in common is that they are only identified by comparing mass spectra with data from the NIST database, i.e. the substances are most likely present in the products, but their identification is more uncertain (compared to using reference substances).

When identifying other volatile substances, the focus is on at least the five largest peaks in each chromatogram and any content of BHT (butylated hydroxytoluene). BHT is suspected of being an endocrine disruptor and is used as an antioxidant in fragrance blends for use in cosmetic products, among other things. There is also a focus on identifying substances that are not listed as typical ingredients in bath products. The other volatile substances identified are therefore primarily alcohols, esters, ethers or similar, which are used e.g. as solvents/extraction agents for the natural/essential oils used in the bath products. In addition, substances such as phenoxyethanol, glycerine and propylene glycol are also identified in some of the products.

It should be noted that TABLE 13 below only lists the most important substances identified in the individual products. As previously mentioned, there are a large number of small peaks in the chromatograms that have not been examined. TABLE 13 shows the most important other volatile substances and which of the 23 products they are identified in. In order not to overwhelm the reader with data, only substances with relevant health classifications (see section 5.1 for selected classifications) are listed in TABLE 13 below. Identified substances with non-relevant classifications in relation to the prioritisation of the substances for hazard assessment and risk assessment in this project are listed in Appendix 3.

TABLE 13. Identified substances (except fragrance ingredients) in the 23 selected bath products. The number of pluses (+, ++, +++) after the product number indicates the quantity in which the substance is identified.

Name of substance	**CAS no.**	**Identified in** (+'s equal the quantity)	**Identification via**	**Comments**
BHT Butylated hydroxytoluene	128-37-0	DK 2 - BK + NEU 33 - BK + NEU 34 - BK + NEU 35 - BK + NEU 39 - VU (+) NEU 41 - KBS ++ NEU 42 - MS ++	The NIST database	Used as an antioxidant and preservative in fragrance blends[20] EDlists.org: List II Not. classification: No health classification
Triethyl citrate	77-93-0	EU 24 - FA +++ EU 29 - MS ++ NEU 41 - KBS +++ NEU 43 - SK +	The NIST database	Used as a solvent in perfume blends Not. classification: Not classified
Diethyl phthalate	84-66-2	DK 2 - BK (+) DK 3 - BK (+) NEU 35 - BK ++ NEU 39 - VU +	The NIST database	Under assessment for ED effects according to ECHA's database[21] Not. classification: Not classified
Isopropyl myristate	110-27-0	DK 2 - BK +++ DK 3 - BK + DK 4 - BK +++ DK 5 - BK ++ DK 14 - KBS +++ DK 15 - MS +++ DK 18 - SK ++ EU 25 - FA +++ EU 31 - GE ++ NEU 33 - BK +++ NEU 34 - BK + NEU 35 - BK+	The NIST database	Used as an extractant for chamomile extracts[22] Not. classification: Not classified

[20] https://www.ulprospector.com/en/la/PersonalCare/Detail/31182/994206/BHT-Butylated-Hydroxy-Toluene?st=1&sl=165442644&crit=a2V5d29yZDpbYmh0XQ%3d%3d&ss=2&k=bht&t=bht

[21] https://echa.europa.eu/da/substance-information/-/substanceinfo/100.001.409

[22] https://www.ulprospector.com/en/la/PersonalCare/Detail/31163/1004688/Chamomile-Herbasol-Extract-IPM

Name of substance	CAS no.	Identified in (+'s equal the quantity)	Identification via	Comments
		NEU 39 - VU + NEU 44 - SL ++		
Mequinol (p-hydroxyanisole)	150-76-5	DK 18 - SK +	The NIST database	Used as an antioxidant according to the CosIng database Not. classification: Acute Tox. 4 H302, Skin Sens 1
Phenoxyethanol	122-99-6	EU 29 - MS +++ NEU 42 - MS +++	The NIST database	Preservative (Annex V/29) Not. classification: Eye Dam. 1, STOT SE 3
Caprylyl glyceryl ether	10438-94-5	EU 29 - MS +++	The NIST database	Used as a surfactant according to CosIng Not. classification: Eye Dam. 1
Dichlorobenzyl alcohol	1777-82-8	NEU 42 - MS +++	The NIST database	Preservative Not. classification: Eye Dam. 1, Acute Tox. 4 H332
Laureth-2	3055-93-4	NEU 42 - MS +++	The NIST database	Not. classification: Eye Dam. 1, Skin Irrit. 2
2,4-dichlorobenzaldehyde	874-42-0	NEU 42 - MS +	The NIST database	Not. classification: Eye Dam. 1, Acute Tox. 4 H332

BK = bath ball, PK = bath beads/crystals, FA = bath colours, VU = bath volcano, KBS = crackle powder/bath salt, MS = modelling soap, SK = foam bath, GE = bath gel, SL = bath slime.

+ = less than one tenth of the standard area, ++ = between one tenth and the standard area, +++ = greater than the standard area, (+) = identification is uncertain.

Not. Classification = notified classification according to ECHA's C&L database.

There are a limited number of other volatile substances identified in the bath products in addition to the fragrance ingredients generally found in the products. A few substances have been identified that are typically used as solvents or extraction agents for natural ingredients (triethyl citrate, isopropyl myristate) as well as BHT and mequinol, which are used as antioxidants in fragrance blends.

8. Selection of substances and products for quantitative analyses

When selecting both products and substances for the quantitative analyses, the focus is partly on the classification/properties of the substances and partly on how many of the substances of concern have been identified in the screening analysis in the individual products, as well as in how many products the individual substances have been identified in.

As a handful of substances must be selected for the hazard assessment and risk assessment, approximately five of the relevant identified substances must be selected and prioritised, for which quantitative analyses are subsequently carried out.

8.1 Relevant substances to prioritise for quantitative analyses and risk assessment

Of the previously listed relevant substances (see section 5.2), the following ingredients (seen from ingredient lists) were identified in relation to the selection/prioritisation of substances:

- The package of fragrance ingredients subject to mandatory labelling (the 24 substances that are subject to mandatory labelling today)
- Suspected endocrine disruptors: BHT, methyl ethyl ketone, benzyl salicylate
- Other substances designated based on classification:
    - Disodium EDTA
    - Sodium lauroyl sarcosinate
    - Cocamidopropylamine oxide
    - Colourants CI 15510; CI 73015; CI 18050; CI 45380

Some of the fragrance ingredients subject to mandatory labelling are identified by the GC-MS screening in 18 out of the 25 products (see TABLE 14 below), and also in products where they are not labelled (which they do not necessarily have to be).

It should be possible to quantify benzyl salicylate (which is one of the 81 fragrance ingredients that will be subject to mandatory labelling) even if the substance was not identified in the screening. It may be a question of detection limit or analysis time on GC-MS. Benzyl salicylate is declared in the product EU 21 - BK.

Methyl ethyl ketone is declared in the list of ingredients for product EU 29 - MS. Methyl ethyl ketone must be analysed by another analytical method by HPLC. Furthermore, the substance requires derivatisation and thus cannot be analysed by the same analytical method as the fragrance ingredients.

Disodium EDTA does not appear in the ingredient list of the products purchased for analysis and is therefore not relevant for a quantitative analysis.

For sodium lauroyl sarcosinate and cocamidopropylamine oxide, new analytical methods must be identified for both substances if these substances are to be prioritised. They are not ex-

pected to be quantifiable by the same analytical method as BHT and fragrances. Sodium lauroyl sarcosinate is according to the list of ingredients in product EU 29 - MS, but cocamidopropylamine oxide does not appear in the list of ingredients for the purchased products.

The four colourants that were previously identified for prioritisation are CI 15510 (due to STOT RE 1 classification), as well as CI 73015, CI 18050 and CI 45380 (due to Skin Sens classification). These colourants are identified in the following products (also marked in bold in TABLE 14 below):

- DK 1 - BK: CI 15510 (orange), CI 45380 (red)
- EU 21 - BK: CI 18050 (red)
- EU 23 - BK: CI 18050 (red)
- EU 24 - FA: CI 73015 (blue)
- EU 29 - MS: CI 15510 (orange)

In addition, there is a possibility that these colourants are present in the red, orange and blue products examined by FT-IR (but which could not be identified).

In addition, further relevant substances are identified by the GC-MS screening (see TABLE 12 and TABLE 13 on the previous pages). Firstly, several (a total of eight) of the upcoming 81 declarable substances have been identified in the 25 products in the GC-MS screening. These substances are interesting because of their allergenic effects. These substances are listed in the overview in TABLE 14 below.

In addition, the following substances are relevant for prioritisation based on TABLE 12 and TABLE 13:

- 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran (abbreviated HHCB, on the EU list of endocrine disruptors)
- *Endo*-borneol (STOT SE 2, H371)
- 3-Methyl-5-phenylpentan-1-ol (STOT RE 2, H373)

Finally, a large number of other fragrance ingredients with a notified classification as Skin Sens. 1 or 1B are identified in several of the 25 products analysed in the GC-MS screening.

8.2 Overview of relevant substances in the purchased products

The results of the identified fragrances and other volatile substances in the 25 analysed products by GC-MS are listed in TABLE 14 below. In the same table, the ingredients of the products are listed. Relevant ingredients are listed in bold in the ingredient list column. Here, relevant means substances discussed above in relation to proposal for further prioritisation for the quantitative analyses and risk assessment. TABLE 14 thus contains more than the 25 products, as non-analysed products with relevant ingredients (i.e. substances mentioned above) are also indicated in bold in the column with the list of ingredients.

TABLE 14 thus provides an overview of the products that contain these relevant substances (either based on GC-MS screening or ingredient lists).

It should be noted that TABLE 14 below only lists the content of substances with the prioritised classifications listed in section 5.1. Other substances identified in the products are not listed.

TABLE 14. Purchased products with relevant ingredients - either identified via ingredient list or via GC-MS analysis. The products' ingredients according to the list of ingredients are listed -

here, substances with suggestions for prioritisation are indicated in bold. ML stands for "mandatory labelling" (i.e., fragrance ingredients subject to mandatory labelling) (see note below the table).

Lab no.	Ingredients according to ingredient list	Substances identified by GC-MS screening
DK 1 - BK	Sodium Bicarbonate, Citric Acid, Magnesium Sulphate, Sodium carbonate, Sodium Sulphate. Polyethylene glycol, CI17200, CI16035, CI42090, **CI45380, CI15510**	*Not selected for GC-MS screening*
DK 2 - BK	Sodium Bicarbonate, Sodium Sulphate, Citric Acid, Helianthus Annuus (sunflower) Seed oil, Prunus Amygdalus Dulcis (Sweet Almond) oil, Olus (vegetable) Oil, Tocopherol, Sodium COCO-Sulphate, Parfum (fragrance), Chamomilla Recutita Flower Extract, Maltodextrin, Aqua (water), +/- CI 19140 (Yellow 5), CI 47005 (Yellow 10). CI 14700 (red 4), CI 45410 (RED 28). CI 42090 (blue 1).	BHT (+)
DK 3 - BK	Sodium Bicarbonate, Citric Acid, Sodium Sulphate, Sorbitol, Maltodextrin, PEG-400, C10-18 Triglycerides, Parfum (+/- CI 19140, CI 42090, CI 45100, CI 16035)	Benzyl alcohol (24 ML)* (+)
DK 4 - BK	Sodium Bicarbonate, Citric Acid, Sodium Sulphate, Sodium Chloride, Sodium C14-16 Olefin Sulfonate, Sodium Coco Sulphate, Aqua (water), Helianthus Annuus (sunflower) Seed oil, Prunus Amygdalus Dulcis (sweet almond) Oil, Parfum, Maltodextrin, Olus (vegetable) Oil, Chamoilla Recutita Flower Extract, Tocopherol, CI 19140 (Yellow 5), CI 42090 (Blue 1), CI45410 (RED 28)	*No substances with the prioritised classifications have been identified*
DK 5 - BK***	Sodium Bicarbonate, Sodium Sulphate, Citric Acid, Hydrogenated Starch Hydrolysate, Parfum (Fragrance), Persea Gratissima (Avocado) Oil, Vitis Vinifera (Grape) Seed Oil, **Linalool, Limonene**, **Citronellol, Geraniol**, Aqua (Water), CI 42090.	Linalool (24 ML)* (+) Citronellol (24 ML)* (+) Geraniol (24 ML)* (+) d-Limonene (24 ML)* (+)
DK 8 - PK	Urea, Sodium Lauryl Sulfoacetate, Tocopherol, Calendula Officinalis Flower Extract, Gardenia and Jasmine Extract, Maltodextrin, Silica, Fragrance, CI 16255	Benzyl alcohol (24 ML)* (+) 4-tert-Butylcyclohexyl acetate (+)
DK 14 - KBS	Sodium Chloride, Sodium Sulphate, Sodium Bicarbonate, Citric Acid, Solanum Tuberosum Starch, Sodium Coco-sulphate, Sodium C14-16 Olefin Sulfonate, Parfum (Fragrance), Helianthus Annuus (sunflower) seed oil, Glycerine, Aqua (water), Prunus Amygdalus Dulcis (Sweet almond) oil, Maltodextrin, Olus (vegetable) oil, Chamomilla Recutita Flower Extract, Tocopherol, CI17200 (red 33), CI 14700 (red 4), CI 45410 (red 28)	*No substances with the prioritised classifications have been identified*
DK 15 - MS	Zea Mays starch, Glycerol, Disodium, Lauryl sulphosuccinate, catearyl alcohol, glyceryl stearate se, butyrospermum perkii butter, caprylic/capric triglyceride, sodium methyloleoyl taurate, methyl propanediol, caprylyl glycol, phenylpropanol, perfume, sucrose, octaacetate, CI47005	Linalool (24 ML)* (++) d-Limonene (24 ML)* (+) Phenylpropanol (+++)
DK 16 - MS	Aqua, Glycerine, Zea Mays Starch, Lauryl Glucoside, Stearyl Alcohol, Cocamidopropyl Betaine, Methylpropanediol, Simmondsia Chinensis Seed Oil, Glycine Soja Oil, Tocopherol, Coco-Glucoside, Panthenol, Calendula Offcinalis Flower Extract,	Linalool (24 ML)* (+) alpha-terpineol (81 ML)** (++) Phenylpropanol (+++) Tetrahydrolinalool (+++)

Lab no.	Ingredients according to ingredient list	Substances identified by GC-MS screening
	Glyceryl Oleate, Caprylyl Glycol, Phenylpropanol, Sodium Hydroxide, Sodium Chloride, Xanthan Gum, Beta-Carotene, Sucrose Octaacetate, Parfum, CI 42051, CI 42090, CI 77891	
DK 18 - SK	Aqua, Butane, Isobutane, Propane, Triethanolamine, Stearic acid, Parfum, CI 42090	Benzyl alcohol (24 ML*) (+)
DK 19 - GE	Sodium Polyacrylate, Parfum Tutti Frutti, Colourants. Solvent: Sodium Chloride, Colourants	Linalool (24 ML)* (+) Benzyl alcohol (24 ML)* (+) Cinnamyl alcohol (24 ML)* (+)
EU 21 - BK	Sodium Bicarbonate, Citric Acid, Theobroma Cacao (Cocoa) Seed Butter, Zea Mays (Corn) Starch, Sucrose, Polysorbate 80, Sodium Lauryl Sulphate, Aqua (Water), Synthetic Fluorphlogopite, Butyrospermum Parkii (Shea Butter), Lac (Milk), Glucose, Parfum (Fragrance), Palm Oil, Xanthan Gum, Glycerine, Lecithin, Aroma (Flavour), Cellulose Gum, Riboflavin, Jasminum Officinale (Jasmine) Oil, Rosa Centifolia Flower Oil, **Benzyl Salicylate, Citral, Citronellol, Geraniol, Linalool**, Beta Vulgaris (Beetroot Red), CI 77891 (Titanium Dioxide), **CI 18050**, CI 77861 (Tin Oxides), CI 77266 (Black 2).	*Not selected for GC-MS screening*
EU 22 - BK	Sodium Bicarbonate, Citric Acid, Monosodium Citrate, Dipropylene Glycol, Maltodextrin, Sodium Coco-Sulphate, Parfum, Zea Mays Starch, Isopropyl Alcohol, Aqua, Cocamidopropyl Betaine, PEG-450, Coumarin, Vegetable Oil, **Linalool**, Prunus Amygdalus Dulcis Oil, Chamomilla Recutita Extract, **Limonene**, **BHT**, Glycerine, CI 74160, Propylene Glycol, Sodium Benzoate.	*Not selected for GC-MS screening*
EU 23 - BK	Sodium Bicarbonate, Citric Acid, Theobroma Cacao (cocoa) Seed Butter, Zea Mays (Corn) Starch, Sucrose, Parfum (fragrance), Aqua (water), Sodium Lauryl Sulphate, Butyrospermum Parkii (shea Butter), Albumen (freom Egg), Oryza Sativa (rice) Starch, Triticum Vulgare (wheat) Starch, Glucose, Acacia Senegal Gum, Aroma (flavour), Maltodextrin, Shellac, Citrus Aurantium Bergarria (Bergamot) Fruit Oil, Citrus Nobilis (mandarin) Peel Oil, Potassium Silicate, Riboflavin, Curcumin, Limonene, **CI 18050**, CI 77499 (Iron Oxides), CI 19140 (yellow 5), CI 75300 (Curcumin), CI 77820 /SIlver)	*Not selected for GC-MS screening*
EU 24 - FA***	Sodium Chloride, Hylocereus Undatus Fruit Extract, Hamamelis Virginiana (Witch Hazel) Leaf Extract, Simmondsia Chinensis (jojoba)Seed Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, **Limonene, Eugenol, Coumarin**, Parfum (fragrance), Polysorbate 20, Sodium Methyl Oleoyl Tayrate, Sodium Carbonate, Glycerin, Aqua (water), Glycine Soja (soybean) Oil, Tocopherol, **CI 73015**, CI 47005	Linalool (24 ML)* (+++) d-Limonene (24 ML)* (++) 1.8-quinol (++) Allylanisole (+) Alpha-isomethyl ionone (24 ML)* (+) Coumarin (24 ML)* (++) alpha-terpineol (81 ML)** (++) Anethole (81 ML)** (++) Phenylpropanol (++) Methyl cinnamate (++)

Lab no.	Ingredients according to ingredient list	Substances identified by GC-MS screening
EU 25 - FA	Sodium Bicarbonate, Sodium Sulphate, Citric Acid, Sodium Chloride, Parfum, Vitis Vinifera Seed Oil, Persea Gratissima Oil, Aqua, CI 19140, CI 42090	Amyl cinnamal (24 ML)* (++) alpha-terpineol (81 ML)** (+)
EU 27 - KBS	*No ingredient list*	*No significant peaks*
EU 29 - MS	Glycerine, PEG-8, Aqua, Lauryl Glucoside, Parfum, **Sodium Lauroyl Sarcosinate**, Phenoxyethanol, Chondrus Crispus Powder, Citric Acid, Ethylhexylglycerin, Alcohol, PEG/PPG-17/6 Copolymer, **CI 15510**, Denatonium Benzoate, **Mek (methylethyl ketone).**	Citral (24 ML)* (+) Linalool (24 ML)* (+) Citronellol (24 ML)* (++) d-Limonene (24 ML)* (++) alpha-terpineol (81 ML)** (++) Tetrahydrolinalool (++) Pinene (81 ML)** (++) Caprylyl glyceryl ether (+++) *endo*-Borneol (uncertain identification) (+)
EU 31 - GE	Sodium Polyacrylate, Glitter, Perfume, Colourants, Sodium Chloride (solvent)	*No substances with the prioritised classifications have been identified*
NEU 33 - BK	*No ingredient list*	Citral (24 ML)* - uncertain identification (+) Linalool (24 ML)* (+) Citronellol (24 ML)* (++) Geraniol (24 ML)* (+) Benzyl alcohol (24 ML*) (++) d-Limonene (24 ML)* Benzyl benzoate (24 ML)* (+++) Allyl cyclopropionate (++) BHT (+) HHCB (hormone, 81 ML) (+)
NEU 34 - BK	Sodium bicarbonate, citric acid, sodium sulphate, amylodextrin, polyglycerine-3, fragrance, red 106	Benzyl benzoate (24 ML)* (+) BHT (+) HHCB (hormone, 81 ML) (+)
NEU 35 - BK	Baking soda, citric acid, sea salt, shea butter, essential oils, perfume oils, colourants	Lilial (on Annex II (prohibited) of the Cosmetics Regulation) (+) Hexyl cinnamal (24 ML)* (+) Linalool (24 ML)* (+) Geraniol (24 ML)* (+) Benzyl alcohol (24 ML*) (+) Coumarin (24 ML)* (+) Benzyl benzoate (24 ML)* (+) HHCB (hormone, 81 ML) (++) Phenylisohexanol (+) *Endo*-borneol (+) BHT (+)
NEU 36 - FA	Sucrose, Maltose, Carbon Dioxide, Colourants	*No substances with the prioritised classifications have been identified*
NEU 39 - VU	Sodium Carbonate, Sodium Bicarbonate, Sodium Sulphate, Citric Acid, Hydroxyethylcellulose, Fragrance, Yellow 5, Blue 1.	Linalool (24 ML)* (+) Citronellol (24 ML)* (+) Benzyl alcohol (24 ML*) (+) BHT (+)

Lab no.	Ingredients according to ingredient list	Substances identified by GC-MS screening
		endo-Borneol (uncertain identification) (+)
NEU 40 - KBS	Sodium Chloride, Sodium Lauryl Sulfoacetate, Maltodextrin, Lavandula Angustifolia (Lavender) Oil, Polysorbate 20.	Linalool (24 ML)* (++) d-Limonene (24 ML)* (++) 1.8-quinol (++) Camphor (81 ML)** (++) Coumarin (24 ML)* (+) *endo*-Borneol (++) Geranyl acetate (81 ML)** (++)
NEU 41 - KBS	Magnesium Sulphate (Epsom Salt), Fragrance (Parfum), Ormenis Multicaulis Extract (Chamomile), Helianthus Annuus (Sunflower) Seed Oil, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis leaf Extract (Decolorized), Sodium Bicarbonate, Melatonin.	Linalool (24 ML)* (+) Geraniol (24 ML)* (+) d-Limonene (24 ML)* (+) BHT (++) 4-tert-Butylcyclohexyl acetate (++) HHCB (hormone, 81 ML) (+++)
NEU 42 - MS	Water, Cocamidopropyl Betaine, Sodium Laureth Sulphate, Glycerine, Phenoxyethanol, Citric Acid, Sodium Benzoate, Fragrance, Hydrogenated Castor Oil, Red 33, Blue 1, Red 40.	d-Limonene (24 ML)* (+) BHT (++) Dichlorobenzyl alcohol (+++) Laureth-2 (+++) 2,4-dichlorobenzaldehyde (+)
NEU 43 - SK	Pure Saccharum Officinarum (Cane Sugar), Lathanol LAL Powder (SLSA), Corn Starch, YumBerry extract.	Linalool (24 ML)* (++) Citronellol (24 ML)* (+) Geraniol (24 ML)* (+) d-Limonene (24 ML)* (+++) alpha-terpineol (81 ML)** (++) Linyl acetate (+)
NEU 44 - SL	Sodium Acrylate Copolymer, Parfum Strawberry, Colourants	*No substances with the prioritised classifications have been identified*

* 24 ML = the substance is among the 24 fragrance ingredients subject to mandatory labelling that must be declared for cosmetic products; ** 81 ML = the substance is among the new fragrance ingredients subject to mandatory labelling that in the future will have to be declared for cosmetic products. *** For these products, the identified fragrance ingredients subject to mandatory labelling are declared on the product.
+ = less than one tenth of the standard area, ++ = between one tenth and the standard area, +++ = greater than the standard area, (+) = identification is uncertain.

8.3 Prioritisation of substances for risk assessment and quantitative analyses

Based on a review of TABLE 12, TABLE 13 and TABLE 14, the following substances with the most critical effects are suggested to be prioritised for further hazard assessment/risk assessment and thus for the quantitative analyses:

- Colourant CI 15510
- Colourant CI 18050
- Colourant CI 45380
- Colourant CI 73015
- BHT
- HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran)
- *Endo-borneol*
- 3-Methyl-5-phenylpentan-1-ol (phenylisohexanol)

The background for the selection of these substances is described below for the individual substances and why some of them are nevertheless excluded.

Colourant CI 15510 (Acid orange). Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzenesulfonate, CAS 633-96-5. The substance is an azo colourant that is REACH registered and classified with STOT RE1 H372. Toxicological data is considered available and relevant for hazard assessment.
The colourant is present in the products DK 1 - BK and EU 29 - MS

Colourant CI 18050 (Acid Red 001). Dinatirum 5-acetylamino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulfonate. CAS 3734-67-6. The substance is an azo colourant that is REACH registered and classified with Skin Sens 1B H317. Toxicological data is considered available and relevant for hazard assessment.
The colourant is present in the products EU 21 - BK and EU 23 - BK.

Colourant CI 45380. Dinatrium 2-(2,4,5,7-tetrabrom-6-oxido-3-oxoxanthen-9-yl)benzoat. CAS 17372-87-1. The substance is not an azo colourant. Is REACH registered with Skin Sens. 1, H317. High NOAEL value of 1000 mg/kg/day for subchronic test, and thus not relevant for hazard assessment.
The colourant occurs in DK 1 - BK.

Colourant CI 73015. Indigotine disulfonate sodium CAS 860-22-0. The substance is not an azo colourant. Is REACH registered with Skin Sens 1, H317. Very high NOAEL value of 1282 mg/kg/day from chronic study, and thus not relevant for hazard assessment.
Occurs in the product EU 24 - FA.

BHT, butylated hydroxytoluene, CAS 128-37-0. Suspected endocrine disruptor. Relevant for hazard assessment.
Occurs in the products NEU 41 - KBS ++ and NEU 42 - MS ++. In addition, in smaller quantities (+) in the products DK 2 - BK, NEU 33 - BK, NEU 34 - BK, NEU 35 - BK and NEU 39 - VU. BHT is also declared on the ingredient list in product EU 22 - BK.

HHCB (1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran), INCI: Hexamethylindanopyran, CAS 1222-05-5. The substance is REACH registered without classification but on the list of suspected endocrine disruptors. Sufficient data and relevant for hazard assessment.
Occurs in the product NEU 33 - BK +, NEU 34 - BK +, NEU 35 - BK ++ og NEU 41 - KBS +++.

***Endo*-borneol,** (DL-borneol), CAS 507-70-0. REACH registered and classified with Eye Damage 1 H318 and STOT SE 2 H371. Tox data is available with a low LOAEL of 9.9 mg/kg/day. Relevant for hazard assessment.
Occurs in product NEU 35 - BK + and NEU 40 - KBS ++, and possibly in EU 29 - MS and in NEU 39 - VU, where the identification in both cases is uncertain (+).

3-Methyl-5-phenylpentan-1-ol, INCI: phenylisohexanol, CAS 55066-48-3. The substance is REACH registered with classification STOT RE 2 with NOAEL of 150 mg/kg/day.
Occurs in NEU 35 - BK +. However, the substance does not appear to be available as a standard for the chemical analyses at the moment. This is a made-to-order item that will not arrive if the project schedule is to be met. In collaboration with the Danish EPA, this substance was therefore excluded from the quantitative analyses and further risk assessment.

8.4 Prioritising products for quantitative analysis

Based on the selection of the above substances and the overview in TABLE 14, it will therefore be relevant to perform quantitative analyses on the products listed in TABLE 15 below.

For some products, the specific colourants were not indicated. It was not possible to identify these colourants in the screening analyses (FT-IR). For this reason, it was decided in collaboration with the Danish EPA that these products without identification of colourants should also be analysed quantitatively for the two selected colourants CI 15510 and CI 18050.

TABLE 15. The 15 products selected for quantitative analysis for certain ingredients

Product	Colourant content CI 15510 and CI 18050	Content of BHT, *endo*-borneol, HHCB
DK 1 - BK	CI 15510 according to the ingredient list	
DK 2 - BK		BHT According to the ingredient list
DK 19 - GE	Unknown red/orange colourant	
EU 21 – BK	CI 18050 according to the ingredient list	
EU 22 – BK		BHT according to GC-MS screening
EU 23 – BK	CI 18050 according to the ingredient list	
EU 29 – MS	CI 15510 according to the ingredient list	Possibly *endo*-borneol according to GC-MS screening
NEU 33 – BK	Unknown orange colourant	BHT and HHCB according to GC-MS screening
NEU 34 – BK		BHT and HHCB according to GC-MS screening
NEU 35 – BK	Unknown red colourant	BHT, *endo*-borneol and HHCB according to GC-MS screening
NEU 36 – FA	Unknown red colourant	
NEU 39 – VU		BHT and possibly *endo*-borneol according to GC-MS screening
NEU 40 – KBS		*Endo*-borneol according to GC-MS screening
NEU 41 – KBS		BHT and HHCB according to GC-MS screening
NEU 42 – MS		BHT according to GC-MS screening

Empty fields indicate that the substances have not been detected in the products via the ingredient list or via the screening analyses.
BK = bath ball; GE = bath gel; MS = modelling soap; FA = bathwater colours; VU = bathwater volcano; KBS = crackling powder/bath salt.

9. Quantitative analyses

In collaboration with the Danish EPA, it was decided that quantitative analyses should be carried out for the following substances:

- Colourant CI 15510 - CAS 633-96-5
- Colourant CI 18050 - CAS 3734-67-6
- BHT - CAS 128-37-0
- HHCB - CAS 1222-05-5
- *Endo*-borneol - CAS 507-70-0

9.1 Quantitative analysis of CI 15510 and CI 18050

The two colourants are analysed using the same analysis method. Therefore, the analysis method and results for both colourants are presented together in this section.

9.1.1 Analysis method for CI 15510 and CI 18050

Approx. 0.25 g of homogenised sample was dissolved in 5 ml of water/methanol 1:1, suspended/dissolved in an ultrasonic bath at 60 °C and filtered through syringe filters into brown vials, after which the sample was analysed on HPLC with DAD detector. The HPLC column used was a LiChrospher 100, RP-18 (5µm) 250-4, column temperature 30 °C, and a gradient eluent[23] (consisting of 20 µmol ammonium acetate solution pH 6.7 and methanol: acetonitrile 1:1) was used for the analysis, with a flow rate of 1.0 ml/min. The wavelengths used for quantification of the colourants were 492 and 536 nm for CI 15510 and CI 18050 respectively.

Duplicate determinations of samples, controls, blanks, performed standard addition to selected samples, and the method was validated. Calibration was done by external calibration against solutions of the pure colourants in analytical grade (i.e. close to 100% purity). The reference substance used for CI 15510 and CI 18050 was 99.2% and 98.1% pure, respectively, which has been corrected for in the analysis results.

The LOD (limit of detection) for the orange colourant (CI 15510) is 0.3 ppm and the limit of quantification (LOQ) is 0.9 ppm when using a sample of 0.25 g. The LOD for the red colourant (CI 18050) is 0.8 ppm and the LOQ is 2 ppm when using a sample of 0.25 g. However, the limits for both the red and orange colourants are higher for two of the samples. This is due to test preparation circumstances. These samples can only be dissolved in a larger volume of liquid than the other samples, as the two samples form a gel and absorb the liquid. Therefore, the degree of dilution and thus the detection limit is higher for these two samples compared to the other samples.

The relative expanded uncertainty for CI 15510 and CI 18050 is 18% and 20% at 100/130 ppm and 12% and 6% at 20 ppm when using 0.25 g sample.

9.1.2 Results of quantitative analyses on the two colourants

The results of the quantitative analyses for the two colourants are listed in TABLE 16 below. As stated in TABLE 15, quantitative analyses were performed on the four products where the two colourants were included in the list of ingredients, but also on the four products where knowledge of the colourant was unknown after the screening analyses.

[23] The mobile phase in an HPLC column, the solvent used to "pull" the compounds through the column.

The results are given as an average of the two true duplicate determinations made for each product. Values indicated as " < " mean that no content of the colourant has been detected in the product above this value (equal to the detection limit). However, for two of the products, the detection limit is higher (bath gel and modelling soap) as the product swells/solidifies when dissolved. Therefore, a higher dilution and thus a higher detection limit was required to perform the quantitative analysis for these products.

TABLE 16. Analysis results for the eight products that were analysed quantitatively for content of the two colourants (respectively CI 15510 and CI 18050)

Product	Content of CI 15510 (in mg/kg)	Content of CI 18050 (in mg/kg)	Comment on knowledge about the two colourants
DK 1 - BK*	< 0,3	< 0,8	Content of CI 15510 according to the ingredient list on the product, but not detected in the quantitative analysis.
DK 19 - GE**	< 13	< 35	Unknown colourant. No information via ingredient list. The two colourants are not detected in the quantitative analysis.
EU 21 - BK	< 0,3	29	Content of CI 18050 according to the ingredient list on the product and detected by the quantitative analysis.
EU 23 - BK	< 0,3	16	Content of CI 18050 according to the ingredient list on the product and detected by the quantitative analysis.
EU 29 - MS**	47	< 1	Content of CI 15510 according to the ingredient list on the product and detected by the quantitative analysis.
NEU 33 - BK	1	< 0,8	No information via ingredient list. Content of CI 15510 identified by the quantitative analysis.
NEU 35 - BK	< 0,3	< 0,8	Unknown colourant. No information via ingredient list. The two colourants are not detected in the quantitative analysis.
NEU 36 - FA	< 0,3	< 0,8	Unknown colourant. No information via ingredient list. The two colourants are not detected in the quantitative analysis.

BK = bath ball; GE = bath gel; FA = bathwater colours, MS = modelling soap.
* The colours coral, pink and purple are analysed. No identification of the colourant in any of the colours.
** A higher degree of dilution is used for the product, otherwise it will solidify/form a non-homogeneous solution.

It can be seen from the results in TABLE 16 that the red colourant CI 18050 was identified in the two products where it was also listed in the ingredient list, i.e. EU 21 - BK and EU 23 - BK, but not in any of the other products studied. The concentrations are small and are 29 and 16 mg/kg respectively. The orange colourant CI 15510 was only identified in one of the two products where it appeared in the ingredient list (EU 29 - MS) and at a concentration of 47 mg/kg. In addition, the orange colourant CI 15510 was identified in a small amount (1 mg/kg) in NEU 33 - BK. During the analysis, it was also confirmed that DK 19 - GE and NEU 36 - FA contain the same red colourant, as seen with TLC. However, the identity of this colourant is unknown.

9.2 Quantitative analysis of BHT, borneol and HHCB

BHT, borneol and HHCB are analysed using the same analysis method. The analysis method and the results of the quantitative analyses for the three substances are therefore presented together in this section.

9.2.1 Analysis method for BHT, *endo*-borneol and HHCB

A purification of the sample was performed, where oils and water are retained and the analytes are extracted. Approximately 0.1 g of homogenized sample was weighed, an internal standard was added, and it was mixed with sodium sulphate and Florisil. This was followed by elution with ethyl acetate, and turbid samples were filtered through a PTFE syringe filter before analysing on GC-MS with a 60 m wax column.

Duplicate determinations of samples, controls, blanks, performed standard addition to selected samples, and the method was validated. Calibration was done with a combination of external and internal calibration, where the internal standard was deuterated BHT (BHT-d3 (m/z 208/223). Quantification was performed on the most intense of the specific ions for each substance, and selected specific ions were used for qualification: BHT (m/z 205/220), *exo*- and *endo-Borneol* (m/z 95/110) and HHCB (m/z 243/213/258).

Reference substances for borneol and HHCB could not be purchased as single isomers in analytical grade within the time available to perform the quantitative analyses. Borneol's reference substance consisted of a mixture of *endo*- and *exo*-borneol. A response factor was used for each isomer. The reference substance used for borneol consisted of 73.8% *endo*-borneol. The *exo*-borneol content was approximately 20%, and the manufacturer was unable to provide the exact value upon request. The *exo*-borneol content was therefore calculated based on the response factor vs. *endo*-borneol in the reference substance. In the analysis results, a correction for this purity has been made.
HHCB has four stereoisomers and in the reference compound, four signals could be identified with appropriate molecular weight and fragmentation pattern. The distribution between these matched the one observed in the samples, and the concentration was therefore calculated based on the two most intense signals. The supplier of the reference substance could not provide the ratio between the different isomers. The reference substance used for HHCB was 85.8% pure, which the analysis result has been corrected for.
The reference substance used for BHT was 99.9% pure, which the analysis result has been corrected for.

The limit of detection (LOD) for BHT was determined to be 0.01 ppm. The corresponding limit of quantification (LOQ) is 0.03 ppm for BHT with a relative expanded uncertainty of 5% at 17 ppm and 2% at 130 ppm. The LOD for *exo*-borneol was determined to be 0.01 ppm and LOQ of 0.02 ppm with a relative expanded uncertainty of 4% at 3 ppm and 2% at 17 ppm. The LOD for *endo*-borneol was determined to be 0.01 ppm and LOQ of 0.02 ppm with a relative expanded uncertainty of 7% at 15 ppm and 3% at 100 ppm. The LOD for HHCB was determined to be 0.01 ppm and LOQ 0.03 ppm with a relative expanded uncertainty of 31% at 140 ppm and 4% at 210 ppm. The expanded uncertainty was measured by standard addition to a sample low in BHT, *exo*- and *endo*-borneol, but high in HHCB. The closer to the quantification limit, the higher the relative expanded uncertainty is expected to be. In addition, the uncertainty is matrix-dependent and is expected to be higher for samples that are difficult to homogenise and where the analytes in the product are unevenly distributed. For the sample used for standard addition, the uncertainty is highest at the low level of HHCB, as the amount of HHCB in the sample is already high and unevenly distributed, which has a greater impact when adding a small amount of HHCB in standard addition than when adding a larger amount.

9.2.2 Results of quantitative analyses for BHT, borneol and HHCB

The results of the quantitative analyses for BHT, borneol and HHCB are listed in TABLE 17 below. As stated in TABLE 15, quantitative analyses were carried out for the ten products where the three substances appeared either in the list of ingredients (BHT) or in the screening analyses.

The results are given as an average of the two true duplicate determinations made for each product. Values indicated as " < " mean that no content of the substances in the product above this value (equal to the detection limit) has been detected. Quantitative values are given for the two isomers *exo*-borneol and *endo*-borneol, as well as the sum of the two isomers. For borneol, there are different detection limits for the different products due to interference in the samples. The value for HHCB is the sum of the four isomers of HHCB.

TABLE 17. The ten products analysed quantitatively for BHT, borneol and HHCB

Product	Content of BHT (mg/kg)	*Exo*-borneol content (mg/kg)	*Endo*-borneol content (mg/kg)	Sum of *endo*- and *exo*-borneol (mg/kg)	Contents of HHCB (mg/kg)
DK 2 - BK	0.6	< 0.01	< 0.04**	< 0,05	0.07***
EU 22 – BK	50	0.02	0.3	0.3	5
EU 29 – MS	< 0.01	< 0.2**	0.5	0.5	0.1***
NEU 33 – BK	5	< 0.1**	< 0.8**	< 0,9	1
NEU 34 – BK	2	< 0.01	< 0.04**	< 0,05	7
NEU 35 – BK	0.5	0.2	2	2	123
NEU 39 – VU	0,01*	0.02**	0.1	0.1	0.6
NEU 40 – KBS	< 0.01	< 0.3**	76	76	0.01*,***
NEU 41 – KBS	27	< 0.3**	0.03*,**	0.03	1862
NEU 42 – MS	28	< 0.01	< 0.08**	< 0.09	0.05

BK = bath ball; GE = bath gel; MS = modelling soap; FA = bathwater colours; VU = bathwater volcano; KBS = crackling powder/bath salt.
The average relative deviation between the double determinations in the reported values is 6% for samples where the measured content of a given substance is ≥ 5 ppm and 11% for samples where the measured content of a given substance is < 5 ppm.
* Detected but below LOQ (limit of quantification). The value is therefore uncertain.
** LOD and LOQ are elevated due to interferences in the sample, any value given is therefore more uncertain.
*** In the analysis, a slight carry-over of HHCB was observed across samples, which for this sample may give rise to an overestimation of the content.

It can be seen from the results in TABLE 17 that BHT is identified in small concentrations in eight of the ten products analysed quantitatively for BHT. The concentration of BHT ranges between 0.01 and 50 mg/kg. All eight products contain fragrance, and for all products BHT may have been used as an antioxidant in the fragrance blends added to the products.

Borneol (both *exo*- and *endo*-borneol) is identified in six of the ten products analysed. Since *exo*-borneol is usually present in much lower concentration than *endo*-borneol, *exo*-borneol is not necessarily identified for products with low *endo*-borneol content close to the limit of quantification. The concentration of borneol ranges between 0.03 and 76 mg/kg in the six products.

HHCB is identified in seven of the ten products. In the three products with the lowest concentration of HHCB, it was assessed that a slight carry-over of HHCB across samples during analysis may lead to a higher value than the sample actually contained. The concentration of HHCB in the seven samples ranges between 0.05 and 1862 mg/kg. The highest measured content is close to 0.2%.

For all three substances BHT, borneol and HHCB, the substances are identified in more products than in the GC-MS screening. This is partly because there is a much lower detection limit (almost 100 times lower) for this quantitative analysis compared to the GC-MS screening. It is estimated that the detection limits for the screening method are approx. 0.2-1 ppm for BHT, *exo*-borneol and *endo*-borneol, but approx. 4 ppm for HHCB. In addition, not all peaks in the screening were identified (see chapter 7), and low levels of BHT, borneol and HHCB may therefore also occur in other products that were not selected for quantitative analysis.

10. Hazard assessment

The following substances have been selected for quantitative analyses and further hazard and risk assessment:

- CI 15510 – CAS nr. 633-96-5
- CI 18050 – CAS nr. 3734-67-6
- BHT – CAS No. 128-37-0
- HHCB – CAS nr. 1222-05-5
- *Endo*-borneol – CAS nr. 507-70-0

Below, the toxicological data for each of the substances are assessed and the critical effects of the substances (i.e., the effects that occur at the lowest exposure) and the N(L)OAEL of the effects are identified. It is considered relevant to focus on both *local effects*, i.e., skin and mucous membrane irritation/skin sensitising effects, and *systemic effects* (i.e., effects on organs after absorption of the substance into the organism) in connection with single and repeated exposure to account for both acute and chronic systemic effects.

For products that are considered to be cosmetic products and that are to be assessed according to the guidelines provided in the SCCS Notes of Guidance (2023), the identified N(L)OAEL levels for the critical effects are subsequently used in the risk assessment as the N(L)OAEL values are subsequently used to determine the systemic exposure of the substance which is used as the Point of Departure (PoD) for the risk assessment where the Margin of Safety (MoS) is calculated:

MoS = PoD/SED

where SED is the calculated systemic exposure of the user.
If the starting point for the NOAEL is from a 90-day animal study, a MoS value of 100 is usually considered sufficient to conclude that the exposure does not pose a risk.

For products that are considered to be toys, the risk of the chemical content is assessed according to the rules of the REACH regulation. In REACH, tolerable exposure levels for the substances are calculated from the identified N(L)OAELs for oral and dermal exposure. This derivation of tolerable exposure levels is, according to The REACH regulation, a part of the hazard assessment of a substance, which is why DNEL values will also be performed in this section. The DNEL values will subsequently be used in the risk assessment to evaluate the products that are considered to be toys in a regulatory sense.

The tolerable exposure level DNEL (Derived No Effect Level) is calculated according to the REACH guidance (ECHA 2012) by dividing the N(L)OAEL value for the critical effect by a number of uncertainty factors called assessment factors (AF):

DNEL = N(L)OAEL / (AF1 x AF2 x ... x Afn)

Where

AF1 = assessment factor for interspecies differences (i.e., uncertainty in transferring animal data to humans). The value is dependent on animal species and exposure route. A value of 10 is used e.g. in oral studies with rats.

AF2 = assessment factor for intraspecies differences, i.e., biological variations in sensitivity between humans. A value of 10 is used for the general population.
AF3.....AFn = factors for other conditions e.g. use of LOAEL value instead of NOAEL value; conversion from short-term exposure to chronic exposure, severity of effect, poor data quality, etc.

The DNEL values will then subsequently in the risk assessment chapter be compared with the estimated exposure from the bath product by calculating a risk characterisation ratio, RCR:

RCR = Estimated exposure / DNEL.

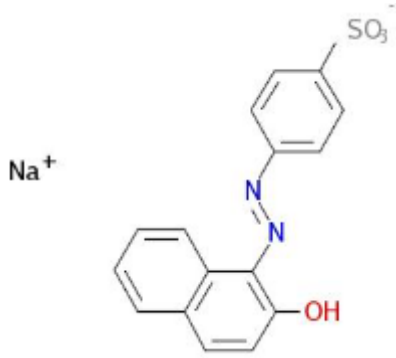
Here, an RCR value below 1 would typically be considered as safe use.

The following data on the substances were obtained from a web search for toxicological data and expert judgements using Google, ECHA website, PubMed and Pubchem databases.

10.1 CI 15510 – CAS nr. 633-96-5

CI 15510 is REACH registered in an annual tonnage level of 10-100 tonnes under the name *sodium 4-[(2-hydroxy-1-naphthyl)azo]benzene sulfonate* and the trivial name *Agent Orange 7*. The registration states that the substance is used as a colourant in a very wide range of products, both for private and professional use and, as stated in Annex IV of the Cosmetics Regulation, may also be used as a colourant in cosmetics.

10.1.1 Physicochemical data

	CI 15510
Chemical structure	
Systematic name	Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzene sulphonate
Chemical formula	C16H12N2O4S.Na
Molecular weight	350.3 (PubChem)
Physical state	Solid
Melting point	290 °C
Boiling point	Decompose
Vapour pressure	Solid
Water solubility	27 g/L at 20 °C
Log Pow	-0.95 at 20 °C

Data is from the REACH registration dossier of the substance

10.1.2 Toxicology

10.1.2.1 Data basis

In connection with the literature search on the substance, the following sources are considered the most suitable starting point for the hazard assessment:

- REACH registration dossier, CI 15510
- SCCS (2014) assessment of Agent Orange 7

The main emphasis is on the independent expert assessment of the SCCS (2014).

10.1.2.2 Classification

The substance is classified in the REACH registration dossier as[24]:

> *STOT RE 1. H372: Causes damage to organs through prolonged or repeated exposure*

10.1.2.3 Absorption and metabolism

SCCS (2014) describes an OECD 428 *in vitro* human skin penetration study in which test formulations containing 0.2 to 0.8% radioactively labelled CI 15510 were applied to skin surfaces for 30 minutes and then skin permeability was measured over the following 72 hours.
From this data, SCCS (2014) concluded skin penetration to be 0.25 µg/cm^2 based on testing a 0.5% CI 15510 test solution. As the total dose of the test solution was 20 mg/cm^2, this corresponded to 0.1 mg/cm^2 (or 100 µg/cm^2) CI 11510. This means that skin absorption in % can be calculated as 0.25 µg/cm^2 x 100 / 100 µg/cm^2 = 0.25% for ½ hour exposure or 0.5% per hour.

In addition to data on dermal absorption, no further test data on the absorption or metabolism of the substance are provided (SCCS 2014; REACH registration, CI 15510).

10.1.2.4 Local effects

Based on the data, SCCS (2014) concludes that CI 15510 may cause mild skin irritation, while there is a lack of relevant data for eye irritation. *In vivo* tests for skin sensitisation showed no allergenic properties.

10.1.2.5 Systemic effects

Acute effects, single exposure
SCCS (2014) states oral LD50 values for mice and rats to be above 10,000 mg/kg i.e., the substance has very low acute toxicity.

Repeated exposure
In a 90-day oral trial in rats dosed at 0, 2.5, 5 and 10 mg/kg bw/day, slight haematological changes (increased methaemoglobin levels and reticulocyte count) were found at the lowest level and more pronounced effects in the blood at the higher levels. Based on this study, SCCS (2014) concluded an oral LOAEL of 2.5 mg/kg bw/day.
In an oral study in which rats were dosed with 0, 5, 40 and 320 mg/kg bw/day from day 6 to day 17 of gestation, a NOAEL for maternal toxicity and foetal development of 5 mg/kg bw/day and 320 mg/kg bw/day, respectively, was found (SCCS (2014)).

[24] The REACH registrant's classification is stated, as it may contain self-classification for other effects in addition to the EU harmonised classification (this is checked).

Mutagenic and carcinogenic effects
Regarding mutagenic/genotoxic effects and based on in *vitro* and *in vivo* studies, SCCS (2014) concluded that the substance is well studied, and data do not indicate any mutagenic/genotoxic effects.
In a chronic skin brushing study, mice were exposed to 0.1 ml of 0.1% CI 15510 once a week without increasing tumour incidence (SCCS (2014)).

10.1.2.6 Identification of critical effects
Based on the above review, the following critical effects and dose levels can be identified for CI 15510:

Local effects
Local effects are not considered critical effects for CI 15510.

S*ystemic effects*
NOAEL (acute systemic): Not applicable due to very low acute toxicity.

LOAEL (repeated dose systemic) = 2.5 mg/kg bw/day for blood, kidney and liver effects, based on oral rat data in connection with 90 days dosing.

10.1.2.7 Calculation of DNEL values
DNEL, systemic
Based on a LOAEL of 2.5 mg/kg bw/day in connection with 90 days exposure, the following chronic DNEL for oral exposure can be calculated:

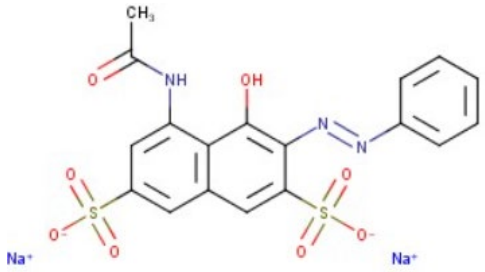
DNEL (chronic) = N(L)OAEL (chronic) / (AF1 x AF2 x ... x Afn)
DNEL (oral, chronic) = 2.5 mg/kg bw/day / (10 x 10 x 3 x 2)
DNEL (oral, chronic) = 0.004 mg/kg bw/day

An AF1 = 10 is used as the data is from a rat study, and an AF2 = 10 to protect the most sensitive in the population. In addition, an AF3 = 2 is used to extrapolate from a 90-day exposure to chronic exposure and an AF4 = 3 to extrapolate from a LOAEL level.

When calculating the DNEL (dermal, chronic), the much lower dermal absorption of 0.5% is taken into account:
DNEL (dermal, chronic) = DNEL (oral, chronic) x oral absorption / dermal absorption
DNEL (dermal, chronic) = 0.004 mg/kg bw/day x 100% / 0.5%
DNEL (dermal, chronic) = 0.8 mg/kg bw/day

10.2 CI 18050 – CAS nr. 3734-67-6
CI 18050 is REACH registered at an annual tonnage level of 10-100 tonnes under the name *disodium 5-acetylamine-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulfonate* and the trivial names *Acid Red 001* and *C.I. Acid Red 1*.
The registration states that the substance is used as a colourant in a very wide range of products, both for professional and private use, especially in cosmetics and in biocide and pesticide products. As specified in Annex IV of the Cosmetics Regulation, CI 18050 may be used as a colourant in cosmetics with the exception of products intended for mucous membranes.
CI 18050 is also used as a food colouring agent under the name *Red 2G (E128*).

10.2.1 Physicochemical data

	CI 18050
Chemical structure	
Systematic name	Disodium 5-acetamido-4-hydroxy-3-(phenyldiaze-nyl)naphthalene-2,7-disulfonate
Chemical formula	C18H15N3O8S2.2Na
Molecular weight	509.4 (Pubchem)
Physical state	Solid
Melting point	Decomposes > 345 °C
Boiling point	-
Vapour pressure	Solid
Water solubility	132 g/L at 20 °C
Log Pow	-2.4 at 20 °C

Data is from the REACH registration dossier of the substance

10.2.2 Toxicology

10.2.2.1 Data basis

In connection with the literature search on the substance, the following sources are considered the most suitable starting point for the hazard assessment:

- REACH registration dossier, CI 18050
- EFSA's assessment of colourant Red 2G (E218) (EFSA 2007)

The emphasis is on the independent expert judgement of EFSA.

10.2.2.2 Classification

The substance is classified in the REACH registration dossier with:

Skin Sens. 1B H317 May cause an allergic skin reaction

10.2.2.3 Absorption and metabolism

EFSA (2007) states an oral absorption of around 80% in rats. Excretion of the substance is in the form of the main metabolite p-aminophenol and the metabolites aniline (up to about 9%) and 2-amino-8-acetamido-1-naphtho-3,6-disulphonic acid.

10.2.2.4 Local effects

Based on *in vitro* tests for skin and eye irritation, the substance is not considered to cause irritation.

Based on an *in vivo* Local Lymph Node Assay, the substance is considered a skin sensitiser with an EC3 value of 2.1% (REACH registration dossier, CI 18050).

10.2.2.5 Systemic effects

Acute effects, single exposure

Oral LD50 values for mice and rats of well over 2000 mg/kg bw are reported (EFSA 2007; REACH registration, CI 18050).

EFSA (2007) states that the metabolite *aniline* in humans at single doses in the range 25-65 mg/kg bw causes methaemoglobin formation in the blood, while doses below 15 mg/kg bw did not cause effects.

Repeated exposure

EFSA (2007) describes three chronic oral studies in rats and mice. In mice, dosing at 179 mg/kg bw/day resulted in an enlarged and discoloured spleen and iron deposit in the spleen and kidneys. In rats, dosing at 32 mg/kg bw/day caused haemolysis of red blood cells, iron deposition and adverse effects on the spleen. The NOAEL for this effect was 8 mg/kg bw/day.

EFSA (2007), focusing on the metabolite aniline, estimated that the conversion to aniline could account for up to 20% of the dose in these trials.

In a foetal development study, rats were orally dosed with CI 18050 from day zero to day 19 of gestation. No effects on foetuses were seen at the highest dose of 100 mg/kg bw/day, while effects on spleen and haematopoiesis were seen in the dams.
In a one-generation study, no effects on the offspring were found at a dose to the dams of 100 mg/kg bw/day.

Mutagenic and carcinogenic effects

EFSA (2007) reported that CI 10850 has caused mutagenic effects in bacteria only after metabolic transformation of the substance and at relatively high concentrations (10 mg/L).

10.2.2.6 Identification of critical effects

Local effects

The skin sensitising effect of the substance is considered a critical effect for the local effects of the substance. However, there is a lack of relevant data for a quantitative hazard and risk assessment for the skin sensitising effect of the substance.

Systemic effects

NOAEL (acute systemic): Not applicable due to very low acute toxicity.

EFSA (2007) pays particular attention to the metabolic conversion of CI 18050 to aniline, which is classified for suspected mutagenic and carcinogenic effects (aniline is harmonised as Muta. 2, and Carc. 2) and concludes that the data base for CI 18050 is not sufficient for the calculation of an Acceptable Daily Intake (ADI) value.

However, it should be noted that in the further assessment of the current food exposure, EFSA indicates a MoE in relation to a previously established ADI in the range 0-0.1 mg/kg bw/day, which was based on a NOAEL of 8 mg/kg bw/day in a chronic rat study.

In connection with this project, it is therefore considered relevant to base the hazard assessment on a NOAEL of 8 mg/kg bw/day obtained in a chronic oral rat study.

NOAEL (repeated dose systemic) = 8 mg/kg bw/day for effects on spleen and red blood cells in a chronic oral rat study.

10.2.2.7 Calculation of DNEL values

DNEL local effects

Data basis is lacking for quantitative assessment of skin sensitising effect.

DNEL, systemic effects

Based on a NOAEL of 8 mg/kg bw/day for chronic exposure in rats, the following chronic DNEL for oral exposure can be calculated:

DNEL(oral, chronic) = N(L)OAEL(chronic) / (AF1 x AF2 x ... x Afn)
DNEL (oral, chronic) = 8 mg/kg bw/day / (10 x 10)
DNEL (oral, chronic) = 0.08 mg/kg bw/day

Using an AF1 = 10 as the NOAEL is based on data from a rat study and an AF2 = 10 to protect the most sensitive in the population.

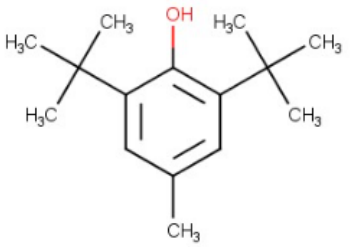
When calculating the DNEL for dermal exposure, it is considered relevant to use the same absorption factor of 0.5% as used in the hazard assessment of CI 15510, as these two substances have a similar chemical structure. The physical chemical data for CI 18050 will immediately suggest a lower dermal absorption due to the substance's higher molecular weight and lower octanol/water partition coefficient (lower Pow value).

DNEL (dermal, chronic) = DNEL (oral, chronic) x oral abs / dermal absorption
DNEL (dermal, chronic) = 0.08 mg/kg bw/day x 100% / 0.5%
DNEL (dermal, chronic) = 16 mg/kg bw/day

10.3 BHT – CAS No. 128-37-0

BHT is REACH registered in an annual tonnage level of 10 000-100 000 tonnes under the name *2,6-di-tert-butyl-p-cresol* and the common names *BHT* and *butylated hydroxytoluene*.
The substance is used as an antioxidant / stabiliser / colourant in a very wide range of products for private and professional use.
The substance is also used as an authorised additive as an antioxidant (E 321) in food.
The substance may not be used as a preservative in cosmetics, as it is not included in Annex V of the Cosmetics Regulation but may be used as an antioxidant in cosmetics.

10.3.1 Physicochemical data

	BHT
Chemical structure	
Systematic name	2,6-di-tert-butyl-4-methylphenol
Chemical formula	C15H24O
Molecular weight	220.4 (PubChem)
Physical state	Crystalline solid
Melting point	69.8 °C
Boiling point	296.5 °C
Vapour pressure	0.39 Pa at 25 °C
Water solubility	0.6 mg/L at 25 °C
Log Pow	5.2

Data is from the REACH registration dossier of the substance

10.3.2 Toxicology

10.3.2.1 Data basis

Extensive toxicological assessments have been carried out on BHT:

- EFSA (2012), Evaluation of BHT (E 321) as a food additive
- SCCS (2021), Assessment of the use of BHT in cosmetics
- DTU (2021), reassessment of BHA and BHT in foods
- Danish Environmental Protection Agency (2022), assessment of endocrine disrupting effects of BHT in consumer products.

10.3.2.2 Classification

The substance is not listed in the REACH registration dossier with any classification.

10.3.2.3 Absorption and metabolism

SCCS (2021) uses an oral absorption of 100% in their assessment of the substance. Dermal absorption is estimated to be 0.4% based on an *in vitro* dermal absorption study on human skin. These values for the absorption of BHT are also used in the risk assessment of BHT in the Danish EPA's previous project (2022).

It is stated that the substance is extensively metabolised in the organism and that the metabolites are efficiently excreted through urine and faeces (EFSA 2012, SCCS 2021).

10.3.2.4 Local effects

The SCCS (2021) concludes, based on previous assessments, that the substance is only mildly irritating to the skin and eyes.
SCCS (2014) concludes, based on a large human data base, that the substance is not a skin sensitiser.

10.3.2.5 Systemic effects

Acute effects, single exposure

EFSA (2012) and SCCS (2021) state that the substance has low acute toxicity based on oral LD50 values for a range of animal species.

Repeated exposure

DTU (2021) has conducted an updated assessment of BHT and, like EFSA (2012), assesses that the reproductive toxicity and endocrine disrupting effects are the most critical effects for the substance. Based on a NOAEL of 25 mg/kg bw/day in a two-generation oral rat study, a tolerable oral exposure level of 0.25 mg/kg bw/day has been established.

Mutagenic and carcinogenic effects

EFSA (2012) and SCCS (2021) concur that the substance is not mutagenic/genotoxic.
BHT has been shown to increase the incidence of lung and liver tumours in mice and rats, but at higher exposure levels than those causing reprotoxic and endocrine disrupting effects (EFSA 2012; SCCS 2021).

10.3.2.6 Identification of critical effects

Based on the above review, the following critical effects and dose levels can be identified for BHT:

Local effects

BHT is not considered to have critical local effects.

Systemic effects

BHT is not considered critical for acute toxicity.

NOAEL (repeated dose systemic) = 25 mg/kg bw/day for reproductive toxicity and endocrine disrupting effects.

10.3.2.7 Calculation of DNEL values

DNEL, systemic

DNEL (oral, chronic) = 0.25 mg/kg bw/day *(EFSA 2012; DTU 2021)*

The further calculation of DNEL (dermal, chronic) takes into account the much lower dermal absorption of 0.4%:

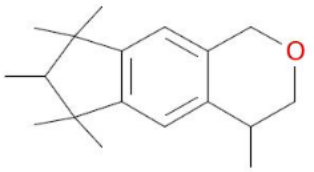
DNEL (dermal, chronic) = DNEL (oral, chronic) x oral absorption/ dermal absorption
DNEL (dermal, chronic) = 0.25 mg/kg bw/day x 100% / 0.4%
DNEL (dermal, chronic) = 62.5 mg/kg bw/day

10.4 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[g]-2-benzopyran; HHCB – CAS No. 1222-05-5

The fragrance HHCB is REACH registered in an annual tonnage level of 1000-10000 tonnes under the name *1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran* and the trivial names *HHCB, Musk 50, Galaxolide*, INCI name *hexamethylindanopyran*.
The registration states that the substance is used in a very wide range of products for private and professional use, including cleaning products and personal care products.
Also used in cosmetics, where the substance is one of the allergenic fragrances subject to mandatory labelling in the future. Due to its allergenic effect, the substance must not be used in toys at concentrations higher than 100 mg/kg.

The substance is suspected and under assessment for endocrine disruptors in the EU, ECHA (2023).

10.4.1 Physicochemical data

	HHCB
Chemical structure	
Systematic name	1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexame-thylindeno[5,6-c]pyran
Chemical formula	C18H26O
Molecular weight	258.4 (PubChem)
Physical state	High viscosity liquid
Melting point	< - 20 °C
Boiling point	318.6 °C
Vapour pressure	0.073 Pa at 25 °C
Water solubility	1.65 mg/L at 25 °C
Log Pow	5.3 at 25 °C

Data is from the REACH registration dossier of the substance

10.4.2 Toxicology

10.4.2.1 Data basis

In connection with the literature search on the substance, the following sources are considered the most suitable starting point for the hazard assessment:

- The REACH registration dossier for HHCB
- EU risk assessment report of HHCB (EU RAR 2008)

10.4.2.2 Classification

The substance is classified in the REACH registration dossier as an environmental hazard:

Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

The substance is not classified for any human health effects.

10.4.2.3 Absorption and metabolism

Based on the physicochemical properties of the substance and an *in vitro* human skin absorption study, oral and dermal absorption is concluded to be 50% and 5.2% respectively (EU RAR 2008; REACH registration dossier, HHCB). In a study with pigs, the half-life of the substance in the blood was found to be around 90 hours. In rats, excretion is primarily seen in faeces and urine.
No data on possible metabolisation of the substance is provided.
In humans, HHCB has been found to be distributed to adipose tissue and breast milk.

10.4.2.4 Local effects

In vivo tests suggest a slight degree of irritation (EU RAR 2008) but based on recent *in vitro* tests for skin and eye irritation, the substance is not considered to cause irritation to a degree that leads to classification (REACH registration, HHCB).
In humans, HHCB has not caused skin irritation upon skin contact with concentrated HHCB in a human allergy test.

In allergy tests with guinea pigs (Guinea Pig Maximisation Test), the substance did not show skin sensitising properties (EU RAR 2008, REACH registration, HHCB).

10.4.2.5 Systemic effects

Acute effects, single exposure
The substance has low acute toxicity as oral and dermal LD50 values in rats are significantly above 2000 mg/kg bw (REACH registration, HHCB).

Repeated exposure
After 14 days of oral exposure to rats with 300 mg HCCB/kg bw/day, increased liver weight and effects on liver cells were found. In a subsequent 90-day study, a NOAEL of 150 mg/kg bw/day was found (EU RAR 2008, REACH registration, HHCB).

Based on a rat study in which dams were exposed during gestation and lactation, the EU RAR (2008) concluded a NOAEL at the highest dose of 20 mg/kg bw/day.
In higher dose trials, evidence of maternal toxicity was found at 150 mg/kg bw/day and effects on the offspring at 500 mg/kg bw/day, with effects on bone development at this dose.

However, the REACH dossier contains more recent data:
In an extended oral one-generation study in rats focusing on endocrine disrupting effects, when dosed with HHCB (administered via the diet at intended doses of 42.5; 75 and 150 mg/kg bw/day), an enlargement of the thyroid was found in the parental generation in both sexes and at all dose levels. Furthermore, blood levels of thyroid hormones were affected (increased TSH and reduced T4 levels). According to the REACH registration, the effects were assessed as marginal and without harmful consequences, which is why the highest dose was considered as the NOAEL for parental generation. Taking into account the actual feed intake of the animals, the highest dose level corresponded to 91.7 mg/kg bw/day.
It should be noted that the relative increased thyroid organ weight was +21% in low-dose females and +28% in high-dose females.
If the relative thyroid weight gain of 21% is considered a harmful effect, a LOAEL of 26.8 mg/kg bw/day (corresponding to the lowest dose level calculated from feed intake) can be derived.

In the same study, dose-related reduced body weight at birth and throughout lactation at all dose levels and increased relative thyroid and liver weights were found in the offspring (relative thyroid weight increased by +25% in low-dose males and +44% in high-dose males, while relative liver weight in these males was increased by +5% and +20%, respectively). TSH and T4 levels were also affected compared to the control animals, but only to a lesser extent. According to the REACH registration, the effects was assessed as marginal and without adverse effects, and the NOAEL was set at the highest dose level. When adjusting for feed intake, a NOAEL of 95.2 mg/kg bw/day could be calculated.
However, if the increased relative thyroid weight of 25% is considered harmful to the low-dose males, a LOAEL for the offspring of 33.9 mg/kg bw/day can be derived for this effect.

Mutagenic and carcinogenic effects
HHCB has been tested and found to have no mutagenic effects in *in vitro* tests with bacteria and mammalian cells and in *in vivo* micronucleus tests (EU RAR 2008; REACH registration, HHCB).
There are no animal experimental data on carcinogenic effects of the substance.

10.4.2.6 Identification of critical effects
Based on the above review, the following critical effects and dose levels can be identified for HHCB:

Local effects
HHCB is considered to be allergenic and the use of the substance in cosmetics will in the future be subject to mandatory labelling if it occurs above a certain level depending on the product type. However, there is a lack of relevant data for a quantitative hazard and risk assessment for the skin sensitising effect of the substance.

Systemic effects
NOAEL(acute systemic): not applicable for the substance due to the low acute toxicity of the substance.

LOAEL (repeated dose systemic) = 26.8 mg/kg bw/day based on thyroid enlargement in female rats in oral, extended one-generation study.

10.4.2.7 Calculation of DNEL values
DNEL, chronic
Based on a LOAEL of 26.8 mg/kg bw/day for repeated exposure, the following chronic DNEL for oral exposure can be calculated:

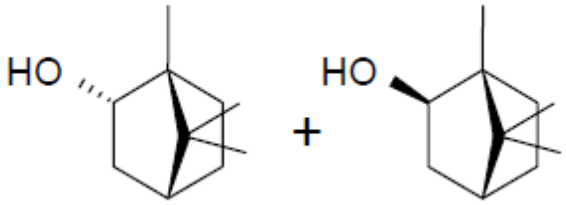
DNEL(oral, chronic) = N(L)OAEL(chronic) / (AF1 x AF2 x ... x Afn)
DNEL (oral, chronic) = 26.8 mg/kg bw/day / (10 x 10 x 3 x 2)
DNEL (oral, chronic) = 0.045 mg/kg bw/day

Using an AF1 = 10 as the NOAEL is based on data from a rat study and an AF2 = 10 to protect the most sensitive in the population. In addition, an AF3 = 2 is used to extrapolate from the dosing duration of one-generation studies to chronic exposure and an AF4 = 3 to extrapolate from a LOAEL level.

When calculating the DNEL (dermal, chronic), the much lower dermal absorption of 5.2% is taken into account:
DNEL (dermal, chronic) = DNEL (oral, chronic) x oral abs / dermal absorption
DNEL (dermal, chronic) = *0.045 mg/kg bw/day x 50%* / 5.2%
DNEL (dermal, chronic) = 0.43 mg/kg bw/day

10.5 Endo-borneol / DL borneol - CAS No. 507-70-0
The substance is REACH registered under the name *DL*-borneol.
It is claimed that the substance is used as a fragrance in cosmetics and personal care products and is used in a number of consumer products such as paints, detergents and waxes, as well as a fuel additive.

10.5.1 Physicochemical data

	***Endo*-borneol; DL-borneol**
Chemical structure	Includes two substance isomers: D- and L-borneol 
Systematic name	1,7,7-trimethylbicyclo[2.2.1]heptan-2-ol
Chemical formula	C10H18O
Molecular weight	154.3 (PubChem)
Physical state	Solid
Melting point	178 °C
Boiling point	194 °C
Vapour pressure	34.2 mm Hg at 25 °C
Water solubility	approx. 0.014 g/L at 20 °C
Log Pow	Approx. 3.6 at 20 °C

Data is from the REACH registration dossier of the substance

10.5.2 Toxicology

10.5.2.1 Data basis

It should be noted that *all* toxicological data in the REACH registration dossier is for the closely related substance *camphor* (chemical name: bornan-2-one, CAS no. 76-22-2) i.e., the oxidised form of *endo*-borneol.

A literature search found very few references on the toxicology of *endo*-borneol. The vast majority of the references found deal with possible medical uses of the substance. These include its possible effects on the central nervous system, anti-inflammatory and analgesic effects, cardiovascular effects and absorption enhancing effects (Mei et al 2023).

The Research Institute for Fragrance Materials (RIFM) has studied the safety of the use of DL borneol in 2008, 2015 and most recently 2022 (RIFM 2008; 2015; 2022). In these assessments, there is also very little data on DL borneol, so the assessments are based on the closely related substances isobornyl acetate (CAS no. 125-12-5) and camphor (CAS no. 76-22-2).

With this as a starting point and as a result of the literature search, the following literature is used for hazard assessment of *endo*-borneol:

- REACH registration data, DL-borneol
- RIFM safety assessments of borneol (RIFM 2008, 2015, 2022)
- EFSA's assessment of camphor (EFSA 2008)
- EFSA's assessment of isobornyl acetate (EFSA 2016)

10.5.2.2 Classification

The substance is classified in the REACH registration dossier with:

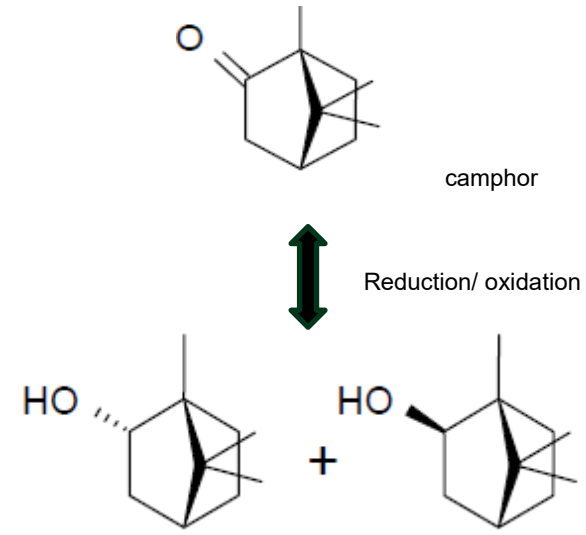
Acute Tox. 4 H332 Harmful if inhaled

Skin Irrit 2 H315 Causes skin irritation
Eye Damage 1 H318 Causes serious eye damage
STOT SE 2 H371 May cause lung damage if inhaled

10.5.2.3 Absorption and metabolism

No concrete data has been found, but the RIFM (2022) and REACH registration assumes 100% absorption by oral and dermal exposure.
Several studies have been found with DL borneol as a skin absorption promoting vehicle for drugs, but the data only includes the drug substance and not absorption data for DL borneol.
Krzystof (2007), based on *in vitro* skin penetration tests, indicates very high levels of skin absorption of a number of terpenes and terpene alcohols, with an absorption of 20-1800 µg/cm^2 skin after 4 hours of exposure when applying the pure substances.

EFSA (2008) lists *endo*-borneol as a metabolite of camphor. Similarly, camphor can also be considered a metabolite of *endo*-borneol, as the substances can be metabolically converted to each other by oxidation/reduction:



Due to this metabolism of the substances, it is considered justified to use data for camphor in the assessment of endo-borneol.

10.5.2.4 Local effects

The substance is considered to be a skin and eye irritant based on *in vitro* tests for skin and eye irritation. The substance is not considered to be a skin sensitiser based on both *in vitro* and *in vivo* testing for camphor (REACH registration, DL-borneol).

10.5.2.5 Systemic effects

Acute effects, single exposure
Animal studies for camphor indicate that the substance is moderately acutely toxic by inhalation with an LC50 in mice of 500 mg/m^3 (REACH registration, DL-borneol).

In humans, ingestion of relatively small doses of camphor can cause symptoms of poisoning, starting with abdominal discomfort, a burning sensation in the throat and oesophagus, nausea and vomiting, and in more severe cases central nervous system effects, muscle twitching and in the most severe cases coma and death (Love et al 2004).

EFSA (2008) states, based on a number of oral poisoning cases in children, that symptoms of poisoning typically occur after ingestion of 3-4.5 grams of camphor. A death in a 19-month-old child has been reported after ingestion of one teaspoon of camphor oil, equivalent to approximately 1 g of camphor. There are reported to be large differences in sensitivity to camphor poisoning, but based on the relatively large number of observations, doses of 2 mg camphor/kg bw and below are not considered to cause symptoms (EFSA 2008).

Repeated exposure
In a 90-day dermal mouse study with a dose level of camphor up to 1000 mg/kg bw/day, a LOAEL and NOAEL for skin effects (as the only effect) of 1000 mg/kg bw/day and 400 mg/kg bw/day, respectively, were found.
In a similar study in rats with a dose level of camphor up to 250 mg/kg bw/day, a NOAEL of 250 mg/kg bw/day was found. However, increased relative lung weights were reported in female rats at 64 and 250 mg/kg bw/day and increased relative kidney weights in males at 64 mg/kg bw/day (REACH registration dossier, DL-borneol).
Furthermore, an oral 890-day study in rats is listed in the REACH registration, but the reporting is too poor to assess this study (REACH registration dossier, DL-borneol).

In an oral 90-day study in rats dosed with camphor, a NOAEL of 15 mg/kg bw/day was found, with increased water intake, increased kidney and liver weight, adverse effects in the kidney tissue and effects in the bile duct at the higher dose levels (RIFM 2022)

In an oral 90-day study in rats dosed with isobornyl acetate, a NOAEL of 15 mg/kg bw/day was found with increased water intake, increased kidney weight and renal tissue effects at the higher dose levels (EFSA 2016).

A study in pregnant rats dosed with 0, 100, 400, 800 mg bw/day from day 6 to day 15 of gestation found reduced motor activity and increased liver weight at the highest dose and increased water intake at all dose levels. No adverse effects on the offspring were found (EFSA 2008; REACH registration dossier, DL-borneol; RIFM 2022).

In an oral one-generation study with isobornyl acetate dosed to rats, no adverse effects were found at the highest dose level of 300 mg/kg bw/day, neither in the dams nor the offspring.

Mutagenic and carcinogenic effects
In *in vitro* mutagenic tests with bacteria and mammalian cells, camphor showed no mutagenic effects, while an *in vitro* micronucleus test in mammalian cells showed genotoxic effects. However, an *in vivo* study in mice showed negative results for micronuclei in bone marrow cells, and the substance is thus not classified for mutagenic effect (REACH registration, DL-borneol).
A similar assessment was given by EFSA (2008).

Furthermore, ECHA (2008) states that brushing camphor on mouse skin for 4.5-6 months did not cause signs of skin cancer.

10.5.2.6 Identification of critical effects
Based on the above review, the following critical effects and dose levels can be identified for *endo*-borneol:

Local effects
The local, moderate irritation effects are not considered to be a critical effect for exposure with *endo*-borneol.

Systemic effects
NOAEL (acute systemic) = 2 mg/kg bw with regard to symptoms of poisoning based on human oral data.

Systemic effects
NOAEL (repeated dose systemic) = 15 mg/kg bw/day for renal and hepatic effects based on oral rat data at 90 days dosing.

Local effects are not considered to be a critical effect for exposure with *endo*-borneol.

10.5.2.7 Calculation of DNEL values

DNELacute
Based on a NOAEL of 2 mg/kg bw for acute human exposure, the following acute DNEL for oral exposure can be calculated:

DNEL (oral, acute) = N(L)OAEL(acute) / (AF1 x AF2 x ... x Afn)
DNEL (oral, acute) = 2 mg/kg bw / (1 x 10)
DNEL (oral, acute) = 0.2 mg/kg bw

Using an AF1 = 1 as the NOAEL is based on human data and an AF2 = 10 to protect the most sensitive in the population.

The same value is used for dermal exposure, as REACH (2012), in the absence of data, assumes the same absorption rate from skin as for oral ingestion, i.e:
DNEL (dermal, acute) = 0.2 mg/kg bw

DNEL, chronic
Based on a NOAEL of 15 mg/kg bw/day for 90 days repeated exposure of rats, the following chronic DNEL for oral exposure can be calculated:

DNEL (oral, chronic) = N(L)OAEL(chronic) / (AF1 x AF2 x ... x Afn)
DNEL (oral, chronic) = 15 mg/kg bw/day / (10 x 10 x 2)
DNEL (oral, chronic) = 0.075 mg/kg bw/day

Using an AF1 = 10 as the NOAEL is based on data from a rat study and an AF2 = 10 to protect the most sensitive in the population. In addition, AF3 = 2 is used to extrapolate from a 90-day study to chronic exposure.

The same value is used for dermal exposure, as REACH (2012) assumes the same absorption rate from skin as for oral ingestion, i.e., in the absence of data:
DNEL (dermal, chronic) = 0.075 mg/kg bw/day

10.6 Summarised hazard assessment

Based on the above review, the following critical effects and N(L)OAEL values have been identified and DNEL values calculated:

TABLE 18. Overview of N(L)OAEL values and DNEL values for the selected substances

	CI 15510 CAS 633-96-5	**CI 18050 CAS 3734-67-6**	**BHT CAS 128-37-0**	**HHCB CAS 1222-05-5**	***endo*-borneol CAS 507-70-0**
Critical local effects					
Critical effect	Local effects not critical	**Skin sensitiser**	Local effects not critical	**Skin sensitiser**	Local effects not critical
N(L)OAEL dermal	Not applicable	No data	Not applicable	No data	Not applicable
DNEL dermal	Not applicable	Cannot be calculated	Not applicable	Cannot be calculated	Not applicable
Critical systemic acute effects					
N(L)OAELoral Effect	None-relevant	None-relevant	None-relevant	None-relevant	NOAEL: 2 mg/kg bw Various poisoning symptoms
DNEL oral	Not applicable	Not applicable	Not applicable	Not applicable	0.2 mg/kg bw
DNEL dermal	Not applicable	Not applicable	Not applicable	Not applicable	0.2 mg/kg bw
Critical systemic chronic effects					
N(L)OAEL oral Effects	LOAEL: 2.5 mg/kg bw/day Effects on blood, kidneys, liver	NOAEL: 8 mg/kg bw/day Effects on the spleen. Haemolysis	NOAEL: 25 mg/kg bw/day Toxic to reproduction; endocrine disruptor	LOAEL: 26.8 mg/kg bw/day Effects on the thyroid. Suspected of being an endocrine disruptor	NOAEL: 15 mg/kg bw/day Effects on kidneys and liver
DNEL oral	0.004 mg/kg bw/day	0.08 mg/kg bw/day	0.25 mg/kg bw/day	0.045 mg/kg bw/day	0.075 mg/kg bw/day
DNEL dermal	0.8 mg/kg bw/day	16 mg/kg bw/day	62.5 mg/kg bw/day	0.43 mg/kg bw/day	0.075 mg/kg bw/day

11. Risk assessment

As a starting point for the risk assessment of the bath products, it is necessary, based on the analysed concentrations of the prioritised substances, to calculate the actual exposure of the child based on the assumptions made in chapter 4 and the examples given in Appendix 4.

11.1 Exposure assessment

The Danish Environmental Protection Agency and the Danish Safety Technology Authority have reviewed the products that were selected for quantitative analyses for the five selected substances with regard to whether they should be considered cosmetics and/or toys in a regulatory context. As the dermal exposure assessment for toys, cf. Annex 4 will result in higher exposure than if the product is considered to be a cosmetic product, the dermal exposure assessment in this report will follow the method for toys if the Danish Safety Technology Authority has assessed the product as a toy. In the event that the Danish Environmental Protection Agency has assessed the product as a cosmetic product and the Danish Safety Technology Authority does not consider the product to be a toy, the dermal exposure assessment is carried out in accordance with the guidelines for cosmetic products.

11.1.1 Dermal exposure assessment, cosmetics

As stated in chapter 4 and Appendix 4, the dermal exposure of a cosmetic product is calculated from the formula:

$$E\ dermal\ (mg/kg\ bw/day) = C\ (mg/g) \times Q\ (g/day) \times F_{ret} / bw\ (kg)$$

$$E\ dermal\ (mg/kg\ bw/day) = C\ (mg/g) \times Q\ (g/day) \times 0.1 / 14\ kg$$

Where

C (mg/g): Concentration of the substance in the product

Q (g/day): Amount of product used per day

F_{ret}: the retention factor on the skin, i.e., the proportion of the product that is considered available for skin absorption/is in direct contact with the skin. For bath products, a retention factor of 0.1 is used as stated in chapter 4.

Bw: Body weight. Here 14 kg is used for a three-year-old child as stated in chapter 4.

The dermal exposure can be calculated as given in TABLE 19, when inserting the analysed concentrations of the prioritised substances and the product volumes used into the above expression.

TABLE 19. Calculation of dermal exposure to the prioritised substances in bath products considered as cosmetic products.

Product / product type	Age group from years / body weight	Usage volume (g)	Prioritised chemical substance	Concentration in the product (mg/g)	Total amount of substance in the used amount of product (mg)	Skin exposure per bath (mg/kg bw)
EU 21 - BK Bath balls	3 years / 14 kg	160	CI 18050	0.029	4.6	0.033
EU 22 - BK Bath balls	3 years / 14 kg	127	BHT	0.05	6.4	0.045
			endo-borneol	0.0003	0.04	0.0003
			HHCB	0.005	0.64	0.005
EU 23 - BK Bath balls	3 years / 14 kg	160	CI 18050	0.016	2.6	0.018
NEU 40 - KBS Crackle powder/bath salts	3 years / 14 kg	Half cup equivalent to 170*	*endo*-borneol	0.076	12.9	0.09
NEU 41 - KBS Crackle powder/bath salts	3 years / 14 kg	A handful equivalent to 88*	BHT	0.027	2.4	0.017
			endo-borneol	0.00003	0.003	0.00002
			HHCB	1.862	164	1.2

* Measured volumes at FORCE Technology

11.1.2 Dermal exposure assessment, toys

As indicated in Appendix 4, the dermal exposure from a product that is considered to be a toy can be calculated using the calculation methods as indicated in the Consexpo and ECETOC TRA models recommended by the European Commission. ECHA (2016):

For hands in contact with the concentrated product, hand exposure is calculated at:

E dermal, hands (mg/kg bw/day) = C (mg/g) x A (cm^2) x H (cm) / bw (kg)
E dermal, hands (mg/kg bw/day) = C (mg/g) x 345 cm^2 x 0.01 cm / 14 (kg)

Where

C (mg/g): Concentration of the substance in the product.
A: Skin area of both hands for a three-year-old child. Here 345 cm^2 is used as specified in Appendix 4.
H: The height/thickness of the liquid layer from which absorption can take place. A value of 0.01 cm is used in the above calculation models as shown in Appendix 4.
bw: Body weight. Here 14 kg is used for a three-year-old child as stated in chapter 4.

For whole-body exposure to the product dissolved in the bathwater, the body exposure from contact with the diluted product dissolved in the bathwater is calculated by:

E dermal, whole body (mg/kg bw/day) = C (mg/g) x Q (g/day) / V (g) x A (cm^2) x H (cm) / bw (kg)
E dermal, whole body (mg/kg bw/day) =
C (mg/g) x Q (g/day) / 30000 g x 6900 cm^2 x 0.01 cm / 14 kg

Where

C (mg/g): Concentration of the substance in the product.
Q (g/day): Amount of product used per day.
V: Bathwater volume. Set to 30 L corresponding to 30000 g.
A: Skin area of the whole body for a three-year-old child. Here 6900 cm^2 is used as specified in Appendix 4.
H: The height/thickness of the liquid layer from which absorption can take place. A value of 0.01 cm is used in the above calculation models as shown in Appendix 4
bw: Body weight. Here 14 kg is used for a three-year-old child as stated in chapter 4.

Inserting the analysed concentrations of the prioritised substances and the product quantities used into the above expression, the dermal exposure on the skin can be calculated as given in TABLE 20.

TABLE 20. Calculation of dermal exposure to the prioritised substances in bath products considered as toys.

Product / product type	Age group / body weight	Amount per use (g)	Prioritised chemical substance	Concentration in the product (mg/g)	Hand exposure (undiluted) (mg/kg bw)	Concentration diluted in 30 L (mg/g)	Body exposure (mg/kg bw)	Total skin exposure per bath (mg/kg bw)
DK 1 - BK Bath ball	3 years / 14 kg	50	No findings	-	-	-	-	-
DK 2 - BK Bath ball	3 years / 14 kg	20	BHT	0.0006	0.00015	0.0000004	0.000002	0.000152
DK 19 - GE Bath gel	3 years / 14 kg	150	No findings	-	-	-	-	-
EU 29 - MS Modelling soap from bucket (reusable)	3 years / 14 kg	66 (200 g is indicated for use in 3 baths)	CI 15510	0.047	0.012	0.0001	0.0005	0.0125
			endo-borneol	0.0005	0.0001	0.000001	0.000005	0.00011
			HHCB	0.0001	0.000025	0.000002	0.000001	0.000026
NEU 33 - BK Bath ball	1 year / 10 kg* Hands: 270 cm^{2*} Whole body: 4900 cm^{2*}	100	CI 15510	0.001	0.00027	0.000003	0.000016	0.00029
			BHT	0.005	0.0014	0.000017	0.00002	0.00148
			HHCB	0.001	0.00027	0.000003	0.000016	0.00029
NEU 34 - BK Bath ball	3 years / 14 kg	75 (one ball in 200 L)	BHT	0.002	0.0005	0.0000008 in 200 L	0.00004	0.0005
			HHCB	0.007	0.0017	0.000003 in 200 L	0.00013	0.0018

Product / product type	Age group / body weight	Amount per use (g)	Prioritised chemical substance	Concentration in the product (mg/g)	Hand exposure (undiluted) (mg/kg bw)	Concentration diluted in 30 L (mg/g)	Body exposure (mg/kg bw)	Total skin exposure per bath (mg/kg bw)
NEU 35 - BK Bath ball	3 years / 14 kg	32	BHT	0.0005	0.0001	0.000005	0.0000026	0.00013
			endo-borneol	0.002	0.0005	0.000002	0.00001	0.00051
			HHCB	0.123	0.030	0.00013	0.0006	0.032
NEU 36 - FA Bathwater colour	3 years / 14 kg	10	No findings	-	-	-	-	-
NEU 39 - VU Bathwater volcano	3 years / 14 kg	50	*endo*-borneol	0.0001	0.000025	0.00000017	0.0000008	0.000025
			HHCB	0.0006	0.00015	0.000001	0.000005	0.00016
NEU 42 - MS Modelling soap from dispenser	3 years / 14 kg	85 per use (428 g / 5)	BHT	0.028	0.007	0.00008	0.0004	0.0074
			HHCB	0.00005	0.00001	0.0000001	0.0000007	0.000011

*Child 1 year. Skin surfaces (US EPA 2009), weight (Patient Handbook, weight for Danish children)

"No findings" means that none of the five selected substances have been identified in the product.

11.1.3 Oral exposure assessment

Endo-borneol is assessed to be the only one of the five prioritised substances that has acute poisoning as a critical effect. For this reason, in the event of accidental swallowing of 50 ml of bathwater, only oral exposure to the products containing *endo*-borneol is calculated.

The oral exposure is calculated in the same way regardless of whether the bath product is considered to be a cosmetic product or a toy. The exposure is calculated from the formula:

$$\textit{Oral exposure} = Q\ (g/day) \times C\ (mg/g) / V\ (g) \times v\ (g) / bw\ (kg)$$

Where

C (mg/g): Concentration of the substance in the product.
Q (g/day): Amount of product used per day.
V: Bathwater volume. Set to 30 L corresponding to 30000 g.
v: Volume of bathwater swallowed. Set to 50 ml corresponding to 50 g, as indicated in chapter 4.
Bw: Body weight. Here 14 kg is used for a three-year-old child as stated in chapter 4.

Inserting the analysed concentrations of *endo*-borneol and the product volumes used in the above expression, the oral exposure can be calculated as given in TABLE 21.

Based on the very low oral exposure values for borneol, it is only considered relevant initially to risk assess product NEU 40 - KBS with the exposure of 0.0015 mg/kg bw *endo*-borneol, as the exposure for the other five products is more than 200 times lower than for this product.

TABLE 21. Calculation of oral exposure to *endo*-borneol in the analysed bath products.

Product / product type	Age group / body weight	Amount per use (g)	Chemical substance	Concentration in the product (mg/g)	Concentration diluted in 30 L (mg/g)	Amount in 50 ml bath-water (mg)	Oral exposure (mg/kg bw)
Cosmetics							
EU 22 - BK Bath balls	3 years / 14 kg	127	*endo*-borneol	0.0003	0.0000013	0.00006	0.000005
NEU 40 - KBS Crackle powder/bath salts	3 years / 14 kg	Half cup equivalent to 170*	*endo*-borneol	0.076	0.00043	0.022	0.0015
NEU 41 - KBS Crackle powder/bath salts	3 years / 14 kg	A handful equivalent to 88*	*endo*-borneol	0.00003	0.00000009	0.000004	0.0000003
Toys							
EU 29 - MS Modelling soap from bucket (reusable)	3 years / 14 kg	66 (200g is indicated for use in 3 baths)	*endo*-borneol	0.0005	0.000001	0.00005	0.000004
NEU 35 - BK Bath ball	3 years / 14 kg	32	*endo*-borneol	0.002	0.000002	0.0001	0.000008
NEU 39 - VU Bathwater volcano	3 years / 14 kg	50	*endo*-borneol	0.0001	0.00000017	0.000009	0.0000006

*Measured quantities at FORCE Technology

11.2 Risk assessment

11.2.1 Dermal exposure risk assessment, cosmetics

When risk assessing a chemical ingredient in a cosmetic product, a Margin of Safety (MoS) value is calculated as mentioned in chapter 4:

MoS = PoDsys / SED

Where SED is the systemic exposure to the substance. This means that dermal exposure is converted to systemic (internal) exposure by multiplying by the dermal absorption factor:

SED = skin exposure x dermal absorption factor

SCCS (2023) uses a baseline value of 50% dermal absorption through the human skin if no concrete data is available. I.e., when a different value is used, this is based on concrete data for the substances, as stated in the substance assessments in chapter 4.

PoDsys is a 'Point of Departure' value that is calculated from the identified N(L)OAEL value, converting N(L)OAEL as the first step to systemic exposure (N(L)OAELsys). Since the N(L)OAEL values in this project are all from oral animal studies, they are converted to systemic NOAEL as follows:

NOAELsys = NOAELoral x oral absorption factor

SCCS (2023) uses a baseline of 50% oral absorption in animal studies if no concrete data is available. I.e., when a different value is used, this is based on concrete data for the substances, as stated in the substance assessments in chapter 4.

Finally, when calculating PoDsys, a division with uncertainty factor(s) is used. Here, SCCS (2023) applies an uncertainty factor of 3 when a LOAEL is used for the assessment instead of a NOAEL. An uncertainty factor of 3 is also applied if the N(L)OAEL is from a 28-day study, whereas a factor of 1 is applied for a 90-day study.

When assessing the calculated MoS value, SCCS (2023) generally considers that a MoS value of at least 100 indicates safe use of the cosmetic product, as such a value includes a safety margin of 10 x 10, which includes uncertainty factors to extrapolate from animal studies to humans (interspecies variation) as well as to account for differences in sensitivity of cosmetic product users (intraspecies variation).

Based on these guidelines, the MoS values for the content of the prioritised substances in the cosmetic bath products can be calculated as stated in TABLE 22.

TABLE 22. MoS calculation for the content of the prioritised substances in the bath products (cosmetics).

Product / product type	Substance	Total skin exposure per bath	Skin absorption factor; Systemic (sys) exposure	N(L)OAEL, oral	Oral absorption factor; N(L)OAELsys	Assessment factor; PoDsys	MoS = PoDsys / sysexp.	Risk assessment MoS ≥ 100 no risk
EU 21 - BK Bath ball	CI 18050	0.033 mg/kg bw	0.5% equivalent to 0.005 0.00017 mg/kg bw	NOAEL 8 mg/kg bw/day	50% NOAELsys: 4 mg/kg bw/day	1 4 mg/kg bw/day	23 529	No risk
EU 22 - BK Bath ball	BHT	0.045 mg/kg bw	0.4% equivalent to 0.004 0.0002 mg/kg bw	NOAEL: 25 mg/kg bw/day	100% NOAELsys: 25 mg/kg bw/day	1 25 mg/kg bw/day	125 000	No risk
	endo-borneol	0.0004 mg/kg bw	50% equivalent to 0.5 0.0002 mg/kg bw	NOAEL: 15 mg/kg bw/day	50% NOAELsys: 7.5 mg/kg bw/day	1 7.5 mg/kg bw/day	37 500	No risk
	HHCB	0.005 mg/kg bw	5.2% equivalent to 0.052 0.0003 mg/kg bw	LOAEL: 26.8 mg/kg bw/day	50% LOAELsys: 13.4 mg/kg bw/day	3 4.5 mg/kg bw/day	15 000	No risk
EU 23 - BK Bath ball	CI 18050	0.018 mg/kg bw	0.5% equivalent to 0.005 0.00009 mg/kg bw	NOAEL: 8 mg/kg bw/day	50% NOAELsys: 4 mg/kg bw/day	1 4 mg/kg bw/day	44 444	No risk
NEU 40 - KBS Crackle powder/ Bath salts	*endo*-borneol	0.09 mg/kg bw	50% equivalent to 0.5 0.045 mg/kg bw	NOAEL: 15 mg/kg bw/day	50% NOAELsys: 7.5 mg/kg bw/day	1 7.5 mg/kg bw/day	167	No risk

Product / product type	Substance	Total skin exposure per bath	Skin absorption factor; Systemic (sys) exposure	N(L)OAEL, oral	Oral absorption factor; N(L)OAELsys	Assessment factor; PoDsys	MoS = PoDsys / sysexp.	Risk assessment MoS ≥ 100 no risk
NEU 41 - KBS Crackle powder/ Bath salts	BHT	0.017 mg/kg bw	0.4% equivalent to 0.004 0.00007 mg/kg bw	NOAEL: 25 mg/kg bw/day	100% NOAELsys: 25 mg/kg bw/day	1 25 mg/kg bw/day	357 143	No risk
	endo-borneol	0.00002 mg/kg bw	50% equivalent to 0.5 0.00001 mg/kg bw	NOAEL: 15 mg/kg bw/day	50% NOAELsys: 7,5 mg/kg bw/day	1 7.5 mg/kg bw/day	750 000	No risk
	HHCB	1.2 mg/kg bw	5.2% equivalent to 0.052 0.062 mg/kg bw	LOAEL: 26.8 mg/kg bw/day	50% LOAELsys: 13.4 mg/kg bw/day	3 4.5 mg/kg bw/day	73	**risk**

As can be seen, very high MoS values are generally achieved, i.e., the specified exposure scenarios are not considered to constitute a risk. For product NEU 41 - KBS crackle powder/bath salt, a MoS value of 73 is obtained due to the very high content of HHCB (0.123 mg/g, see TABLE 19) and the high exposure of 1.2 mg HHCB/kg bw from the product. Therefore, the product cannot be considered safe for repeated exposure and is considered to constitute a risk.

11.2.2 Risk assessment of dermal exposure, toys

In the risk assessment of toys, a risk characterisation ratio RCR is calculated using the following formula:

RCR = dermal exposure / DNELdermal

From the calculated exposures in TABLE 20 and from the dermal DNEL values given in TABLE 18, the RCR values for the content of the prioritised substances can be calculated as given below in TABLE 23.

TABLE 23. RCR calculation for the content of the prioritised substances in the bath products (toys).

Product / product type	Substance	Total skin exposure per bath (mg/kg bw)	DNEL dermal (mg/kg bw/day)	RCR = exp./ DNEL	Risk assessment RCR < 1, no risk
DK 1 - BK Bath balls	No findings	-	-	-	-
DK 2 - BK Bath bombs	BHT	0.000152	62.5	0.000002	No risk
DK 19 - GE Powder for bath gel	No findings	-	-	-	-
EU 29 - MS Modelling soap/ reusable in bucket	CI 15510	0.0125	0.8	0.02	No risk
	endo-borneol	0.00011	0.075	0.001	No risk
	HCCB	0.00026	0.43	0.0006	No risk
NEU 33 - BK Bath balls	CI 15510	0.00029	0.8	0.0004	No risk
	BHT	0.00148	62.5	0,00002	No risk
	HHCB	0.00029	0.43	0.0007	No risk
NEU 34 - BK Bath balls	BHT	0.0005	62.5	0.00008	No risk
	HHCB	0.0018	0.43	0.004	No risk
NEU 35 - BK Bath balls	BHT	0.00013	62.5	0.000002	No risk
	endo-borneol	0.00051	0.075	0.007	No risk
	HHCB	0.032	0.43	0.07	No risk
NEU 36 - FA Bathwater colour	No findings	-	-	-	-
NEU 39 - VU Bathwater volcano	*endo*-borneol	0.000025	0.075	0.003	No risk
	HHCB	0.00016	0.43	0.0004	No risk
NEU 42 - MS Modelling soap from dispenser	BHT	0.0074	62.5	0.0001	No risk

"No findings" means that none of the five selected substances have been identified in the product.

As can be seen, all RCR values are significantly below 1 and therefore there is considered to be no risk associated with the concentrations of the prioritised substances in the investigated products.

11.2.3 Risk assessment of oral exposure and acute poisoning

Only products containing *endo*-borneol are risk assessed for oral exposure in connection with the swallowing of 50 ml of bathwater in which the product is mixed. Based on the exposure assessment, only the product NEU 40 - KBS (crackle powder/bath salt) is considered relevant for risk assessment, as this product had by far the highest content of *endo*-borneol. TABLE 24 below provides the MoS calculation for this exposure scenario, as NEU 40 - KBS (crackle powder/bath salt) is considered to be a cosmetic product.

TABLE 24. MoS calculation for oral exposure with *endo*-borneol.

Product / product type	Substance	Oral exposure	Human oral absorption factor; Systemic (sys) exposure	N(L)OAEL, oral	Oral absorption factor; N(L)OAELsys	Assessment factor; PoDsys	MoS = PoDsys / sys exp.	Risk assessment MoS ≥ 10*. no risk
NEU 40 - KBS Crackle powder/bath salts	*endo*-borneol	0.0015 mg/kg bw	100% 0.0015 mg/kg bw	NOAEL: 2 mg/kg bw	100%; 2 mg/kg bw	1 2 mg/kg bw	133	No risk

*It is considered that an MoS value of 10 is sufficient to assess the scenario as being without risk, as the NOAEL and thus the PoDsys are based on human data

12. Discussion and conclusion

The purpose of the project has been to build knowledge about which ingredients are used in different bath products targeted at children. Including which fragrance ingredients, colourings, preservatives and other potentially problematic substances these types of bath products contain. In addition, the purpose of the project was to investigate whether the bath products could constitute a risk to children. This chapter discusses the report's research and findings and provides an overall conclusion to the study.

12.1 Survey

The survey shows that there are many different types of bath products for children and that many of the products contain ingredients that are typical for cosmetic products. However, products like bath gel and bath slime are significantly different as they typically consist of a polyacrylate (bath gel) and polyacrylamide or polycarboxylate (bath slime) as the primary ingredients to form the jelly-like or slimy consistency. In addition, bath gels and bath slimes contain colourants and fragrance ingredients just like all the other types of bath products examined in the project.

The literature study conducted in the survey shows that the main health concern regarding bath products for children is that the majority of the products contain allergenic fragrances and that some of the products may contain carcinogenic azo dyes.

This picture was confirmed by the survey conducted by reviewing the ingredient list of selected products. A search was conducted for approximately 90 bath products for children across Danish, European and international websites. Based on this search, ingredient lists for a total of 45 bath products were identified via product websites. For these 45 bath products with ingredient lists, the following was observed:

- 82% of the products contain perfume and/or essential oils (37 out of 45 products).
- 73% of the products are coloured and contain one or more colourants (33 out of 45 products), although the colourants were not necessarily specifically declared on the products.

For ten of the products containing fragrances (i.e., approx. a quarter of the fragranced products), one or more of the 24 fragrances subject to mandatory labelling are also labelled. However, it should be pointed out that not all 45 products with ingredient lists were completely as required for cosmetic products. This may be because not all products are cosmetic products, but toys. In addition, the ingredient list on products outside the EU is often incomplete.

The majority of the 12 products that do not contain colourants are foam bath products. 9 out of 11 foam bath products are not coloured. Otherwise, only the product types of crackle powder/bath salt (two of five products) and bathwater volcano (one of two products) do not contain colourants.

In addition, for many of the products without an ingredient list, it was suggested that the products contained perfume and/or essential oils, as they were advertised with some kind of scent such as watermelon, strawberry or other. Many of the products without an ingredient list were also coloured.

12.2 Prioritising ingredients and purchasing products

The 45 products with ingredient lists contained a total of approximately 180 different ingredients, all of which were identified in the EU CosIng database[25] as "active" ingredients, i.e., current ingredients used in cosmetic products or listed in an annex of the Cosmetics Regulation (EU Regulation 1223/2009).

From this ingredients list, a prioritisation of ingredients was made based on the classification of the substances and thus which products should be purchased for the chemical analyses. When prioritising ingredients, knowledge was used for the half of the products where ingredient information was available. In practice, substances were prioritised based on the knowledge available.

45 bath products were selected and purchased for the chemical analyses. Of these, there was information on the webshop about the ingredients for 24 of the products, i.e., just over half of the products. For these 24 products, products containing prioritised azo dyes, BHT and fragrance ingredients were deliberately purchased. The rest of the 45 products were bought to ensure that the different types of bath products for children were represented from different manufacturers and to ensure a fixed distribution between products purchased in Denmark (50%), in the EU (25%) and outside the EU (25%). This means that when purchasing, the content of any problematic ingredients (the prioritised substances) was taken into account, and random bath products for children were purchased. Thus, when purchasing and selecting products, the focus was on choosing products that could be suspected to contain problematic substances.

Of the 45 products purchased, 42 arrived before the analyses were initiated. The majority of these products (40 out of 42) had ingredient lists on the products, which were reviewed in relation to the final prioritisation of substances for the chemical analyses.

12.3 Chemical analyses and selection of prioritised substances

Based on the ingredient lists of the 42 products purchased for analysis, a prioritisation of ingredients was made based on the classification of the substances and thus which screening analyses should be focused on initially in the chemical analyses. To identify potential substances of concern, all ingredients listed in the products' ingredient list were listed and then screened based on the hazard classification of the substances (EU harmonised classification or classified in the REACH registration dossier), as well as whether the substances belong to the group of fragrances subject to mandatory labelling or are listed as suspected endocrine disruptors in the EU.

In addition, the following screening analyses were prioritised:

- Measuring the pH value of the products, as many ingredients are classified as skin and/or eye irritants and some ingredients are classified with Eye Dam. 1, meaning they can cause serious eye damage in high concentrations.
- GC-MS screening to identify as many volatile organic substances as possible, such as allergenic fragrance ingredients, as well as BHT and other substances suspected of being endocrine disruptors.

The results of the measured pH values of the 42 products showed values between 2.5 and 10.2. The pH values were measured in a concentrated solution/slurry, where 1 g of product was dissolved in 15 ml of water. Two individual products gave low pH values of 2.5 (bubble

[25] https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-ingredient-database_en

bath) and 5.2 (crackle powder/bath salts); the pH values of the solutions of the remaining products were between 6.1 and 10.2. For many cosmetic products such as creams, lotions, perfumes, oils and lip products, the pH value is often between 5 and 7, but can be up to pH 10-11 for rinse-off products such as shampoo and body wash. Thus, there is nothing alarming about the pH value of the purchased and tested bath products for children.

GC-MS screening was performed on 23 selected products of the 42 products purchased. Products containing the term "perfume" or "fragrance" were screened to analyse the content of some of the substances subject to mandatory labelling or that will be subject to mandatory labelling in the future. In addition, two products without an ingredient list were analysed.

The results of the GC-MS screening showed that all products contain a wide range of different volatile organic substances in small amounts. Up to about 120 different substances (or isomers of substances) were seen in a single product. This is an indication that the plant extracts used in some of the products contain a wide range of different chemical substances. As this was a screening analysis, the focus was on at least the five largest peaks in the GC-MS chromatograms, as well as the fragrance ingredients subject to mandatory labelling and BHT.

A total of 150 different substances were identified in the analysed products in the GC-MS screening. Half (12) of the 24 fragrance ingredients subject to mandatory labelling were identified in several of the 23 selected products, and eight of the substances that will be subject to mandatory labelling in the future were identified in some of the analysed products. BHT was identified in seven products.

Based on the results of the screening analyses, the hazardousness of the substances, the availability of toxicological data and the availability of the substances as reference substances, the following five substances were in focus in the subsequent quantitative analyses:

- Colourant CI 15510 as the substance is an azo dye and classified for organ toxicity (STOT RE 1, H372).
- Colourant CI 18050, as the substance is an azo dye and is classified as allergenic.
- BHT, as the substance is suspected of being an endocrine disruptor.
- HHCB, as the substance is suspected of being an endocrine disruptor and is also one of the fragrance ingredients that will be subject to mandatory labelling in the future.
- *Endo*-borneol as the substance is classified for organ toxicity (STOT SE 2, H371).

15 products were selected for quantitative analyses for some or all of these five prioritised substances. Of these, seven products were selected for analysis of BHT, HHCB and *endo*-borneol, five products were selected for analysis of CI 15510 and CI 18050 products, and three products were selected for analysis of all five prioritised substances. Two of the products selected for colourant analysis were selected solely to identify if one of the two prioritised colourants was present in the products, as these two products did not have an ingredient list but were coloured.

The results of the quantitative analyses were as follows:

- The colourant CI 15510 was identified in two of eight products at concentrations of 1 and 47 mg/kg respectively.
- The colourant CI 18050 was identified in two of eight products at concentrations of 16 and 29 mg/kg, respectively.
- BHT was identified in eight out of ten products at concentrations between 0.01 and 50 mg/kg.
- HHCB was identified in all ten products at concentrations between 0.01 and 1862 mg/kg.
- *Endo*-borneol was identified in six out of ten products at concentrations between 0.03 and 76 mg/kg.

With the exception of two products containing HHCB at 123 and 1862 mg/kg, the concentrations of the five prioritised substances identified are generally low, below 100 ppm.

Choosing the five prioritised substances in this project was primarily due to their hazardousness, but also because they have been identified in several of the analysed products during the screening. As the screening has identified more than 100 different substances in several of the products, it has not been possible to identify and assess the hazardousness of all these substances. As described, the focus was on the substances with the highest content in the products.

It should be noted that quantitative analyses and risk assessment of the substance phenylisohexanol were excluded, even though the substance also had a classification of concern (as stated in chapter 5 "Initial screening of ingredients"). The exclusion was due to the fact that it was not available as reference material at the time of conducting the quantitative analyses. Phenylisohexanol was observed in one product in the GC-MS screening. Thus, there may be other substances with health properties of concern that have not been the focus of this study, but if so, these have not been among the five substances that gave rise to the highest response (the five highest peaks in the chromatograms) in the individual product. The choice to focus on the five highest peaks was part of the screening process for selecting substances, as stated in chapter 8.

Of the 15 products selected for the quantitative analyses, the distribution between products from the three regions DK, EU and non-EU was as follows:

- Three products were purchased in Denmark - one product contained one of the prioritised substances.
- Four products were purchased in the EU - all containing between one and three of the prioritised substances.
- Eight products were purchased outside the EU - seven products contained between one and three of the prioritised substances.

It should be noted that two of the products (one Danish and one non-EU) were only selected for the quantitative analyses to be sure whether the selected prioritised colourants were used in these products or not.

Considering that 50% of the products were purchased from Danish shops/web shops and 25% each from EU and non-EU, it is striking that one or more of the five prioritised substances were identified in twice as many non-EU products as in EU and DK products combined. It should be noted, however, that this is a low number to make a statistical statement about. As the products purchased outside the EU do not necessarily contain an ingredient list, the results of this project show that there is reason to be aware of purchasing these types of products outside the EU.

12.4 Hazard assessment

The prioritised substances in TABLE 25 below were hazard assessed and the most critical effects and relevant N(L)OAELs were identified for the subsequent risk assessment.

TABLE 25. Hazard assessment of the five prioritised substances.

Substance	CI 15510	CI 18050	BHT	HHCB	*endo*--borneol
CAS no.	633-96-5	3734-67-6	128-37-0	1222-05-5	507-70-0
Function	Azo dye	Azo dye	Antioxidant	Musk fragrance	Fragrance
Classification	STOT RE 1 H372	Skin Sens. 1B H317	Not classified	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Acute Tox. 4 H322 Skin Irrit 2 H315 Eye Damage 1 H318 STOT SE 2 H371
Suspected endocrine disruptor	no	no	yes	yes	no
Acute poisoning hazard	no	no	no	No	NOAEL: 2 mg/kg bw humandata
Organ effects, repeated exposure (animal experimental data)	LOAEL: 2.5 mg/kg bw/day Effects on blood, kidneys, liver	NOAEL: 8 mg/kg bw/day Haemolysis and effects on spleen	NOAEL: 25 mg/kg bw/day Toxic to reproduction; endocrine disruptor	LOAEL: 26.8 mg/kg bw/day Effects on the thyroid	NOAEL: 15 mg/kg bw/day Effects on kidneys and liver
DNEL oral, acute	Not applicable	Not applicable	Not applicable	Not applicable	0.2 mg/kg bw
DNEL dermal	0.8 mg/kg bw/day	16 mg/kg bw/day	62.5 mg/kg bw/day	0.43 mg/kg bw/day	0.075 mg/kg bw

For all five substances, there is considered to be a well-established toxicological database for the identification of critical effects and the determination of the N(L)OAEL values for further use in risk assessment. On this basis, the uncertainties associated with the assessments of the substances are considered to be limited.

12.5 Exposure assessment

Upon reviewing the home-purchased bath products, the Danish Environmental Protection Agency and the Danish Safety Technology Authority, based on the product design, packaging information, the sales platform (website), and the intended use, assessed that some of the products were to be considered as toys, while others were to be considered as cosmetic products. Some products were also assessed to be covered by both sets of legislation.

Depending on the legislation and guidelines developed for the risk assessment of cosmetic products and toys, different methods are used for the risk assessment of the products. Therefore, depending on whether the bath product is a toy and/or a cosmetic, different assumptions adapted to the different risk assessment methods must be made.

In connection with exposure assessment of cosmetics, a so-called retention factor is used, i.e., the proportion of the product that becomes available for absorption in the body during use. For hair shampoo and bath gel, the retention factor is set by SCCS (2023) to 0.01 or 1%. For leave-on products such as creams, SCCS (2023) uses a retention factor of 1, i.e., 100% of the cream's ingredients are considered available for absorption. In connection with children's bath products, the project group, in co-operation with the Danish EPA, assessed that a factor of 0.01 was far too low, as the child in a bathtub is supposed to play with the product for a long

time (up to 1 hour[26]), while bath shampoo and body shampoo are typically used for a short time (a few minutes) and quickly rinsed out. A retention factor of 0.1 was therefore chosen for the cosmetic bath products, which was deemed to be an appropriate assumption, also considering that the child's skin in the lukewarm water will soften and wrinkle, thus increasing retention.

Exposure assessment for toys according to the guidelines in connection with the REACH regulation takes into account the area of skin that is exposed and assumes a thickness of fluid on the skin from which absorption of the chemical substances can occur. This is based on a liquid thickness of 0.01 cm on the skin for easy-flowing consumer products. For the assessment in this project, the project team assumed that the child would be exposed to the concentrated product on their hands during play and would be exposed on the entire body surface area to the diluted product when dissolved in 30 litres of bathwater[27].

Based on these assumptions, exposures were then calculated. It was not the intention of the project to analyse the methods in more detail to see if one method is more realistic than the other. As stated in Appendix 4, the calculated exposure values for a hypothetical product calculated by both methods show quite similar dermal exposure values for the chosen bathing scenario for a three-year-old child. However, it is clear from these calculations that the use of a retention factor of 0.1 for the products when calculating the skin exposure from a cosmetic product is a crucial parameter for the size of the exposure value and thus for the outcome of the risk assessment. The same applies to the calculation of dermal exposure from toys, where the absorption of ingredients is assumed to be relevant only for the innermost 0.01 cm thick liquid layer in contact with the skin. However, these assumptions have been used as no more specific and validated exposure models addressing child bathing scenarios have been found in the relevant guidance or literature.

12.6 Risk assessment

The risk assessment of the analysed products with regard to the concentrations of the prioritised substances found generally indicates very high MoS values for the cosmetic products and very low RCR values for the toy products. The only exception is the product NEU - 41 KBS (crackling powder/bath salt), where the content of 1.86 mg HHCB/g (corresponding to 0.18%) resulted in a MoS value of 73. This means that repeated use of this product is considered to constitute a risk to children. The substance is a suspected endocrine disruptor and has caused thyroid enlargement in animal studies. Finally, the substance is also a skin sensitiser, which is why a content of 0.18% in the product is considered problematic. NEU - 41 KBS is a product purchased and produced outside the EU. If sold on the market in the EU after the legislation regarding the upcoming mandatory labelling of fragrance ingredients comes into force, HHCB would have to be labelled on the product due to its high content.

It should be pointed out that the product NEU - 41 KBS ends up with a MoS value of less than 100, corresponding to a health risk, both because of the high content of HHCB in the product, but also because the project group/monitoring group chose a retention factor of 0.1, as a middle ground between rinse-off (0.01) and leave-on (1). In their risk assessment method for cosmetic products, SCCS (2023) has not taken into account cosmetic products, such as the type of bath products studied in this project, where a longer exposure time occurs than for regular

[26] According to the survey, the recommended bathing time for some of the products was between 10-20 minutes, but the project team estimated that for several of the products, where there is also an element of play involved, the bathing time can be expected to be up to 60 minutes.

[27] The 30 litres of water is chosen as a worst case scenario based on a small bathtub for a 3-year-old (see section 4.2).

rinse-off products, such as shampoo. Bath products for children are sold to make bathing fun, i.e., bath time is extended and the skin softens with prolonged contact with warm water.

For all other products, no risk could be detected with regard to the content of the prioritised substances, i.e., these substances alone do not constitute a risk in the individual products. It must be emphasised that the risk assessment has only been carried out with regard to the content of the prioritised substances, and that the assessment does not include other known/unknown substances.

However, the content of a number of skin sensitising substances (typically in the form of fragrance ingredients) in a large number of the purchased bath products (over 80%) is considered very inappropriate, especially when it comes to relatively intensive skin exposure in young children.

To screen the bath products for the risk of irritant effects, pH values were measured in concentrated solutions of all the purchased products. In general, the measured pH values were not a cause for concern. However, two products had a pH between 10.1 and 10.2, but this is still well below the classification limit for chemical mixtures as corrosive (pH ≥ 11.5). In general, soap products are considered to have some degree of irritant properties and especially children's eye contact should be avoided as it can cause severe stinging.

12.7 Overall conclusion

In this project, 42 different bath products for children were purchased and analysed. The products were divided into product types such as bath balls/bath bombs, bathwater colours, foam bath products, bath pearls, bathwater volcanoes, crackle powder/bath salts, modelling soap, and bath slime/bath gel.

Based on the ingredient lists on the products and chemical screening analyses, 15 products were selected and quantitatively analysed for five substances with health effects of concern. A risk assessment of the analysed content of these substances in the products showed that for the vast majority of products, there was no health risk related to exposure to these substances. However, for one product NEU 41 - KBS (crackling powder/bath salt purchased and produced outside the EU), the content of the fragrance HHCB is so high (0.18%) that the substance, which is a skin sensitiser and suspected endocrine disruptor, is assessed to constitute a risk with repeated use of the bath salt product.

Of the 15 products selected for the quantitative analyses, over half (eight) of them were purchased outside the EU. Considering that 50% of the products were purchased from Danish shops/web shops and 25% each from EU and non-EU, it is striking that one or more of the five prioritised substances were identified in twice as many non-EU products as in EU and DK products combined. As products purchased outside the EU often do not contain an ingredient list, the results of this project show that there is reason to be aware of purchasing these types of products outside the EU.

It must be emphasised that the risk assessment has only been carried out with regard to the content of the five prioritised substances, and that the assessment does not include other known/unknown substances. However, the content of a number of skin sensitising substances (typically in the form of fragrance ingredients) in over 80% of the purchased bath products is considered highly inappropriate, especially when it comes to relatively intensive skin exposure to this type of product in young children.

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Appendix 1. Ingredients in bath products for children

This appendix contains an overview of all approximately 180 ingredients identified in the survey via ingredient lists available online (and on a few purchased products).

"REACH registration CLP" indicates that the classification is listed in connection with the registration and REACH dossier.

EDLists.org indicates whether the identified ingredients appear on the EU lists (Endocrine Disruptor List (edlists.org)) of substances suspected of endocrine disrupting effects (Endocrine Disruptor List (edlists.org)).

TABLE 26. Identified ingredients in 45 bath products for children with a list of ingredients. Empty spaces indicate that the substance cannot be found in the REACH database or that the substance does not appear in the EU list of suspected endocrine disruptors.

INCI name	CAS no.	REACH registration CLP	EU harmonised classification, Annex VI	EDLists.org
Ascorbic acid	50-81-7			
Glucose	50-99-7			
Glycerine	56-81-5	Not classified		
Stearic acid	57-11-4	Not classified		
Sucrose	57-50-1			
Propylene glycol	57-55-6	Not classified		
Lactose	63-42-3			
Tetrasodium EDTA	64-02-8		Acute Tox. 4; Eye Dam. 1	
Alcohol	64-17-5		Flam. Liq. 2	
Isopropyl alcohol	67-63-0		Flam. Liq. 2; Eye Irrit. 2; STOT SE 3	
Sodium citrate	68-04-2	Not classified		
Maltose	69-79-4	Not classified		
Melatonin	73-31-4			
Propane	74-98-6		Press. Gas; Flam. Gas 1	
Citric acid	77-92-9	Eye Irrit. 2; STOT SE 3		
Linalool	78-70-6		Skin Sens. 1B	
Mek	78-93-3		Flam. Liq. 2; Eye Irrit. 2; STOT SE 3	Liste II

INCI name	CAS no.	REACH registration CLP	EU harmonised classification, Annex VI	EDLists.org
Butylphenyl methylpropional (Lilial)	80-54-6		Repr. 1B H360Fd	Liste II
Panthenol	81-13-0	Not classified		
Riboflavin	83-88-5	Not classified		
Gluconolactone	90-80-2	Not classified		
Coumarin	91-64-5	Acute Tox. 4; Skin Sens. 1; Aquatic Chronic 3		
Eugenol	97-53-0	Skin Sens. 1B; Eye Irrit. 2		
Trehalose	99-20-7	Not classified		
Benzyl alcohol	100-51-6		Acute Tox. 4; Acute Tox. 4	
Hexyl cinnamal	101-86-0			
Triethanolamine	102-71-6	Not classified		
Citronellol	106-22-9	Skin Irrit. 2; Skin Sens. 1B; Eye Irrit. 2		
Geraniol	106-24-1		Skin Sens. 1	
Butane	106-97-8		"Press. Gas Flam. Gas 1	
Hydroxycitronellal	107-75-5	Skin Sens. 1B; Eye Irrit. 2		
Succinic acid	110-15-6	Eye Dam. 1		
Dipropylene glycol	110-98-5			
Benzyl salicylate	118-58-1	Skin Sens. 1B; Eye Irrit. 2; Aquatic Chronic 3		Liste II
Benzyl benzoate	120-51-4		Acute Tox. 4; Aquatic Chronic 2	
Phenoxyethanol	122-99-6		Acute Tox. 4; Eye Dam. 1; STOT SE 3	
Carbon dioxide	124-38-9			
BHT	128-37-0	Aquatic Chronic 1		Liste II
Tartaric acid	133-37-9	Eye Dam. 1		
Sodium lauroyl sarcosinate	137-16-6	Skin Irrit. 2; Eye Dam. 1; Acute Tox. 2		
Sodium methyl oleoyl taurate	137-20-2			
Limonene	138-86-3		Flam. Liq. 3; Skin Irrit. 2; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1	

INCI name	CAS no.	REACH registration CLP	EU harmonised classification, Annex VI	EDLists.org
Disodium EDTA	139-33-3	Acute Tox. 4; STOT RE 2		
Sodium bicarbonate	144-55-8	Not classified		
CI 74160	147-14-8	Not classified		
Calcium gluconate	299-28-5	Not classified		
Calcium carbonate	471-34-1	Not classified		
Sodium carbonate; soda ash	497-19-8		Eye Irrit. 2	
Dehydroacetic acid	520-45-6		Acute Tox. 4	
Sodium benzoate	532-32-1	Eye Irrit. 2A		
Pantolactone	599-04-2	Eye Irrit. 2		
Glycol distearate	627-83-8	Not classified		
CI 15510	633-96-5	STOT RE 1; Aquatic Chronic 3		
CI 73015	860-22-0	Skin Sens. 1		
CI 16185	915-67-3	Eye Irrit. 2		
Ammonium bicarbonate	1066-33-7	Acute Tox. 4		
Sodium hydroxide	1310-73-2		Skin Corr. 1A	
CI 77266	1333-86-4	Not classified		
Iron oxide	1345-25-1	Not classified		
CI 75470	1390-65-4	Not classified		
Tocopherol	1406-66-2	Not classified		
Sodium lauryl sulfoacetate	1847-58-1			
CI 19140	1934-21-0	Not classified		
CI 16255	2611-82-7	Not classified		
CI 42090	2650-18-2	Not classified		
CI 15985	2783-94-0	Not classified		
CI 44090	3087-16-9			
Sodium laureth sulfate	3088-31-1			
CI 45100	3520-42-1			
CI 42051	3536-49-0	Not classified		
CI 17200	3567-66-6	Not classified		
Denatonium benzoate	3734-33-6	Acute Tox. 4; Eye Dam. 1; Acute Tox. 4		
CI 18050	3734-67-6	Skin Sens. 1B		
CI 14700	4548-53-2	Not classified		
Citral	5392-40-5		Skin Irrit. 2; Skin Sens. 1	
Magnesium sulfate	7487-88-9	Not classified		
Silica	7631-86-9	Not classified		
Sodium chloride	7647-14-5	Not classified		
Tocopheryl acetate	7695-91-2	Not classified		
Sodium sulfate	7727-73-3			

INCI name	CAS no.	REACH registra-tion CLP	EU harmonised classification, Annex VI	EDLists.org
Magnesium citrate	7779-25-1			
Sunflower seed oil	8001-21-6			
Cocos nucifera oil	8001-31-8			
Lecithin	8002-43-5			
CI 47005	8004-92-0			
Lanolin	8006-54-0			
Mentha piperita oil	8006-90-4			
Citrus aurantium bergamia fruit oil	8007-75-8			
Citrus Nobilis peel oil	8008-31-9			
Citrus aurantium dulcis peel oil	8008-57-9			
Sesamum indicum seed oil	8008-74-0			
Salvia sclarea oil	8016-63-5			
Jasminum officinale oil	8022-96-6			
Palm oil	8023-79-8			
Persea gratissima oil	8024-32-6			
Citrus aurantium dulcis flower extract	8028-48-6	Flam. Liq. 3; Asp. Tox. 1; Skin Irrit. 2; Skin Sens. 1; Aquatic Chronic 2		
Chondrus crispus powder	9000-07-1			
Shellac	9000-59-3			
Sodium polyacrylate	9003-04-7			
PEG/PPG-17/6 copolymer	9003-11-6			
Zea mays starch	9005-25-8			
Polysorbate 20	9005-64-5	Not classified		
Polysorbate 80	9005-65-6			
Amylodextrin	9005-84-9			
Albumen	9006-50-2	-	-	
Maltodextrin	9050-36-6			
Naringin	10236-47-2	Not classified		
Xanthan gum	11138-66-2			
Mica	12001-26-2			
Synthetic fluorphlogopite	12003-38-2	Not classified		
CI 77891	13463-67-7		Carc. 2	
Sodium phytate	14306-25-3	Acute Tox. 4		
CI 45380	17372-87-1	Skin Sens. 1; Eye Irrit. 2		
CI 77861	18282-10-5	Not classified		
CI 45410	18472-87-2	Eye Irrit. 2		
Monosodium citrate	18996-35-5	Not classified		
Potassium sorbate	24634-61-5		Eye Irrit. 2	
PEG-400	25322-68-3	Not classified		

INCI name	CAS no.	REACH registration CLP	EU harmonised classification, Annex VI	EDLists.org
Glyceryl oleate	25496-72-4			
CI 16035	25956-17-6	Not classified		
Sodium lauroyl glutamate	29923-31-7	Eye Irrit. 2		
Decyl glucoside	54549-25-6			
Polyglycerin-3	56090-54-1			
Guar hydroxypropyltrimonium chloride	65497-29-2			
Cocamide MEA	68140-00-1			
Cocamidopropylamine oxide	68155-09-9	Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; STOT RE 2		
PEG-7 glyceryl cocoate	68201-46-7			
Coco-betaine	68424-94-2			
Sodium C14-16 olefin sulfonate	68439-57-6	Skin Irrit. 2; Eye Dam. 1		
Caprylyl/capryl glucoside	68515-73-1	Eye Dam. 1		
Sodium lauryl sulfate	68585-47-7			
Citrus aurantium amara peel oil	68916-04-1			
Sambucus nigra seed oil	68916-55-2	-	-	
Olus oil	68956-68-3			
Quillaja Saponaria Bark Extract	68990-67-0	Eye Irrit. 2; STOT SE 3		
Ethylhexylglycerin	70445-33-9		Eye Dam. 1; Aquatic Chronic 3	
Cananga Odorata flower oil	83863-30-3	Notified C&L	Harmonised C&L	
Chamomilla recutita flower extract	84082-60-0	Asp. Tox. 1; Skin Irrit. 2; Skin Sens. 1B; Eye Irrit. 2; Aquatic Chronic 2		
Melissa officinalis flower/leaf/stem extract	84082-61-1			
Rosa Centifolia flower oil	84604-12-6			
Rosmarinus officinalis leaf extract	84604-14-8	Flam. Liq. 3; Asp. Tox. 1; Skin Irrit. 2; Skin Sens. 1B; Eye Irrit. 2; STOT SE 2; Aquatic Chronic 2		
Cymbopogon martini herb oil	84649-81-0			
Anthemis nobilis flower oil	84649-86-5			
Theobroma cacao extract	84649-99-0	Not classified		
Hamamelis virginiana extract	84696-19-5			

INCI name	CAS no.	REACH registration CLP	EU harmonised classification, Annex VI	EDLists.org
Helianthus annuus seed oil	84776-03-4	-	-	
Calendula officinalis flower extract	84776-23-8	Flam. Liq. 3		
Aloe barbadensis leaf extract	85507-69-3			
Vitis vinifera seed oil	85594-37-2			
C10-18 triglycerides	85665-33-4			
Beta vulgaris extract	89957-89-1			
Simmondsia Chinensis seed oil	90045-98-0			
Lavandula angustifolia oil	90063-37-9	Asp. Tox. 1; Skin Sens. 1B; Eye Irrit. 2; Aquatic Chronic 3		
Prunus amygdalus dulcis oil	90320-37-9	Not classified		
Saccharum officinarum extract	91722-22-4			
Adansonia Digitata Fruit Extract	91745-12-9			
Ormenis multicaulis extract	92202-02-3			
Hydrolyzed gardenia florida extract	92457-01-7			
Hydrolyzed wheat protein	94350-06-8			
Sodium coco-sulfate	97375-27-4			
Cocamidopropyl betaine	97862-59-4	Eye Dam. 1; Aquatic Chronic 3		
Lauryl glucoside	110615-47-9	Skin Irrit. 2; Eye Dam. 1		
Callitris Columellaris Leaf/Twig oil	192526-11-7	-	-	
Butyrospermum parkii butter	194043-92-0			
Shea butter	194043-92-0			
Spirulina platensis extract	223751-80-2			
Sorbitol	1259528-21-6	-	-	
Chenopodium quinoa seed extract	223749-71-1			
Sodium lauroyl methyl isethionate	156572-81-5	Eye Irrit. 2		
Callitris Glaucophylla leaf extract	1174327-51-5/ 919-739-3	-	-	
Pogostemon cablin (patchouli) oil	1450625-49-6			

Appendix 2. Fragrance ingredients not identified by GC-MS screening

This appendix contains an overview of the fragrance ingredients that were looked for in the GC-MS screening but could not be identified. The fragrance ingredients in this appendix have been performed with reference substances, i.e. they are unlikely to have been present in the products in quantities that could be identified. Alternatively, it may be because small quantities of these substances have been hidden by the numerous signals (peaks) in the chromatograms.

TABLE 27. Fragrance ingredients not identified by GC-MS screening in the 23 products.

Name of substance	CAS no.	Comments
Phenylacetaldehyde	122-78-1	
Citral	5392-40-5	One of the 24 fragrance ingredients subject to mandatory labelling
Hydroxycitronellal	107-75-5	One of the 24 fragrance ingredients subject to mandatory labelling
Cinnamal	104-55-2	One of the 24 fragrance ingredients subject to mandatory labelling
Hydorxyisohexyl-3-cyclohexene carboxaldehyde (Lyral)	31906-04-4	Previously one of the 24 fragrance ingredients subject to mandatory labelling, but now banned and on Annex II of the Cosmetics Regulation
Methyl eugenol	93-15-2	
Aniseed alcohol	105-13-5	
Farnesol	4602-84-0	One of the 24 fragrance ingredients subject to mandatory labelling
Amylcinnamyl alcohol	101-85-9	One of the 24 fragrance ingredients subject to mandatory labelling
Methyl 2-octynoate	111-12-6	One of the 24 fragrance ingredients subject to mandatory labelling
Methyl octine carbonate	111-80-8	
Safrole	94-59-7	
Benzyl cinnamate	103-41-3	One of the 24 fragrance ingredients subject to mandatory labelling
Isopropyl methoxypyrazine	25773-40-4	
Isobutyl-methoxypyrazine	24683-00-9	
trans-non-2-enal	18829-56-6	
Isovaleric acid	503-74-2	
Phenethyl acetate	103-45-7	
Ethyl hydroxypyrone	4940-11-8	
Raspberry ketone	5471-51-2	

Appendix 3. Non-relevant identified substances during screening

This appendix contains an overview of the substances that were identified in the 23 (25) bath products during GC-MS screening, but do not have relevant classifications for inclusion in the prioritization process.

TABLE 28. Substances identified by GC-MS screening, but where the classification of the substances are not interesting for a prioritisation of the substances. Only the most significant classifications are listed in the table.

Name of substance	CAS no.	Harmonised classification	Notified classification	EDlists.org
Pentan-2,4-dion (Acetylacetone)	123-54-6	Acute Tox. 4, H302		No
Ethyllinalool	998430-72-3	Not in the ECHA database		No
Dimethyl phenetyl butyrate	10094-34-5		Skin Irrit. 2	No
Isopropyl myristate	110-27-0		Not classified	No
Gamma-decalactone	706-14-9		Not classified	No
But-2-enyl propyl ester sebacic acid,	998356-10-9	Not in the ECHA database		No
Methyldihydrojasmonate	24851-98-7		Not classified	No
Dodecyl octyl ether	99840-38-4	Not in the ECHA database		No
Raspberry ketone methyl ether	104-20-1		Not classified	No
dl-Menthol	89-78-1		Skin Irrit. 2 Eye Irrit. 2	No
Alpha-Ionone	127-41-3		Not classified	No
Gamma-dodecalactone	2305-05-7		Skin Irrit. 2	No
2,4,4-Trimethyl-3-(3-oxo-1-butenyl)-2-cyclohexen-1-one,	27185-77-9	Not in the ECHA database		No
Ethyl vanillin	121-32-4		Eye Irrit. 2	No
Benzyl acetate	140-11-4		Aquatic Chronic 3	No
Gamma-nonalactone	104-61-0		Not classified	No
Methyl anthranilite	134-20-3		Eye Irrit. 2	No
Dipropylene glycol	110-98-5		Not classified	No

Name of substance	CAS no.	Harmonised classification	Notified classification	EDlists.org
2-(2-hydroxypropoxy)propanol	106-62-7		Not classified	No
1-[1-methyl-2-(2-propenyl-oxy)ethoxy]-2-Propanol,	55956-25-7	Not in the ECHA database		No
2,7-dimethyl-1-Octanol,	15250-22-3	Not in the ECHA database		No
Lauryl alcohol	112-53-8		Eye Irrit. 2	No
Stearyl alcohol	112-92-5		Not classified	No
1-Hexadecanol	353-82-4	Not in the ECHA database		No
Lauryl laurate	13945-76-1		Not classified	No
Methylpropanediol	2163-42-0		Not classified	No
Caprylyl glycol	1117-86-8		Eye Irrit. 2	No
2-phenoxyethyl ester Butanoic acid,	23511-70-8	Not in the ECHA database		No
Glycerin	56-81-5		Not classified	No
Myristyl alcohol	112-72-1		Not classified	No
Cetyl caprylate	29710-31-4	Not in the ECHA database		No
Heptadecan-1-ol	1454-85-9		Not classified	No
Pentadecan-1-ol	629-76-5		Not classified	No
Propylene glycol	57-55-6		Not classified	No
trans-3-methyl-3-phenylethyl ester Oxiranecarboxylic acid	19464-92-7	Not in the ECHA database		No
cis-3-methyl-3-phenylethyl ester Oxiranecarboxylic acid	19464-95-0	Not in the ECHA database		No
Ethyl-2,6-dimethylbenzoate	36596-67-5	Not in the ECHA database		No
Ethyl acetoacetate ethylene acetal	6413-10-0	Not in the ECHA database		No
2-t-Butylcyclohexyl acetate	88-41-5		Aquatic Chronic 2	No
Hexylacetate	142-92-7		Flam. Liquid 2	No
Ethyl cinnamate	103-36-6		Not classified	No
Isopropyl laurate	10233-13-3		Not classified	No
Bicyclosesquiphellandrene	54324-03-7	Not in the ECHA database		No
2-methyl-, 2,3-dihydro-2-hydroxy-1H-indenyl ester Propanoic acid,	998132-24-1	Not in the ECHA database		No
(3aR,4S,7S,7aS)-3a,4,5,6,7,7a-Hexahydro-1H-4,7-methanoinden-6-yl propionate	998498-52-8	Not in the ECHA database		No
2-octyl ester butanoic acid,	20286-44-6	Not in the ECHA database		No

Name of substance	CAS no.	Harmonised classification	Notified classification	EDlists.org
3,6,9-trioxaundecane-1,11-diol (Tetraethylene glycol)	112-60-7		Not classified	No
Delta-decalactone	705-86-2		Aquatic Chronic 2	No
Ethyl hexanoate	123-66-0		Skin Irrit. 2	No
trans-Rose oxide	876-18-6	Not in the ECHA database		No
3,6,9,12,15-pentaoxahexadecane-1,17-diol (Hexaethylene glycol)	2615-15-8		Not classified	No
Amberonne (isomer 2)	998470-69-8	Not in the ECHA database		No
(3R,3aS,6S,7R)-3,6,8,8-Tetramethyloctahydro-1H-3a,7-methanoazulen-6-ol	19903-73-2	Not in the ECHA database		No
Amberonne (isomer 3)	998470-69-9	Not in the ECHA database		No
8-Ethyl-4,6,6,8-tetramethyl-3,4,6,7-tetrahydro-1H-cyclopenta(G)-2-benzopyran	998432-48-9	Not in the ECHA database		No
Isopropyl palmitate	142-91-6		Not classified	No
Ethyl laurate	106-33-2		Not classified	No
5-[3-(4-Methoxyphenyl)oxaziridin-2-yl]pentan-1-ol	998192-77-6	Not in the ECHA database		No
Cedrol	77-53-2		Aquatic Chronic 2	No
2,6-dimethyl-1,7-Octadiene-3,6-diol	51276-33-6	Not in the ECHA database		No
2,6-dimethyl-3,7-Octadiene-2,6-diol	13741-21-4	Not in the ECHA database		No
Ethyl 2-(5-methyl-5-vinyltetrahydrofuran-2-yl)propan-2-yl carbonate	998373-80-3	Not in the ECHA database		No
Tetrahydro-trimethyl-5-vinylfuran-2-methanol (furanoid)	34995-77-2		Acute Tox. 4, Skin Irrit. 2	No
Ethyl-2-(5-methyl-5-vinyltetrahydrofuran-2-yl)propan-2-yl carbonate	998373-80-3	Not in the ECHA database		No
Caryophyllene oxide	1139-30-6		Aquatic Chronic 2	No
Lavandulyl acetate	25905-14-0		Not classified	No
Dihydro-5-methyl-5-vinylfuran-2(3H)-one	1073-11-6		Not classified	No
(.+-.)-4-(acetyloxy)-4-methyl-5-Hexenal,	70130-95-9	Not in the ECHA database		No
trans-Ascaridol glycol	21473-37-0	Not in the ECHA database		No
Isopropylidene-methyl-cyclohexyl acetate	10235-63-9	Not in the ECHA database		No

Name of substance	CAS no.	Harmonised classification	Notified classification	EDlists.org
Dodecyl octyl ether	998406-38-4	Not in the ECHA database		No
(-)-*trans*-Myrtanyl acetate	998157-78-3	Not in the ECHA database		No
Gamma-caprolactone	695-06-7		Skin Irrit. 2	No
Amberonne (isomer 2)	998470-69-8	Not in the ECHA database		No
Amberonne (isomer 1)	998470-69-7	Not in the ECHA database		No
Ocimene	13877-91-3		Asp. Tox 1 H304, Skin Irrit. 2	No
1,4-epidioxy-2-p-menthene (Ascaridole)	512-85-6	Not in the ECHA database		No
Laureth-1	4536-30-5		Not classified	No
α.-Damascone	31089-90-4	Not in the ECHA database		No

Appendix 4. Example, calculation of skin exposure from a bath product

Calculation of systemic skin exposure from a bath product defined as a cosmetic product and based on the method specified by SCCS (2023)

Starting point:

According to chapter 4, the dermal exposure (E dermal (mg/kg bw/day)) for a product marketed for children from 3 years of age can be calculated using the following formula:

E dermal (mg/kg bw/day) = C (mg/g) x Q (g/day) x 0.1 / 14.0 kg bw

Where
C (mg/g): Concentration of the substance in the product
Q (g/day): Amount of product used per day
Fret: The retention factor on the skin, i.e., the proportion of the product that is considered available for skin absorption/is in direct contact with the skin.

Product weight: 30 grams
Content: 3% Substance A; equivalent to 30 mg A/gram
Body weight: 14.0 kg
Bath time: 1 hour
Retention factor: 0.1 (see section 4.1.1)

Exposure calculation:

Skin exposure = product weight x conc. substance x retention factor / weight
Skin exposure = 30 g x 30 mg A/g x 0.1 / 14 kg bw
Skin exposure = 6.4 mg A/kg bw

If no data is available for the dermal absorption of substance A, SCCS (2023) uses an absorption of 50% as a general assumption, i.e., the systemic exposure will be:

Systemic exposure = Skin exposure x absorption percentage
Systemic exposure = 6.4 mg A/kg bw x 50% = ***3.2 mg A/kg bw***

Calculation of systemic dermal exposure from bath products defined as toys and based on the methodology for toys, REACH regulation

Starting point

ECHA (2015) provides guidelines for consumer exposure assessment, including reference to the Consexpo; ECETOC TRA models.

These models are based on how much of a chemical substance is available for skin absorption per cm^2, the so-called dermal load (L_{der}):

$$L_{der} = C_{der} \cdot TH_{der}$$

C_{der} is the concentration of the substance in contact with the skin and TH_{der} is the thickness of the liquid from which absorption can take place. For aqueous solutions, ECHA (2015) uses a starting value of **0.01 cm for the thickness/height of the liquid layer**.

The total exposure available for dermal absorption D_{der}) can then be calculated:

$$D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW}$$

Where A_{skin} is the exposed skin area, n is the number of exposures per day and BW is the body weight.

For 3-year-old children, the following values are used:

Body weight: 14kg

Body surface area: 0.69 m^2; 6900 cm^2. Rivm (2014) for 3-6 year old children as a baseline for exposure calculations.

Surface area of hands: 345 cm^2. Rivm (2014) states a surface area of the hands of 5% of the body surface area for 3-6 year old children: 0.05 x 0.69 m^2 = 0.0345 m^2; 345 cm^2.

Exposure assessment

For hand contact with the concentrated product:

Skin exposure, hands = C_{der} x H_{der} x A_{skin} x n / BW

Skin exposure, hands = 30 mg A/ cm^3 x 0,01 cm x 345 cm^2 x 1 / 14 kg

Skin exposure, hands = 7.4 mg A/kg bw (exposure)

For body contact with product dissolved in bathwater:

Concentration in the bathwater = product weight x conc A in product / bathwater volume

Concentration in bathwater = 30 g x 30 mg/g / 30,000 g = 0.03 mg A/ g

Skin exposure, body = C_{der} x H_{der} x A_{skin} x n / BW

Skin exposure, body = 0.03 mg A/ cm^3 x 0.01 cm x 6900 cm cm^2 x 1 / 14 kg

Skin exposure, whole body = 0.15 mg A/kg bw (exposure)

Total exposure = ***7.4 mg A/kg bw + 0.15 mg A/kg bw = 7.6 mg A/ kg bw (exposure)***

ECHA (2016) indicates 100% skin absorption for substances where an exact value is not known, i.e.:

Systemic exposure = 7.6 mg A/ kg bw

Comment:

As can be seen, the magnitude of dermal exposure is relatively close for the two methods and the given assumptions (6.4 mg A/kg bw for a cosmetic product and 7.6 mg A/kg bw for a toy with the same content concentration).

Furthermore, it can be noted that the REACH/ECHA 2016 guidelines mean that the skin exposure of the hands to the concentrated product is approximately 50 times higher than the whole-body skin exposure to the diluted product in the bathwater.
So if hand exposure to the concentrated product does not occur, the REACH method will result in an approx. 40 times lower dermal exposure than the SCCS method (REACH method: 0.15 mg A/kg bw *vs.* SCCS method 6.4 mg A/ kg bw).

At the same time, it can be seen that with the stated assumptions and parameters, the systemic dermal exposure to a substance for which the skin absorption is not known, using the REACH guidelines for consumer exposure, will result in a systemic dermal exposure approximately 2½ times higher than using the SCCS (2023) guidelines (3.2 mg A/kg bw for a cosmetic product and 7.6 mg A/kg bw for a toy with the same content concentration).

For substances where the actual dermal absorption is known, the difference between the two methods will only be half as large (i.e., virtually the same systemic exposure in both calculations), as the actual dermal absorption is used in both calculation methods instead of the baseline values of 50% (SCCS method) and 100% (REACH method).

Appendix 5. Assessing whether products are cosmetics and/or toys

In relation to the risk assessment of the products, both the Danish Safety Technology Authority and the Danish Environmental Protection Agency (Danish EPA) have assessed whether the 15 products selected for quantitative analysis should be assessed as a cosmetic product or as a toy or as both. I.e. The Danish Safety Technology Authority and the Danish EPA have assessed which regulations the 15 products will be subject to. The assessment is based solely on images of the products and the presentation of the products on the websites where they were purchased. The assessment of the products is presented in TABLE 29 below.

TABLE 29. Assessment of which legislation the 15 products for quantitative analysis are subject to. The assessment is carried out by the Danish Safety Technology Authority (Danish STA) and the Danish EPA.

Product no.	Rating Danish STA	Rating Danish EPA
DK 1 - BK	**Toys**	Not cosmetics
DK 2 - BK	**Toys**	Not cosmetics
DK 19 - GE	**Toys**	**Cosmetics**
EU 21 – BK	Not a toy	**Cosmetics**
EU 22 – BK	Not a toy	**Cosmetics**
EU 23 – BK	Not a toy	**Cosmetics**
EU 29 – MS	**Toys**	**Cosmetics**
NEU 33 – BK	**Toys**	Not cosmetics
NEU 34 – BK	**Toys**	Not cosmetics
NEU 35 – BK	**Toys**	Not cosmetics
NEU 36 – FA	**Toys**	Not cosmetics
NEU 39 – VU	**Toys**	Not cosmetics
NEU 40 – KBS	Not a toy	**Cosmetics**
NEU 41 – KBS	Not a toy	**Cosmetics**
NEU 42 – MS	**Toys**	**Cosmetics**

BK = bath ball; GE = bath gel; MS = modelling soap; FA = bathwater colours; VU = bathwater volcano; KBS = crackling powder/bath salt.

Survey and risk assessment of bath products for children

Bath products for children are added to bath water with the purpose of making bathing fun. The bath products can create foam, change the color of the water, or even transform the bath water into slime or jelly. Many of these bath products contain fragrances like strawberries or watermelon, for example. Depending on their purpose, these products may fall under the regulations for either toys or cosmetics, or both.

The goal of this project was to gain knowledge about the ingredients used in various children's bath products. This includes the types of fra-grances and colorants, as well as any other potentially problematic sub-stances these products may contain. Additionally, the project aimed to investigate if these products could pose a risk to children's health during use.

The research showed that there is a wide variety of children's bath prod-ucts. The majority of the products examined contained perfume and/or essential oils (82%) and colorants (73%), several of which have allergenic properties. 15 products were analyzed for the presence of five prioritized substances. For most of the products, there is no health risk in terms of exposure to these substances. However, for one product (purchased and produced outside the EU), the content of the fragrance HHCB is so high (0.18%) that the substance, which is skin sensitizing and suspected of being an endocrine disruptor, is considered to pose a risk to children with repeated use of the product

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