Ministry of Environment of Denmark
Environmental Protection Agency

Survey and risk assessment of free formaldehyde in cosmetic products

Survey of chemical substances in consumer products No. 194

September 2023

Publisher: The Danish Environmental Protection Agency

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ISBN: 978-87-7038-558-9

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Preface

Survey and risk assessment of free formaldehyde in cosmetic products

This project investigated the occurrence of free formaldehyde in 150 selected cosmetic products, with a primary focus on cosmetic products which do not contain a so-called formaldehyde releaser according to the list of ingredients. Formaldehyde releasers are preservatives used in cosmetic products, which are known to be capable of releasing formaldehyde.

The results of the survey, chemical analyses, and risk assessment are presented in this report.

This project was conducted by FORCE Technology, with the Danish Allergy Research Centre as a subcontractor with a view to describe the allergenic properties of formaldehyde and the risk assessment for allergic reactions.

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The project was financed by the Danish Environmental Protection Agency (Danish EPA).

The project was conducted in the period from March 2021 to September 2022.

Summary

In this project, 150 different cosmetic products distributed on seven product types were purchased and analysed to test the products for a content of free formaldehyde.

Background
Formaldehyde is an allergen, and the cosmetics legislation prohibits the use of formaldehyde as an ingredient in cosmetic products. However, the addition of several so-called formaldehyde releasers is allowed. Formaldehyde releasers are preservatives that have a preservative effect by releasing formaldehyde into the cosmetic product over time.

Scientific studies have identified free formaldehyde in cosmetic products that did not have a formaldehyde releaser on the list of ingredients. Thus, in previous studies, a content of free formaldehyde in cosmetic products was observed, where the source could not be immediately explained. The studies question the origin of the free formaldehyde. Therefore, it is desired to clarify the source of free formaldehyde, which does not originate from added formaldehyde releasers.

Moreover, the background of this project was that the Danish EPA had received reports of undesirable effects in consumers when using cosmetic products. Often, these are allergic reactions. Preservatives are one of the most frequent reasons for allergic reactions caused by cosmetic products. Due to formaldehyde being an allergen, a content of undeclared formaldehyde (or sources of formaldehyde) should be limited out of consideration to the consumers.

Purpose
The purpose of the project was to acquire knowledge on formaldehyde in cosmetic products, including the origin of formaldehyde in products where there is no known formaldehyde releaser on the list of ingredients. The purpose was also to assess, whether the identified levels of formaldehyde constitute a risk to the consumers, including a risk of allergy.

Survey
The approach of the project was a survey of what may have an impact on the release or content of free formaldehyde in cosmetic products. Different ingredients, packaging and physical/chemical conditions were investigated. The survey showed that some ingredients could contain free formaldehyde as an impurity in the raw material, while other ingredients could release formaldehyde through oxidation depending on the physical conditions. For example, the release of formaldehyde from certain ingredients such as glycerine only occurs at high temperatures (above 200 °C), which are not relevant for cosmetic products. The survey also showed that certain types of packaging can release formaldehyde in small quantities to the product. Literature search for the physical/chemical parameters showed that elevated temperature, pH and storage time also are factors that influence the formation of free formaldehyde, but also that some ingredients can inhibit the formation of formaldehyde, such as antioxidants.

Focus on certain ingredients and packaging
Based on the survey results, a decision was made with the Danish EPA that the project should focus on the following ingredients (focus substances) used in cosmetic products. The background of the selection of the specific ingredients is shown below:

- Glycerine: The formation of formaldehyde occurs with heating and at higher temperatures. However, the ingredient is used in more than half of the cosmetic products on the market in Denmark.
- Polysorbate 80: According to the literature, it can release formaldehyde through oxidation.

- PEG compounds (polyethylene glycols): According to the literature, it can release formaldehyde through oxidation.
- Cocamidopropyl betaine: The raw material itself may contain impurities of formaldehyde.
- DHA (dihydroxyacetone): The raw material itself may contain impurities of formaldehyde.

In addition, a decision was made to investigate products packaged in PET (polyethylene terephthalate), as this type of plastic is used for many cosmetic products (mainly skin tonics and make-up removers) and as the release of formaldehyde from PET plastic containers to water has been shown in the past.

Thus, the types of cosmetic products in which these above ingredients and PET packaging are used were deliberately selected. This selection of product types was made based on an extract from the Danish Consumer Council and their database behind the Danish app Kemiluppen. Kemiluppen is an app that assesses the ingredients in more than 13,000 cosmetic products on the Danish market. In addition, a deliberate focus was chosen on leave-on products, where the risk of allergic reactions will be highest due to the longer exposure time compared to rinse-off products. Among others, face creams and eye creams were selected because these two product types were overrepresented in the reports concerning undesirable effects from cosmetic products that the Danish EPA has received from consumers. The selected seven types of cosmetic products were:

- Face cream
- Body Lotion
- Hand cream
- Make-up remover
- Self-tanner
- Skin tonic
- Eye cream

Purchase of cosmetic products for analysis
A total of 150 cosmetic products were purchased, equally distributed among the seven product types, with 50% of the products purchased from Danish websites or at Danish shops, 25% from EU websites and 25% from non-EU websites. Twelve of the 150 cosmetic products were deliberately purchased with a content of formaldehyde releaser according to the list of ingredients. This was in order to have a basis for comparison with regard to the content of free formaldehyde.

Semi-quantitative analysis for free formaldehyde in 150 cosmetic products
All 150 cosmetic products were analysed semi-quantitatively by the so-called CA method, a colour reaction method where any free formaldehyde in a cosmetic product evaporates over two days into a test tube containing a reagent liquid, which turns purple in the presence of formaldehyde. The stronger the purple colour, the higher the concentration of free formaldehyde is in the cosmetic product.

However, of the 150 products purchased, there were eight products where the list of ingredients could not be read for various reasons (i.e. a content of possible formaldehyde releasers could not be confirmed). Twelve products had a content of a formaldehyde releaser according to the list of ingredients. For the remaining 130 products without a formaldehyde releaser on the list of ingredients, the result was that 23 cosmetic products (18%) had a free formaldehyde content above 2.5 ppm according to the CA method used. These 23 products were distributed on one face cream, two body lotions, one hand cream, one make-up remover, 14 self-tanners, one skin tonic and three eye creams. Thus, self-tanners were strongly overrepresented among the products with an identified content of free formaldehyde above 2.5 ppm.

The results of the semi-quantitative analyses were assessed in relation to the five selected focus substances. The review showed that for the ingredient DHA, which is only used in self-tanners, there was a clear trend that DHA could be the cause of the content of free formaldehyde in these products. There were no clear trends for neither the four other focus substances nor products packaged in PET material as to whether these could be the cause of the presence of free formaldehyde.

The results of the semi-quantitative analyses showed that there is no immediate difference for products purchased in DK, the EU and non-EU regarding the possible content of free formaldehyde in products without a formaldehyde releaser on the list of ingredients.

Quantitative analysis for free formaldehyde in 31 cosmetic products
Based on the semi-quantitative results, a decision was made to analyse all of the 23 products mentioned above, which did not have a formaldehyde releaser on the list of ingredients and which contained free formaldehyde above 2.5 ppm according to the CA method, plus eight products containing formaldehyde releasers according to the list of ingredients, with a quantitative analytical method. The results showed a free formaldehyde content of between 1 and 637 ppm (mg/kg), of which the average for products with a formaldehyde releaser was 355 ppm (between 75 and 637 ppm), and the average for products without a formaldehyde releaser was 105 ppm (between 1 and 529 ppm).

Four products contained free formaldehyde above 500 ppm, which is the current limit for labelling cosmetic products in the EU with the warning "contains formaldehyde". 24 of the 31 products tested had a free formaldehyde content above 10 ppm, which is the new limit value that the EU Commission has adopted regarding labelling a warning on released formaldehyde on cosmetic products. Of these 24 products, 14 were without a formaldehyde releaser, and 10 were with a declared formaldehyde releaser. When comparing this with the results from the semi-quantitative analyses, the results show that the following proportion of the purchased products had a free formaldehyde content above 10 ppm:
- 14 out of 130 products without a formaldehyde releaser according to the list of ingredients, corresponding to 11%
- 10 out of 12 products with a formaldehyde releaser according to the list of ingredients, corresponding to 83%

A content of a formaldehyde releaser is thus a major cause of a measurable content of free formaldehyde in cosmetic products. However, this project also shows that cosmetic products with a content of free formaldehyde, but without a formaldehyde releaser on the list of ingredients, do exist on the market. Three cosmetic products have been identified which do not contain either a formaldehyde releaser or the ingredient DHA, but where the content of free formaldehyde exceeds the adopted new limit value for labelling cosmetic products which release formaldehyde with a warning. These three products had a free formaldehyde content between 191 and 356 ppm.

Physical/chemical conditions studied
The experiments carried out with PET packaging, raw materials, temperature and pH did not provide a clear explanation to the content of free formaldehyde in products without DHA and formaldehyde releasers. However, the results of the follow-up studies showed that an alkaline pH seems to lead to an increased release of formaldehyde.

Follow-up studies on three products with a content of free formaldehyde
For the three cosmetic products that did not contain neither formaldehyde-releasers nor the ingredient DHA, but where the content of free formaldehyde exceeds the new limit value adopted by the EU Commission for labelling a warning concerning released formaldehyde on

cosmetic products, follow-up studies of both packaging and ingredients were carried out. Unused packaging was only provided from one of the three producers. The results showed that there is no indication that the packaging material should be the cause of the measured content of free formaldehyde in the three products.

An examination of the constituents on the list of ingredients demonstrated that two raw materials (disodium EDTA and hydroxyethylcellulose), which are used in two of the three products, can contain impurities of free formaldehyde. However, the impurities of formaldehyde are not present in concentrations that can explain the entire content of free formaldehyde measured by the quantitative analysis carried out in this project. Accordingly, there must be other causes to free formaldehyde in these products as well. However, these causes have not been identified in this project.

The risk of allergy

As mentioned above, the quantitative analyses found that 24 out of 31 analysed cosmetic products contained more than 10 ppm of free formaldehyde. A content of free formaldehyde above 10 ppm is the new limit value adopted by the EU Commission for labelling a warning on cosmetic products regarding released formaldehyde. It is also the level at which allergic eczema can occur in sensitised individuals with eczema skin when exposed to leave-on products. In relation to allergy, the concepts of sensitisation and elicitation are used. To be sensitised to a given substance means to become allergic to that substance, while elicitation is the triggering of an allergic reaction in an already sensitised person. The levels of free formaldehyde ranged from 12 to 637 ppm for the 24 products with content values above 10 ppm. Thus, all these 24 products constitute a risk of elicitation. The higher the formaldehyde content, the higher is the risk that people who have already developed an allergy to formaldehyde will get an allergic reaction.

The sensitisation level for leave-on products was in this project calculated using the perfume industry's so-called QRA method (risk assessment model) to be between 110 and 165 ppm and between 375 and 565 ppm for rinse-off make-up removers. The risk assessment model assumes daily use, while most self-tanners are probably used less frequently. Thus, the upper sensitisation level (165 ppm) is used for the assessment of this product type. The SCCS does not officially accept the fragrance industry's risk assessment model, but it is currently the available possibility to estimate levels for sensitisation when exposed dermally to cosmetic products. By using this risk assessment model for sensitisation, it can be concluded for those products where the content of free formaldehyde has been measured quantitatively that:

- Seven out of eight creams (face creams, body lotions and eye creams) exceed both the lower and upper sensitisation levels of 110 and 165 ppm, respectively, and according to the model, constitute a risk of sensitisation. Five of these contain a formaldehyde releaser according to the list of ingredients.
- Four out of 15 (27%) self-tanners have a content higher than the upper level of 165 ppm and may thus constitute a risk of sensitisation during use. One of the self-tanners contains a formaldehyde releaser according to the list of ingredients.
- One out of two make-up removers exceeds the lower sensitisation level of 375 ppm, but none of the two make-up removers exceeds the upper sensitisation level of 565 ppm. However, the second make-up remover contains a level of formaldehyde (355 ppm) close to the current limit, i.e. it cannot be ruled out that there might also be a risk of sensitisation when using this product.

For 12 out of a total of 31 (39%) products analysed (with the quantitative method of analysis), there could be a risk of sensitisation, i.e. there is a risk that non-allergic individuals could develop an allergy.

Except for products that contain a formaldehyde releaser according to the list of ingredients and products that contain DHA, there are still a total of three products containing free formaldehyde at levels above 10 ppm, for which there is a risk of elicitation (one make-up remover and two eye creams).

Based on the models used in this report, some of the products containing this so-called hidden formaldehyde would constitute a significant risk for both sensitisation and elicitation. Thus, it is of concern that hidden formaldehyde has been found in so many products.

Risk of other effects
The critical effect of formaldehyde when the substance is in contact with the skin is allergy. The critical effect is the effect seen at the lowest concentration. There is no absorption of formaldehyde through the skin, as formaldehyde reacts with the skin's water content, which means that when assessing effects from dermal exposure of the products, it does not make sense to assess effects other than allergy. Thus, when a risk assessment of formaldehyde for other effects is to be conducted, it only makes sense to perform this assessment for products applied via a spray, since a risk of exposure through inhalation exists for these products. This is the case for one of the purchased self-tanners, where a quantitative analysis of the content of free formaldehyde was also performed. For this self-tanner product, a risk assessment of possible health effects from using the self-tanner was conducted.

In addition to being allergenic, formaldehyde is a carcinogen, but the carcinogenic effects through inhalation (nasal cancer) are seen at higher concentrations than the so-called sensory effects of formaldehyde. The critical effect for formaldehyde through inhalation is thus sensory effects, such as irritation of the respiratory tract and irritation of the eyes, which is seen by increased blinking of the eyes. The risk assessment is based on these levels and on a worst-case assumption that all formaldehyde contained in the self-tanner evaporates in the inhalation zone (at the head). It is also assumed that no venting takes place. The calculations are thus based on theoretical worst-case considerations. No real measurements of the actual concentration have been made.

Under these worst-case conditions, the calculations suggest that there may be a short-term exceedance of the limit value for acute effects in the form of sensory irritation, i.e. there may be discomfort (more rapid eye blinking) when using this self-tanner directly in the inhalation zone. Whether the concentration will actually be as high as theoretically calculated can only be verified by measurements. However, if sensory irritation does occur in practice, it is likely to be short-lived, partly because formaldehyde reacts/oxidises rapidly in air, and partly because there will always be some form of natural ventilation in the room. The use of this self-tanning spray will contribute to an increase in the general indoor concentration of formaldehyde, but it is a product that is probably used twice a week at most. It cannot be concluded whether there will be a risk of sensory irritation or not, as this depends on the actual concentration of formaldehyde in the spray mist, which has only been calculated theoretically in this project and not measured. However, worst-case calculations show that there will be no risk of developing nasal cancer from using this self-tanning spray twice a week for a prolonged period of time.

1. Introduction

Formaldehyde has a harmonised classification as both a carcinogen and an allergen[1]. According to the EU's Scientific Committee on Consumer Safety (SCCS), formaldehyde allergy occurs in between 0.7% and 3.6% of clinical patients in Europe, while formaldehyde allergy occurs in less than 0.5% of the general population (SCCS/1538/14, 2014).

The use of formaldehyde in cosmetic products has been restricted for many years. For several decades, formaldehyde was only permitted in nail hardening products (at a maximum concentration of 5%) and as a preservative (at a maximum concentration of 0.2%) in cosmetic products. The Cosmetics Regulation[2] is the overall legislation regarding cosmetic products. This Regulation encompasses all cosmetic products within the EU. In May 2019, the use of formaldehyde in cosmetic products was prohibited after formaldehyde was added to annex II of the Cosmetics Regulation, which is the list of substances that may not be used in cosmetic products[3]. However, formaldehyde may still legally be present in cosmetic products, since the use of several formaldehyde releasers is permitted. These are preservatives, whose mechanism of action involves a slowly release of formaldehyde into a cosmetic product.

1.1 Background

The background of this project is that the Danish EPA has received reports on undesirable effects from consumers' use of cosmetic products. These undesirable effects are often allergic reactions. Preservatives, including formaldehyde, are among the most common causes of allergic reactions from cosmetic products.

The literature describes several studies in which formaldehyde was identified in analyses of cosmetic products despite the lack of a formaldehyde releaser declared on the products. Thus, these studies question the source of the formaldehyde in these products.

1.2 Purpose

The purpose of this project is to gain knowledge on formaldehyde in cosmetic products, including the origin of formaldehyde in products without any declared formaldehyde releasers. Its purpose is also to assess, whether the detected levels of formaldehyde pose any risk to the consumers, including the risk of allergic reactions - in terms of both sensitisation (the phase in which one develops an allergy) and elicitation (the phase in which an allergic reaction occurs in a person who has developed an allergy).

1.3 Scope and priorities

The primary focus of this project is to investigate the origin of formaldehyde in cosmetic products without a declared formaldehyde releaser. In this investigation it is assumed that the analysed cosmetic products are correctly declared; that is, that the products do not contain a formaldehyde releaser if one is not declared on the product.

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[1] Carc. 1B H350 "May cause cancer" and Skin Sens. 1 H317 "May cause an allergic skin reaction" according to the ECHA's C&L database.

[2] Regulation (EC) no 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (EU Regulation 1223/2009).

[3] Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (EU Regulation 831/2019).

This project is limited to studying, analysing, and assessing the presence of formaldehyde in cosmetic products that are *not* intended to be rinsed off after use; that is, "leave-on" products like body lotions, face creams, hand creams, and similar products. Make-up removers, which may be either rinse-off or leave-on products, depending on the product's usage instructions, are also included in the project.

In the reports, which the Danish EPA received regarding allergic reactions to cosmetic products, eye and face creams were overrepresented product categories. For this reason, it was decided to include eye and face creams in this project, though other types of leave-on products are also included in the study.

This project does not have any particular focus on cosmetic products designed for use on e.g. eczematous skin, damaged skin, or dry skin. During the purchasing process, it was noted, whether each product targeted a particular group of consumers. Similarly, there is no particular focus on products for children; this is a consequence of the fact that the project focuses on products like eye creams, face creams, and hand creams, which are primarily used by adult consumers.

1.3.1 Formaldehyde release and migration

Preservatives which are formaldehyde releasers are defined in greater detail in chapter 2, which also describes the formaldehyde releasers most commonly used in cosmetic products today.

Formaldehyde releasers may release formaldehyde (e.g. due to breakdown or decomposition (Halla et al., 2018)), but this project also investigated other ingredients that may release formaldehyde into a cosmetic product. In other words, it investigated the existence of ingredients other than known formaldehyde releasers, which are used in cosmetic products and which may release formaldehyde during breakdown or oxidation.

There are, however, some ingredients, which contain formaldehyde impurities. These cases do not involve the release of formaldehyde; rather, these products unintentionally contain formaldehyde originating in e.g. the production process for an ingredient.

Lastly, it is possible for formaldehyde to migrate from certain types of packaging that may contain traces of formaldehyde (unreacted remnants from a manufacturing process). In these cases, the packaging may release formaldehyde into a cosmetic product.

Note, that this project is not limited to a particular type of formaldehyde source in cosmetic products, but there are different ways in which formaldehyde can occur in cosmetic products. All the same, as described above, this project is limited to focusing on cosmetic products, which do not declare the presence of any formaldehyde releasers (preservatives). For comparative purposes, some products which contain known formaldehyde releasers are also included for analysis.

2. Formaldehyde releasers

Formaldehyde releasers are substances that release formaldehyde into the products to which they are added, thereby functioning as preservatives. This chapter defines formaldehyde releasers, and it describes the formaldehyde releasers that are permitted and used in cosmetic products today. It also describes the legislation that applies to these preservatives.

2.1 Definition of a formaldehyde releaser

Various definitions of formaldehyde releasers exist. The usual interpretation of a formaldehyde releaser is a preservative that releases formaldehyde into a cosmetic product. According to Halla et al. (2018) and Lv et al. (2015), formaldehyde is released through the breakdown or decomposition of the formaldehyde releaser. The formaldehyde releaser has a preservative effect because formaldehyde is released through hydrolysis when water is present in the product. However, other factors are also relevant to the release of formaldehyde, such as the composition of the cosmetic product, its pH, its time in storage, and especially its temperature. Higher temperatures result in greater quantities of formaldehyde being released.

De Groot et al. (2009) define formaldehyde releasers as substances that release formaldehyde as a result of their decomposition. Malinauskiene et al. (2015) use a slightly different description, defining formaldehyde releasers as preservatives that release formaldehyde in the presence of water (Malinauskiene et al., 2015).

In a report on formaldehyde and formaldehyde releasers, ECHA (2017) indicates that there are various categories of formaldehyde releasers:

1. Formaldehyde releasers which release formaldehyde intentionally. These may be covered by the Biocidal Products Regulation or the Regulation on Cosmetic Products, but they may also be used in products such as pharmaceuticals. In cosmetic products, the use of certain formaldehyde releasers as preservatives is permitted.
2. Formaldehyde releasers described in scientific literature; that is, substances described in the literature as being capable of releasing formaldehyde.
3. Substances registered under REACH which contain formaldehyde, whether as a component of the substance or as an impurity. ECHA calls this last group "potential formaldehyde releasers".

This report uses the following definition of a formaldehyde releaser: A preservative which may release formaldehyde, including the preservatives listed in annex V of the Regulation on Cosmetic Products.

2.2 Which substances are formaldehyde releasers?

The Danish Allergy Research Centre (2013) has listed 11 formaldehyde-releasing ingredients which are or were previously used in cosmetic products. Since this list was created, the annexes to the Regulation on Cosmetic Products have been updated; consequently, fewer formaldehyde releasers are permitted today.

De Groot et al. (2009) developed a list of 35 substances that can be considered formaldehyde releasers, plus seven substances described as formaldehyde releasers in the literature which have not been conclusively shown to release formaldehyde. Comparing this list of 42 substances to the Regulation on Cosmetic Products results in the following list of 21 formaldehyde releasers which are permitted in cosmetic products (see TABLE 1). Of these, 10 are permitted as preservatives (according to annex V of the Regulation on Cosmetic Products).

TABLE 1. List of formaldehyde releasers permitted in cosmetic products.

CAS no.	INCI name	Chemical name or synonym	Comments***
30007-47-7*	5-Bromo-5-nitro-1,3-dioxane	5-Bromo-5-nitro-1,3-dioxane	Index no. 20 in annex V**** of the Regulation on Cosmetic Products
52-51-7	2-Bromo-2-nitropropane-1,3-diol	Bronopol	Index no. 21 in annex V of the Regulation on Cosmetic Products
39236-46-9	Imidazolidinyl urea	N, N''-Methylenbis[N'- [3-(hydroxymethyl)- 2,5-dioxoimidazolidin- 4-yl]urea]	Index no. 27 in annex V of the Regulation on Cosmetic Products
100-97-0	Methenamine	Methenamine	Index no. 30 in annex V of the Regulation on Cosmetic Products
6440-58-0	DMDM hydantoin	1,3-Bis(hydroxymethyl)-5, 5-dimethyl-imidazolidine-2,4-dione	Index no. 33 in annex V of the Regulation on Cosmetic Products
51200-87-4**	Dimethyl oxazolidine	4,4-Dimethyloxazolidine	Index no. 45 in annex V of the Regulation on Cosmetic Products
78491-02-8	Diazolidinyl urea	N-(Hydroxymethyl)- N-(dihydroxymethyl- 1,3-dioxo-2,5-imidazolidinyl-4)-N'-(hydroxymethyl)urea	Index no. 46 in annex V of the Regulation on Cosmetic Products
7747-35-5	7-ethylbicyclooxazolidine	5-ethyl-3,7-dioxa-1- azabicyclo [3.3.0] octane	Index no. 49 in annex V of the Regulation on Cosmetic Products
70161-44-3	Sodium hydroxymethylglycinate	Sodium hydroxymethylglycinate	Index no. 51 in annex V of the Regulation on Cosmetic Products
14548-60-8	Benzylhemiformal	Phenylmethoxymethanol	Index no. 55 in annex V of the Regulation on Cosmetic Products
26811-08-5	Dimethylhydantoin formaldehyde resin	5,5-Dimethylimidazolidine-2,4-dione, formaldehyde	Allowed in cosmetic products. Listed in the CosIng database as "film-forming".
140-95-4	Dimethylol urea	1,3-Bis(hydroxymethyl) urea	Allowed in cosmetic products. Listed in the CosIng database as "antimicrobial".
120-93-4	Ethylene urea	Imidazolidin-2-one	Allowed in cosmetic products. Listed in the CosIng database as "perfuming/deodorant".
116-25-6	MDM hydantoin	1-(Hydroxymethyl)-5,5-dimethyl-imidazolidine-2,4-dione	Allowed in cosmetic products. Listed in the CosIng database as "antimicrobial".
9003-08-1	Polyoxymethylene melamine	Polyoxymethylene melamine	Allowed in cosmetic products. Listed in the CosIng database as "film-forming".
9011-05-6	Polyoxymethylene urea	Formaldehyde; urea	Allowed in cosmetic products. Listed in the CosIng database as "bulking".
5395-50-6	Tetramethylol acetylenediurea	2,4,6,8-Tetrakis(hydroxymethyl)-2,4,6,8-tetraazabicyclo[3.3.0] octane-3,7-dione	Allowed in cosmetic products. Listed in the CosIng database as "antimicrobial".
4719-04-4	Tris(N-hydroxyethyl) hexahydrotriazine	2-[4,6-Bis(2-hydroxyethyl)1,3,5-triazinan-2-yl]ethanol	Allowed in cosmetic products. Listed in the CosIng database as "skin conditioning".

CAS no.	INCI name	Chemical name or synonym	Comments***
126-11-4	Tris(hydroxymethyl)-nitromethane	2-(Hydroxymethyl)-2-nitro-propane-1,3-diol	Allowed in cosmetic products. Listed in the CosIng database as "antimicrobial".
3586-55-8	1,6-Dihydroxy-2,5- dioxahexane	2-(Hydroxymethoxy) ethoxymethanol	Allowed in cosmetic products. Listed in the CosIng database as "antimicrobial".
109-87-5	Methylal	Dimethoxymethane	Allowed in cosmetic products. Listed in the CosIng database as "solvent".

* Permitted only in rinse-off products.
** pH > 6.
*** The CosIng (cosmetic ingredient) database is the European Commission's database of information on ingredients in cosmetic products. The fact that an ingredient is listed in the CosIng database does not necessarily mean that its use is permitted, as the CosIng database also contains information on ingredients which are prohibited in cosmetic products (https://ec.europa.eu/growth/tools-databases/cosing/). It contains both active and historic (inactive) information. CosIng is strictly informational and has no legal value. Additionally, it is not necessarily up to date at all times.
**** Annex V of the Regulation on Cosmetic Products lists preservatives that are permitted in cosmetic products.

2.3 Relevant formaldehyde releasers used today

The chemistry division of the Danish Consumer Council (Forbrugerrådet Tænk Kemi) has developed an app called "Kemiluppen" which displays letter grades (A, B, and C) assigned to cosmetic products based on the Danish Consumer Council's assessment of the ingredients declared on the product. The database behind Kemiluppen contains information on all of the ingredients declared in the roughly 13,200 products from the Danish market that are currently recognised by the app (as of April 2021). For this project, the Danish Consumer Council tabulated and extracted in April 2021 a list of products containing ingredients which, according to the literature, may release formaldehyde (the ingredients listed in TABLE 1). Beyond the ingredients listed in TABLE 1, the same process was repeated for the ingredients quaternium-15, paraformaldehyde, and formaldehyde (listed in TABLE 3), as the use of these ingredients in cosmetic products was recently forbidden in the EU (in May 2019, EU Regulation 831/2019). These ingredients may still be in use in non-EU markets.

The goal of the Danish Consumer Council's data extraction was partially to gain information on the use and occurrence of these ingredients in the EU, but also to discover which specific products in Denmark (and possibly the rest of the EU) contain formaldehyde releasers. The information on specific cosmetic products containing formaldehyde releasers was used later in this project to aid the purchasing of products for chemical analysis.

The results of searching the Kemiluppen database are presented below in TABLE 2.

The data from the Danish Consumer Council was extracted from the list of "current" products, which are those products that, according to the knowledge of the Council, have not been retired from the market. However, this does not necessarily mean that the products were still available on the market, as the Danish Consumer Council is not able to review all of the products with regard to their currency. The Danish Consumer Council among others relies on manufacturers to inform them of any changes in product formulations. Not all manufacturers do so to the same extent. Consequently, the existence of products in the database as of April 2021 which contained prohibited ingredients does not necessarily mean that those products were on the Danish market at that point in time. Alongside the number of current products at the time of the data extraction, the number of “retired products” containing each listed formaldehyde releaser is also presented to give readers an idea of how widespread in use each ingredient was previously. The third column in TABLE 2 gives the number of all current products containing the listed ingredient as of April 2021. The difference between "all registered products" and "current products" is the number of “retired products”. Kemiluppen contains more than 20,000 cosmetic products, about 7000 of which are “retired products”. This leaves about 13,000 "current" products - that is, products which the Danish Consumer Council believes to still be on the market with the listed formulation, given that the Council has neither itself reviewed the ingredients declared on the product as currently marketed, nor received information from its manufacturer informing it of a change.

The last column of TABLE 2 gives examples of product types which the listed formaldehyde releasers occur in.

TABLE 2. Occurrence of formaldehyde releasers in cosmetic products in Denmark. Data extracted from April 2021 from the database maintained by The Danish Consumer Council (Forbrugerrådet Tænk Kemi) for its Kemiluppen app. The percentage of current products in which the substance occurs is given in the third column. Leave-on products, which are the focus of this project, are shown in boldface in the rightmost column.

CAS no.	Substance name	No. of current products containing ingredient	Types of cosmetic products (current only)
30007-47-7[1]	5-Bromo-5-nitro-1,3-dioxane	1 (0.01%)	Shampoo (1)
52-51-7	2-Bromo-2-nitropropane-1,3-diol	30 (0.2%)	Facial cleansing wipes (2) Conditioner (2) Hair gel (1) Shampoo (4) Pomade (1) Nail polish (1) **Body lotion (3)** **Hand and nail cream (3)** Body scrub (1) **Self-tanner (7)** Body wash (1) Liquid hand soap (2) Wet wipes (2)
39236-46-9	Imidazolidinyl urea	36 (0.3%)	**Face cream (2)** **Skin toner (1)** Hair remover (2) Theatrical make-up (1) Conditioner (9) Hair gel (2) Hair dye (4) Hairspray (2) Hair mousse (1) Shampoo (3) Mascara (1) Eye liner (1) **Body lotion (3)** **Hand cream (4)**
100-97-0	Methenamine	0	-
6440-58-0	DMDM hydantoin	220 (1.7%)	**Make-up remover (3)** **Face cream (4)** Facial mask (7)

CAS no.	Substance name	No. of current products containing ingredient	Types of cosmetic products (current only)
			Skin toner (1) **Night face cream (1)** Facial cleansing wipes (2) Facial serum (1) Aftershave (1) Shaving foam (2) Conditioner (62) Hair gel (5) Hair cream (3) Hairspray (12) Hair mousse (3) Hair oil (2) Shampoo (54) Pomade (6) Nail care (1) **Body lotion (3)** **Foot care (1)** **Hand cream (4)** Body scrub (1) **After-sun lotion (1)** **Self-tanner (3)** Body wash (37)
51200-87-4[2]	Dimethyl oxazolidine	0	-
78491-02-8	Diazolidinyl urea	52 (0.4%)	**Make-up remover (3)** Facial mask (3) Facial cleansing wipes (1) Facial scrub (2) **Eye cream (1)** **Eye make-up remover (1)** Conditioner (4) Hair gel (2) Hair cream (1) Hairspray (2) Hair mousse (3) Shampoo (7) Pomade (6) **Blush (1)** **Foundation (4)** **Body lotion (6)** **Hand cream (2)** Body wash (1) Wet wipes (2)
7747-35-5	7-ethylbicyclooxazolidine	0	-

CAS no.	Substance name	No. of current products containing ingredient	Types of cosmetic products (current only)
70161-44-3	Sodium hydroxymethylglycinate	26 (0.2%)	**Make-up remover (3)** **Face cream (3)** Facial mask (1) **Night face cream (1)** **Facial serum (2)** Hair gel (6) Hair lotion (2) Shampoo (6) **Body lotion (1)** Body wash (1)
14548-60-8	Benzylhemiformal	0	-
26811-08-5	Dimethylhydantoin formaldehyde resin	0	-
140-95-4	Dimethylol urea	0	-
120-93-4	Ethylene urea	0	-
116-25-6	MDM hydantoin	1	**Face cream (1)**
9003-08-1	Polyoxymethylene melamine	0	-
9011-05-6	Polyoxymethylene urea	0	-
5395-50-6	Tetramethylol acetylenediurea	0	-
4719-04-4	Tris(N-hydroxyethyl) hexahydrotriazine	0	-
126-11-4	Tris(hydroxymethyl)-nitromethane	0	-
3586-55-8	1,6-Dihydroxy-2,5- dioxahexane	0	-
109-87-5	Methylal	0	-
51229-78-8[3]	Quaternium-15	0	-
50-00-0[3]	Formaldehyde	0	-
30525-89-4[3]	Paraformaldehyde	0 Not present in Kemiluppen	-
5625-90-1[4]	4,4'-Methylenedimorpholine	0 Not present in Kemiluppen	-

1. Permitted only in rinse-off products.
2. pH > 6.
3. May not be used in cosmetic products within the EU.
4. May not be used in cosmetic products within the EU if the maximum theoretical concentration of released formaldehyde is ≥ 0.1% w/w.

As shown in TABLE 2 above, only six of the ten formaldehyde releasers permitted for use as preservatives actually occur in cosmetic products on the Danish market. They are listed below, from most to least commonly used:

- DMDM hydantoin (in 220 products)
- Diazolidinyl urea (in 52 products)
- Imidazolidinyl urea (in 36 products)
- 2-Bromo-2-nitropropane-1,3-diol (in 30 products)
- Sodium hydroxymethylglycinate (in 26 products)
- 5-Bromo-5-nitro-1,3-dioxane (in one product)

DMDM hydantoin appears to be the most broadly used formaldehyde releaser. However, it should also be taken into account that the substance is used in only 1.7% of the current cosmetic products listed in the Kemiluppen database.

A Swedish study (Hauksson et al., 2015a) of 245 cosmetic products also showed that DMDM hydantoin was the most broadly used formaldehyde releaser, followed by imidazolidinyl urea, quaternium-15, and 2-bromo-2-nitropropane-1,3-diol (in order of frequency). Today, the use of quaternium-15 in cosmetic products is prohibited.

MDM hydantoin is the only one of the remaining ingredients (i.e., formaldehyde releasers not permitted as preservatives, but which are used for other properties) used in cosmetic products on the Danish market. However, according to the Kemiluppen database, MDM hydantoin is used in only one product (a face cream). As mentioned above, this information may be outdated, although the product is listed in Kemiluppen as a current product. According to the CosIng database, MDM hydantoin is used for its antimicrobial properties.

Looking more closely into the kinds of cosmetic products formaldehyde releasers are used in, a considerable majority are rinse-off products. Leave-on products that typically contain formaldehyde releasers as preservatives are:
- Face cream
- Body lotion
- Self-tanner
- Hand cream
- Foundation
- Make-up remover
- Night face cream
- Facial serum
- Eye cream
- Blush
- After-sun lotion
- Foot cream / other foot care products
- Skin toner

2.4 Legislation on formaldehyde releasers

The formaldehyde releasers listed in annex V of the Regulation on Cosmetic Products ("List of preservatives allowed in cosmetic products") are only permitted in cosmetic products if they meet certain conditions. These conditions include maximum permitted concentrations of substances in finished products and particular types of cosmetic products in which substances are permitted. Additionally, all finished products containing a permitted formaldehyde releaser (and which therefore release formaldehyde) must be labelled with the warning "contains formaldehyde" if the concentration of formaldehyde in the finished product exceeds 0.05% (i.e., 500 ppm). (EU Regulation 1223/2009, Annex V).

The permitted conditions for formaldehyde releasers used as preservatives are presented in TABLE 3 below.

TABLE 3. Legislation on formaldehyde releasers in cosmetic products

CAS no.	INCI name	Restrictions in the Regulation on Cosmetic Products	Comments
30007-47-7	5-Bromo-5-nitro-1,3-dioxane	Maximum permitted concentration 0.1% Permitted only in rinse-off products	Index no. 20 in annex V

CAS no.	INCI name	Restrictions in the Regulation on Cosmetic Products	Comments
52-51-7	2-Bromo-2-nitropropane-1,3-diol	Maximum permitted concentration 0.1%	Index no. 21 in annex V
39236-46-9	Imidazolidinyl urea	Maximum permitted concentration 0.6%	Index no. 27 in annex V
100-97-0	Methenamine	Maximum permitted concentration 0.15%	Index no. 30 in annex V
6440-58-0	DMDM hydantoin	Maximum permitted concentration 0.6%	Index no. 33 in annex V
51200-87-4	Dimethyl oxazolidine	Maximum permitted concentration 0.1% pH > 6	Index no. 45 in annex V
78491-02-8	Diazolidinyl urea	Maximum permitted concentration 0.5%	Index no. 46 in annex V
7747-35-5	7-ethylbicyclooxazolidine	Maximum permitted concentration 0.3% May not be used in oral care products or products applied to mucous membranes	Index no. 49 in annex V
70161-44-3	Sodium hydroxymethylglycinate	Maximum permitted concentration 0.5%	Index no. 51 in annex V
14548-60-8	Benzylhemiformal	Maximum permitted concentration 0.15% Permitted only in rinse-off products	Index no. 55 in annex V
51229-78-8	Quaternium-15	No longer permitted in cosmetic products (added to annex II in May 2019)	Index no. 1386 in annex II
50-00-0	Formaldehyde	No longer permitted in cosmetic products (added to annex II in May 2019)	Index no. 1577 in annex II
30525-89-4	Paraformaldehyde	No longer permitted in cosmetic products (added to annex II in May 2019)	Index no. 1578 in annex II
5625-90-1	4,4'-Methylenedimorpholine	No longer permitted in cosmetic products (added to annex II in May 2019) if the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is ≥ 0.1% w/w	Index no. 1605 in annex II

2.4.1 Labelling with warning of released formaldehyde in cosmetic products

In spring 2021, the SCCS published a Scientific Advice (SCCS/1632/2021, 2021) on the labelling of cosmetic products with a warning at presence of released formaldehyde. According to the preamble of annex V of the Regulation on Cosmetic Products, all finished cosmetic products today must bear the warning "contains formaldehyde" if they contain a substance listed in annex V, which releases formaldehyde so that the concentration of formaldehyde in the finished product exceeds 0.05% (500 ppm). In light of new information that the Commission received, indicating that the limit value of 500 ppm is too high in order to ensure that consumers with an existing formaldehyde allergy do not get allergic reactions, the European Commission requested the SCCS to publish a Scientific Advice on this topic.

In the published Scientific Advice, the SCCS evaluates that it does not consider the current limit value (at which cosmetic products containing a substance from annex V and release formaldehyde must be marked with the warning "contains formaldehyde") sufficient to protect consumers. The SCCS is of the opinion that lowering the limit value from >500 ppm to >10 ppm would protect most consumers with formaldehyde allergy.

Therefore, the EU Commission has in the summer 2022 adopted a new regulation (EU Regulation 1181, 2022) lowering the limit value to 10 ppm based on the Scientific Advice by SCCS. According to article 1 of this regulation, the warning “releases formaldehyde” must be labelled on all finished cosmetic products containing substances listed in Annex V of the Regulation of Cosmetic Products and which releases formaldehyde, if the total concentration of formaldehyde released in the finished product exceeds 0.001% (10 ppm), irrespective of whether the finished product contains one or more substances releasing formaldehyde.

The new regulation was published in the Official Journal of the European Union on July 11, 2022, and will enter into force on the twentieth day following the publication. The transition period will be 24 months for placing products on the market and 48 months for making cosmetic products available on the market, from the date of entry into force, respectively.

3. Survey

This chapter describes the results of the survey performed in this project. The survey was based on existing knowledge regarding free formaldehyde in cosmetic products that do not contain formaldehyde releasers. For this reason, a literature search was conducted, and selected organisations and manufacturers in the industry were contacted.

The following activities were carried out during the survey:

- Contacting selected relevant organisations and manufacturers of cosmetic products or the producers of ingredients used in cosmetic products.
- Contacting selected certification and labelling organisations (environmental and allergenic).
- Conducting a literature review / internet searches for relevant knowledge regarding ingredients and packaging.
- Searching for relevant ingredients in Kemiluppen[4] (The Danish Consumer Council)
- Searching for specific product samples on the market in Denmark, in other EU countries, and in countries outside the EU.

In general, relevant ingredients and packaging materials which may contain or release formaldehyde were identified based on the information obtained from industry contacts and the literature search. Subsequently, the Danish Consumer Council extracted data from its Kemiluppen database using this list of ingredients in order to gain an understanding of the use of these ingredients in cosmetic products on the Danish market. It is expected that many of the same products that can be purchased in Denmark will also be available in other EU markets, though there will likely be some differences in them as well. The survey focused on both the ingredients' general frequency of use and the particular types of cosmetic products in which they are used. For this project, it was decided to focus on the most frequently used of the other relevant ingredients in leave-on products; namely, ingredients expected to contain or potentially release formaldehyde.

This chapter describes the basis on which relevant ingredients and packaging types were selected, as well as the product types chosen to be the focus of the subsequent chemical analyses.

3.1 Formaldehyde in products which do not contain releasers

Some studies have identified formaldehyde in cosmetic products with no declared formaldehyde releasers. This report focuses on the results for leave-on products, since these products are the focus of this project. The studies are described below:

- A Swedish study from 2015 (Hauksson et al., 2015a) found that 26 of the 126 leave-on cosmetic products tested contained free formaldehyde, though 17 of the products did not declare the presence of a formaldehyde releaser. Thus, for 17 out of 26 leave-on products (65%) in which formaldehyde was detected, its presence was not due to the presence of a formaldehyde releaser. The levels of free formaldehyde ranged from 2.5 ppm to >40 ppm of formaldehyde (levels above 40 ppm were not measured using this method).
- A Lithuanian study from 2015 (Malinauskiene et al., 2015) analysed a total of 42 cosmetic products (24 of which were leave-on products) for the presence of formaldehyde. The per-

[4] Kemiluppen is an app managed by the Danish Consumer Council. The app gives consumers the ability to scan cosmetic products and access assessments of their ingredients from environmental and health-related perspectives.

centage of products containing formaldehyde in the absence of a declared formaldehyde releaser is not indicated, but the study does supply an example of a face cream in which the concentration of free formaldehyde was measured at 532 ppm with no formaldehyde or formaldehyde releasers declared.
- An Australian study from 2010 (ACCC, 2010) analysed 32 cosmetic products for the presence of free formaldehyde. The two products with the highest concentrations of formaldehyde (1.3% and 2.2%, equivalent to 13,000 and 22,000 ppm) did not declare the presence of formaldehyde or formaldehyde releasers. Both were rinse-off products.
- A 2020 study from the United Arab emirates (Jairoun, 2020) studied 69 cosmetic products from around the world. Nine of them (13%) contained formaldehyde at concentrations above 2000 ppm, though their list of ingredients did not include formaldehyde or formaldehyde releasers. Only one of the nine products was a leave-on product. This product was from China, and it contained formaldehyde at a concentration of 3400 ppm.

Only a small number of the identified articles and reports discussed possible reasons for the presence of formaldehyde in cosmetic products with no declared formaldehyde releasers. The few reasons proposed are as follows:
- Addition of formaldehyde to raw ingredients (Hauksson et al., 2015a).
- Release of formaldehyde from other chemicals or ingredients, particularly under high temperatures and humidity levels (Hauksson et al., 2015a) and during oxidation (Goon et al., 2003).
- Formaldehyde-based plastics and other packaging materials, such as melamine-formaldehyde or carbamide-formaldehyde plastics (Hauksson et al., 2015a; Malinauskiene et al., 2015; Goon et al., 2003).

These proposals from the literature are discussed in greater detail below as part of the literature review.

3.2 Contact to the industry

Selected relevant organisations were contacted in order to obtain information on free formaldehyde in cosmetic products that do not contain formaldehyde releasers. The following organisations were contacted:
- The Danish Association of Cosmetics and Detergents
- The Danish Cleaning, Cosmetic, and Household Product Industry
- Cosmetics Europe (the European industry association for cosmetic products)
- Selected manufacturers of cosmetic products
- Selected manufacturers of raw materials for cosmetic products
- Ecolabelling Denmark
- AllergyCertified

The industry organisations were asked for general information on this area, as well as information on the types of packaging identified in this project as relevant in terms of their potential to release traces of formaldehyde. The overall impression produced by contacting industry associations and cosmetic product manufacturers was that there is not much knowledge regarding the issue of formaldehyde in products which do not contain formaldehyde releasers. Our inquiries were forwarded to various contacts in these organisations, and the information we received is described below.

We also held a meeting with some interested members of the Danish Association of Cosmetics and Detergents. The impression we got from this meeting was that the presence of formaldehyde in cosmetic products which contain no formaldehyde releasers is not generally considered a problem, though knowledge on the topic is scarce.

We also contacted Ecolabelling Denmark and AllergyCertified, as the requirements for both certifications stipulate that formaldehyde may not be present in cosmetic products[5]. However, these organisations do not maintain lists of ingredients whose use they do not permit in cosmetic products for formaldehyde-related reasons (whether because the ingredients contain formaldehyde or because they may release it).

In general, industry contacts supplied the following reasons for the presence of formaldehyde in cosmetic products with no declared formaldehyde releasers:

- Certain ingredients (raw materials) may release formaldehyde (discussed in greater detail below). Some substances are also known to release formaldehyde when heated.
- Certain ingredients may contain formaldehyde as impurities from their production processes.
- Some vendors may e.g. add formaldehyde releasers to ingredients as preservatives.
- Packaging materials could be associated with the release of formaldehyde.

Below, these individual topics are discussed in greater detail relative to the information received from the industry organisations.

One of the manufacturers contacted described a case in which chemical analysis of some cosmetic products revealed the presence of small amounts of formaldehyde, though it was not possible to determine the source of the formaldehyde in the product. None of the ingredients were formaldehyde releasers, and all of their vendors were contacted to investigate possible reasons for the presence of a formaldehyde source. The packaging materials used were also analysed for formaldehyde migration. The manufacturer was ultimately unable to find an explanation for the formaldehyde detected in the cosmetic product. Therefore, this issue is not new to the industry, but the industry has limited knowledge of the reason for the presence of formaldehyde in products which do not contain formaldehyde releasers.

3.2.1 Specific ingredients

Industry contacts listed the following substances which may either release formaldehyde or contain it as an impurity:

- Cellulose
- Cocamidopropyl betaine
- Silicones
- Dihydroxyacetone (DHA)

This section does not discuss these ingredients in greater detail, but they are discussed in the literature review together with existing literature that may offer support for the information we received.

Some manufacturers in the industry also indicated that some ingredients appear to be capable of releasing formaldehyde when heated. However, the temperatures required for this may not be relevant to cosmetic products.

3.2.2 Preservatives in raw materials

A known issue in the industry which may explain the presence of small amounts of formaldehyde in products without declared formaldehyde releasers is the practice whereby vendors occasionally use formaldehyde releasers as preservatives in their raw materials. In some cases, this information is not necessarily conveyed to cosmetic product manufacturers. The concentration of these raw materials in finished products is low, resulting in a low concentration of formaldehyde releasers in the products. Obtaining information about all relevant ingredients requires close contact with vendors of raw materials.

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[5] https://allergycertified.com/da/how-to-certify/criteria/ and https://www.ecolabel.dk/-/criteriadoc/5338

3.2.3 Packaging

Feedback from industry organisations generally indicated that it would be relevant to further investigate packaging as a possible source of free formaldehyde in cosmetic products where its presence is not explained by the use of formaldehyde releasers (see section 3.2.2). However, industry contacts were broadly unaware of the specific kinds of packaging that ought to be in focus.

One industry association reported that the industry typically uses food-safe plastics for cosmetic products. The reason for this is that a safety report must be prepared for all cosmetic products, and one of the requirements for this report is a safety assessment for migration from packaging materials to the cosmetic product in question. According to article 17 of the Regulation on Cosmetic Products, the transfer of small quantities of prohibited substances from the packaging to the cosmetic product is permitted, provided that it remains safe for human health in accordance with article 3.

3.2.3.1 Restrictions on formaldehyde in EU regulations on food contact materials

Based on the feedback from the cosmetic industry regarding the use of food-safe plastics in packaging, we looked into the requirements in the Food Contact Plastics Regulation[6] on the presence of formaldehyde in plastics intended for food contact use.

According to annex 1 of the Food Contact Plastics Regulation, migration of up to 15 mg of formaldehyde per kilogramme of food is permitted. Additionally, in situations where formaldehyde migration is relevant, the following conditions are permitted for food contact plastics:

- Formaldehyde may be used as an additive or polymerisation aid, and it may be used as a monomer for the production of plastics, provided that the migration limit of 15 mg formaldehyde per kg of food is not exceeded.
- Hexamethylenetetramine (CAS no. 100-97-0) may be used as an additive or polymerisation aid, and it may be used as a monomer for the production of plastics, provided that the migration limit of 15 mg formaldehyde per kg of food is not exceeded. Hexamethylenetetramine is also known as methenamine[7]. Methanamine can react with water and acids to produce formaldehyde (Susak et al., 1996). According to the Granta Selector database[8], methenamine is not found as a monomer; consequently, its use in plastics and packaging is likely limited.
- 1,4-butanediolformal (CAS no. 505-65-7) is permitted as a monomer, provided that the migration limit of 15 mg formaldehyde per kg of food is not exceeded. However, this monomer is not among those typically used. According to ECHA[9], the substance is registered, but it is neither produced in nor imported to the EU. Therefore, if this monomer is used to produce plastic packaging materials at all, its use can be considered minimal.

In practice, this means that for plastics used for cosmetic products, a concentration of up to 15 ppm in the cosmetic product may result even from the use of plastics approved for contact with food. Theoretically, though, this is only the case if the same storage conditions (e.g., time and temperature) that apply to food contact materials are also used for cosmetic products. In terms of storage periods, there may be a significant difference between plastics used for food contact purposes and plastics used for cosmetic products. Long-term storage is a possibility for

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[6] Commission Regulation (EU) no. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (EU Regulation 10/2011).

[7] The substance may be used as a preservative in cosmetic products, but according to the Kemiluppen database, methenamine is not used in cosmetic products sold on the Danish market.

[8] Granta Selector is a materials database containing descriptions and uses of a wide variety of monomers and polymers. This data was retrieved from Granta Selector 2020.

[9] https://echa.europa.eu/da/substance-information/-/substanceinfo/100.007.287

cosmetic products. Cosmetic products may be manufactured well before they appear in stores, and they may have an indicated shelf life after opening of up to two years[10].

According to annex V of the Food Contact Plastics Regulation, migration analyses must be performed with relevant simulated foods, such as ethanol solutions to simulate hydrophilic foods (i.e., foods which attract moisture or dissolve in water), acetic acid to simulate acidic foods, and vegetable oil to simulate fatty foods.

Materials designed for contact with all types of foods must be tested with three of these simulated foods: simulations A (a 10% ethanol solution), B (3% acetic acid), and D2 (vegetable oil). The test conditions depend on the temperature and storage time of the food. The longest test duration specified in the regulation is >30 days. The regulation also specifies that for "long-term storage" at room temperature, a 10-day test at an elevated temperature of 60°C must be performed. This applies to storage for more than six months at room temperature, including filling at e.g. up to 100°C. For many uses of food contact materials, storage for up to six months (and thereby, testing for 10 days at 60°C) is not relevant, so many packaging materials approved for food contact uses will not be tested under these conditions.

One of the contacted manufacturers of cosmetic products indicated that it typically stress-tests its packaging for three to four months at 45°C. This may mean that in theory, plastics approved for food contact uses may be capable of releasing amounts that exceed the limit value of 15 ppm, since cosmetic products may be stored for as long as two years. This is longer than the maximum tested storage time for food contact materials, which is up to six months. Studying the significance of this difference more closely is relevant to this project (see the literature review in section 3.3.2 "Packaging materials that may release formaldehyde").

3.3 Literature review and investigation into possible origins of formaldehyde

We conducted a general literature review on this topic, searching for reports and articles on ingredients in cosmetic products and types of packaging material that may contain or release formaldehyde. The results of the review are described below.

The Danish Consumer Council searched the database used in their Kemiluppen app for each of the ingredients or groups of substances identified as possible sources of formaldehyde in cosmetic products. The purpose of this search was to develop an overview of the identified ingredients which occur most commonly in cosmetic products in Kemiluppen – and thereby in Denmark. This is discussed in greater detail in section 3.4 "Relevant ingredients in Kemiluppen".

3.3.1 Ingredients that may contain or release formaldehyde

We conducted a general search for ingredients used in cosmetic products that may contain or release formaldehyde. Some of the ingredients returned by this search are not currently permitted in cosmetic products (e.g., methylene glycol). These ingredients are not discussed in detail in this report.

The search returned the following ingredients of interest, each of which is discussed in greater detail below:

- Glycerol/glycerine (CAS 56-81-5) (Ooi et al., 2019; NASEM, 2018)
- Silicones (mentioned by industry contacts)
- Cellulose (CAS 9004-34-6) (mentioned by industry contacts)

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[10] Cosmetic products typically have a shelf life after opening of one year (12 months), but some products have been observed to indicate a shelf life after opening of up to 24 months.

- Sorbitan/polysorbate (CAS 9005-65-6) - ethoxylated surfactants used as emulsifiers in oil/water (Malinauskiene et al., 2015; Berg et al., 1998; Goon et al., 2003; Latorre et al., 2011)
- Polyethylene glycols (Carbowax, macrogol) (Goon et al., 2003; Malinauskiene et al., 2015)
- Timonacic (timanoic acid) (CAS 444-27-9 / 34592-47-7) (ACCC, 2010; OSHA, 2011)
- Cocamidopropyl betaine[11] (CAS 61789-40-0)
- DHA, dihydroxyacetone (CAS 96-26-4) (SCCS, 2020)
- Glyoxal[12] (Jairoun et al., 2020)

3.3.1.1 Glycerine

Information about the release of formaldehyde from glycerine in cosmetic products was not found, but it is known that formaldehyde is produced in e-cigarettes during the vaporisation process (Ooi et al., 2019; NASEM, 2018). This is partially because glycerine is one of the two solvents that are primary ingredients in the "e-liquids" used in e-cigarettes. The solvent in e-liquids is generally a mixture of glycerine and propylene glycol, but according to Ooi et al. (2019), glycerine is the main factor in the production of formaldehyde. This is in line with the fact that when heated, glycerine may give off water and ultimately dissociated into acrolein, formaldehyde, and acetaldehyde (Jensen, 2016), all of which have been detected in e-liquid vapour (Ooi et al., 2019; NASEM, 2018).

According to Moldoveanu and Chou (2018), high temperatures are required for glycerine to decompose into formaldehyde, possibly in excess of 350°C. However, they measured high concentrations of formaldehyde (above 0.5%) primarily at high temperatures, so it is not clear whether lesser amounts of formaldehyde are released at lower temperatures. Geiss et al. (2016) showed that the production of formaldehyde in e-cigarettes clearly increases with temperature, and that formaldehyde production begins at about 100°C. Taken together with information from industry contacts, who indicated that cosmetic products are produced at temperatures no greater than 85°C, this may indicate that glycerine is not necessarily a source of formaldehyde released into cosmetic products, although the literature is not conclusive on this matter.

According to the data extracted by the Danish Consumer Council from its Kemiluppen database, glycerine is broadly used in cosmetic products. Glycerine is present in more than half of the cosmetic products in the Kemiluppen app's database (7822 out of about 13,000 current cosmetic products in the database).

3.3.1.2 Silicones

According to the industry, silicones can release formaldehyde when heated. However, no literature was found to support this information in the context of cosmetic products. An American safety data sheet for silicone oil indicates that formaldehyde is produced when silicone decomposes at high temperatures[13]. In a discussion forum[14] on the internet, it was mentioned that silicone products (kitchen equipment) may release formaldehyde when heated, though it was also indicated that formaldehyde is only measurable in ppm levels at temperatures of 200/250°C and above. This is supported by a referenced source (GE Silicones, 1999) and by newer sources, such as Soroory et al. (2013), who indicated that formaldehyde release is caused by oxidation at high temperatures. Thus, this information is assumed to be irrelevant

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[11] https://chemistryconnection.com/sds/data/pdf/Coco_Betaine_SDS.pdf

[12] According to the Regulation on Cosmetic Products, glyoxal may be used at a maximum concentration of 100 mg/lkg (annex III, index number 194)

[13] https://datasheets.scbt.com/sc-215854.pdf

[14] https://www.debralynndadd.com/q-a/formaldehyde-emissions-silicone-materials/

for cosmetic products, which are produced at temperatures no greater than 85°C according to industry contacts.

3.3.1.3 Cellulose

According to one of the contacted institutions/businesses, cellulose may be a source of formaldehyde, given that cellulose is plant-based and it is known that formaldehyde occurs naturally in such materials as wood. However, no literature was found to support this claim.

According to the data which the Danish Consumer Council extracted from its Kemiluppen database, cellulose is not used particularly frequently in cosmetic products; of the roughly 13,000 cosmetic products in Kemiluppen, only 86 contain cellulose.

3.3.1.4 Sorbitan and polysorbates

Sorbitan and polysorbates are ethoxylated surfactants used as emulsifiers in oil- and water-based products. These compounds are often long, organic chains with one lipophilic end and one (ethoxylated) hydrophilic end. These can produce formaldehyde through autoxidation when in (long-term) storage (Goon et al., 2003) and at concentrations above 500 ppm (Malinauskiene et al., 2015; Bergh et al., 1998). Sorbitan and polysorbate compounds are examples of ethoxylated surfactants.

In an article, Bergh et al. (1998) describe experiments performed with an ingredient called Tween® 80, which is used in cosmetic products and detergents, among other product types. Tween® 80 is an ethoxylated nonionic surfactant. They observed that the surfactant formed formaldehyde and peroxides when exposed to air, and that the concentration of these substances increased with the length of exposure to air. For eight months, they exposed the surfactant to plain air while stirring it for an hour per day and stored it at or below 22°C. At the conclusion of this process, the concentration of formaldehyde had reached 2950 ppm. Immediately after opening its container, the concentration of formaldehyde in the substance was as low as 0.4 ppm. The substance's vendor assured the authors that no formaldehyde had been added to it as a preservative. This suggests that ordinary oxidation of Tween® 80 with oxygen in the air can lead to a chemical reaction in which formaldehyde is formed.
Tween® 80 is a sorbitan compound with CAS number 9005-65-6. It appears in the CosIng database under a variety of INCI names, including:

- PEG-12 sorbitan trioleate
- PEG-20 sorbitan oleate
- PEG-3 sorbitan oleate
- PEG-40 sorbitan oleate
- PEG-6 sorbitan oleate
- Polysorbate 80
- Polysorbate 81

Latorre et al. (2011) also indicated that formaldehyde can form during oxidation of polysorbate 80.

Consequently, the Danish Consumer Council was asked to investigate the occurrence of these ingredients in cosmetic products on the Danish market. The results showed that only polysorbate 80 is used (found in 266 current products out of roughly 13,000 cosmetic products in Kemiluppen).

3.3.1.5 PEG (polyethylene glycols)

PEG compounds are long, organic compounds; unlike the sorbitan and polysorbate compounds described above, these are exclusively hydrophilic. Formaldehyde has been detected in polyethylene glycols (Carbowax and macrogol) and derivatives of them that can be used in many kinds of cosmetic product (Goon et al., 2003; Malinauskiene et al., 2015). According to

Goon et al. (2003) and Hemenway et al. (2012), this is because autoxidation of PEG compounds produces formaldehyde.

Hemenway et al. (2012) studied its release from a particular compound, PEG-400 (CAS 25322-68-3) under various conditions. According to the CosIng database, PEG-400 can be used as a binder, solvent, or emulsion stabiliser in cosmetic products. Hemenway et al. (2012) showed that formaldehyde forms in pure PEG-400 held at 40°C, and that the highest concentration (approximately 100 ppm) occurs after about 14–21 days, after which the concentration appears to fall again (after 90 days). The 100 ppm concentration of formaldehyde was measured in pure PEG-400; cosmetic products do not contain large volumes of PEG-400.

Other notable results were as follows:
- The presence of water appears to promote the formation of formaldehyde. However, a portion of the formaldehyde produced reacts to form formic acid in the presence of water.
- The use of antioxidants, such as BHA, BHT, and vitamin E, inhibits the production of formaldehyde. This is in line with the fact that formaldehyde is produced through oxidation. However, acidic antioxidants, such as citric acid, had no inhibitory effect on the production of formaldehyde, according to Hemenway's experiment (with pH values between 4 and 6).
- A very low pH of about 2 did inhibit the production of formaldehyde (experiments typically carried out at pH values between 4 and 6).
- A temperature of 50°C did not result in a greater formaldehyde concentration than the concentration obtained at 40°C.

Both Hemenway et al. (2012) and Robnik et al. (2020) showed that the presence of iron oxide (an orange colourant, CI 77489) may lead to greater concentrations of formaldehyde, but also an increased conversion of formaldehyde into formic acid.

CAS number 25322-68-3 covers a wide variety of PEG compounds which have various INCI names, according to the CosIng database. PEG-400 was included in the list of ingredients for which the Danish Consumer Council extracted product data from its database. According to the results, this compound is used in just nine current cosmetic products on the Danish market. That said, a broad assortment of PEG compounds is used in cosmetic products. The Danish Consumer Council also extracted data for ingredients whose INCI names contain "PEG". The results showed that approximately one-third of the cosmetic products registered in the database contained some kind of PEG compound.

3.3.1.6 Timonacic

According to the CosIng database, timonacic is used for its "skin conditioning" properties. According to the ACCC (2010) and OSHA (2011), this substance could potentially release formaldehyde. Experiments conducted by the ACCC showed that as an ingredient, timonacic can be transmuted into a formaldehyde concentration of 0.81% (8100 ppm) after 6.5 hours. The initial concentration of timonacic was not specified. The OSHA (2011) indicates that timonacic is used in hair straightening products in the United States.

According to the data which the Danish Consumer Council retrieved from its Kemiluppen database, this ingredient is used in just one of the more than 13,000 current cosmetic products in the database. Thus, timonacic is not very broadly used in cosmetic products on the Danish market today.

3.3.1.7 Cocamidopropyl betaine

Another ingredient which industry contacts mentioned is cocamidopropyl betaine (CAS no. 61789-40-0). Formaldehyde has been found to occur in this ingredient. An American safety data sheet for the substance from 2019 directly states that formaldehyde may occur in the substance as an impurity, at concentrations ≤2% (20,000 ppm)[15]. Naturally, the concentration of cocamidopropyl betaine (and thereby, formaldehyde) in finished cosmetic products is low.

According to the Danish Consumer Council, cocamidopropyl betaine is used in 1782 of the roughly 13,000 current cosmetic products listed in Kemiluppen. Cocamidopropyl betaine is thus broadly used in cosmetic products on the Danish market.

3.3.1.8 DHA

Danish industry organisations have reported that DHA (dihydroxyacetone; CAS nr. 96-26-4) is known to release formaldehyde. According to an opinion on DHA published by the SCCS (SCCS/1612/19, 2020), this is due to the fact that formaldehyde is present in it as an impurity at concentrations ≤50 ppm. The SCCS also stated that even when stored at a temperature of 5°C, the concentration of formaldehyde in DHA continues to increase. However, even after 18 months of storage, the concentration does not exceed 50 ppm. The concentrations measured in their experiments ranged between 15 and 32 ppm. Whether storage at higher temperatures could increase the concentration of formaldehyde is unknown.

According to the cosmetics industry, DHA is primarily used in self-tanners; the data extracted by the Danish Consumer Council confirms this. The data extracted from Kemiluppen shows that DHA is used in 142 products out of the roughly 13,000 current cosmetic products in Kemiluppen, and 136 of them are self-tanners.

In July 2021, a restriction on DHA in cosmetic products came into force. DHA (dihydroxyacetone) is listed under reference number 321 in Annex III of the Cosmetics Regulation. Annex III of the Cosmetics Regulation is a list of substances which cosmetic products must not contain except subject to the restrictions laid down. Before the new restriction on DHA came into force, the substance was allowed to be used freely in cosmetic products. The restriction is that DHA may only be used as a hair dye in non-oxidative hair dye products at a concentration not exceeding 6.25% and in self-tanners at a concentration not exceeding 10%. The background for the restriction of DHA in cosmetic products is two opinions from the SCCS from 2010 and 2020 (SCCS/1347/10, 2010; SCCS/1612/19, 2020).

3.3.1.9 Glyoxal

Jairoun et al. (2020) named glyoxal as one of a number of formaldehyde releasers. However, De Groot et al. (2009) did not name glyoxal as a formaldehyde releaser (see chapter 2 "Formaldehyde releasers"). In the CosIng database, glyoxal is listed not as a preservative, but as an ingredient with antimicrobial properties. Per the Regulation on Cosmetic Products, glyoxal may be used in cosmetic products at a maximum concentration of 100 mg/kg (ppm).

According to the Danish Consumer Council and its Kemiluppen database, glyoxal is used in only nine products out of the roughly 13,000 current cosmetic products registered in the database. Thus, the use of glyoxal in the cosmetic products registered in Kemiluppen appears to be quite limited.

3.3.2 Packaging materials that may release formaldehyde

A literature review was conducted to identify packaging materials that may release formaldehyde. The review returned the following packaging materials, described in greater detail below:

- PET (polyethylene terephthalate)[16] (Bach et al., 2012; Bach et al., 2014)

[15] https://chemistryconnection.com/sds/data/pdf/Coco_Betaine_SDS.pdf

[16] https://theconversation.com/scientists-warn-of-chemical-dangers-in-food-packaging-but-not-without-their-critics-23446

- Melamine plastics[17] (Ebner et al., 2020; European Commission recommendation no. 794, 2019; Latorre et al., 2011)
- Urea-formaldehyde plastics (Songprasirt et al., 2015; Latorre et al., 2011))
- Carbamide-formaldehyde plastics (Goon et al., 2003; Latorre et al., 2011)

COWI (2013) indicated that monomers - small, gaseous molecules like formaldehyde - in plastics have a high tendency to migrate from plastics, migrating rapidly at even ordinary temperatures (e.g., at room temperature). PET and melamine plastics are two of the 15 types of plastic used most throughout Europe. Neither urea-formaldehyde plastic or carbamide-formaldehyde plastic are among the 15 most commonly used types of plastic in Europe according to COWI (2013). Consequently, we do not expect them to be used particularly frequently to package cosmetic products.

3.3.2.1 PET

Bach et al. (2012 and 2014) indicated that formaldehyde can migrate from PET, and they studied the migration of formaldehyde from PET water bottles into water. Formaldehyde is produced when the polymer decomposes, and the quantity of formaldehyde depends on the molecular weight of the polymer and on the temperature at which the plastics are blow moulded (Bach et al., 2012). The production of formaldehyde in PET can be minimised through the use of stabilisers (Bach et al., 2012).

Bach et al. (2012) referenced older studies which measured levels of formaldehyde as high as 3.0 µg per g of PET, and levels of formaldehyde migrated from PET bottles ranging between 1 and 60 µg per litre of water. Levels of formaldehyde in drinking water stored in PET water bottles increase if the bottles are exposed to sunlight and high temperatures. Bach et al. (2014) measured levels of formaldehyde migrated from PET bottles into drinking water as high as 11 µg per litre of water after 10 days of storage. The concentration of formaldehyde increases with storage time (only measured up to 10 days) and with exposure to sunlight. However, the maximum measured concentration of 11 µg/litre of water, corresponding to 0.011 mg/kg (ppm) of product, is far below the permitted formaldehyde migration level of 15 mg/kg, according to the EU's Food Contact Plastics Regulation (EU Regulation no. 10, 2011).

Industry contacts confirmed that PET is a type of plastic used to package cosmetic products, though PE (polyethylene) and PP (polypropylene) packaging are more commonly used. It was observed in the survey that PET containers are used to package e.g. skin toner and face creams with dispensing pumps. These containers are often transparent.

3.3.2.2 Melamine plastics

The materials used to make melamine plastics include melamine and formaldehyde (Ebner et al., 2020). Consequently, there may be traces of formaldehyde present in the plastics that can migrate into their surroundings. Ebner et al. (2020) measured formaldehyde migration of up to 28 mg/dm^2 from melamine plastic spoons held at 100°C for two hours. They showed that the release of formaldehyde depends on the pH value: Compared to the quantity of formaldehyde released into a 3% acetic acid solution (food simulation B) with a pH value of 2.7, the quantity released into water, which has a neutral pH, was significantly smaller (about one-fifth). Their results also indicate that the longer melamine plastic is held in a liquid, the greater the migration of formaldehyde into the liquid will be. Additionally, they showed that the quality of the plastic is also connected to the release of formaldehyde, since such factors as the hardening process can affect the amount of free formaldehyde present in the plastic.

[17] https://theconversation.com/scientists-warn-of-chemical-dangers-in-food-packaging-but-not-without-their-critics-23446

Goon et al. (2003) stated that water-based creams can absorb formaldehyde if stored in e.g. tubes coated with a melamine-formaldehyde coating. Along the same line, Latorre et al. (2011) noted that melamine is used to coat plastic tubes in which cosmetic products are stored.

The European Commission recommends in particular that melamine plastic kitchen equipment from China be tested carefully for formaldehyde migration, since numerous regulatory violations have been observed in this regard (European Commission recommendation no. 794, 2019). However, melamine plastics do not seem to be in especially common use for cosmetic products. According to COWI (2013), cosmetic product packaging is not among the most important uses of melamine plastics; instead, those uses are laminated surfaces such products as furniture and kitchen equipment. According to Granta Selector[18], melamine is not especially commonly used for packaging. This can be confirmed by the industry in Denmark which has not stated any use of melamine plastics for packaging of cosmetic. A couple of European producers of product packaging material for cosmetic products were contacted. These packaging producers also confirm that melamine plastics are not used for packaging of cosmetic products, and that no melamine-based coating is used in tubes for cosmetic products.

3.3.2.3 Urea-formaldehyde plastics

In terms of appearance, urea-formaldehyde plastics are similar to melamine plastics, and are produced using two monomers: urea and formaldehyde (Songprasirt et al., 2015). As a result, traces of formaldehyde may remain in the plastic and migrate into the mixture stored in the plastic. Songprasirt et al. (2015) analysed the migration of formaldehyde from urea-formaldehyde plastics used as packaging for instant noodles in Thailand. They measured formaldehyde migration ranging from 0.2 to 5.0 mg per package. The packaging weighed 60 g, resulting in a maximum migration of 83 mg/kg (or 83 ppm). They indicated that high temperatures (initially 80°C) and low pH (about 4.4) were significant factors that resulted in increased formaldehyde migration. At a more neutral pH of about 6, formaldehyde migration was lower. Migration was highest during the first use of the packaging. Formaldehyde migration increased with longer storage times. Migration after 23 minutes was not measured, as storage times longer than this are not relevant for heated instant noodles.

However, urea-formaldehyde plastics do not seem to be in especially common use for cosmetic products. According to Packaging 360[19], an Indian website that serves as a knowledge exchange platform for the Indian packaging industry, urea-formaldehyde plastics are used for cosmetic products, but only to a limited extent, since these plastics are expensive to produce. Within the industry, urea-formaldehyde plastics are primarily used for the lids of nail polish bottles, since the solvents present in the products dissolve other kinds of plastics. According to the Granta Selector material database, urea-formaldehyde plastics are not used to package cosmetic products. This is confirmed by the industry in Denmark which has not stated any use of this type of plastic for packaging of cosmetic products. A couple of European producers of product packaging material for cosmetic products were contacted. These packaging producers also confirm that this type of plastic is not used for packaging of cosmetic products.

3.3.2.4 Carbamide-formaldehyde plastics

Goon et al. (2003) stated that water-based creams can absorb formaldehyde if stored in e.g. tubes coated with a carbamide-formaldehyde coating. Along the same line, Latorre et al. (2011) noted that carbamide-formaldehyde is used to coat plastic tubes in which cosmetic products are stored.

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[18] Granta Selector is a materials database containing descriptions and uses of a wide variety of monomers and polymers. This data was retrieved from Granta Selector 2020.

[19] https://packaging360.in/insights/packaging-of-cosmetic-products/#

Chemically, carbamide is highly similar to urea. Carbamide-formaldehyde plastics are not listed in the Granta Selector material database, so their use is assumed to be limited. This is confirmed by the industry in Denmark which has not stated any use of this type of plastic for packaging of cosmetic products. A couple of European producers of product packaging material for cosmetic products were contacted. These packaging producers also confirm that this type of plastic is not used for packaging of cosmetic products, and that no carbamide-formaldehyde based coating is used in tubes for cosmetic products.

3.3.3 Physical/chemical factors relevant to the release of formaldehyde

Several physical and chemical factors which are significant for the release of formaldehyde from either ingredients or packaging are listed here:

- Heat
- Storage time
- Oxidation
- pH value

Numerous sources indicate that the release of formaldehyde into cosmetic products increases with both temperature and storage time (Latorre et al., 2011; Hauksson et al., 2015a; Kajimura et al., 2008). This also applies to packaging (Bach et al., 2012; Ebner et al., 2020; Songprasirt et al., 2015). Kajimura et al. (2008) further noted that there is a clear seasonal difference in the release of formaldehyde into cosmetic products that contain formaldehyde releasers. The release of formaldehyde was clearly lower in the winter. Kajimura et al. (2008) suppose that this difference is a product of seasonal changes in the ambient (outdoor) air temperature in Japan.

It is indicated that some ingredients (such as silicones and glycerine) most likely release significant quantities of formaldehyde primarily when held at temperatures of 200–250°C and above. Given that, according to the industry, cosmetic products are manufactured at temperatures no greater than 85°C, it is likely that these ingredients release only minimal quantities of formaldehyde into cosmetic products. Even so, there is evidence to suggest that glycerine may release small amounts of formaldehyde at low temperatures. Whether the quantities released are measurable is a relevant line of inquiry, since glycerine is used in many cosmetic products.

For some ingredients, such as PEG compounds, oxidation (i.e., reaction in the presence of oxygen) is the cause of formaldehyde production (Goon et al., 2003; Bergh et al., 1998; Hemenway et al., 2012; Latorre et al., 2011). The use of certain antioxidants also appears to inhibit the production of formaldehyde (Hemenway et al., 2012).

Numerous sources indicate that most formaldehyde releasers release greater quantities of formaldehyde in alkaline environments (Latorre et al., 2011; Kajimura et al., 2008). Conversely, it appears that ingredients like PEG release formaldehyde in acidic environments (pH between 4 and 6) (Hemenway et al., 2012). For packaging materials (melamine and urea-formaldehyde), formaldehyde release is greater at acidic pH values (2.7 to 4.4) than at a neutral pH (Ebner et al., 2020; Songprasirt et al., 2015).

Additionally, there may be other ingredients that inhibit the production of formaldehyde. For example, Doi et al. (2010) stated that various amines, amides, and hydrolysed proteins inhibit the production of formaldehyde in formaldehyde releasers. Doi et al. (2010) found a lower concentration of formaldehyde in cosmetic products containing these substances compared to cosmetic products that do not contain them; all the products contained formaldehyde releasers. The difference was statistically significant. Similarly, experiments conducted by De Groot et al. (2010) showed that the formaldehyde released into protein-enriched shampoos containing formaldehyde releasers was about one-fourth of the amount released into protein-free shampoos containing equivalent amounts of formaldehyde releasers.

3.3.4 Summary

Taken together, the information from our industry contacts, the literature review, and the Danish Consumer Council's database of cosmetic products on the Danish market (used in its Kemiluppen app) show that the following ingredients may be of interest for further investigation in terms of their formaldehyde content and release:

- Glycerine: Formaldehyde is likely produced only when glycerine is heated to high temperatures, though according to the Danish Consumer Council's database, glycerine is present in more than half of the cosmetic products in its Kemiluppen database.
- Polysorbate 80: Appears to release formaldehyde during oxidation.
- PEG compounds (polyethylene glycols): Appear to release formaldehyde during oxidation.
- Cocamidopropyl betaine: Contains formaldehyde impurities as a raw material.
- DHA (dihydroxyacetone): Contains formaldehyde impurities as a raw material.

As far as packaging materials are concerned, PET packaging is of interest for further investigation into the possibility of formaldehyde migrating into cosmetic products. Of the types listed, PET is the only type of packaging that can release formaldehyde, and which is broadly used to package cosmetic products. The other listed types of packaging materials do not seem to be used for cosmetic products, neither in Denmark, nor the EU. There is no knowledge regarding packaging material for cosmetic products produced outside the EU, e.g., in China.

According to the literature, temperature, pH, and storage time are all parameters that affect the formation of formaldehyde. Simultaneously, there are ingredients that can inhibit the formation of formaldehyde, such as antioxidants.

3.4 Relevant ingredients in Kemiluppen

Using the list of relevant ingredients generated during the survey, the Danish Consumer Council extracted data from the database used in its Kemiluppen app to determine which ingredients are used in cosmetic products and how many products each is used in. As described previously, searches for individual ingredients were conducted, as well as certain other database searches:

- Searches for ingredients where the literature shows that formaldehyde may be released under certain conditions (briefly described in section 3.3.1 above the individual substances).
- A general search for ingredients whose name contains "formaldehyde".
- Searches for ingredients returned by a search for "formaldehyde" in the CosIng database. This search also returned ingredients which are e.g. based on formaldehyde or produced using formaldehyde. Formaldehyde impurities could therefore be present in these ingredients.

The results of these searches are presented below in TABLE 4.

TABLE 4. Data for specific ingredients extracted from Kemiluppen. Ingredients shown in boldface with a green background are those of greatest interest, given their apparent widespread use in cosmetic products in Denmark. Ingredients marked in bold and green background are chosen as focus areas for the purchased products.

CAS no.	INCI name	All registered products / current products*
Ingredients whose names contain "formaldehyde"		
-	ACETYLENEDIUREA/FORMALDEHYDE/TOSYLAMIDE CROSSPOLYMER	No products
-	BENZOGUANAMINE/FORMALDEHYDE/MELAMINE CROSSPOLYMER	1/0

CAS no.	INCI name	All registered products / current products*
94333-73-0	EUGENIA CARYOPHYLLUS EXTRACT/ FORMALDEHYDE	No products
58567-11-6	FORMALDEHYDE CYCLODECYL ETHYL ACETAL	no products
42604-12-6	FORMALDEHYDE CYCLODECYL METHYL ACETAL	No products
39277-28-6	FORMALDEHYDE/MELAMINE/TOSYLAMIDE COPOLYMER	12/7
65997-07-1	ROSIN/FORMALDEHYDE COPOLYMER	No products
25035-71-6	TOSYLAMIDE/FORMALDEHYDE RESIN	8/3
24887-06-7	ZINC FORMALDEHYDE SULFOXYLATE	No products
Ingredients whose description in the CosIng database mentions formaldehyde (e.g., produced using formaldehyde)		
9003-08-1	OXYMETHYLENE/MELAMINE COPOLYMER	No products
25398-55-4	ACETOPHENONE/OXYMETHYLENE COPOLYMER	No products
68002-19-7	BUTYLATED POLYOXYMETHYLENE UREA	No products
68441-83-8	HYDROGENATED ACETOPHENONE/OXYMETHYLENE CO-POLYMER	13/13
142702-41-8	CALCIUM POLYOXYMETHYLENE PYRROLIDONE	No products
68002-20-0	METHOXYPOLYOXYMETHYLENE MELAMINE	3/3
27968-41-8	POLYOXYMETHYLENE CYANOGUANIDINE UREA	No products
64334-59-4	POLYOXYMETHYLENE GLYCOL UREA	No products
25036-13-9	POLYOXYMETHYLENE MELAMINE UREA"	No products
68611-64-3 / 9011-05-6	POLYOXYMETHYLENE UREA"	No products
-	ALCOHOL DENAT. SD ALCOHOL 38-C	No products
-	ALCOHOL DENAT. SD ALCOHOL 38-D	No products
80262-44-8 259886-49-2 259886-50-5 259886-51-6	CURCUBITURILS	No products
9065-13-8 / 26811-08-5	DMHF	1/0
129870-75-3	HYDROGENATED ACETOPHENONE/OXYMETHYLENE/IPDI COPOLYMER"	No products
24969-11-7	POLYOXYMETHYLENE RESORCINOL"	No products
502761-95-7	POLYURETHANE-72	No products
-	SD ALCOHOL 38-C	No products
-	SD ALCOHOL 38-D	No products
149-44-0	SODIUM OXYMETHYLENE SULFOXYLATE"	2/2
9084-06-4	SODIUM POLYNAPHTHALENESULFONATE	77/37
Ingredients based on literature review and industry-supplied information		
56-81-5	**GLYCERINE**	**?/7822****
9004-34-6	CELLULOSE	123/86
444-27-9 / 34592-47-7	TIMONACIC (timanoic acid)	1/1
9005-65-6	PEG-12 SORBITAN TRIOLEATE	No products
9005-65-6	PEG-20 SORBITAN OLEATE	No products
9005-65-6	PEG-3 SORBITAN OLEATE	No products

CAS no.	INCI name	All registered products / current products*
9005-65-6	PEG-40 SORBITAN OLEATE	No products
9005-65-6	PEG-6 SORBITAN OLEATE	No products
9005-65-6	**POLYSORBATE 80**	**392/266**
9005-65-6	POLYSORBATE 81	No products
107-22-2	GLYOXAL	29/9
25322-68-3	PEG-20	21/20
25322-68-3	PEG-150	16/13
25322-68-3	PEG-32	102/64
25322-68-3	PEG-4	54/38
25322-68-3	PEG-75	26/19
25322-68-3	PEG-400	29/9
9004-99-3	PEG-40 STEARATE	78/63
61789-40-0	**COCAMIDOPROPYL BETAINE**	**2820/1782**
96-26-4	**DIHYDROXYACETONE**	**212/142**
-	**PEG substances**	**?/4315****

- Indicates no CAS number exists.
* The number before the slash is out of all of the roughly 20,000 registered products in the Kemiluppen database. The number after the slash is current products only, out of the roughly 13,000 current products in the database. In other words, registered products – discontinued products = current products.
** The database queries for glycerine and PEG compounds took a considerable amount of time to execute and returned very large volumes of data. As a result, only a selection of current products is presented here.

Searching the Kemiluppen database offers insight into how broadly the listed ingredients appear to be used in cosmetic products in Denmark. Based on the extracted data, the ingredients listed below were selected as relevant for further investigation because they appear to be the most broadly used ingredients which either contain or may release formaldehyde:

- Glycerine
- Polysorbate 80
- Cocamidopropyl betaine
- DHA, dihydroxyacetone
- PEG compounds (polyethylene glycols)

Subsequently, the Danish Consumer Council's database was queried for the types of cosmetic products which these ingredients occur in, out of all products in the database. The types of products in which these ingredients are most commonly used are presented below in TABLE 5. Given the project's scope, only leave-on products are listed in the table with the exception of make-up removers (which may be a leave-on[20] or rinse-off[21] product), as these also contain the substances listed above.

[20] A leave-on product is defined in the preamble to annexes II-VI of the Regulation on Cosmetic Products as "a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes".

[21] A rinse-off product is defined in the preamble to annexes II-VI of the Regulation on Cosmetic Products as "a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes".

TABLE 5. The most common types of products in which the five ingredients of interest are present. The number of products of each type listed is indicated in the cells. The sum of all cosmetic products containing each listed ingredient is given at the bottom of the table, both as the sum of the 11 product types listed and out of all products in the database. Only the most common product types are listed.

Product type	Glycerine	PEG	Cocamidopropyl betaine	Polysorbate 80	DHA
Face cream	736	355	1	43	0
Body lotion	658	251	3	27	2
Make-up remover	344	208	112	6	0
Hand cream	384	91	2	7	0
Sunscreen	252	91	0	3	0
Self-tanner	105	61	28	0	136
Foundation	127	161	0	0	0
Roll-on deodorant	203	57	1	0	0
Skin toner	154	85	1	4	0
Facial serum	143	53	0	6	0
Eye cream	109	47	0	12	0
Sum	3215	1460	148	108	138
All products	7882	4315	1782	267	142

Based on the use of the five ingredients of interest in various product types and on the fact that PET is often used to produce transparent packaging (e.g., for skin toners and face creams with dispensing pumps), we made a joint decision with the Danish Danish EPA to focus on the following product types when choosing products for chemical analyses:

- Face cream: This type of product is included because it is over-represented in the EPA's reports of undesirable effects (often allergic reactions). Additionally, three of the five ingredients of interest occur in many products of this kind.
- Eye cream: This type of product is included because it is over-represented in the EPA's reports of undesirable effects (often allergic reactions). Additionally, three of the five ingredients of interest occur in many products of this kind.
- Skin toner: This type of product is included primarily because it is often sold in PET packaging. Many skin toners also contain glycerine, PEG compounds, or both.
- Self-tanner: This type of product is included because DHA mostly occurs as an ingredient in these products. Additionally, a large proportion of the body's surface area is exposed to this type of product when used.
- Body lotion: This type of product is included because a large proportion of the body's surface area is exposed to these products when used. Additionally, three of the five ingredients of interest occur in this type of product.
- Hand cream: This type of product is included because three of the five ingredients of interest occur in these products. Hand cream is also a product which can be used multiple times per day.
- Make-up remover: This type of product is included because cocamidopropyl betaine mostly occurs as an ingredient in these products. Make-up removers can be rinse-off or leave-on products, depending on each product's usage instructions.

3.5 Survey and purchasing of products on the market

During the survey, we searched for the seven selected types of cosmetic products available for purchase online in Denmark (DK), within the EU but excluding Denmark (EU), and outside the EU (non-EU) in order to select products for our chemical analyses. For non-EU products, we focused on such websites as Amazon and Wish, since delivery of non-EU products to Denmark is primarily offered by these kinds of sites. Given that this project focuses on formaldehyde in products without a declared formaldehyde releaser, it was important to discern whether products contained a formaldehyde releaser before purchasing them. Consequently, we only purchased cosmetic products whose ingredients were listed on the sites selling them, whether in the form of text on a product page or an image of the product. The Regulation on Cosmetic Products does not require websites to supply a textual list of ingredients in cosmetic products available for purchase online, but the ingredients must be listed on products' packaging.

On Amazon, it was possible to find list of ingredients for most relevant products, but shipping costs were often high, such as when purchasing products from the United States. In contrast, while products and shipping were typically less expensive from Wish[22], it was much harder to find list of ingredients for the products on the site. The site lacks information about the ingredients in a majority of its products.

Products from the EU (not including Denmark) were found on a variety of online shops. For this category, we were generally able to find products whose ingredients were listed in the text on the web site. For products from Denmark, whether the ingredients in a given product were listed on the site or not was unpredictable. Smaller online shops sometimes listed the ingredients in products on their respective web pages.

The goal was to purchase a total of 150 cosmetic products, some of which would have a formaldehyde releaser listed among their ingredients for the purpose of comparing levels of formaldehyde in products with and without formaldehyde releasers. We first prepared a list of approximately 250 unique cosmetic products, including all seven of the selected product types from the non-EU, EU, and DK categories. Based on this preliminary list, we then selected a total of 156 products to purchase for chemical analyses. We deliberately purchased a slightly higher number of non-EU products to mitigate the possibility of some products not arriving before the start-up of the chemical analyses.

The products chosen to be purchased for chemical analysis were selected according to the following criteria (in order of priority):

1. Products were primarily purchased from websites which presented their ingredients either textually or in product photos. This was because knowledge of whether each product contains a formaldehyde releaser or not is important to the project's results. We did, however, deem it acceptable to purchase products with a photo indicating the presence of a list of ingredients printed on the product, even if the list was not legible in the photo. Upon arrival, we could consult the list of ingredients on the products to determine whether they contained formaldehyde releasers. In some cases, we selected products based solely on the list of ingredients retrieved for them from the Kemiluppen database, assuming that the actual ingredients would be the same as those which the Danish Consumer Council had recorded in Kemiluppen.
2. The chosen target distribution for the products was 25% non-EU, 25% EU, and 50% DK, prioritising products from Denmark in light of the information drawn from the Kemiluppen database about products on the Danish market.

[22] However, the price of shipping from non-EU countries, such as China, has changed as of 1 July 2021. We managed to order products for this project before the increase in shipping rates.

3. The purchased products were distributed roughly evenly across product types. Product types were divided into non-EU, EU, and DK categories according to the target distribution above. We purchased approximately 21 products of each type.
4. Fourteen products declared the presence of a formaldehyde releaser. Purchasing these products makes it possible to compare the levels of free formaldehyde in products with and without declared formaldehyde releasers. To the extent that this was possible, products with declared formaldehyde releasers were distributed across product types and according to the target distribution of non-EU, EU, and DK products. While these products contain various formaldehyde releasers, it was easiest to find products containing the most common formaldehyde releasers, meaning that there are more products containing the most commonly used formaldehyde releasers.
5. The remaining 136 cosmetic products with no declared formaldehyde releasers include non-EU, EU, and DK examples of each product type that contain one or more of the five substances of interest which may contain or release formaldehyde. As glycerine is very broadly used, glycerine occurs more frequently than the other substances of interest in the purchased products.
6. For each product type, we selected some cosmetic products that appeared to come in PET packaging, where possible. However, we were unable to find packaging information in advance; we purchased these products based on assumptions that their packaging was made of PET. However, we primarily chose products which both appeared to come in PET packaging and contained one or more of the five substances of interest. Only one product was selected exclusively because we suspected its packaging was made of PET.
7. When selecting non-EU products, we primarily purchased cosmetic products that were either cheaper than products available in Denmark (including shipping) or from brands not readily available in Denmark. The purpose of this was to simulate realistic consumer behaviours. Consumers will likely be motivated to shop online outside of the EU only if the products they desire are cheaper from these shops or unavailable in Denmark.

4. Products purchased for chemical analysis

Based on the survey and the resulting list of roughly 250 unique cosmetic products, we selected and purchased a total of 156 cosmetic products for chemical analyses. Six products did not arrive before the beginning of the chemical analyses. Three of these were from the EU, and three were from outside the EU.

Generally, for products with a volume of at least 50 mL, we purchased two units of each product. Additional units were purchased for products with lesser volumes. The purpose of this was to ensure that a sufficient volume of each product would be available for chemical analysis. We expected to receive products with identical batch numbers, as we requested this during the purchasing process where possible. The batch numbers were identical for 128 (85%) of the products received. Of the remaining products, 15 had a different batch number on each unit, and seven products (six of which came from outside of the EU) had either no batch numbers or illegible batch numbers.

In two cases, one of the two units of a purchased product was not sealed, causing some of its contents to leak out while in transit. We analysed the sole intact unit of each of these products.

All products were purchased with the intention that they would be leave-on products. This also applies to the product type make-up removers for which products were purchased, which indicated at the time of purchase that they did not need to be rinsed off. However, on receipt of the products, it appeared that some of the make-up removers were labelled to be rinsed off. These products were included in the study anyway.

An overview of the 150 purchased products which arrived in time for the chemical analyses is presented below in TABLE 6. The table indicates the distribution of the products according to:
- Vendor location (DK, EU, and non-EU)
- Product type (out of the seven selected types)
- Presence of a formaldehyde releaser based on the listed ingredients
- Presence of substances of interest based on the listed ingredients (i.e., the five selected ingredients which may contain or release formaldehyde)
- Packaging type (whether the packaging is made of PET)

As shown in TABLE 6, we achieved a distribution very close to the target distribution of 50% DK, 25% EU, and 25% non-EU products. (The actual distribution of the purchased products was 50%, 23%, and 27%, respectively.) Three products purchased from the same vendor within the EU did not arrive within the timeframe of the project. Among these three EU products were two make-up removers; this resulted in a slightly uneven distribution across the seven product types and across products purchased from each of the three regions (DK, EU, and non-EU).

For comparative purposes, we deliberately purchased 14 products with a declared formaldehyde releaser listed in the ingredients. A plurality of these products (six) came from non-EU vendors. In the survey, we observed that formaldehyde releasers appear to be in greater use outside the EU than in Denmark and the EU (not including Denmark). This observation is based on the fact that it was easier to identify products containing formaldehyde releasers outside the EU than within the EU. Three products with a formaldehyde releaser among the listed ingredients came from the EU. Five products with a formaldehyde releaser listed among the ingredients were purchased from Denmark. These products were relatively easy to find with the help of the Danish Consumer Council's Kemiluppen database.

We purchased products containing formaldehyde releasers based on our knowledge at the time of purchase; that is, based on the ingredients listed on the vendor's website (whether as text or in an image of the product). Upon inspection, it turned out that two of the 14 products expected to contain a formaldehyde releaser did not actually list a formaldehyde releaser among their ingredients. These two products were purchased from within Denmark, and the information supplied online did not match the ingredients as listed on the products. However, it should be noted that many websites indicate that the ingredients listed online may not be updated to reflect the current composition of each product. There is no legal requirement for vendors to supply list of ingredients on their websites when marketing cosmetic products.

The purchased products which listed formaldehyde releasers among their ingredients contained the following formaldehyde releasers:
- DMDM hydantoin, in four products (three non-EU, one EU)
- Diazolidinyl urea, in four products (two non-EU, one EU, one DK)
- Imidazolidinyl urea, in two products (one EU, one DK)
- Sodium hydroxymethylglycinate (one DK product)
- 2-bromo-2-nitropropane-1,3-diol (one non-EU product)

TABLE 6. Information on the distribution of the 150 cosmetic products in the project

Parameter	Products purchased within DK	Products purchased within the EU (excluding DK)	Products purchased outside the EU	Sum
All products	75 (50%)	35 (23%)	40 (27%)	150 (100%)
Product types	Face cream: 11 Body lotion: 12 Hand cream: 10 Make-up remover: 10 Self-tanner: 11 Skin toner: 11 Eye cream: 10	Face cream: 5 Body lotion: 6 Hand cream: 5 Make-up remover: 3 Self-tanner: 6 Skin toner: 5 Eye cream: 5	Face cream: 5 Body lotion: 5 Hand cream: 6 Make-up remover: 6 Self-tanner: 6 Skin toner: 6 Eye cream: 6	21 23 21 19 23 22 21
With formaldehyde releaser	3 Distributed as follows: Face cream: 1 Body lotion: 2	3 Distributed as follows: Face cream: 1 Hand cream: 1 Self-tanner: 1	6 Distributed as follows: Body lotion: 2 Hand cream: 1 Make-up remover: 1 Self-tanner: 1 Eye cream: 1	12
Containing cocamidopropyl betaine	7 Distributed as follows: Make-up remover (3) Self-tanner (4)	2 Distributed as follows: Make-up remover (1) Self-tanner (1)	0	9
Containing dihydroxyacetone	11 Self-tanners only	5 Self-tanners only	5 Self-tanners only	21
Containing PEG compounds	66	30	25	121

Parameter	Products purchased within DK	Products purchased within the EU (excluding DK)	Products purchased outside the EU	Sum
	Distributed as follows: Face cream: 10 Body lotion: 9 Hand cream: 10 Make-up remover: 9 Self-tanner: 9 Skin toner: 11 Eye cream: 8	Distributed as follows: Face cream: 5 Body lotion: 5 Hand cream: 5 Make-up remover: 2 Self-tanner: 4 Skin toner: 4 Eye cream: 5	Distributed as follows: Face cream: 3 Body lotion: 5 Hand cream: 3 Make-up remover: 2 Self-tanner: 2 Skin toner: 6 Eye cream: 4	
Containing polysorbate 80	23 Distributed as follows: Face cream: 5 Body lotion: 4 Hand cream: 2 Make-up remover: 3 Skin toner: 3 Eye cream: 6	4 Distributed as follows: Face cream: 1 Body lotion: 1 Hand cream: 2	2 Distributed as follows: Face cream: 1 Self-tanner: 1	29
Containing glycerine	63 Distributed as follows: Face cream: 7 Body lotion: 11 Hand cream: 10 Make-up remover: 9 Self-tanner: 9 Skin toner: 9 Eye cream: 8	30 Distributed as follows: Face cream: 4 Body lotion: 5 Hand cream: 5 Make-up remover: 2 Self-tanner: 4 Skin toner: 5 Eye cream: 5	29 Distributed as follows: Face cream: 3 Body lotion: 4 Hand cream: 5 Make-up remover: 4 Self-tanner: 5 Skin toner: 4 Eye cream: 4	122
With PET packaging	16 Distributed as follows: Face cream: 2 Hand cream: 1 Make-up remover: 4 Self-tanner: 3 Skin toner: 6	10 Distributed as follows: Make-up remover: 1 Self-tanner: 3 Skin toner: 4 Eye cream: 2	12 Distributed as follows: Body lotion: 1 Make-up remover: 5 Self-tanner: 1 Skin toner: 4 Eye cream: 1	38

The breakdown of products containing these ingredients is based on the list of ingredients on the products, rather than the information that was available during the purchasing process.

The products' prices varied depending on the region from which each product was purchased (DK, EU, and non-EU) and on the type of each product. Products from both well-known and less familiar brands were purchased. The list of ingredients for each product was the primary factor that guided the purchasing process, although some effort was made to choose products from different brands and manufacturers. Even so, this was only possible to a limited extent, since certain manufacturers have clear tendencies to use particular substances, such as cocamidopropyl betaine. The minimum, maximum, and mean prices for each product type are presented below in TABLE 7. Shipping costs are not included in these prices; the prices indicated are for the products alone.

Overall, it seems that products purchased within the EU (i.e., excluding Denmark) are cheaper than those purchased from Denmark; this impression also guided the purchasing process for the project. The cheapest products are those purchased outside the EU. The products studied in this project were purchased before the recent change to duties and customs fees on products coming from outside of the EU. Thus, shipping costs for these products may be significantly higher today.

TABLE 7. Prices of the 150 products purchased, according to purchase region and product type

Product type	Products purchased within DK	Products purchased within the EU (excluding DK)	Products purchased outside the EU
Face cream	Min.: 112 DKK Max.: 569 DKK Avg.: 304 DKK	Min.: 90 DKK Max.: 480 DKK Avg.: 181 DKK	Min.: 28 DKK Max.: 142 DKK Avg.: 84 DKK
Body lotion	Min.: 20 DKK Max.: 340 DKK Avg.: 120 DKK	Min.: 112 DKK Max.: 216 DKK Avg.: 162 DKK	Min.: 36 DKK Max.: 87 DKK Avg.: 58 DKK
Hand cream	Min.: 10 DKK Max.: 260 DKK Avg.: 85 DKK	Min.: 14 DKK Max.: 183 DKK Avg.: 75 DKK	Min.: 25 DKK Max.: 93 DKK Avg.: 58 DKK
Make-up remover	Min.: 30 DKK Max.: 425 DKK Avg.: 156 DKK	Min.: 34 DKK Max.: 297 DKK Avg.: 127 DKK	Min.: 25 DKK Max.: 105 DKK Avg.: 59 DKK
Self-tanner	Min.: 73 DKK Max.: 345 DKK Avg.: 184 DKK	Min.: 121 DKK Max.: 295 DKK Avg.: 180 DKK	Min.: 28 DKK Max.: 205 DKK Avg.: 116 DKK
Skin toner	Min.: 45 DKK Max.: 315 DKK Avg.: 142 DKK	Min.: 27 DKK Max.: 102 DKK Avg.: 65 DKK	Min.: 21 DKK Max.: 87 DKK Avg.: 60 DKK
Eye cream	Min.: 49 DKK Max.: 515 DKK Avg.: 211 DKK	Min.: 34 DKK Max.: 369 DKK Avg.: 126 DKK	Min.: 22 DKK Max.: 154 DKK Avg.: 85 DKK

5. Levels of elicitation and sensitisation

5.1 General information on contact allergy

5.1.1 Mechanism

The mechanism behind contact allergy has two phases. One phase is the induction phase, also called sensitisation, where the immune system is activated to recognise the allergen (which in this project is formaldehyde). In this process, memory cells are formed that can recognise the allergen in the future. The sensitisation process takes place without symptoms. When a person sensitised to an allergen is re-exposed to it in sufficient concentration, symptoms of allergic contact dermatitis occur. This is the second phase, called the elicitation or provocation phase. In this phase, the immune system reacts to the allergy-provoking substance, and an inflammatory reaction occurs in the skin due to the allergic reaction. The skin swells, itches, turns red, and pimples and blisters may appear. Allergic contact dermatitis occurs on the area of skin that comes into contact with the allergen. However, it can spread to neighbouring regions of the body and, if exposure continues, can lead to widespread, almost universal dermatitis, i.e. dermatitis that extends over the entire body.

5.1.2 Dose metric

In many areas of toxicology, it is the total dose that defines whether an effect occurs. However, for contact allergy, the quantity of allergen per unit area of skin to which the individual is exposed is the critical factor (White, 1986), which is usually expressed in $\mu g/cm^2$ (Basketter, 2008).

5.1.3 General information on sensitisation studies

The sensitisation phase can only be studied by experiments, most of which are conducted on animals, especially guinea pigs and mice. However, there are a number of historical publications where sensitisation of healthy people has been carried out experimentally e.g. Marzulli and Maibach (1974) and Kligman (1966). In these tests, a healthy person is repeatedly exposed to an allergen over a period of weeks. After a rest period, elicitation is performed by applying the allergen to a new area of skin. A dose-response is observed in both humans and animals, meaning that the higher the allergen dose, the more people develop allergies and the more sensitive the individual becomes (Friedmann, 2014). Highly potent allergens can sensitise everyone in a group, while less potent allergens sensitise fewer individuals (Kligman, 1966). This type of study is considered unethical in the EU, but there is a tradition of using historical data of sufficient quality (SCCS/1589/17, 2018).

The outcome of sensitisation studies in humans and some animal tests depends on elicitation, i.e. measuring whether sensitisation has occurred by re-exposure to the allergen. It has been shown experimentally in mice that the greater the concentration (dose) of allergen in the sensitisation phase, the more allergic the animal becomes and the smaller the amount of allergen required to elicit, i.e. for allergic symptoms to occur. Conversely, the smaller the sensitising dose, the more it takes to elicit (Scott, 2002).

The sensitisation doses found in these experiments cannot be applied directly but must be adjusted for differences between the experimental set-up and actual application. Thus, in experiments higher doses and few applications of allergen are often used.

5.1.4 Risk assessment models: General information on levels of sensitisation

There is no accepted risk assessment model for sensitisation by skin contact. The fragrance industry has been working on developing a quantitative risk assessment (QRA) model for allergenic fragrance ingredients in cosmetics in order to propose safe levels of use (Api et al., 2008; 2020). The general principles for the risk assessment of allergies of other substances in cosmetics, such as preservatives, including formaldehyde, will be the same.

The model developed is based on the ability to determine a no-effect level for sensitisation, also referred to as the no-expected-sensitisation-induction level (NESIL), through experiments on animals or humans.

NESIL is adjusted by a safety factor (SAF) determined from the specific exposure scenario. This is the Acceptable Exposure Level (AEL) to which the Consumer Exposure Level (CEL) must be below for there to be no risk of sensitisation.
The acceptable exposure level, which is assumed not to cause sensitisation, i.e. induction of allergy, is calculated as follows:

Accepted Exposure Level (AEL) = NESIL (µg/cm^2)/ SAF x CEL (µg/cm^2) (Api et al., 2020)

This model (QRA) has been assessed by the SCCS several times, most recently in 2018 (SCCS/1589/17, 2018), where the committee concluded:

”*It is not yet possible to use the QRA2 to establish a concentration at which induction of sensitisation of fragrance is unlikely to occur. Several aspects of the methodology are not clear and the scientific rationale behind the methodology needs to be better described*.”

Thus, there is no officially recognised model for assessing risk of sensitisation in the EU.
In the following (section 5.2), the current model (QRA) will be attempted to be applied to formaldehyde with the limitations of validity that this gives, as there are currently no other ways to describe sensitisation levels.

5.1.5 General information on elicitation studies

5.1.5.1 Patch test

Elicitation is the disease of allergic contact dermatitis and is thus immediately objectively detectable. This is used in the diagnostic test, epicutaneous test or patch test, where a mini provocation with the suspected allergenic substances is performed, and the occurrence of allergic eczema in the area is recorded. In this test, a small amount of allergen is applied, either dissolved in water or Vaseline in a plastic or aluminium chamber of around 0.5 cm^2 attached with a patch for two days on the upper part of the back (Johansen, 2015). The patch is then removed, and an allergic reaction is recorded using an internationally recognised reading scale (Johansen, 2015). You can test with several concentrations of a substance in this test, called serial dilution. This can provide input on how allergic a patient is to a substance and determine what doses different proportions of patients react to in groups of patients. Thus, ED10% is often used: Elicitation dose for 10% of those tested (Fischer, 2009).

5.1.5.2 Use tests

In people who have developed patch-tested allergy, an attempt can be made to provoke allergic eczema under more realistic conditions in the form of a repeated open application test (ROAT) or use test. Here, the allergic person applies a product or solution with a defined allergen content, usually twice a day for 1-4 weeks, usually to small areas on the arms (Johansen, 2015). This is often relevant for allergens present in cosmetics and can be used to determine levels of elicitation (Johansen, 2015; SCCS/1567/15, 2015).

It has been shown that the number of applications per day matters, thus application four times a day of a smaller dose (e.g. 100 ppm) will give the same result as a single large dose (400 ppm) (Jensen, 2005). Therefore, it is the total concentration per skin area per day that is crucial for the allergic reaction. The length of the provocation matters such that 54% of the patients who developed a positive application test with the fragrance compound cinnamal had symptoms in the first week of provocation and 46% after the first week of provocation (Johansen, 1998). The lower the concentrations of allergen used, the longer time it takes for a reaction to develop (Andersen, 2001).

5.1.6 Risk assessment models: General information on levels of elicitation

A number of allergens, including formaldehyde, have been patch tested in serial dilutions to generate dose-response curves for elicitation. A comprehensive statistical analysis of these results has been published (Fischer, 2009) and can be used in risk assessment (SCCS/1567/15, 2015). This pooled statistical analysis of serial dilution patch tests has been attempted to be used to set a standard safe limit for a number of allergenic fragrance substances 'of special concern' (SCCS/1459/11, 2012), in other words fragrance substances that have given rise to an exceptionally high number of allergy cases. The proposed safe level of sensitisation and elicitation determined in this way was 100 ppm (SCCS/1459/11, 2012).

The results of well-conducted use tests have been used several times to regulate contact allergens, most recently for methylisothiazolinone in cosmetics.

A comparative analysis of elicitation levels determined by patch and use tests for the same substance found that under simulated normal use, a smaller dose per application is required to elicit than in patch tests - typically in the order of 10-30 times less (Fischer, 2009). This means that the patch test itself is less useful for directly determining elicitation levels in the case of cosmetic products, for example, where several applications are made daily.

In the following, data from application studies of cosmetic products preserved with formaldehyde releasers will be used to estimate elicitation levels since these studies are directly relevant for the disease allergic eczema and the exposure to leave-on products such as creams/lotions. No studies with rinse-off products are available.

5.2 Results for formaldehyde: Levels of sensitisation

5.2.1 General use

Most cases of formaldehyde allergy detected in individuals suspected of allergic eczema can be associated with the use of cosmetics (DeGroot, 2010). Therefore, as a starting point, the allergy can be considered to be caused by the levels of free formaldehyde present in cosmetic products.

5.2.2 Experimental sensitisation studies in humans (historical data)

In the 1960s, Kligman established an experimental model for the induction of allergy, called the Maximisation test. The model involved exposing healthy people to doses of suspected allergens on the same area of skin repeatedly, preferably five times every 48 hours, alternating with soap for 24 hours without a break between exposures. The soap was used to cause skin irritation. With this model, substances could then be classified according to how many of a panel of 25 people developed allergies. Formalin 5% was used for induction in this study (Kligman, 1966). Formalin is a 37% solution of formaldehyde, which is why the actual concentration was 1.85%, and the elicitation concentration was 0.37% (1% formalin). A total of 18 out of 25 persons were sensitised (72%), which classified formaldehyde as a grade IV out of V allergen, i.e. a strong allergen. No other concentrations were tested and thus the lowest sensitisation level was not determined.

In a later study by Marzulli and Maibach (1974), different concentrations of formaldehyde (formalin) were tested in a slightly different model than above, called the Draize procedure. In this procedure, 10 applications are made over a 3-5 week period to the same skin area, often the upper arm, followed by a two week rest period and then elicitation. Formalin 0.1%, equivalent to 0.037% formaldehyde, sensitised no individuals, while 0.37% sensitised 4/89 healthy individuals (4.5%). Thus, in this study, the lowest sensitising concentration of formaldehyde was between 0.037% and 0.37% formaldehyde.

5.2.3 Experimental sensitisation studies on mice

In the Local Lymph Node Assay, which is performed on mice, the immune system's response to three consecutive daily applications of an allergen in solution to the ears is measured. A threefold increase in the proliferation of immune cells in the regional (anatomically proximal) lymph node compared to animals treated with vehicle (carrier) alone is taken to indicate that sensitisation has occurred. The concentration producing this proliferation is called EC3.

The EC3 value for formaldehyde is given as 0.61% (Gerberick, 2005), corresponding to 150 μg/cm^2, based on the experimental details in Hilton (1998) and in another study by Basketter (2001) to 0.4% corresponding to 100 μg/cm^2.

Although this is not an actual no-effect level but more a low-effect level, the industry often uses these values as a dose not expected to cause allergy (NESIL) on the same terms with human data without further adjustment. This lack of adjustment for extrapolation between species has recently been criticised, at least for certain substances (Ezendam, 2018) and in a recent opinion of the Scientific Committee on Consumer Products, which advises the commission on safety issues, which considers that an adjustment by a factor of 3 should be made when converting from animals to humans (SCCS/1589/17, 2018).

No other LLNA studies for formaldehyde were found in the literature search, but the same study (Hilton, 1998) is mentioned in several articles.

5.2.4 Risk assessment (model prediction) for sensitisation

Doses

The dose, which is experimentally the no-effect level of sensitisation in humans, was in the article by Marzulli and Maibach (1974) 0.037% (corresponding to 370 ppm). It is impossible to translate this directly into risk upon using products such as creams as the dose cannot be converted to μg/cm^2 due to a lack of information on the size of the area exposed. However, Basketter (2008) assumed that the area was about 5 cm^2 and, on this basis, calculated the level not expected to sensitise (NESIL) to be 37 μg/cm^2 formaldehyde.
In LLNA, the EC3 value has been estimated to be 0.61% for formaldehyde (Hilton, 1998; Gerberick, 2005), corresponding to 150 μg/cm^2. Therefore, the literature has used the estimated 37 μg/cm^2 from the studies on humans as a conservative starting point for calculating the risk of sensitisation to formaldehyde (Basketter, 2008).

Safety factors (SAFs)
There is an overall safety factor (SAF) of 100 (Basketter, 2008; Api 2020) for products used as leave-on on the face and body and applied with palms. This safety factor aims to correct for variation between individuals (factor 10), skin area (factor 3) and the possibility of pre-existing eczema (factor 3[23]).

Exposure in realistic use of products (CEL)
According to notes of guidance from SCCS (SCCS/1628/21, 2021), exposure levels are given for several leave-on products, but not for, e.g. skin tonic, eye cream and self-tanner. The fragrance industry has further developed the risk assessment model (Api et al., 2020) to calculate a standard level for leave-on products applied to the face and/or body with the hands of 3.02 $mg/cm^2/day$ (3020 $\mu g/cm^2/day$). This standard level is based on the product type giving rise to the highest exposure per unit area. This value will be used in the following. Make-up removers can either be marketed as a leave-on product or as a rinse-off product. For rinse-off make-up remover products, it is estimated that only 1/10 of the product remains on the skin[24] (SCCS/1628/21). There are no specific data on the use of self-tanners, but they are considered comparable to creams and the leave-on group of products. The particularity is that self-tanners are probably not applied every day as assumed in the risk assessment model. However, in an opinion on the active substance DHA, the SCCS has made a worst-case calculation of the risk of systemic toxicity based on daily use, but states that the worst-case scenario is unrealistic, and that weekly or monthly use is more realistic (SCCS/1347/10, 2010).

Estimated sensitisation level in leave-on products
The dose estimated not to sensitise is called the acceptable exposure level (AEL).
If there is to be no risk, the amount (dose) of formaldehyde used in leave-on products for the face and/or body (Consumer Exposure Level CEL) must be at least equal to or less than the AEL.

The AEL is calculated from the formula above and for formaldehyde will be:

$$AEL = 37\ \mu g/cm^2 / 100 \times 3020\ \mu g/cm^2 = 0.000122\ (0.0122\%)$$

According to the model, if the formaldehyde concentration in leave-on products for the face and/or body is ≥0.0122% (122 ppm), there is a risk of sensitisation.

If the result from LLNA (NESIL) = 150 ug/cm^2 or 100 $\mu g/cm^2$ is used instead in the model with correction (factor 3) for interspecies variation, the sensitisation level could be calculated as ≥0.0165% (165 ppm) and ≥0.011% (110 ppm), respectively,

According to SCCS notes of guidance concerning make-up removers, 0.5 g/day would be left on the skin of the face (565 cm^2), corresponding to 885 $\mu g/cm^2$ for make-up removers, which are rinsed-off after use. Which means the sensitisation level is between 375 and 565 ppm, for make-up removers that are cleaned after use.

Conclusion**:** Overall, the calculated sensitisation levels in leave-on products applied to the face and/or body with the hands are in the range 110-165 ppm.

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[23] Usually, √10 = 3.16 - is used, but this value is usually referred to as a safety factor of 3

[24] It should be noted that most make-up removers were purchased as potential leave-on products, i.e. they either directly stated that they should not be rinsed off or there was no information on the necessity of it. However, the make-up removers that contained free formaldehyde in the analyses are products recommended to be wiped off with a damp cloth afterwards. For this reason, the so-called retention factor of 1/10 has been used.

5.3 Results for formaldehyde: Levels of elicitation

Levels of elicitation by exposure to formaldehyde can be directly observed in individuals with proven formaldehyde allergy when exposed to formaldehyde on the skin under various conditions. Studies that have aimed to identify elicitation levels for formaldehyde under realistic use conditions are mentioned in TABLE 8.

The studies are of different types, but they are all based on people who have been found to have a contact allergy to formaldehyde by patch testing, which is the internationally standardised and accepted test for contact allergy (Johansen, 2015). Four studies were found in which use tests were performed with moisturisers applied to the upper arm for one week (Flyvholm, 1997), to the upper arm with pre-irritated skin (eczema) for up to four weeks (Hauksson et al., 2015a), successively on the upper arm, neck and face for two weeks on each area (Zachariae, 2005) or on the forearm for up to one week (DeGroot,1988). All four studies apply twice daily to the skin areas, and three of the studies include a healthy control group. In the three studies applying the cream to normal skin, 5/20 (20%) of the formaldehyde-allergic subjects (Flyvholm, 1997) reacted to creams containing 291-367 ppm formaldehyde; 2/10 (20%) to creams containing 370 ppm formaldehyde (Zachariae, 2005) and 1/4 (25%) to a cream containing an estimated 200 ppm formaldehyde (DeGroot, 1988). In one study (Zachariae, 2005), a retest was performed with a product containing 130 ppm formaldehyde, which was negative.

Thus, the lowest elicitation level detected in these studies is 200 ppm formaldehyde, but reaction at lower levels is possible and may actually be between 130 and 200 ppm.
Several of the studies are performed on the arms, while in the study by Zachariae et al., 2005, it is seen that more people respond to application on the face than on the upper arm.

When special conditions apply, as in the study by Hauksson et al. (2015a), where the skin was pre-irritated with soap, 2/15 (13%) formaldehyde-allergic subjects reacted to moisturisers containing between 2.5 and 10 ppm formaldehyde. In an older study (Jordan, 1979), reaction was seen in 4/9 (44%) subjects at three closed (occluded) applications of formaldehyde 30 ppm in one week. However, it is impossible to calculate whether the dose under the given conditions is realistic compared to general use. In the same study, a reaction was seen in the axilla when sprayed with 30 ppm formaldehyde (Jordan, 1979).

In the two studies with specific exposure conditions, pre-irritated skin/closed environment, the elicitation level is approximately 10-80 times lower than the studies with open application to normal skin.

Conclusion**:** Overall, the lowest reported elicitation level for formaldehyde in creams is between 130 and 200 ppm for short-term use (1-2 weeks) on normal skin and 2.5-10 ppm formaldehyde for use on eczema skin (pre-irritated skin) for up to four weeks.

TABLE 8. Threshold values for reaction to formaldehyde (elicitation) under different realistic exposure scenarios among formaldehyde-allergic individuals

Method	Solution/product	Threshold value in ppm	μg/cm^2	Reference
Patch test repeated x 3 on the same area. Within 1 week. Vehicle methanol/water.	100 ppm 60 30 0	6/9 (67%) 5/9 (56%) 4/9 (44%) 0	Chamber size unknown	Jordan, 1979
Spray in armpit	30 ppm formaldehyde	2/7 (29%)	Not stated	Jordan,1979

Method	Solution/product	Threshold value in ppm	µg/cm²	Reference
0.7 mg solution (water/methanol) with 30 ppm formaldehyde in 1 armpit x 2 daily for 14 days. Vehicle in opposite armpit.				
Repeated open application with cream x 2 on forearm for up to 1 week. Dose not mentioned. No controls.	Cream with -1% DMDM hydantoin - retest of the 4 who reacted to cream with 0.25% DMDM, estimated 200 ppm formaldehyde	4/12 (33%) reacted 1/4 (25%) reacted	Not stated	De Groot, 1988
Repeated open exposure 5 x 5 cm upper arm 0.1 ml x 2 for 1 week. 20 patients with formaldehyde allergy and 20 healthy controls.	Moisturiser with 300 ppm free formaldehyde Donor: Germall-115 (imidiazolidinyl urea)	5/20 (25%) patients reacted (weak reactions: follicles) Conc. 258-367 ppm (measured) 0/20 (0%) controls	0.71-2.92	Flyvholm,1997*
Repeated open exposure of face cream on upper arm, if negative then on neck and then on face. 2 weeks on each area x 2 daily. Approx. 5 x 5 cm with 0.1 ml per time. On the face: estimated 500 cm². 3 groups of 10 people And a healthy control group of 10 people.	Face cream with 1500 ppm 730 370 130 Donor: diazolidinyl urea (0.05%-0.6%)	Number with reaction/ tested 7/10 (70%) 7/10 (70%) 2/10 (20%) 0 Controls: negative	 0.57 0.30 0.18 0.05 Calculated for diazolidinyl urea exposure to face	Zachariae, 2005*
Repeated open application x 2 daily with steroid cream on upper arms where allergic nickel eczema was previously induced.	Corticosteroid cream with approx. 200 ppm. Formaldehyde Against corticosteroid cream without formaldehyde	2/7 (29%) healed 12/17 (70%) healed Difference significance (p=0.04)	Not stated	Isaksson, 2006
Repeated open exposure to 2 mg cream/cm2 on upper arm: Pre-irritated skin 3 x 3 cm. Use equivalent to 2 mg/cm2 x 2 max 4 weeks. Randomised, blinded.	Moisturiser with >40 ppm 20-40 ppm 2.5-10 ppm 0 ppm Donor DMDM hydantoin (0.6%-0.33%-0.06%-0)	Number with reaction/tested 9/15 (60%) 6/15 (40%) 2/15 (13%) 0	Not stated	Hauksson, 2015a#

Method	Solution/product	Threshold value in ppm	µg/cm^2	Reference
Experimentally sensitised healthy subjects				
Repeated open application x 2 daily:	Individuals who were all experimentally sensitised to formaldehyde		Not stated	Marzulli, 1979
Right part of face and forearm.	Lotion with 0.5% formaldehyde	5 out of 10 (50%) reacted		
Left part of face and forearm.	Cleansing cream with 0.4% formaldehyde	4 out of 10 (40%) reacted		
Right shoulder.	Bath oil with 0.6% formaldehyde	2 out of 10 (20%) reacted		

* These studies have been carried out together with the cosmetics industry, which has supplied the creams and been responsible for checking formaldehyde levels. No independent verification has been carried out.
# Levels of formaldehyde measured semi-quantitatively.

5.4 Discussion and conclusion/summary

Overall, the estimated sensitisation levels in leave-on products for the face and/or body are in the range of 110-165 ppm and for make-up removers (they are rinsed-off) between 375 and 565 ppm. The result of the calculation depends on the quality of the data, which in the case of experimental studies on humans is historical and consists of partially incomplete data. It has therefore been necessary to use an estimated sensitisation dose (NESIL), which toxicologists from industry have previously calculated based on their insight into this type of study (Basketter, 2008). Data from the two animal studies (LLNA) that have been published give a sensitisation level (110-165 ppm) of the same order of magnitude as that based on the human sensitisation test (122 ppm). These levels of formaldehyde are within those found in e.g. creams and are consistent with the observation that formaldehyde allergy can often be associated with the use of cosmetics (DeGroot, 2010). The risk assessment model used for the calculations (QRA) is widely used in the perfume and cosmetics industry, but has not been adopted by the SCCS, which has assessed that it is not yet possible to use the model to identify levels at which sensitisation is unlikely (SCCS/1589/17, 2018). Thus implicit in this criticism is that the levels the model predicts as safe may be too high. SCCS points out that there are several aspects of the methodology where the scientific rationale is unclear (SCCS/1589/17, 2018). Thus, this also applies to the calculations made in this report on sensitisation levels.

Among other things, the SCCS believes that it is unclear when/why individual safety factors (SAFs) should be applied. This ultimately has an impact on the calculated sensitisation levels. In this report, the SAFs that are standard in the proposed QRA model (Api et al., 2020) are used. These SAFs are built into the total factor of the QRA method.

Another criticism has been that the original model did not take into account that a person may use several different products with the same allergen, e.g. formaldehyde, on the same skin area. Thus, in addition to moisturiser, a person could be exposed in a day to facial cleansers, soaps, shampoos, make-up, etc., all of which could potentially contain free formaldehyde. Attempts have been made to build the possible aggregate exposure into the new model as an adjustment factor. However, understanding the rationale and application of these factors is very complicated (SCCS/1589/17, 2018). It has not been possible to take aggregate exposure into account, i.e. the fact that several products containing formaldehyde may be used on the same skin area and contribute to the total exposure, since there is no scientific consensus on the method.

Thus, there are many uncertainties in the data and in the calculation of sensitisation levels, which may be lower than 110-165 ppm. The sensitisation phase takes place without symptoms. Therefore, it is inherent that a calculated sensitisation level is an estimate and can never or very rarely be verified in relation to the normal use of different types of products.

For this reason, such calculated sensitisation levels should be used with great caution in the regulation and prevention of contact allergy, especially in the case of substances known to cause allergic reactions in the population, where elicitation data should be used more as a basis for decision-making (SCCS/1567/15, 2015).

The lowest reported elicitation levels of formaldehyde from moisturiser use were between 130 and 200 ppm when used for a short time (1-2 weeks) on normal skin. Where 130 ppm gave no reaction among 10 formaldehyde allergic patients and 200 ppm gave reaction in 1/4 patients who underwent a re-test after reacting to a higher concentration (DeGroot, 1988). There are many differences in the performance of the individual use tests in the skin area, exposure duration and concentrations, which may partly explain the variation seen between the outcomes of the studies (TABLE 8). Several studies use short exposure periods (1-2 weeks), where a more prolonged exposure would likely make more people react (Johansen, 1998;2015). In addition, different creams and thus possibly different matrices may result in varying retention/release of formaldehyde. Different formaldehyde releasers are used. Whether this is significant is unknown. Formaldehyde is a small molecule and very easily evaporable, and thus storage of the test materials could significantly impact the effective actual concentration delivered to the skin. This will also apply in a use situation. This is supported by the fact that in the study where evaporation is prevented (closed repeated application), the elicitation level is seen to be 30 ppm (Jordan, 1979).

Application rates vary in the experiments and no attempt has been made to adjust for this, due to lack of information in the publications. The results are therefore taken directly without further adjustment or modelling. The concentrations of formaldehyde in the products have in some cases been estimated (calculated) as in DeGroot, 1988, in others analysed semi-quantitatively (Hauksson et al., 2015a), while in studies involving the cosmetics industry, more thorough analyses have been performed (Flyvholm, 1997; Zachariae, 2005), but without independent control.

Although the lowest reported elicitation level (200 ppm) is based on a small genetic testing study of four formaldehyde-allergic individuals, where the formaldehyde level was calculated (DeGroot, 1988), this result is supported by several of the other studies, where the measured level is 258-370 ppm (Flyvholm, 1997; Zachariae, 2005), which is thus in the same order of magnitude.

Approximately 40% of the Danish population experience eczema at some point in their lives, and 10% experience facial eczema (Heede, 2016). Therefore, it is relevant to study elicitation levels on eczema skin. In Hauksson et al. (2015a), the lowest elicitation level was found to be 2.5-10 ppm on pre-irritated skin at exposure up to four weeks, which would be potentially relevant for many consumers.

Overall, the amounts found in cosmetic products, including face creams, could sometimes lead to sensitisation. The elicitation level is in the same order of magnitude for leave-on products for the face and body, except for application on irritated skin, where the minimum amount that can elicit will be 10-40 times lower.

6. Chemical analysis – formaldehyde content

This chapter describes the choice of analytical methods for the identification of free formaldehyde and the results of the chemical analyses performed for the content of free formaldehyde in the purchased products. For the purchased products, a screening (semi-quantitative analyses) of the free formaldehyde content was first performed, after which some products were selected for the quantitative determination of the free formaldehyde content.

6.1 Semi-quantitative analyses

The approach chosen in the project was to purchase a large number (150) of cosmetic products, which were screened for the content of free formaldehyde by a semi-quantitative analytical method described and used by Hauksson et al. (2015a). The choice of analytical method for the screening is justified below.

6.1.1 Analytical method for the semi-quantitative determination of free formaldehyde

Several different screening analyses for formaldehyde exist in the literature and on the market. These are all so-called colorimetric methods, and ready-made kits for testing the content of free formaldehyde can be purchased. However, the measurement range of formaldehyde concentration differs from test to test depending on their purpose, and typically the tests cover a limited measurement range.

The EU Directive on methods of analysis necessary for checking the composition of cosmetic products[25] specifies a colorimetric method using Schiff's reagent with a detection limit of 100 mg/litre. However, this detection limit is too high to comment on the risk of allergy (see chapter 5 "Levels of elicitation and sensitisation") and the opinion of the SCCS on the recommendation to lower the limit value for declaring the presence of free formaldehyde in cosmetic products to 10 ppm (SCCS, 2021)). Test kits from Merck cover either a range from 0.1 mg/l up to 2.5 mg/l and from 10 mg/l up to 100 mg/l. A measurement range from 2.5 mg/l up to 40 mg/l seems to be more relevant in relation to the risk of allergic reactions in persons who have already developed an allergy to formaldehyde (elicitation). As indicated in chapter 5 "Levels of elicitation and sensitisation", elicitation levels as low as 2.5-10 ppm formaldehyde have been observed when used on eczema skin (pre-irritated skin).

The so-called CA method (Chromotropic Acid) is a screening analysis for the free formaldehyde in cosmetic products (i.e. the formaldehyde evaporating from the cosmetic product). This method is described and used in scientific studies (e.g. Hauksson et al. (2015a)). The CA method is a semi-quantitative method that can indicate the result in ranges based on a colour response. It is originally described in Contact Dermatitis, 5th edition (2011). The CA method is used by the National Allergy Research Center in their laboratory since the method is considered to give a result sufficient to make a statement on the risk of allergy, except in the case of discolouration.

[25] Commission Directive of 4 April 1990 amending the Second Directive 82/434/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (EU Directive 90/207/EEC).

The original CA method describes that levels of formaldehyde can be identified in ranges up to 40 ppm and in a level above 40 ppm. For more precise concentrations or identification of high concentration levels, the use of a quantitative method to determine the true level of free formaldehyde is recommended.

This semi-quantitative method of analysis determines by a colour reaction whether the cosmetic product contains free formaldehyde. If the free formaldehyde content in the sample is above 2.5 ppm, formaldehyde evaporates from the cosmetic product and dissolves in the reagent solution separated from the cosmetic product. The reaction with the reagent gives a pink colour to the reagent liquid. The higher the concentration of formaldehyde in the sample, the more intense the colour of the reagent liquid. The colour changes from pink to a dark violet (see FIGURE 1).

This screening method is very sensitive to formaldehyde. However, other aldehydes can cause cross-reactions that can be seen by a change in colour (discolouration compared to the pink/purple colour). The intensity of the colour of the reagent liquid is compared with the colours of reference solutions of known formaldehyde content (2,5, 10, 20 and 40 ppm), thus giving a semi-quantitative concentration of formaldehyde in the product in ranges. The reference solutions are prepared from formaldehyde standards where the concentration of formaldehyde is determined quantitatively by titration to ensure that the reference samples have the correct concentrations. A standard addition was performed by adding a known amount of formaldehyde to selected samples to check that the method works.

When using this CA method, it is important to be aware of the so-called "laboratory-blind", i.e. the inclusion of formaldehyde via the laboratory air. Therefore, a laboratory blank was always used to ensure that no formaldehyde was introduced from the environment.

For the semi-quantitative analyses of the 150 cosmetic products, the CA method was modified to also prepare a reference solution with 100 ppm free formaldehyde. This means that the results for the content of free formaldehyde in the 150 cosmetic products can be given in the following ranges:

- < 2.5 ppm
- $2.5 \leq x < 5$
- $5 \leq x < 10$
- $10 \leq x < 20$
- $20 \leq x < 40$
- $40 \leq x < 100$
- ≥ 100

The reference solutions including the blank are given in FIGURE 1 below.

The analysis is performed by placing a weighed quantity of the cosmetic product in the bottom of a closed glass flask. A test tube containing the reagent liquid is placed in the flask. The reagent liquid changes colour upon reaction with free formaldehyde evaporating from the cosmetic product. The stronger the colour, the higher the concentration of free formaldehyde.

FIGURE 1. Prepared reference solutions including blank. From left: blank, 2.5 ppm formaldehyde, 5 ppm, 10 ppm, 20 ppm, 40 ppm, 100 ppm.

An example of analysed samples and colour reactions is given in FIGURE 2below.

FIGURE 2. Examples of five of the analysed cosmetic products and the colour reactions developed. A precisely weighed quantity of the cosmetic product is placed in the bottom of the flask. Free formaldehyde degassing in the closed flask colours the liquid in the tube. The stronger the colour, the higher the concentration of free formaldehyde.

In practice, the colour of each product is read after 48 hours by placing it next to the prepared reference solutions. Two to three persons assess the colour and thus the resulting concentration range of free formaldehyde.

6.1.2 Naming of the cosmetic products

As described in chapter 4 “Products purchased for chemical analysis”, the following seven types of cosmetic products were purchased from three different regions: Denmark (DK), EU but not Denmark (referred to as EU) and outside the EU (referred to as NEU for non-EU).

- Face cream
- Body Lotion
- Hand cream
- Make-up remover

- Self-tanner
- Skin tonic
- Eye cream

The 150 cosmetic products included in the project have been named with a letter code depending on where they were purchased and a number between 1 and 170. The reason why there are more numbers than the 150 analysed products is that extra products were purchased in case there were products that did not arrive before the start of the analyses.

6.1.3 Results of the semi-quantitative chemical analyses

The results of the semi-quantitative analyses for free formaldehyde for the 150 cosmetic products are detailed in Annex 1, "Results of the semi-quantitative analyses". Based on the list of ingredients, information on the content of the five focus substances and the content of any formaldehyde releases is also given here.

Below in TABLE 9 up to and including TABLE 12, the results are summarised and discussed in relation to the following parameters:

- Levels of free formaldehyde for all 150 cosmetic products in the project both with and without formaldehyde releaser in the list of ingredients (see TABLE 9)
- Levels of free formaldehyde by products purchased from DK, EU and non-EU (see TABLE 10)
- Levels of free formaldehyde by product type (see TABLE 11)
- Levels of free formaldehyde distributed among products with the different ingredients in focus and PET packaging (see TABLE 12)

In TABLE 9, the total overview of the levels of free formaldehyde in the 150 analysed products is given below. It can be seen that for 112 out of 150 products, corresponding to 75%, no colouring or a very slight colouring of the test solution is observed, corresponding to a level of free formaldehyde apparently below 2.5 ppm. As the CA method is a semi-quantitative method and the reading of the concentration of free formaldehyde is taken on a colour scale, some uncertainty in the method is to be expected (see also section 6.1.3.1 "Uncertainties in the semi-quantitative analysis").

For 14 products, a level of free formaldehyde in the cosmetic product above 100 ppm was identified. Eight of these 14 products (57%) had a formaldehyde releaser (preservative) listed in the list of ingredients. In other words, six products without formaldehyde releaser content, based on the list of ingredients, also had a high content of free formaldehyde above 100 ppm (according to the CA method).

As described in chapter 4, "Products purchased for chemical analysis", 12 of the 150 purchased products with formaldehyde releaser were listed in the list of ingredients. For most of these products (10 out of 12), the screening method measured a level of free formaldehyde of 20 ppm and above.

In addition, there are eight products for which there was no list of ingredients on the products or only a list of ingredients in Chinese, which cannot be deciphered. None of the products contain a formaldehyde releaser, according to the list of ingredients available via the website. However, as the content of ingredients cannot be confirmed via the product itself or its packaging (is lacking in all cases), these eight products are generally excluded from the lists below. These eight products are distributed as follows:

- Six products from non-EU, one product from the EU (list of ingredients is on the label at the bottom, but it is stuck together so well that it cannot be opened and read), and one product from DK
- Three eye creams, two face creams, a hand cream, a self-tanner and a make-up remover

- For four products the content of free formaldehyde is below 2.5 ppm, for one product from 20 ppm and below 40 ppm, for two products from 40 ppm and up to 100 ppm, and for the last product above 100 ppm

For the remaining 130 purchased products with a list of ingredients not showing a formaldehyde releaser, a total of 107 products (representing 82%) appear to contain free formaldehyde at concentrations below 2.5 ppm based on the semi-quantitative results. Of the 130 products, 12 (corresponding to 9%) appear to contain free formaldehyde at concentrations between 2,5 and 10 ppm, five products (corresponding to 4%) appear to contain free formaldehyde at concentrations between 10 and 40 ppm, while a total of six products (corresponding to 5%) appear to contain free formaldehyde at concentrations above 40 ppm. What ingredients these products contain is discussed later in this section.

TABLE 9. Levels of free formaldehyde based on the semi-quantitative analysis (CA method) for the 150 cosmetic products studied

Free formaldehyde/product category (total number)	< 2.5 ppm	2.5 ≤ x < 5 ppm	5 ≤ x < 10 ppm	10 ≤ x < 20 ppm	20 ≤ x < 40 ppm	40 ≤ x < 100 ppm	≥ 100 ppm	Number > 2.5 ppm (% of total number)
Total products (150)	112	10	3	4	3	4	14	**38 (25%)**
Products with formaldehyde releaser* (12)	1	1	0	0	1	1	8	**11 (92%)**
Products without list of ingredients (8)	4	0	0	0	1	2	1	**4 (50%)**
Products with list of ingredients and without formaldehyde releaser* (130)	107	9	3	4	1	1	5	**23 (18%)**

* The information is based on the list of ingredients on the product

In TABLE 10 below, the 130 cosmetic products without known formaldehyde releaser are divided into products purchased in DK, in the EU and outside the EU (NEU). It should be noted that the designation only indicates where the products were purchased (websites belonging to Denmark, the EU or outside the EU) and not where the products were produced.

The results of TABLE 10 do not suggest that a higher percentage of products purchased outside the EU (non-EU) emit formaldehyde than products purchased in DK and the EU. However, this is mainly because four products from non-EU with a formaldehyde release above 2.5 ppm are not included in the statement below, as it cannot be confirmed whether they contain formaldehyde releaser or not due to a lack of a list of ingredients. According to the list of ingredients on the website, they did not. In that case, 36% of the products (10 out of 28) from non-EU would release formaldehyde above 2.5 ppm and thus represent a higher percentage of the products than products purchased in the EU and DK.

TABLE 10. Levels of free formaldehyde by region of purchase. The table includes only products without formaldehyde releaser. Product numbers as a percentage of the 130 products without formaldehyde releaser are given in brackets below the actual number.

Free formaldehyde (total number)	< 2.5 ppm	2.5 ≤ x < 5 ppm	5 ≤ x < 10 ppm	10 ≤ x < 20 ppm	20 ≤ x < 40 ppm	40 ≤ x < 100 ppm	≥ 100 ppm	Number > 2.5 ppm (% of total number)
Products with list of ingredients without formaldehyde releaser* (130)	107	9	3	4	1	1	5	**23 (18%)**
Products bought in DK (71)	58	4	1	3	1	1	3	**13 (18%)**
Products bought in the EU (31)	26	3	1	1	0	0	0	**5 (16%)**
Products purchased in non-EU (28)	23	2	1	0	0	0	2	**5 (18%)**

* The information is based on the list of ingredients on the product

In TABLE 11 below, the 130 products with list of ingredients and without formaldehyde releaser are divided by product type. From this, it can be seen that for a few products (one to three) within each product type, a content of free formaldehyde above 2.5 ppm was found. However, this does not apply to self-tanners, where 14 products out of a total of 20 self-tanner have a measured content of free formaldehyde above 2.5 ppm. Thus, self-tanners are clearly over-represented as products that emit free formaldehyde but do not contain a formaldehyde releaser. As indicated in TABLE 9, a total of 23 products (out of 130 products with list of ingredients and without a content of formaldehyde releaser) with a free formaldehyde content above 2.5 ppm have been identified. Of these 23 products, 14 are self-tanners (corresponding to 61%).

For eye creams, three products contain higher concentrations of free formaldehyde. Two of the products emit concentrations above 100 ppm formaldehyde. These involve a product purchased in Denmark and a product purchased outside the EU.

TABLE 11. Levels of free formaldehyde distributed among the seven product types studied.

Free formaldehyde (total number)	< 2.5 ppm	2.5 ≤ x < 5 ppm	5 ≤ x < 10 ppm	10 ≤ x < 20 ppm	20 ≤ x < 40 ppm	40 ≤ x < 100 ppm	≥ 100 ppm	Number > 2.5 ppm (% of total number)
Face cream (17)	16	1	0	0	0	0	0	**1 (6%)**
Body Lotion (19)	17	2	0	0	0	0	0	**2 (11%)**
Hand cream (18)	17	1	0	0	0	0	0	**1 (6%)**

Free formaldehyde (total number)	< 2.5 ppm	2.5 ≤ x < 5 ppm	5 ≤ x < 10 ppm	10 ≤ x < 20 ppm	20 ≤ x < 40 ppm	40 ≤ x < 100 ppm	≥ 100 ppm	Number > 2.5 ppm (% of total number)
Make-up remover (17)	16	0	0	0	0	0	1	**1 (6%)**
Self-tanner (20)	6	4	2	4	1	1	2	**14 (70%)**
Skin tonic (22)	21	1	0	0	0	0	0	**1 (5%)**
Eye cream (17)	14	0	1	0	0	0	2	**3 (18%)**
Total (130)	**107**	**9**	**3**	**4**	**1**	**1**	**5**	**23 (18%)**

In TABLE 12, the 130 products with list of ingredients and without formaldehyde releaser are divided according to which of the five focus substances they contain. The number of products with the measured content of free formaldehyde both with and without the ingredient is listed. The table should be read in the sense that for each row in the table, the 130 products for each of the five focus substances are divided according to how many products contain that ingredient and how many do not. For example, the 130 products are divided into 113 products that contain glycerine ("with") and 17 products that do not contain glycerine ("without"). The measured levels of free formaldehyde, divided into ranges according to the CA method, are listed in each column.

As seen in TABLE 12, there is no clear correlation between measured concentrations of free formaldehyde and products with and without glycerine. A total of six of the products containing glycerine contain free formaldehyde in concentrations above 40 ppm, but this may be due to other ingredients as glycerine is present in a large number of products. In total, 122 of the 150 cosmetic products purchased contain glycerine.

Similarly, for the ingredients polysorbate 80 and PEG compounds, there is no clear correlation between measured concentrations of free formaldehyde and products with and without these ingredients.

However, there seems to be a trend for the ingredient DHA (dihydroxyacetone), which is used exclusively in self-tanners. In total, 14 out of 19 products (corresponding to 74%) containing DHA contain free formaldehyde at concentrations above 2.5 ppm, whereas 9 out of 111 products (corresponding to 8%) of those without DHA contain free formaldehyde at concentrations above 2.5 ppm. Thus, products with content of DHA seem to be overrepresented amongst products that emit free formaldehyde but do not contain a formaldehyde releaser.

For cocamidopropyl betaine (denoted as CB in the table), the results for the products without a formaldehyde releaser in the list of ingredients indicate that there is an immediate overrepresentation of products with cocamidopropyl betaine containing free formaldehyde compared to products not containing this ingredient. However, it should be noted that, in general, it is difficult to identify a clear pattern, as only nine of the 130 products contain this ingredient. Another important point is that for the nine products with cocamidopropyl betaine, five of them also contain DHA. Four of these five products are products with a content of free formaldehyde above 2.5 ppm. The reason for the overrepresentation of the content of free formaldehyde may therefore be due to the content of DHA rather than to the content of cocamidopropyl betaine.

For the cosmetic products packaged in a PET container, there is no immediate correlation between measured concentrations of free formaldehyde and products with and without PET packaging.

TABLE 12. Levels of free formaldehyde distributed among the products containing ("with") or not containing ("without") the investigated focus substances or having PET packaging. None of the products have a formaldehyde releaser on the list of ingredients. Empty fields mean 0 products in this category.

Free formaldehyde (total number)	< 2.5 ppm	2.5 ≤ x < 5 ppm	5 ≤ x < 10 ppm	10 ≤ x < 20 ppm	20 ≤ x < 40 ppm	40 ≤ x < 100 ppm	≥ 100 ppm	Number > 2.5 ppm (% of total number)
Glycerine								
- with (113)	92	9	2	4		1	5	**21 (19%)**
- without (17)	15		1		1			**2 (12%)**
Polysorbate 80								
- with (29)	25	1	2				1	**4 (14%)**
- without (101)	82	8	1	4	1	1	4	**19 (19%)**
DHA								
- with (19)	5	4	2	4	1	1	2	**14 (74%)**
- without (111)	102	5	1				3	**9 (8%)**
PEG compound								
- with (65)	57	6					2	**8 (12%)**
- without (65)	50	3	3	4	1	1	3	**15 (23%)**
CB*								
- with (9)	4	1		1	1	1	1	**5 (56%)**
- without (121)	103	8	3	3			4	**18 (15%)**
PET packaging								
- with (34)	29	2		1		1	1	**5 (15%)**
- without (96)	78	7	3	3	1		4	**18 (19%)**

* CB stands for cocamidopropyl betaine

For the 23 cosmetic products where a content of free formaldehyde above 2.5 ppm was measured, most products do not specifically state that the products are particularly suitable for dry skin or eczema skin. For two of the 23 products where a free formaldehyde content above 2.5 ppm was measured, the products are labelled as recommended for dry skin. For both products, the content of free formaldehyde has been measured to be between 2.5 and 5 ppm.

6.1.3.1 Uncertainties in the semi-quantitative analysis

The semi-quantitative method is a screening method that makes use of a subjective assessment of a colour intensity. The uncertainty will therefore lie in the estimate of the range, which is expected to differ by plus or minus one concentration interval.

Some samples show a colour other than pink or purple. Some of the samples give a slightly yellowish colour. These samples are not considered to be discoloured. However, samples may be designated as discoloured if they show colours such as orange, reddish or brown.

A known amount of formaldehyde was added to some selected samples. Some of the samples showed a yellow colour in the semi-quantitative analysis, and after the addition of formaldehyde, the purple colour could be clearly seen after this so-called "standard addition".

In total, 22 of the 150 products examined showed discolouration, which is considered to have a possible impact on the reading of the concentration range. These 22 products are distributed in the following concentration ranges (of which a total of 10 of the aforementioned 23 products with formaldehyde concentration above 2.5 ppm):

- 11 products with assessment of < 2.5 ppm free formaldehyde (different product types)
- Six products with assessment of free formaldehyde in the range 2.5 ≤ x < 5 ppm (different product types)
- One product with an assessment of free formaldehyde in the range 5 ≤ x < 10 ppm (self-tanner)
- Two products with assessment of free formaldehyde in the range 10 ≤ x < 20 ppm (self tanners only)
- One product with an assessment of free formaldehyde in the range 20 ≤ x < 40 ppm (self-tanner)
- No products with assessment of free formaldehyde in the range 40 ≤ x < 100 ppm
- One product with an assessment of free formaldehyde in the range ≥ 100 ppm (self-tanner)

Thus, it could suggest that self-tanners, in particular, contain ingredients that can interfere with results. As it is not known with certainty what causes the other deviating colours and whether they influence the result of the semi-quantitative analysis, it would make sense to examine more samples showing discolouration with the quantitative method for the determination of formaldehyde content. The correlation between the semi-quantitative results and the HPLC method can thus also be examined, which can help to assess the uncertainty of the results from the semi-quantitative method compared to the HPLC method. In cooperation with the Danish EPA, it was decided that for all products with a colour change corresponding to a content of free formaldehyde above 2.5 ppm, a quantitative analysis of the content of free formaldehyde was carried out. See further explanation later in the report.

6.1.4 Summary of the results of the semi-quantitative analyses

A total of 150 cosmetic products were purchased, 12 of which contained a formaldehyde releaser according to the list of ingredients. Eight of the purchased products did not contain a list of ingredients and therefore the results from these products are not included in the discussion of the results.

The results show that for the 130 products purchased with a list of ingredients where no formaldehyde releaser is listed, a total of 107 products (82%) contain free formaldehyde at concentrations below 2.5 ppm. The 2.5 ppm is the detection limit of the method, i.e. it is not possible to comment on the concentration of formaldehyde below this concentration. 23 products out of the 130 products (corresponding to 18%) thus contain free formaldehyde in concentrations above 2.5 ppm. Of the 23 products, 11 products (corresponding to 8% of the 130 products) contain free formaldehyde at a concentration above 10 ppm, which is the new adopted limit value for labelling of cosmetic products with the warning "releases formaldehyde".

A review of product types and ingredients shows that among the product type self-tanners, there is a clear overrepresentation of products with a higher content of free formaldehyde compared to the remaining product types. The same is true for the products with the ingredient DHA. This is because the ingredient DHA is used exclusively in self-tanners. These self-tanners were subsequently further investigated by the quantification of free formaldehyde, as several of the self-tanners caused discolouration of the samples in the screening analysis. The trend seen in the screening analysis has thus been investigated by quantitative analysis (see results later).

For the ingredient cocamidopropyl betaine, there are too few products with this ingredient and too much overlap between the content of this ingredient and the content of DHA to conclude definitively on the release of formaldehyde from the ingredient based on the semi-quantitative results.

6.1.5 Selection of products for quantitative analysis

Based on the semi-quantitative results for the content of free formaldehyde, it was decided in cooperation with the Danish EPA to carry out quantitative analyses of the content of free formaldehyde of a total of 30 products, distributed as follows:

- The 23 products with a content of free formaldehyde above 2.5 ppm according to the CA method were selected
- Seven products containing formaldehyde releasers were selected to represent different formaldehyde releasers, different product types and different purchasing points (DK, EU and non-EU)

6.2 Quantitative analysis of free formaldehyde

As described above, it was decided that a total of 30 quantitative analyses for free formaldehyde on the 150 products purchased was to be carried out. Discussion of the method of analysis, description of the chosen analytical method, and the results of the analyses are described below.

6.2.1 Discussion of method of analysis

The EU Directive relating to methods of analysis necessary for checking the composition of cosmetic products[26] specifies two methods for the quantitative determination of formaldehyde in cosmetic products: one for the determination of formaldehyde in products without the presence of formaldehyde releasers, called the colorimetric method, and one used for the determination of formaldehyde in products with formaldehyde releasers, called the chromatographic method.
The colorimetric method is not used for products with formaldehyde releasers, as the determined amount of formaldehyde would correspond to the total amount of formaldehyde, i.e. both free formaldehyde and "bound" formaldehyde from the releasers. The chromatographic method is more selective and determines the free amount of formaldehyde, where the free formaldehyde is first separated chromatographically from the formaldehyde releaser and then reacted with a derivatising reagent (acetylacetone) in a so-called post-column reactor at 80 °C. This converts the free formaldehyde into a UV-active substance that can be measured using a UV detector. As this method requires special equipment which few laboratories have available, in this project another method has been chosen to determine free formaldehyde quantitatively, but still using liquid chromatography to ensure the selectivity of the method.

The proposed analytical method is based on a method described by the German paint and varnish industry. Paints and varnishes also occur as water-based products, and they also contain formaldehyde releasers. The content of formaldehyde in paints and varnishes is also regulated by law.

The method description "VdL-Guideline 03" (VdL-R03) (VdL, 2018) states that free formaldehyde is measured by a colorimetric/photometric method with the reagent acetylacetone. The VdL-R03 method thus uses the same reagent as both the chromatographic and colorimetric methods of the EU Directive (EU Directive relating to methods of analysis necessary for checking the composition of cosmetic products). However, there are differences in implementing the derivatising in the VdL method and the colorimetric method from the EU Directive. In the VdL method, the reagent is added directly to the sample, then diluted with water and the

[26] Commission Directive of 4 April 1990 amending the Second Directive 82/434/EEC on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (EU Directive 90/207/EEC).

sample is left for two hours at room temperature, after which it is centrifuged and the concentration is measured quantitatively by colorimetry/photometry. In the colorimetric method of the EU Directive, the sample is first diluted and then, after the reagent addition, the samples are placed in a hot water bath (60 °C) for 10 minutes and then the dye is extracted into butanol and the sample is quantitatively measured by photometry/colorimetry.

The differences in the analytical methods are listed in TABLE 13 below.

TABLE 13. Differences in the different methods of analysis described. The colorimetric method is not used as it determines total formaldehyde.

Method of analysis	**EU Directive Colorimetric method**	**EU Directive Chromatographic method**	**The VdL-R03 method**	**FORCE's analysis method M2.200**
Type	Colorimetric	Chromatographic (HPLC-UV/VIS)	Colorimetric	Chromatographic (HPLC-UV/VIS)
Purpose	Total formaldehyde (both free and bound)	Free formaldehyde	Free formaldehyde	Free formaldehyde
Derivatising reagent	Acetylacetone in hydrochloric acid (pH 6)	Acetylacetone in diluted 0.002 M hydrochloric acid	Acetylacetone in acetate buffer (pH 4,75)	Acetylacetone in acetate buffer (pH 4,75)
Temperature at derivatisation	60 °C	80 °C	20 °C	20 °C
Detection	Photometry	UV/VIS detector	Photometry	UV/VIS detector
Procedure	Dilution with water Reagent is added Stand for 10 min at 60 °C Extraction with ethanol Quantification by colorimetry/photometry	First, formaldehyde is separated chromatographically and, in a post-column reactor, formaldehyde is derivatised with acetylacetone, which is then measured by UV/VIS detector.	Reagent in acetate buffer is added Dilution with water Stand for two hours at 20 °C Centrifugation Quantification by colorimetry/photometry	Reagent in acetate buffer is added Dilution with water Stand for two hours at 20 °C Centrifugation Quantification by HPLC-UV/VIS

FORCE Technology believes that the different temperatures at derivatisation time of 60 °C and 20 °C respectively means that only the free formaldehyde is derivatised in the VdL method, whereas both the free and bound formaldehyde are derivatised in the colorimetric method of the EU Directive. At the higher temperature, the equilibrium between free formaldehyde and bound formaldehyde is changed, releasing bound formaldehyde from the formaldehyde releaser. Therefore, total formaldehyde is measured by the colorimetric method of the above-mentioned directive and the free formaldehyde from the VdL method, which takes place at a lower temperature (20 ° C).

Based on the above, FORCE Technology believes that the determination of free formaldehyde can be performed either as a colorimetric/photometric determination according to the VdL method or according to a comparable derivatisation method of formaldehyde as in the VdL method (at room temperature with acetylacetone) with a chromatographic HPLC/UV method. A chromatographic method has the advantage that derivatives of other aldehydes, if present, can be separated from the derivative of formaldehyde. On this basis, FORCE Technology has chosen to use the HPLC/UV method and not the VdL method.

The difference between the analytical method used in this project and the method described in the EU Directive relating to methods of analysis necessary for checking the composition of cosmetic products is that derivatisation with acetylacetone is carried out at different times and under different conditions (temperatures). The analytical method used in this project derivatises formaldehyde with acetylacetone at room temperature prior to analysis, whereas the method described in the above-mentioned EU Directive derivatises only after formaldehyde is separated chromatographically in a post-column reactor at 80 °C.

6.2.1.1 Comments from the industry

The above description of the analytical methods was sent to the cosmetics and hygiene industry, which also commented on the above choice of analytical method. The cosmetics and hygiene industry indicate that they disagree with the methodology as they believe it may lead to a significant overestimation of the measured values for free formaldehyde. The cosmetics and hygiene industry states that the above method is not designed for reliable measurements of free formaldehyde in cosmetic matrices.

The cosmetics and hygiene industry points out that for the VdL method it is indicated that the determination of free formaldehyde has limited suitability in matrices containing pigment, as the colour of the sample may in some cases have an effect on the colorimetric/photometric quantification method.

6.2.1.2 Discussion of the industry comments

The cosmetics and hygiene industry indicates that they consider the method not suitable, mainly because it is a different method from the one specified in the EU Directive on methods of analysis for checking the composition of cosmetic products. The remark on the VdL method that pigments can interfere with the measurement is addressed to the paint and varnish industry (as the method was developed for this industry) and not to cosmetics. These are pigments in paints and not in dyes in cosmetics. It would probably only be in sunscreen that pigments (titanium dioxide) could be present, which are also found in paint. However, sunscreens are not included in the purchased products investigated in this project.

In this project, FORCE Technology has chosen to use the same derivatisation as described in the VdL method, but not the analysis method itself, which is photometry. Here HPLC with UV/VIS detection is used instead. This means that it is possible to separate any interfering substances from the analyte, so the presence of any pigments in the cosmetics will not influence the measured amount of formaldehyde.

In general, it should be pointed out that measuring free formaldehyde in cosmetic products is a difficult task. Formaldehyde is a small molecule that is volatile, so it will evaporate relatively easily. The equilibrium between free formaldehyde and the formaldehyde-releasing substance can easily be shifted as soon as the sample is exposed.

The VdL method is specifically designed to measure free formaldehyde in liquid and is a milder derivatisation than that used to determine total formaldehyde concentration, as the sample is not heated but left for two hours at room temperature. According to FORCE Technology, the methodology of the EU Directive on methods of analysis for checking the composition of cosmetic products changes the balance between free and bound formaldehyde. In the method described in the above-mentioned EU Directive, a solution of creams and the like is prepared by adding dichloromethane and hydrochloric acid, shaking and centrifuging the sample, and then purifying the aqueous phase on a solid-phase column. Lotions and shampoos are treated in a different way, where they are simply diluted with a buffer that has a pH of 2.1. Thus, there is a risk that the equilibrium between free formaldehyde and formaldehyde releaser is changed during sample preparation.

FORCE Technology has tested and validated the method in terms of derivatisation time and robustness, which is common practice in chemical analyses. It was shown that the measured amount of formaldehyde in a sample was stable for at least 15 hours after derivatisation. To test the selectivity of the analytical method itself, the method was tested with selected available aldehydes. None of the aldehydes tested gave rise to interference that could be confused with the formaldehyde derivative during the analysis.

The relative expanded uncertainty was calculated to be 16% for a body lotion measured at a free formaldehyde content of 280 ppm and 5% measured for a make-up remover at a free formaldehyde content of 360 ppm.

Standard addition and true blanks were used in each analysis series. In the quantitative analyses, a variation in the recoveries was observed for the standard addition of formaldehyde to different cosmetic products. In other words, the recovery was matrix dependent, which is frequently observed in cosmetic products. Recovery was performed six-fold on spiked samples of DK-56, where recovery was measured at 91-113%, proving the accuracy of the analytical method.

The limit of detection (LOD) of the method was calculated to be 0.06 mg/kg (ppm) and the limit of quantification (LOQ) was calculated to be 0.2 mg/kg. The limit of detection is the limit at which the substance can be identified (seen by the method), whereas the quantification limit is the limit at which it is possible to measure the concentration. The uncertainty of the measurement method is significantly higher in the range 0.2-1 mg/kg where an overestimation of the content of formaldehyde was observed.

6.2.2 Results of the quantitative analyses for the content of free formaldehyde

The results of the quantitative analyses for the content of free formaldehyde in the 30 selected products are given TABLE 14 below. The table covers a total of 31 products, as sample DK-56 was included for standard addition for quality reasons. It should be noted that for some of the products additional analyses have been performed due to major discrepancies between the results of the two single determinations or due to other quality considerations. In addition, 2 x duplicate determinations were performed for four products as part of quality assurance, as low recoveries were observed by standard addition (addition of a known amount of formaldehyde to a sample) in some analytical series (i.e. analyses run simultaneously). In both cases, all results (reported as the average of the performed duplicate determinations) are shown in TABLE 14.

TABLE 14. Results of the quantitative analyses of the content of free formaldehyde in 31 cosmetic products. The values are given in mg/kg which corresponds to the unit ppm. The values are the average of the duplicate determinations.

Lab. no.	Description of the product	Semi-quantitative result (mg/kg)	Result quantitative** (mg/kg)	Comments
DK-32	Face cream With formaldehyde releaser in the list of ingredients[1]	40 ≤ x < 100	75	

Lab. no.	Description of the product	Semi-quantitative result (mg/kg)	Result quantitative** (mg/kg)	Comments
DK-41	Body Lotion With formaldehyde releaser in the list of ingredients[3]	≥ 100	253 289 293 283 283	The product is a so-called body butter. This product was used for the implementation and validation of the method. Therefore 5 x duplicate determinations were performed.
DK-68	Body Lotion With formaldehyde releaser in the list of ingredients[2]	≥ 100	176 208 162	Due to large differences in the analyses performed, 3 x duplicate determinations were made. The combination of the product's density and hydrophobic properties meant that the product was challenging to derivatise properly. Hence a wide variation in results was observed.
EU-5	Face cream With formaldehyde releaser in the list of ingredients[3]	≥ 100	561 611	The product was used for quality assurance between batches, so duplicate determinations were made on two separate days.
EU-108	Self-tanner With formaldehyde releaser in the list of ingredients[4]	≥ 100	300	
NEU-28	Body Lotion With formaldehyde releaser in the list of ingredients[3]	≥ 100	637	
NEU-92	Make-up remover With formaldehyde releaser in the list of ingredients[4]	≥ 100	421 < 4	This product was a two-phase product where it was not possible to take a homogeneous sample. The large difference represents the lower phase (bottom) and the upper phase (top) of the product, respectively. Bottom with highest value.
NEU-159	Eye cream With formaldehyde releaser in the list of ingredients[4]	≥ 100	366 345	The product was used for quality assurance between batches, so duplicate determinations were made on two separate days.
Average: with formaldehyde releaser			355	Average amount of free formaldehyde in the eight products with formaldehyde releaser
DK-56	Hand cream	2.5 ≤ x < 5	0.5	The sample is included for quality reasons. As only a low content of formaldehyde is detected in the sample, it is used for standard addition to an "empty" sample across analytical series.
DK-89	Make-up remover	≥ 100	344 357 361 353 363	This product was used for the implementation and validation of the method. Therefore 5 x duplicate determinations were performed.
DK-107	Self-tanner	≥ 100	210	

Lab. no.	Description of the product	Semi-quantitative result (mg/kg)	Result quantitative** (mg/kg)	Comments
DK-113*	Self-tanner	20 ≤ x < 40	507	
DK-114*	Self-tanner	2.5 ≤ x < 5	22	
DK-115	Self-tanner	10 ≤ x < 20	19	
DK-117	Self-tanner	40 ≤ x < 100	76	
DK-118	Self-tanner	10 ≤ x < 20	69 39 83	Due to large differences in the analyses performed, 3 x duplicate determinations were made. This product is a spray where it was not possible to open the can in any other way without destroying it. Therefore, the sample for analysis is sprayed out, which in itself results in differences in levels.
DK-119*	Self-tanner	2.5 ≤ x < 5	14	
DK-120	Self-tanner	10 ≤ x < 20	14	
DK-122	Self-tanner	2.5 ≤ x < 5	8	
DK-151	Eye cream	5 ≤ x < 10	3	
DK-152	Eye cream	≥ 100	179 204	The product was used for quality assurance between batches, so duplicate determinations were made on two separate days.
EU-11	Face cream	2.5 ≤ x < 5	1	
EU-33	Body Lotion	2.5 ≤ x < 5	1	
EU-102*	Self-tanner	5 ≤ x < 10	28	
EU-103*	Self-tanner	10 ≤ x < 20	103	
EU-137	Skin tonic	2.5 ≤ x < 5	0.5	
NEU-29	Body Lotion	2.5 ≤ x < 5	1	
NEU-104*	Self-tanner	2.5 ≤ x < 5	12	
NEU-111	Self-tanner	≥ 100	529 432	Due to large differences in the analyses performed, 2 x duplicate determinations were made.
NEU-123*	Self-tanner	5 ≤ x < 10	42 36	The product was used for quality assurance between batches, so duplicate determinations were made on two separate days.
NEU-160	Eye cream	≥ 100	262	
Average: without formaldehyde releaser			105	Average amount of free formaldehyde in the 23 products without formaldehyde releaser

1. Contains imidazolidinylurea; 2. Contains sodium hydroxymethylglycinate; 3. Contains diazolidinyl urea; 4. Contains DMDM hydantoin

* for these products, there is more than one scale step difference between the results of the semi-quantitative analysis method and the quantitative analysis method

** Data are reported with higher accuracy than the uncertainty of the method requires. Due to the expanded uncertainty of the analyses, the results of the quantitative analyses should only be reported with two significant digits, i.e. a value of 176 mg/kg, in reality, should be reported as 0.018%. However, the figures are small, so for the sake of clarity, they are reported in mg/kg instead.

The recovery of formaldehyde by standard addition was product-dependent and varied relatively widely between individual products. Thus, in addition to replicates of individual analyses, sample DK-56 (which according to the analyses contains a small amount of free formaldehyde) was included for standard addition as the sample reproducibly gave acceptable recoveries.

As can be seen from the results of NEU-92, a two-phase make-up remover that must be shaken before use, there can be large differences in levels of free formaldehyde when the product is not homogeneous. In addition, for several products, particularly the creams, a tendency was observed for the product not to be completely soluble in the reaction mixture, which gives rise to a greater dispersion of the results in duplicate determinations. This is reflected in a greater expanded uncertainty for the creams.

The results show that in general a content of free formaldehyde between 0.5 and 637 ppm (mg/kg) was determined in the 31 cosmetic products examined. Four of the products contained free formaldehyde above 500 ppm, which is the current limit for labelling the products with the warning "contains formaldehyde". Two of the products contain a formaldehyde releaser, but no formaldehyde releaser is mentioned in the list of ingredients for the other two. It concerns one product bought in the UK, one product bought in the EU and two products bought outside the EU, but all products are produced outside the EU (in respectively, the UK, USA (two) and Russia). None of the products state the warning "contains formaldehyde" on the product label (neither container nor packaging).

For 24 of the 31 products examined, a formaldehyde content above 10 ppm (mg/kg) was identified, which is the new limit value adopted by the EU Commission for the labelling of cosmetic products with a warning about free formaldehyde.

The eight products for which a formaldehyde releaser is listed in the list of ingredients contain between 75 and 637 ppm free formaldehyde (average 355 ppm). In contrast, the remaining 23 cosmetic products analysed without a formaldehyde releaser on the list of ingredients have a content between 0.5 and 529 ppm (average 105 ppm). As expected, the purchased cosmetic products with a formaldehyde releaser on the list of ingredients contain the highest amount of free formaldehyde. However, in total, 24 of the 150 purchased and examined cosmetic products (i.e. 16%) contain free formaldehyde at a concentration above 10 ppm (of which 10 out of 12 with formaldehyde releaser), which is adopted by the EU Commission as a new limit value for labelling with a warning about free formaldehyde in cosmetic products. Out of the 150 products, the 12 purchased products represented 8% with a formaldehyde releaser in the list of ingredients. In other words, the following proportion of the purchased products had a free formaldehyde content above 10 ppm:

- 14 out of 130 products without formaldehyde releaser, corresponding to 11%
- 10 out of 12 products with formaldehyde releaser, corresponding to 83%

As seen in TABLE 14, many of the 30 products analysed are self-tanners containing the ingredient DHA. This suggests that the content of this ingredient may be the cause of a higher likelihood of free formaldehyde (see also section 7.3 "Experiments with ingredients (raw materials) "). However, the quantitative analyses carried out for free formaldehyde show that, excluding products containing formaldehyde releaser and products containing the ingredient DHA, there are still 9 cosmetic products in which a level of free formaldehyde between 0.5 ppm and 356 ppm (average of 90 ppm) has been measured. However, only three products have a free formaldehyde content above 10 ppm. There is no clear pattern for these products. They all contain one or more of the other four focus substances and represent different product categories, with a slight predominance of eye creams (two eye creams and one make-up remover). The make-up remover has the highest free formaldehyde content (356 ppm), and the two eye creams have free formaldehyde values of 191 and 262 ppm respectively.

TABLE 14 contains a column with the results of the semi-quantitative analysis (CA colour reaction method). It can be seen that there is a fair correspondence between the results of this semi-quantitative method and the quantitative method of analysis if it is taken into account that the uncertainty of the colour reaction method (the semi-quantitative method) is a range with respect to the reading of the correct colour scale. However, there are eight products that stand out with a greater difference. These are:

- Products with a content < 20 ppm with the CA method
  - DK-114, DK-119 and NEU-104 – a content of 22, 14 and 12 ppm has been identified here, but the color reaction method indicated a content of between 2.5 and 5 ppm
  - EU-102 and NEU-123 – a content of 28 and 36/42 ppm has been identified here, but the colour reaction method indicated a content of between 5 and 10 ppm
- Products with a content > 20 ppm with the CA method
  - DK-113 – a content above 500 ppm has been identified here, but the colour reaction method indicated a content between 20 and 40 ppm
  - EU-103 – a content of 103 ppm has been identified here, but the colour reaction method indicated a content of between 10 and 20 ppm

However, it is mainly the latter two products where there is a significant difference (more than a factor of 10) in the results of the two analytical methods. All of the above products are self-tanners, which can be coloured themselves. For the vast majority of self-tanners, a discolouration of the solution was observed with the semi-quantitative method, which was so strong that it made it difficult to read the colour in relation to the colour range correctly. Thus, the CA method (the semi-quantitative method) gives immediately reasonable results compared with the results of the quantitative method of analysis, as long as there is no severe discolouration of the liquid from which the colour is to be read (see FIGURE 1and FIGURE 2). It must be emphasized that for about 50% of the analysed self-tanners there is a good correlation between the results of the CA-method and the quantitative method of analysis. However, the quantitative method has a lower detection limit than the semi-quantitative method of analysis, so it is possible that there are levels that are not detected by the semi-quantitative method.

6.3 Main results of the chemical analyses

A semi-quantitative analysis of the content of free formaldehyde in all 150 purchased cosmetic products was conducted. Of these, 12 products contained a formaldehyde releaser according to the list of ingredients and eight products did not have a list of ingredients, therefore these products are not included in the discussion of the results. The results for the 130 products purchased with a list of ingredients but without a formaldehyde releaser according to the list of ingredients showed that:

- 107 products (82%) contained free formaldehyde below 2.5 ppm (detection limit of the semi-quantitative method)
- 23 products (18%) contained free formaldehyde at concentrations above 2.5 ppm, of which 11 products (8% of the 130 products) contained free formaldehyde above 10 ppm, which is the new limit value for labelling with a warning of free formaldehyde, which has been adopted by the EU Commission

A review of product types and ingredients showed that among the product type self-tanners and for the ingredient DHA (this is only present in self-tanners), there is a clear overrepresentation of products with a content of free formaldehyde compared to the remaining product types.

All 23 products without a formaldehyde releaser in the list of ingredients and with a free formaldehyde content above 2.5 ppm according to the semi-quantitative analysis were analysed quantitatively for formaldehyde. In addition, eight products containing formaldehyde releaser according to the list of ingredients were analysed quantitatively. The results showed that:

- The 31 products had a content of free formaldehyde between 0.5 and 637 ppm, of which four products had a content of free formaldehyde above 500 ppm. The distribution between products with and without formaldehyde releaser on the list of ingredients was:
  - With: 8 products with a content of free formaldehyde between 75 and 637 ppm (average of 355 ppm)
  - Without: 23 products with a content of free formaldehyde between 0,5 and 507 ppm (average of 105 ppm)
- Of these, 24 of the 31 products had a free formaldehyde content above 10 ppm, which is the new limit value for labelling with a warning about free formaldehyde, which the EU Commission has adopted. The distribution between products with and without formaldehyde releaser on the list of ingredients was:
  - With: 8 out of 8 products had a content of free formaldehyde above 10 ppm
  - Without: 16 out of 23 products had a content of free formaldehyde above 10 ppm

However, it should be noted that only 8 out of the 12 products with a formaldehyde releaser in the list of ingredients were quantitatively analysed for a content of free formaldehyde. Therefore, the above average of 355 ppm is only representative of the eight products analysed.

In TABLE 15 below the overall results of the semi-quantitative analyses for the content of free formaldehyde are compared to where the products were purchased, i.e. via Danish websites/shops (DK), European websites (EU) or websites outside the EU (non-EU). The results reflect the 142 products with a list of ingredients that could be read, i.e. where it is known whether the product contained formaldehyde releaser or not. The results show that there is no immediate difference in the possible content of free formaldehyde in products without a formaldehyde releaser in the list of ingredients for products purchased in the UK, EU and non-EU. For the 12 products with a formaldehyde releaser in the list of ingredients, there is an overrepresentation of products with a content of free formaldehyde purchased in the EU (3 pcs.) and non-EU (5 pcs.) compared to products purchased in DK (3 pcs.). However, this is due to the fact that more products with a formaldehyde releaser from the EU and non-EU have been purchased for this project than from Denmark (when taking into account the otherwise used composition of 50% products from the EU and 25% from the EU and non-EU respectively). This was because it was easier to identify products with a formaldehyde releaser on EU and non-EU websites than on DK websites for the purchased product types.

TABLE 15. Summary of the content of free formaldehyde according to the semi-quantitative CA method in relation to where the products were purchased for the 142 products with a list of ingredients, to determine whether products contained formaldehyde releaser or not

	Number of products purchased	**Content of free formaldehyde (ppm)** (percent of total in parentheses – values are rounded)		
Products bought in	**With or without formaldehyde releaser**	**< 2.5**	**2.5 - 100**	**> 100**
DK	With - 3 (2%) Without - 71 (50%)	0 (0%) 58 (41%)	1 (0.7%) 10 (7%)	2 (1.4%) 3 (2%)
EU	With - 3 (2%) Without - 31 (22%)	0 (0%) 26 (18%)	1 (0.7%) 5 (4%)	2 (1.4%) 0 (0%)
Non-EU	With - 6 (4%) Without - 28 (20%)	1 (0.7%) 23 (16%)	1 (0.7%) 3 (2%)	4 (3%) 2 (1.4%)
Total	**With - 12 (8%)** **Without - 130 (92%)**	**1** (0.7%) **107** (75%)	**3** (2%) **18** (13%)	**8** (6%) **5** (4%)

7. Investigation of ingredients, physico-chemical conditions and packaging

Based on the results of the survey and the results of the quantitative analyses of the content of free formaldehyde in the cosmetic products, it was decided, in co-operation with the Danish EPA, to proceed with a further investigation of certain ingredients, certain physico-chemical conditions and one type of packaging. The aim of the detailed studies was to learn whether specific ingredients or specific physico-chemical conditions can influence the formation of free formaldehyde in cosmetic products. Nevertheless, the quantitative analyses of free formaldehyde in the cosmetic products showed that 10% of the purchased products contained free formaldehyde in concentrations above 10 ppm, even if there is no formaldehyde releaser in the product according to the list of ingredient.

The following ingredients were further investigated in the follow-up chemical analyses (this is described in 7.3 "Experiments with ingredients"):

- DHA (dihydroxyacetone)
- Cocamidopropyl betaine
- Polysorbate 80
- PEG compounds (CAS 25322-68-3)
- Glycerine

In addition, a decision was made to investigate the PET packaging used for cosmetic products to assess whether its possible release of formaldehyde could impact the content of free formaldehyde in cosmetic products. Finally, a decision was made to investigate whether changes in temperature and pH might impact the content of free formaldehyde in cosmetic products. The results of these studies are described below.

7.1 Overall approach to the follow-up studies

PET packaging and the pure raw materials were either purchased online or sourced through cosmetic manufacturers.

Simple tests were performed on the pure raw materials, the raw materials mixed in a cosmetic product (in two different concentrations), and at three different temperatures and pH values. All experiments were performed using the semi-quantitative method (CA method/colour reaction method). If it was found that there was an effect, i.e. a colour reaction, which is consistent with a content of free formaldehyde, quantitative analyses were performed to determine the level of free formaldehyde. The same method of analysis was used as described in chapter 6.2 and duplicate determinations were performed. In terms of budget, a certain number of quantitative analyses of free formaldehyde had been set aside, so in some cases a decision was made as to which quantitative analyses should be carried out as a priority. For several of the experiments, e.g. on the pure raw materials, priority was given to quantitative analyses despite the fact that the semi-quantitative levels were below 2.5 ppm. This was in order to confirm/dismiss the release of formaldehyde.

For the experiments, the purchased cosmetic products were used as the base product, in which the purchased raw materials were mixed. However, the cosmetic products used in the experiments had to comply with the following requirements in order to be selected:

- The result of the semi-quantitative analyses should be no colour change, corresponding to a content of free formaldehyde of less than 2.5 ppm. In other words, the starting point for the mixing product was no colour reaction with the CA method.
- The product purchased had to be purchased in large volume, i.e. it is typically body lotions that are used instead of eye creams, which often contain only 15-30 g in a product. This ensured that we had enough material to carry out all experiments.
- The product in which a raw material was to be mixed should, optimally, not contain the other raw materials or formaldehyde releasers. In other words, when testing cocamidopropyl betaine, tests were performed on a product that already contained this ingredient but none of the other focus substances (glycerine, PEG compound, polysorbate 80 or dihydroxyacetone). However, this was not possible in all cases – especially for glycerine, an ingredient found in over half of the products purchased.
- Cosmetic products were selected in which the raw material is also typically used.

The cosmetic products selected for all the mixing experiments were:
- For DHA, the self-tanner NEU-106 was used, although it also contains glycerine in addition to DHA.
- For cocamidopropyl betaine, the make-up remover EU-79 was used, although it also contains glycerine.
- For polysorbate 80, body lotion DK-43 was used, which does not contain any of the other focus substances.
- For PEG-100 stearate, the face cream NEU-7 was used, although it also contains glycerine.
- For glycerine, the hand cream DK-63 was used, which does not contain any of the other focus substances.
- For the PET packaging experiments, body lotion NEU-30 was used, which of the five focus substances contains only glycerine.

All experiments are described in more detail below. An overview of the tests performed with the raw materials is given in TABLE 16 below. In addition, PET packaging has been tested and is described in the section 7.2.

TABLE 16. Overview of the tests performed for the follow-up studies for the five raw materials (focus substances)

Test	Type analysis for determination of FH	The pure cosmetic product (CP)	15% raw material mixed in CP	30% raw material mixed in CP	100% raw material
At room temperature (approx. 20 °C)	Semi-quantitative	All five raw materials	All five raw materials	All five raw materials	
	Quantitative			Four out of five raw materials *	All five raw materials
At 40 °C	Semi-quantitative			All five raw materials	
	Quantitative	Four out of five raw materials		Four out of five raw materials *	
At 60 °C	Semi-quantitative			All five raw materials	
	Quantitative				
At pH 4	Semi-quantitative			All five raw materials	
	Quantitative			One in five raw materials **	

Test	Type analysis for determination of FH	The pure cosmetic product (CP)	15% raw material mixed in CP	30% raw material mixed in CP	100% raw material
At pH 8.5	Semi-quantitative			All five raw materials	
	Quantitative			One in five raw materials **	

FH = formaldehyde; CP = cosmetic product
Empty green cells mean that tests have not been performed
* For all ingredients except glycerine, quantitative analyses were performed
** Only for DHA, quantitative analyses were performed

7.2 Tests with PET packaging

A decision was made that no experiments should be carried out on the packaging of the purchased cosmetic products, some of which consisted of PET packaging (a total of 34 products). This is because it is not possible to know how long the purchased products have been on the shelves since production, and thus how long migration from PET packaging has potentially taken place. For example, if the product is several months old, any content of free formaldehyde in the PET packaging may already have been released, so a negative result would not necessarily mean that the PET packaging does not release formaldehyde. Therefore, it was decided that new, unused PET packaging should be purchased on which to carry out the experiments.

A total of three different PET packaging materials for cosmetic products were examined. One PET bottle was received from a Danish cosmetics manufacturer, and two other PET containers were purchased over the internet from a website recommended by another cosmetics manufacturer.

There was a discussion as to which types of analyses should be performed on the PET packaging, i.e. whether content analyses should be performed directly on the PET material or migration analyses from the packaging to aqueous/fatty media. As it was impossible within the framework of the project to conduct both content analyses in the packaging and migration analyses, conducting migration analyses was deemed the most appropriate. This was partly to assess whether any migration from the material to the cosmetic product takes place and partly to determine whether it is high enough to cause some of the relatively high levels of free formaldehyde measured in the cosmetic products examined.

The first experiment was the release of formaldehyde to water in PET bottles at 40 °C after two hours. Water was chosen as the content of the PET bottles, as formaldehyde is easily soluble in water. For example, the method of analysis for formaldehyde content in textiles is to extract textiles with a mixture of water and acetylacetone reagent at 40 degrees[27].

For tests with the PET packaging, semi-quantitative analyses were not performed first, as possible formaldehyde release was expected to be low beforehand.

Experiments were conducted under the following conditions and in the following order:

- PET containers filled with water – storage for two hours in an incubator at 40 °C. Analysis made on the water.
- PET containers filled with water – storage for six days in an incubator at 40 °C. Analysis made on the water.
- PET containers filled with NEU-30 (body lotion) – storage for 12 days in an incubator at 40 °C. Analysis made on the body lotion.

[27] DS/EN ISO 14184-1 Textiles - Determination of formaldehyde - Part 1: Free and hydrolysed formaldehyde (aqueous extraction test)

- Blank test with the NEU-30 body lotion alone at both room temperature and after 12 days in a hot store at 40 °C, i.e. without the use of PET packaging. Here, the concentration in the body lotion alone is quantified under the same conditions as for the analyses of the PET containers. This is in order to assess whether any measured amount of formaldehyde originates from the cosmetic product or the PET packaging (i.e. the so-called blank value was measured for the body lotion in question).

NEU-30 was selected to fill the PET packaging since this body lotion of the selected focus substances contained only glycerine and the semi-quantitative analyses measured a content of free formaldehyde < 2.5 ppm. Migration to both water and body lotion was chosen in order to assess the difference in migration to different media.

Tests were performed at 40 °C only, mainly because some of the semi-quantitative analyses showed discolouration of the cosmetic product at 60 °C, and the analysis at 60 °C was therefore not considered to be useful. A temperature of 40 °C is assumed to be a realistic temperature for storage, for example, when sunlight falls on a shelf with a cosmetic product standing in a PET container. Ideally, the experiments should be carried out over several months, even up to a year, in order to be able to comment on formaldehyde residues from PET packaging, which in theory can migrate into the cosmetic product over time. For example, Bach et al. (2012) found formaldehyde in water stored in PET bottles for 170 days. Due to limited time for the experiments, this has not been possible to implement in this project.

One option could be to use heating at 60°C for 10 days, which is considered conditions that meet long-term storage (more than 30 days) in the Regulation on plastic materials and articles intended to come into contact with food (EU Regulation No 10/2011[28]). However, heating at 60 °C was not chosen, partly because some of the semi-quantitative analyses showed discolouration of the cosmetic product itself at this temperature, and partly because it was considered too high a temperature to release any formaldehyde in the cream without the formaldehyde degrading in the cream and subsequently not being measurable in the analysis.

Migration experiments were first performed by storing water in the PET bottles for six days at 40 °C, but without measuring a higher level of free formaldehyde in the water. Water was used initially as it is the medium frequently used in various quantitative analyses of formaldehyde in products (due to the high solubility of formaldehyde in water). Therefore, in the last round of experiments, storage of body lotion NEU-30 in PET bottles for 12 days (the maximum possible number of days for the remaining time period of the project) was carried out.

The results of the quantitative analyses are given below in TABLE 17. Duplicate determinations have been implemented for all analyses. The average of the two single determinations is reported in the table.

[28] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (https://eur-lex.europa.eu/legal-content/DA/TXT/PDF/?uri=CELEX:02011R0010-20200923&qid=1630496240984&from=EN)

TABLE 17. Quantitative analyses of free formaldehyde migrated from PET packaging under different conditions. In all cases, the water/cream that has been in the PET packaging has been analysed.

Material	40 °C for 2 hours Water in packaging (mg/kg)	40 °C for 6 days Water in packaging (mg/kg)	40 °C for 12 days NEU-30 in packaging (mg/kg)
PET-1 125 ml small bottle	< 0.2	< 0.2	0.6
PET-2 250 ml low jar	< 0.2	< 0.2	0.5
PET-1 250 ml high bottle	< 0.2	< 0.2	0.5
Blank values for body lotion NEU-30 alone	-	-	0.5 (40 °C for 12 days) 0.9 (room temperature)

As seen in TABLE 17, only small amounts of free formaldehyde (maximum 1 mg/kg) were measured in the case where a body lotion was used for storage in the PET packaging for 12 days at an elevated temperature of 40 °C. No migration of formaldehyde from any of the PET packaging to water was identified.

Blank samples for body lotion (NEU-30) were performed for comparison, with analysis performed both at room temperature (directly from the container of body lotion) and after 12 days of storage at an elevated temperature of 40 °C. In all cases, the content of free formaldehyde in the body lotion between 0.5 and 1 mg/kg was identified. From these blank samples, it can be seen that the low level of free formaldehyde measured is most likely due to the content of free formaldehyde in the body lotion used and not in the PET packaging. This is because there is no significant difference in the measured content of free formaldehyde in body lotion stored without PET packaging compared to body lotion stored in PET packaging when considering the uncertainty of the measurement results, which is higher in the range near the limit of quantification.

Thus, based on the tests performed with PET packaging, there is no indication that PET packaging alone can be the cause of increased concentrations of free formaldehyde in cosmetic products, which, according to the list of ingredients, do not contain a formaldehyde releaser. However, it should be pointed out that in this project, only a few tests were carried out with a low number of PET packages (three different kinds), that the tests were only conducted for 12 days, and only in one cream. It is possible that a higher migration of free formaldehyde in the cosmetic product could have been identified if long-term storage at room temperature or if elevated temperatures had been tested in several different cosmetic products. On the other hand, if PET packaging is indeed a significant factor in the migration of free formaldehyde, the results reported in TABLE 12 for the semi-quantitative tests on the 150 purchased products should be more conclusive as to the likelihood of the occurrence of a higher level of free formaldehyde for the 34 products consisting of PET packaging. The products purchased here may in fact have been produced several months before purchase, but there is no knowledge of this. This means that the cosmetic product may have been stored in the packaging for several months before purchase, so that any migration of substances from packaging to the product may already have occurred at the time of purchase.

7.3 Experiments with ingredients (raw materials)

Based on the initial semi-quantitative analytical results and an assessment of the results against content with or without the five focus substances, it was decided to proceed with follow-up studies of all five focus substances which, according to the mapping, appear likely to contain or release free formaldehyde. However, on the basis of the results of the semi-quantitative analyses (see TABLE 12), it was mainly dihydroxyacetone (DHA) which led to the conclusion that this ingredient seems to be more likely to cause the presence of free formaldehyde in cosmetic products. The results were not clear-cut for the ingredient cocamidopropyl betaine, as many of the products containing cocamidopropyl betaine also contained DHA.

The follow-up studies with the five ingredients are described in detail below:

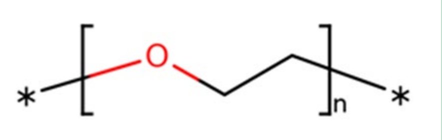
- DHA (dihydroxyacetone) (CAS 96-26-4)
- Cocamidopropyl betaine (CAS 61789-40-0)
- Polysorbate 80 (CAS 9005-65-6)
- PEG-100 stearate (CAS 9004-99-3)
- Glycerin (CAS 56-81-5)

Of the above raw materials, DHA, polysorbate 80 and glycerine were purchased on the internet via raw material suppliers. The focus substance PEG-400 (CAS 25322-68-3), which according to the literature (see section 3.3.1.5 "PEG (polyethylene glycols)"), appears to be capable of releasing formaldehyde, was originally intended to be investigated further. However, it was not possible to purchase either cocamidopropyl betaine or PEG-400. Thus, Danish cosmetics manufacturers were contacted to see if they could send samples for testing. From here the raw material cocamidopropyl betaine was received, but it was not possible to obtain PEG-400.

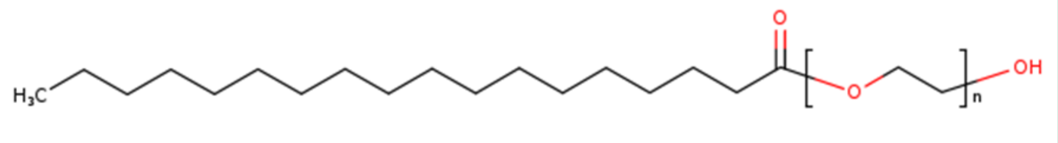
Instead of PEG-400, it was possible to obtain PEG-100-stearate (CAS 9004-99-3) from a Danish cosmetics manufacturer. Therefore, it was decided that the raw material PEG-100 stearate should be investigated instead of PEG-400. This was for several reasons:

- It was available – the alternative would have been not to analyse a PEG compound.
- Structurally it is very similar to PEG-400 (see FIGURE 3), which means that if the release of formaldehyde occurs due to e.g. oxidation, it could also occur in PEG-100 stearate.
- Several of the 150 products purchased contained precisely PEG-100 stearate as a PEG compound, i.e. it is also a PEG compound used in cosmetic products today.

The structure of the two different PEG compounds is given below in FIGURE 3. As described in section 3.3.1.5 "PEG (polyethylene glycols)", PEG compounds in general are reported to be able to release formaldehyde, but it is in particular the PEG-400 compound where experiments have been performed that confirm this. PEG-100 stearate contains the same "building blocks" as PEG-400 and in addition a long carbon chain (the stearate part).



PEG-400 (* means organic chain with carbon and hydrogen of unknown length)



PEG-100 stearate

FIGURE 3. The chemical structure of respectively PEG-400 and PEG-100 stearate according to ChemID-plus

The following experiments were conducted for the five focus substances:

1. Semi-quantitative analysis of free formaldehyde in a cosmetic product with 15% of the raw material mixed in.
2. Semi-quantitative analysis of free formaldehyde in a cosmetic product with 30% of the raw material mixed in.

As described earlier, specific cosmetic products were selected for these analyses, which did not include the four of the five raw materials other than the raw material of focus in the experiment. This approach was chosen in order to avoid that other ingredients influenced the result for the level of free formaldehyde. The results of the semi-quantitative analyses were that no colour change was observed, which means a level of free formaldehyde below 2.5 ppm (mg/kg) for all products added with one of the five focus substances. The results are given in TABLE 18 below.

TABLE 18. Semi-quantitative analyses of free formaldehyde in selected cosmetic products with 15% and 30% of the raw material mixed in, respectively

Raw material	15% of raw material mixed in cosmetic product (mg/kg)	30% of raw material mixed in cosmetic product (mg/kg)
DHA (mixed in the face cream) NEU-106)	< 2.5	< 2.5
Cocamidopropyl betaine (mixed in the make-up remover EU-79)	< 2.5	< 2.5
Polysorbate 80 (mixed in body lotion DK-43)	< 2.5	< 2.5
PEG-100 stearate (mixed in the face cream NEU-7)	< 2.5	< 2.5
Glycerine (mixed in the hand cream DK-63)	< 2.5	< 2.5

Given that free formaldehyde could not be detected in the semi-quantitative analyses, a decision was made to conduct the following tests, in which quantitative analyses of free formaldehyde were carried out instead, since the quantitative method can detect formaldehyde in concentrations 10 times lower than in the semi-quantitative method:

1. Quantitative analysis of free formaldehyde in the raw material alone (100% raw material).
2. Quantitative analysis of free formaldehyde in a cosmetic product with 30% of the raw material mixed in.

For test No 2, where the raw material is mixed into a cosmetic product, this mixing was carried out at room temperature, and a quantitative analysis was performed immediately after mixing.

However, for glycerine, where no content of free formaldehyde was identified in the pure raw material, no quantitative tests were performed with the ingredient mixed in a cosmetic product. The results of the quantitative analyses are given in TABLE 19 below.

TABLE 19. Quantitative analyses of free formaldehyde in the five raw materials – both pure and as a 30% mixture in a cosmetic product

Raw material	100% pure raw material (mg/kg)	30% raw material mixed in cosmetic product, room temperature (mg/kg)
DHA	291	16 (mixed in the face cream NEU-106)
Cocamidopropyl betaine	0.5	1 (mixed in make-up remover EU-79)
Polysorbate 80	3	1 (mixed in body lotion DK-43)
PEG-100 stearate	1	1 (mixed in the face cream NEU-7)
Glycerine	< 0.5	Not conducted quantitatively

As seen in TABLE 19, it is only for DHA that a high content of free formaldehyde was identified in the pure raw material. The raw material was purchased online from raw materials supplier. The measured content is significantly higher than the levels of free formaldehyde listed in DHA raw materials by SCCS/1612/19 (< 50 mg/kg). No free formaldehyde was identified for glycerine as pure raw material, and only low levels just above the quantification limit were identified in the pure raw material for cocamidopropyl betaine. For polysorbate and PEG-100 stearate, only a small content of free formaldehyde (3 and 1 mg/kg, respectively) is observed in the pure raw material.

None of the ingredients are used 100% in a cosmetic product, i.e. detected concentrations of free formaldehyde will be lower (due to dilution) in the final cosmetic product. Tests were performed with 30% of the raw material mixed in a cosmetic product to assess whether the complex matrix of a cosmetic product has any influence on the release of formaldehyde. The concentration of 30% was chosen to avoid too much dilution so that there was something to measure, well aware that few ingredients in cosmetic products are used in this high concentration. These tests were carried out on the four raw materials – glycerine excluded.

When mixing the four raw materials in a 30% concentration in a cosmetic product, it can be seen that for three of the raw materials (cocamidopropyl betaine, polysorbate 80 and PEG-100 stearate), a content of free formaldehyde of 1 mg/kg was measured. These pure cosmetic products have not been subjected to blank tests, as this low content is not necessarily due to the raw material but may be due to the cosmetic product itself without mixing the tested raw material. For DHA, a decrease from 291 mg/kg to 16 mg/kg is observed in the pure raw material to a 30% mixture in a cosmetic product. This decrease is far greater than an approximately 3 x dilution can explain.

There is thus some evidence that the pure raw material DHA contains or releases free formaldehyde, but that this is not necessarily so pronounced when it is incorporated into a cosmetic product. For example, different antioxidants may have been added to the cosmetic product, or different conditions such as pH and temperature may have an impact on the possible content of free formaldehyde as described in the survey. This is also supported by the fact that a variation in recoveries was observed for the standard addition of formaldehyde to different products in the quantitative analyses.

7.4 Tests with temperature

Experiments with temperature were conducted where the five raw materials were mixed at a concentration of 30% in a selected cosmetic product (the same cosmetic product for the specific raw material as previously analysed). The high added concentration of the raw material was deliberately chosen in the hope of detecting free formaldehyde in the semi-quantitative method of analysis.

Tests were performed at temperatures of 40 °C and 60 °C for all five raw materials mixed in the selected cosmetic products. Since the semi-quantitative method must be left for two days before reading the result, all samples were left at the specific temperature for two days. The results of the semi-quantitative analyses for free formaldehyde are given in TABLE 20 below.

TABLE 20. Semi-quantitative analysis of free formaldehyde in a selected cosmetic product with 30% of the raw material mixed in at temperatures of 40 °C and 60 °C

Raw material	30% raw material mixed in cosmetic product, 40 °C for 2 days (mg/kg)	30% raw material mixed in cosmetic product, 60 °C for 2 days (mg/kg)
DHA (mixed in the face cream NEU-106)	$2.5 \leq x < 5$ (sample discoloured - reddish)	$2.5 \leq x < 5$ (sample discoloured - clearly reddish)
Cocamidopropyl betaine (mixed in make-up remover EU-79)	< 2.5 (appears slightly purple, but < 2.5)	< 2.5 (discolored)
Polysorbate 80 (mixed in body lotion DK-43)	< 2.5 (slightly discoloured)	< 2.5 (slightly discoloured)
PEG-100 stearate (mixed in the face cream NEU-7)	< 2.5 (discolored)	< 2.5 (discolored)
Glycerine (mixed in the hand cream DK-63)	< 2.5	< 2.5 (discolored)

The results showed that a release of formaldehyde apparently occurred when DHA was heated. However, a clear discolouration of a reddish and brownish colour took place for many of the samples. Especially for the heating at 60 °C, the results were not clear, as also the cosmetic product for all five products changed a lot (turned brown) with the intense heating at 60 ° C. For this reason, a decision was made to proceed with quantitative analyses at 40 °C, as this is also considered to be a more realistic storage temperature for cosmetic products during specific periods (e.g. in a solar-heated room, a hot car, or heated because sun rays fall on the product on the shelf).

Quantitative analyses were only performed for four of the raw materials (glycerine excluded), as no free formaldehyde was observed due to heating when using glycerine as a raw material. The opt-out was also justified in the previous results with glycerine.

The results of the quantitative analyses for free formaldehyde are given in TABLE 21 below.

TABLE 21. Quantitative analyses of free formaldehyde in the five cosmetic products with and without mixing of the five raw materials at a concentration of 30% after heating to 40 °C for 7 days

Raw material	The cosmetic product without mixing of raw material heated at 40 °C for 7 days (mg/kg)	30% raw material mixed in cosmetic product heated at 40 °C for 7 days (mg/kg)
DHA	3	2 (mixed in the face cream NEU-106)
Cocamidopropyl betaine	2	1 (mixed in make-up remover EU-79)
Polysorbate 80	0.4	1 (mixed in body lotion DK-43)
PEG-100 stearate	0.5	4 (mixed in the face cream NEU-7)
Glycerine	Not conducted quantitatively	Not conducted quantitatively

From the quantitative analytical results for free formaldehyde content, it can be seen that heating to 40 °C may have a small effect on the release of free formaldehyde for PEG-100 stearate. However, the quantities are always small and it is difficult to draw conclusions from the low concentrations, given the uncertainties in the analyses. Furthermore, these low concentrations may not be seen when using lower (and more realistic) concentrations of the focus substances used in cosmetic products.

For the experiments with the ingredient DHA a content of free formaldehyde of 2 mg/kg was measured for 30% raw material mixed in a cosmetic product and stored at 40 °C for seven days (TABLE 21). In comparison 16 mg/kg of free formaldehyde (see TABLE 19) was measured for the same ratio between raw material and cosmetic product directly after mixing, without heating. The same value of 16 mg/kg of free formaldehyde was also measured by adjusting the pH value to 8.5 (see TABLE 23). This indicates that formaldehyde is being degraded or possibly reacting with the ingredients in the face cream.

7.5 Tests with pH-value

According to the results of the survey, the pH value may have an influence on the release of free formaldehyde (see e.g. section 3.3.3 "Relevant physical/chemical factors in relation to release"). Follow-up tests were therefore performed with the different focus substances mixed in cosmetic products at different pH values.

According to Proksch (2018), the pH of human skin is somewhere between 4.1 and 5.8, with an average of 4.9. In comparison, according to a study by Won Kim et al. (2020), the pH of cosmetic products ranges from about 4.5 to 6.7 for products such as creams, whereas cleansing products can have much higher pH values, e.g. up to pH 11.

A decision was made to test at two different pH values in addition to the mixture's own pH value. Adjustments were made to about pH 4 and about pH 8.5 to see any differences in both acidic and alkaline environments. These two pH values were chosen as they represent the extremes in pH for the products investigated in this project.

A 30% mixture of the five focus substances was carried out in the same cosmetic products as in the previous analyses described in this chapter, and the pH value was measured in the mixture itself, as well as at pH adjusted to approximately 4 and 8.5, respectively. The pH was adjusted by adding dilute hydrochloric acid and sodium hydroxide, respectively. Semi-quantitative analyses were then performed with the CA method to assess any change in the content of free formaldehyde. The results of the semi-quantitative analyses are reported in TABLE 22 below.

TABLE 22. Semi-quantitative results for free formaldehyde (FH) in cosmetic products added to the five raw materials at different pH values. All tests were carried out at room temperature (approx. 20 °C).

Focus substance/raw material	pH value of the pure cosmetic product	Mixture of 30% raw material and cosmetic product (mg/kg)	Mixture of 30% raw material and cosmetic product adjusted to about pH 4 (mg/kg)	Mixture of 30% raw material and cosmetic product adjusted to about pH 8.5 (mg/kg)
DHA (mixed in face cream NEU-106)	pH = 4.4	FH < 2.5 pH = 3.8	FH < 2.5 Possibly weak colour, but < 2.5 pH = 4.0	FH < 2.5 Possibly weak colour, but < 2.5 pH = 8.4
Cocamidopropyl betaine (mixed in make-up remover EU-79)	pH = 8.5	FH < 2.5 pH = 8.1	FH < 2.5 pH = 7.2 It was not possible to adjust the pH further, possibly due to the presence of strong buffer in the product	FH < 2.5 pH = 8.5 It was not possible to adjust the pH further, possibly due to the presence of strong buffer in the product
Polysorbate 80 (mixed in body lotion DK-43)	pH = 7.2	FH < 2.5 pH = 7.0	FH < 2.5 pH = 4.1	FH < 2.5 pH = 8.6
PEG-100 stearate (mixed in the face cream NEU-7)	pH = 5.1	FH < 2.5 pH = 4.5	FH < 2.5 pH = 4.0	FH < 2.5 pH = 8.6
Glycerine (mixed in the hand cream DK-63)	pH = 4.8	FH < 2.5 pH = 4.8	FH < 2.5 pH = 4.0	FH < 2.5 pH = 8.5

As seen in TABLE 22, all the tests with the different pH values showed a content of free formaldehyde below 2,5 mg/kg (ppm), regardless of whether the raw material was added and regardless of the pH value (i.e. irrespective of the pH value of the product itself or the pH value adjusted to about 4 or about 8.5). However, for the make-up remover (EU-79) in which the raw material cocamidopropyl betaine was tested, it was not possible to adjust the pH very much (only between 7.2 and 8.5), as this cosmetic product contained a strong buffer which did not allow a change of pH despite the addition of large amounts of acid or base.

The only raw material where there appeared to be a minimal colour change was for DHA. Still, the colour change was immediately so small that the concentration of free formaldehyde would be below 2.5 mg/kg according to the colour scale reading. However, the cosmetic product containing the raw material DHA was coloured, making it difficult to read a faint colour on the colour scale. Based on these experiments and knowing that semi-quantitative results are challenging to assess for self-tanners, quantitative analyses of free formaldehyde were performed only in the product NEU-106 with 30% DHA mixed in, adjusted to pH 4 and pH 8.5, respectively. The results of these quantitative analyses are given in TABLE 23 below.

TABLE 23. Quantitative analysis of free formaldehyde in cosmetic product with 30% DHA at pH ca. 4 and pH ca. 8.5

Raw material	30% raw material mixed in the cosmetic product at pH 4 (mg/kg)	30% raw material mixed in the cosmetic product at pH 8.5 (mg/kg)
DHA (mixed in the face cream NEU-106)	1	16

As seen in TABLE 23, a slightly alkaline pH (here 8.5) seems to lead to a higher release of free formaldehyde, even though the concentration of free formaldehyde is limited. This is consistent with observations in the literature, where several sources indicate that it is true for most formaldehyde releasers to release larger amounts of formaldehyde in alkaline environments (Latorre et al., 2011; Kajimura et al., 2008). The results of the quantitative analyses differ from the semi-quantitative analyses, which may be due to the colouring of the cosmetic product itself, which gives higher uncertainties in the reading of a colour on a colour scale with the semi-quantitative method. The former remarks regarding the correlation between the semi-quantitative and the quantitative method of analysis illustrate that for about half of the products with a content of DHA, a good correlation between the results of the two methods of analysis is found. In other words. the measured values from the two methods are close to each other.

7.6 Discussion and conclusion of the investigation of ingredients, physico-chemical conditions and packaging

The analyses carried out in this report have shown that cosmetic products without a formaldehyde releaser in the list of ingredients exist, but still contain free formaldehyde and even in some cases in significant amounts close to or above the existing limits of 500 ppm for requirements on labelling of formaldehyde content warnings.

Investigations of ingredients show that the ingredient dihydroxyacetone (DHA) stands out from the other focus substances studied, as the pure raw material has a relatively high content of free formaldehyde of 291 ppm. When mixed in a cosmetic product, the free formaldehyde content decreases more than the "dilution" used in the mixing, suggesting that ingredients such as antioxidants or other conditions in the cosmetic product may help prevent the formation of free formaldehyde.

However, the analyses carried out in this project indicate that the content of DHA in cosmetic products may seem to be the cause of a higher likelihood of the presence of free formaldehyde. Of the 30 cosmetic products analysed quantitatively for the content of free formaldehyde (because of high concentrations measured by the semi-quantitative method), 14 contained DHA, and all of these were self-tanners.

Excluding products containing formaldehyde releaser and products containing the ingredient DHA, there are still three cosmetic products where the free formaldehyde content is above 10 ppm. For these three products there is no clear pattern in relation to a possible explanation for the high content of free formaldehyde. They all contain one or more of the five focus substances. A make-up remover has the highest content of free formaldehyde (356 ppm) and two eye creams with a content of free formaldehyde of 191 and 262 ppm, respectively.

The tests carried out on the PET packaging did not show any evidence that PET packaging could be the cause of the relatively high concentrations of free formaldehyde observed in some cosmetic products without added formaldehyde releaser and without the content of DHA. For the three products mentioned above with a content of free formaldehyde above 10 ppm and without formaldehyde releaser or DHA, only the make-up remover is stored in PET packaging. The other cosmetic products are either packaged in glass or in ordinary plastic (PP or PE). However, it is not known whether more extended storage (half to full years) in PET packaging could have an impact on the release of higher amounts of free formaldehyde. This would need to be further investigated.

Other types of plastic packaging mentioned in the survey are, according to the industry in both Denmark and the EU, not very common and are probably not the cause of free formaldehyde in the three products mentioned above. The survey also identified that tubes coated with a melamine formaldehyde coating could possibly be the cause of free formaldehyde in creams (Goon et al., 2003). One-third of the cosmetic products surveyed are packaged in some kind of a tube. Furthermore, the semi-quantitative analyses show that for 74% of the products in tubes, no content of free formaldehyde was identified (< 2.5 ppm), and for 86% of the products in tubes, the free formaldehyde content was below 10 ppm.

In order to investigate whether the packaging material could be the cause of the identified content of free formaldehyde (above 10 ppm) in the three products that neither contain a formaldehyde-releaser nor DHA, it was decided to examine the packaging material more closely for these three products. These investigations are described in more details in chapter 8 “Follow-up studies”.

The experiments carried out with raw materials along with temperature and pH do not give a clear answer as to what the explanation for the content of free formaldehyde in products without DHA may be. There is no evidence to suggest that the other investigated raw materials may be the cause of the relatively high levels of free formaldehyde identified. However, the results of the follow-up studies show that an alkaline pH seems to lead to an increased release of formaldehyde. A make-up remover tested in the experiments was found to have a pH value around 8. If the make-up remover mentioned above (without a content of DHA and a content of formaldehyde releaser, but with a content of free formaldehyde of 356 ppm) has the same pH value, this may be a contributing factor to the high content of free formaldehyde, but it may not be the whole explanation. Resolving this will require further investigation.

Kimyon et al. (2021) indicate that one explanation for an otherwise unexplained formaldehyde content may be the release of formaldehyde from botanical (natural) ingredients. However, these issues have not been further investigated in this project.

8. Follow-up studies

When disregarding products containing a formaldehyde-releaser and DHA according to the list of ingredients, three products still contain free formaldehyde above 10 ppm, which is the new limit value adopted by the EU Commission for labelling of cosmetic products with a warning of release of formaldehyde (EU Regulation 1181, 2022). For these three products, no clear pattern was seen, regarding an explanation of the high content of free formaldehyde being measured in the products. All three products contain one or more of the five focus substances. For this reason, it was decided to carry out a range of follow-up investigations, primarily of the packaging material of these products, in order to investigate whether the packaging material could be a possible cause to the identified content of formaldehyde in these three products.

The follow-up studies listed below were carried out for one or more of the three products, and are described in detail below:

- Contact to the producers of the three products
- Investigation of the packaging material of the products by use of microscope and FTIR[29]
- Review of the ingredients of the products
- Migration analyses of packaging material received from the producers

8.1 Contact to the producers of the three products

The three products without content of neither a formaldehyde-releaser nor the ingredient DHA, but with a measured content of free formaldehyde above 10 ppm, are:

- DK-89 (make-up remover in PET container) – 356 ppm free formaldehyde was measured
- DK-152 (eye cream in plastic container of unknown type) – 191 ppm free formaldehyde was measured
- NEU-160 (eye cream in plastic container of unknown type) – 262 ppm free formaldehyde was measured

The producer of each of the three products was contacted. Two were American producers and one was a European producer. It was possible to get in contact with two of the three producers, but only one of the producers (DK-152) agreed to ship empty product containers for chemical analysis. For this reason, migration analyses only for this packaging material of this product have been carried out (see section 8.4 "Migration analyses of packaging material of DK-152").

The producer of DK-152 informed that their container material consists of PP with some minor parts in PE. This means that this container consists of the same material as many other containers used for cosmetic products (see section 3.3.2.1).

8.2 Microscopy and FTIR analysis of packaging material

The producer of the product DK-152 shipped both empty containers for analysis and information regarding the packaging material used in the container. For this reason, it was decided that the packaging material for the two other products should be examined by use of microscopy and FTIR analysis in order to identify the used materials. The containers were emptied (the cosmetic content removed), cut open and analysed by use of FTIR and microscope. The examinations showed the following results:

[29] FTIR analysis stands for Fourier-transform infrared spectroscopy and is an analysis that can be used for identification of materials, as the obtained spectrum can be compared with spectra from a reference library.

- The packaging material of DK-89 consists of a screw cap consisting of PP with a pad of polystyrene (PS) in the cap. The actual container of DK-89 consists of a coloured, but transparent PET or copolymer[30] of PET[31]. A plastic film is on the inside of the bottle. This plastic film also consists of PET or a copolymer of PET.
- NEU-160 is a tube that consists of a coloured non-transparent plastic based on a poly(alkylmethacrylate) or a copolymer of a poly(alkylmethacrylate) on the outside. The inside is covered with a plastic film of PE, i.e. the plastic PE film is in contact with the cosmetic product. The screw cap consists of PP.

For the three cosmetic products (DK-89, DK-152 and NEU-160), only well-known plastic types (PET, PP and PE) are in contact with the cosmetic product and used for storage of the cosmetic product. Therefore, the material combination used does not indicate that the packaging material could be the cause of the measured content of free formaldehyde in the three products. However, migration analyses were carried out on the empty containers received for DK-152 (se section 8.4) in order to verify this. Subsequently, it was assessed whether other ingredients in the products could be a source of the measured formaldehyde content.

8.3 Review of ingredients in the products

A review of the ingredients of the three products were performed in order to assess whether some of the other ingredients (than investigated in this report) could be the cause of the measured content of free formaldehyde. In TABLE 24 below it is listed, which of the focus substances that the products contain as well as other ingredients, which could be relevant with regard to a content of free formaldehyde.

TABLE 24. Relevant ingredients in the three products without formaldehyde-releasers or DHA.

Product	DK-89*	DK-152	NEU-160
Product type	Make-up remover	Eye cream	Eye cream
Measured content of free formaldehyde	356 mg/kg	191 mg/kg	262 mg/kg
Packaging material	Bottle of PET with a film of PET on the indside	Bottle primarily consisting of PP (container and cap) Smaller parts in PE	Tube with PE inside in contact with the cosmetic product The outer layer of the tube consists of poly(alkylmethacrylate)
Ingredients in focus (focus substances)	Cocamidopropyl betaine PEG-30 Glycerine	Glycerine PEG-8 Polysorbate 80	Glycerine
Other relevant ingredients	Hydroxyethylcellulose	Disodium EDTA	None identified

* Product DK-89 was selected for this study because of a listed content of DMDM hydatoin (a formaldehyde releaser) according to the web site of purchase. However, according to the list of ingredients on the product, no formaldehyde-releasers are used in the product.

All ingredients in the three products were examined by searching for the name of the ingredients and “formaldehyde” on the internet. For the sake of anonymity of the products, not all ingredients are listed in TABLE 24 above, but only the relevant ingredients.

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[30] A copolymer is a polymer formed by polymerisation of two or more different monomers (Reference: https://plast.dk/det-store-plastleksikon/co-polymer/)

[31] There is no direct match with PET in the FTIR analysis. This means that it is probably a kind of copolymer of PET. The comparison is made by use of existing spectre in the reference library.

The first articles of each search were reviewed in order to assess whether some of the other ingredients than the focus substances investigated in this project could be tied to a possible release or content of free formaldehyde. For NEU-160 no ingredients which seem to be relevant for the release or content of free formaldehyde were identified. However, for the two other products, two ingredients were identified (one ingredient in each of the two products DK-89 and DK-152), which could contain a smaller residue of free formaldehyde in the actual raw material. These two ingredients are described in more detail below.

8.3.1 Hydroxyethylcellulose in DK-89

The make-up remover DK-89 contains hydroxyethylcellulose listed as ingredient number eight out of 20 on the list of ingredients. The main part of the product is water. Ingredients must be listed on the list of ingredients in descending order after their concentration. For this reason, a high concentration of hydroxyethylcellulose is not expected in DK-89.

Safety data sheets for hydroxyethylcellulose as an ingredient in cosmetic products (Dow Chemical Company, 2018; Ashland, 2015), that illustrate that the raw material hydroxyethylcellulose can contain up to 0.1 % (corresponding to 1000 mg/kg) free formaldehyde in the actual raw material were identified. In one of these safety data sheets it is described that hydroxyethylcellulose can decompose (break down) to formaldehyde depending on the temperature, accessibility to air and the presence of other materials (Dow Deutschland, 2021).

If the content of free formaldehyde in the raw material itself is 1000 mg/kg, the product DK-89 must contain about 36% hydroxyethylcellulose if this ingredient is the only source of the measured content of free formaldehyde of 356 mg/kg. Such a high content of hydroxyethylcellulose in a make-up remover, where the main part of the product most likely is water, does not seem to be plausible. However, the content of hydroxyethylcellulose can explain some of the measured content of free formaldehyde. It is not known whether the product DK-89 contains ingredients, which are able to increase the decomposition process of hydroxyethylcellulose to formaldehyde in the product.

8.3.2 Disodium EDTA in DK-152

The eye cream DK-152 contains the ingredient disodium EDTA listed as ingredient number 17 of 30 ingredients. For this reason, only a minor content of disodium EDTA is expected in DK-152.

According to Cosmetic Ingredient Review (CIR, 2002) different EDTA compounds are produced by use of formaldehyde. For this reason, a content of formaldehyde can be present in EDTA ingredients as an impurity. Therefore, the content of formaldehyde must depend on the purity of the used raw material. According to CIR (2002), a content of free formaldehyde of up to 100 mg/kg can be possible in the raw material disodium EDTA.

A content of free formaldehyde in the raw material disodium EDTA of 100 mg/kg, will not be able to explain the measured content of free formaldehyde in DK-152 of 191 mg/kg. Hence, other aspects must be the cause of the identified level of free formaldehyde in the product. However, such other aspects have not been identified in this project.

8.4 Migration analyses of packaging material of DK-152

Empty containers were only received from one of three producers of the three products for which follow-up studies were carried out. For this reason, migration analyses were only conducted on the container (of DK-152) from this one producer.

The migration analyses were generally speaking carried out as described in section 7.2 ”Tests with PET packaging”.Tests were carried out under the conditions listed below, where the free formaldehyde was determined by the method M2.200 of FORCE Technology, which is described in detail in section 6.2 ”Quantitative analysis of free formaldehyde”:

- DK-152 containers filled with water – storage for 6 and 14 days in a hot store at 40 °C. Chemical analysis was conducted on the water.
- DK-152 containers filled with NEU-30 (body lotion) – storage for 14 days in a hot store at 40 °C. Chemical analysis was conducted on body lotion.
- Blank test with the NEU-30 body lotion in a container of glass at both room temperature (corresponding to the content in the body lotion at the start of the test) and after 14 days in a hot store at 40 °C. Here, the concentration in the body lotion alone is quantified under the same conditions as for the analyses of the DK-152 containers. This is in order to assess based on these reference measurements whether any measured amount of formaldehyde originates from the cosmetic product or the DK-152 packaging.

In comparison with the migrations analyses carried out on PET packaging material, a testing time of 14 days has been used instead of 12 days, when testing of the DK-152 packaging material. This was done because it was possible within the time frame of the project. However, no quantification of the level of free formaldehyde was carried out at two hours, as the result of the migration analyses for the PET packaging material did not result in a content of free formaldehyde at this time. TABLE 25 shows the result of the migration analyses for DK-152, which primarily consists of PP.

TABLE 25. Quantitative analyses of free formaldehyde migrated from DK-152 containers under different conditions. The analyses are carried out on the water or body lotion, respectively, which has been filled in the DK-152 containers for the different analyses.

Material	Initial at room temperature (mg/kg)	40 °C for 6 days Water in container (mg/kg)	40 °C for 14 days Water in container (mg/kg)	40 °C for 14 days NEU-30 in container (mg/kg)
DK-152 Container primarily of PP, but also PE	-	< 0.2	< 0.2*	1.3** (0.5 – 3.1)
Blank value for body lotion NEU-30	0.7 (from own container)	-	-	0.4 (stored in glass vial)
Blank value for water	< 0.2 (stored in glass vial)	-	< 0.2 (stored in glass vial)	-

* Quadruple determination has been carried out. All values are < 0.2 mg/kg.

** Quadruple determination has been carried out due to large variations. The average of all four measurements is 1.3 mg/kg.

From the results listed in TABLE 25, it can be seen that only small amounts of free formaldehyde (about 1 mg/kg) have been identified in the situation where the body lotion has been stored in the DK-152 container for 14 days at increased temperature (40 °C). No migration of formaldehyde was identified from the DK-152 packaging material to water.

In order to be able to rule out that the used body lotion is the cause of release of formaldehyde under the used conditions, blank values were measured for the body lotion (NEU-30). This means that chemical analyses were carried out on the body lotion directly from the original container at room temperature and also after 14 days of storage in a glass vial at 40 °C. In both cases, a low content of free formaldehyde was measured of 0.7 and 0.4 mg/kg, respectively. From these blank samples, it can be concluded that the measured content of free formaldehyde can be due to the content of free formaldehyde in the used body lotion. The results of the chemical analyses on free formaldehyde in the body lotion (0.7 mg/kg at room temperature and 0.4 mg/kg at 40 °C for 14 days) are on the same level as the previously measured blank values for body lotion NEU-30 (0.9 mg/kg at room temperature and 0.5 mg/kg at 40 °C for 12 days). The time between these blank value measurements was nine months, primarily due to time used for the follow-up studies.

Hence, there is no measurable migration of free formaldehyde to water from the packaging material of DK-152, whereas a weak increase in the content of free formaldehyde by migration to body lotion from the packaging material of DK-152 was identified (when disregarding the measured blank value of the body lotion). However, the measured concentration of formaldehyde is not on a level, where it is likely that the packaging material is the only cause of the concentration of free formaldehyde measured in product DK-152 (se section 6.2.2).

It should be noticed that the uncertainty (variation) of the analysis result is high for concentrations close to the quantification limit (0.2 mg/kg), see also section 6.2.1.2. Based on the uncertainty of the measured values, it cannot be ruled out that an overestimation of the content of free formaldehyde at migration from the container DK-152 to the body lotion NEU-30 has occurred. This is also illustrated by the fact that the single analyses result for migration of formaldehyde from the container DK-152 to the body lotion NEU-30 at 40 °C for 14 days varies between 0.5 and 3.1 mg/kg for the four single determinations carried out.

Simultaneously with the aforementioned investigations, control analyses were carried out, where a known amount of formaldehyde was added to both water and body lotion NEU-30, and afterwards analysed and the recovery rate was determined. The results of these control analyses carried out on water with addition of a known amount of formaldehyde produce homogenous results and a good recovery for formaldehyde, whereas larger variations of the results can be found for the control analyses carried out on the body lotion NEU-30 with addition of a known amount of formaldehyde. The reason for this is unknown. It is not known whether this variation is e.g. caused by a reaction between formaldehyde and the ingredients in the body lotion or whether the variations are due to e.g. poor miscibility of the added formaldehyde with the body lotion.

8.5 Discussion and conclusion of the follow-up studies

When disregarding products containing a formaldehyde-releaser and the ingredient DHA, the investigation of 150 cosmetic products carried out in this project shows that three products still contain free formaldehyde, where a content of free formaldehyde above 10 ppm has been measured. This means that there are three products, where there is no immediate explanation of the content of free formaldehyde.

Based on the experiments carried out with migration from empty containers for one of the three products (DK-152), there is no indication of the packaging material being the cause of the measured concentration of free formaldehyde in DK-152. A determination of the packaging materials for the two other products shows that they consist of known plastic types (PET, PP and PE), which are in contact with the cosmetic product. Hence, there is no indication of the packaging material being the cause of the identified content of free formaldehyde.

As described in section 8.3.2, a content of free formaldehyde in the raw materials, which are used for two of the three products, can be an explanation for some of the measured content of free formaldehyde in the products. A review of the ingredients in the three products shows that the raw materials disodium EDTA (for DK-152) and hydroxyethylcellulose (for DK-89) can be an explanation of some of the measured content of free formaldehyde. However, these raw materials cannot explain the entire measured content of free formaldehyde in this project. A review of the ingredients in the third product (NEU-160) gave no explanation of the measured content of free formaldehyde. Consequently, other sources may be the cause of the free formaldehyde, but the sources have not been identified in this project.

9. Hazard assessment of formaldehyde

This hazard assessment of formaldehyde focuses exclusively on the health effects of formaldehyde other than contact allergy, which is instead described in chapter 5 ”Levels of elicitation and sensitisation”.

The hazard assessment is based on previous assessments of formaldehyde, including EFSA's assessment of formaldehyde as a preservative in food (EFSA, 2006), the Danish EPA's LOUS report on formaldehyde (Andersen et al., 2014), the SCCS' opinion on formaldehyde in nail hardeners (SCCS/1538/14, 2014) and a number of other sources. This hazard assessment is based on the latest assessment of formaldehyde carried out in the Danish EPA's survey project on chemicals in knitting yarn (Larsen et al., 2021) and chemicals in fabric face masks (Poulsen et al., 2021).

9.1 Identification, classification and physicochemical parameters

Formaldehyde is a small molecule with the simple molecular formula CH_2O. Formaldehyde is a gas at room temperature, where it photooxidises into carbon dioxide in the air. The half-life is estimated to be approximately one hour (WHO, 2010). The physicochemical parameters of formaldehyde are described in TABLE 26 below.

TABLE 26. The physicochemical parameters for formaldehyde (ECHA, 2021)

Chemical name	Formaldehyde
Synonyms	Methyl aldehyde, formalin, methanal
CAS No. / EC No.	50-00-0 / 200-001-8
Mass density	815 kg/m³
Molecular formula	CH_2O
Molecular mass	30.031 g/mol
Physical state (at 20 °C)	Colourless gas
Density	0.62 g/cm³
Melting point	-118.3°C
Boiling point (at 1013 hPa)	-21°C
Steam pressure (at 20 °C)	12.6 hPa
Octanol/water partition coefficient (Log KOW) (at 25 °C)	0.35
Water solubility (at 20 °C)	High water solubility 550 g/litre
Solubility in ethanol (at 30 °C)	Is soluble

Formaldehyde has the following harmonised classification (ECHA C&L, 2021):

- Acute Tox 3 H301 "Toxic if swallowed"; H311 "Toxic in contact with skin"; H331 "Toxic if inhalation"
- Skin. Corr. 1B H314 "Causes severe skin burns and eye damage"
- Skin Sens. 1. H317 (for concentrations "C" ≥ 0.2%) "May cause an allergic skin reaction"

- Muta. 2 H341 "Suspected of causing genetic defects"
- Carc. 1B H350 "May cause cancer"

The limit value for formaldehyde in the working environment is set at 0.28 ppm or 0.437 mg/m^3. Formaldehyde is labelled LEK, which means that in the context of the working environment it is a ceiling value (L) that must not be exceeded, that the substance has an EU limit value (E) and that the substance is carcinogenic (K). Furthermore, the substance has a remark concerning skin sensitisation (Executive Order 1426, 2021).

9.2 Use

Formaldehyde occurs naturally in most living systems, such as wood, and is also naturally present in fruit and certain foods (Andersen et al., 2014). In addition, formaldehyde has a wide range of applications, from consumer products intended as an intermediate in the chemical industry for the production of condensed resins for the wood, paper and textile processing industry and in chemical synthesis, i.e. the production of other chemical substances from formaldehyde (Andersen et al., 2014).

As described in the survey (Chapter 3), formaldehyde is also used in formaldehyde plastics, which is a common name for a wide range of plastic materials formed by the reaction between formaldehyde and, for example, urea, melamine, phenol or furfuryl alcohol (Andersen et al., 2014). As described in this project, formaldehyde is used as a preservative (formaldehyde releaser), not only in cosmetic products, but also in e.g. household cleaning products (Andersen et al., 2014). Formaldehyde can also be found in impregnating agents that make textiles crease-free, shrink-free and colourfast (Danish Allergy Research Centre, 2006). However, the substance is also used in the textile industry in dyes (Andersen et al., 2014).

Denmark has a relatively large production of chipboards, and formaldehyde is used in this production, but there has been a decrease in the number of different products containing formaldehyde (Andersen et al., 2014).

9.2.1 Background levels

The general population is exposed to formaldehyde from many sources, making exposure to the substance complex. One of the main sources of background exposure for the general consumer is formaldehyde in indoor air from various sources such as building materials, including evaporation from pressed wood products, insulation and carpets (Andersen et al., 2014).

Ambient formaldehyde concentrations are usually below 0.001 mg/m^3 in rural areas and below 0.02 mg/m^3 in urban areas (IARC, 2006). According to WHO (2010), the average concentration of formaldehyde in bedrooms in the UK in 1997-1999 was 0.0022 mg/m^3. Wolkoff & Nielsen (2011) state that the average concentration in homes in the USA and Europe is often below 0.05 mg/m^3. Andersen et al. (2014) refer to several sources that collectively indicate that indoor levels at homes in Europe are between 0.002 and 0.004 mg/m^3.

Another exposure to formaldehyde is directly through diet and indirectly through food contact materials (FCM), which may also contain formaldehyde. The regulation on plastic materials that come into contact with food (EU Regulation 10/2011) sets a limit value of 15 mg/kg for the migration of formaldehyde into food. The natural content of formaldehyde in food is in the range of 1.6 mg/kg BW/day (1.4 from food and 0.2 from FCM). The contribution to formaldehyde exposure from food is considered safe as it is at least 600 times lower than the natural endogenous turnover of formaldehyde in the body (see further explanation in section 9.3 below) (EFSA, 2014).

Other exposures originate from consumer products such as detergents and textiles, where allergy is the main risk due to dermal exposure (Andersen et al., 2014).

9.3 Absorption and distribution

Formaldehyde is a so-called endogenous metabolite, i.e. formaldehyde is formed naturally in the body. Formaldehyde is thus present in considerable concentrations within the body. EFSA (2014) estimated the endogenous turnover of formaldehyde to be approximately 0.61-0.91 mg/kg bw per minute and 878-1310 mg/kg bw/day assuming a half-life of 1-1.5 min. Compared to formaldehyde metabolism and background levels of formaldehyde from food sources (1.4-1.7 mg/kg BW/day for a 60-70 kg person), the relative contribution of exogenous formaldehyde from consumption of animal products (milk and meat) - from animals exposed to formaldehyde-treated feed - is negligible (< 0.001%).

Upon exposure, formaldehyde reacts with the contact site, and therefore there is no systemic absorption through dermal exposure, oral exposure or inhalation. There is no evidence of systemic toxicity or a systemic target organ following long-term exposure to formaldehyde (WHO, 2010). The classifications of formaldehyde as Carc. 1B and Muta. 2 are due to changes at the actual point of contact by inhalation, where there is a risk of nasal cancer.

9.4 Acute and chronic effects

In case of skin contact, the allergenic effect of formaldehyde is considered to be the critical effect (Larsen et al., 2021). This is described in chapter 5 "Levels of elicitation and sensitisation". The critical effect is the effect seen at the lowest concentration.

Sensitive persons may smell formaldehyde at concentrations down to 0.03 mg/m^3 (WHO, 2000). The NOAEC (No Observed Adverse Effect Concentration) for eye and nose irritation (so-called sensory irritation) is set at 0.38 mg/m^3 (WHO, 2010). Based on this NOAEC value, WHO has set a guideline limit value of 0.1 mg/m^3 for the maximum 30-minute average exposure in indoor air (WHO, 2000).

Eye irritation is the critical effect of exposure to formaldehyde in the air, as it is the effect seen at the lowest concentrations of formaldehyde. Therefore, outbreaks of eye irritation are assumed to provide a margin of safety in relation to irritation-induced cytotoxicity (toxicity to cells) and cell proliferation (cell division), which only occurs at higher formaldehyde concentrations. According to WHO (2010), sensory irritation (increased frequency of eye blinking) is observed at levels of 0.38 mg/m^3 and they state this value as a NOAEC value, although it is actually a LOAEC value, as the differences between unobserved (NOAEC) and lowest observed adverse effects (LOAEC) were negligible. Levels for sensory irritation of the respiratory tract are somewhat higher than for the eyes.

No systemic absorption of formaldehyde has been reported and systemic effects such as cancer from dermal exposure are considered unlikely as formaldehyde rapidly reacts with the mucosal surface upon exposure and is thus no longer available for systemic intake (Andersen et al., 2014; ECHA, 2020).

Based on animal experimental data, WHO (2005) and EFSA (2006) established a NOAEL of 15 mg/kg BW/day based on a long-term rat study with dosing via drinking water, as higher exposure levels resulted in effects in the mucous membrane of the stomach. Based on this, WHO (2005) and EFSA (2006), using an uncertainty factor of 100 for intraspecies and interspecies variation, established a Tolerable Daily Intake (TDI) value of 0.15 mg/kg BW/day. The WHO has concluded that 2.6 mg formaldehyde/litre in drinking water is considered an acceptable concentration.

The SCCS assesses formaldehyde's respiratory irritant and carcinogenic effects as the most important inhalation effects (SCCS/1538/14, 2014). ECHA (2019) states in their substance evaluation report for formaldehyde that the substance is shown to be carcinogenic in inhalation when exposure exceeds a certain threshold value. Here, 0.1 mg/m^3 is set as a tolerable exposure level for humans without risk of a carcinogenic effect and irritation of the eyes and respiratory tract. This value was originally set by WHO in 2010 as an indicative limit value for indoor air, as indicated above. ECHA (2019) also states that the value of 0.1 mg/m^3 covers long-term local effects in the form of respiratory irritation, sensory irritation and cancer.

According to ECHA (2020), long-term animal studies (subchronic studies with rats and mice) have shown nasal tumours when exposed to formaldehyde at concentrations of 7.45 mg/m^3 and above for six hours per day for five days per week. The RAC (Committee for Risk Assessment) has concluded that the formation of tumours in the nose is concentration-dependent and that a concentration of 2.5 mg/m^3 should be considered the lowest value (LOAEC) at which the first signs of tumour formation are seen. A formaldehyde concentration of 1.24 mg/m^3 can be considered as NOAEC for cell division leading to the formation of tumours in the nose (nasal cancer).

However, this value of 0.1 mg/m^3 has been proposed for a reduction by the ECHA in 2020 in the context of an updated assessment (ECHA, 2020). Here, however, the RAC concludes that the original studies on which this value is based contain too few observations and too much variation in the data. Thus, the RAC proposes using other studies leading to a proposed limit value of 0.05 mg/m^3 instead of being based on a NOAEL value set as 0.37 mg/m^3 for sensory irritation[32] (ECHA, 2020). This value of 0.05 mg/m^3 is proposed as a new limit value for the degasification of formaldehyde from consumer products in general, meaning that it is the maximum concentration that may be degassed from a consumer product measured in a climate chamber after a maximum of 28 days (ECHA, 2020c – Annex X).

9.5 Critical effect and indication of the NOAEL-value

As mentioned above, allergy is the primary critical effect of formaldehyde for dermal exposure. For this reason, only the effects of formaldehyde for exposure routes other than skin contact are assessed. Thus, for effects other than allergy, inhalation will be the relevant exposure route to assess for the cosmetic products investigated in the present project, as oral exposure is not considered relevant in this study. The products studied are various creams (face cream, body lotion, hand cream and eye cream), make-up remover, skin tonics and self-tanners. Self-tanners are predominantly creams, liquids or mousses (for some self-tanners) sold in tubes, cans or bottles that are applied with the hands. The only exception is two of the purchased self-tanners, which appear as sprays in cans.

Thus, for the risk assessment of these spray products, the NOAEC value of 0.37 mg/m^3 for sensory irritation (more frequent blinking of the eyes) and the NOAEC value of 7.45 mg/m^3 for the development of nasal cancer are used.

[32] This value is probably identical to the reported value of 0.38 mg/m^3 given by WHO (2010). This is more likely due to rounding of values converted from ppm from the experiments.

10. Risk assessment

This chapter provides a risk assessment of the identified levels of formaldehyde for the 31 products analysed quantitatively for free formaldehyde. A risk assessment has been carried out based on the allergy considerations alone and then a risk assessment based on effects other than allergy.

10.1 Allergy

In chapter 5 of this report, a calculation has been made of which levels are assessed to be sensitising, i.e. to cause allergy and an inventory of which levels of formaldehyde have been observed to elicit, i.e. to cause allergic eczema, in persons already allergic to formaldehyde.

There is a difference in the basis of assessment, as sensitisation is an 'invisible' (symptom-less) process of the immune system. Hence, the assessment depends partly on the results of experiments and partly on a computational model with a number of assumptions. By its very nature, a calculated sensitisation level will be an estimate that can never or rarely be verified.

Symptoms occur at elicitation and can initially be observed here. Elicitation levels are reported in a number of scientific publications, which may also have methodological weaknesses. Thus, there are a number of uncertainties in determining sensitisation and elicitation levels. Please refer to the chapter 5 of this report for a more detailed review.

The products in this report are of the leave-on type except for a few make-up removers, which are either wiped off or removed with water (rinse-off) after application. Overall, the calculated sensitisation levels for leave-on products applied to the face and/or body by hand are in the range of 110-165 ppm formaldehyde. If a product exceeds these levels, it is considered to constitute a risk of sensitisation.

The lowest reported elicitation level for formaldehyde in creams (leave-on product) was between 130 and 200 ppm when used for a short time (1-2 weeks) on normal skin and 2.5-10 ppm formaldehyde when used on eczema skin (pre-irritated skin) for up to four weeks. A limit value of 10 ppm has recently been adopted, requiring a warning about the release of formaldehyde on the labelling of cosmetic products in the EU. The current limit value for this is 500 ppm.

The levels of formaldehyde, which constitutes a risk of sensitisation and elicitation, respectively, for leave-on products applied to the body or face with the hands (e.g. creams), overlap and are between 110-200 ppm. In eczema skin, the levels of formaldehyde, which constitute a risk of sensitisation and elicitation, are in this assessment set to 10 ppm for both sensitisation and elicitation.

For make-up removers that are washed off the skin, i.e. a rinse-off product, the calculated sensitisation levels are 375-565 ppm. The two make-up removers (respectively with and without a formaldehyde releaser in the list of ingredients), where free formaldehyde was found in the quantitative analyses, are of the type that is cleaned off after use. There are no studies on elicitation levels from the use of make-up removers, but the 10 ppm limit for warning labelling covers all products and will thus also be used for make-up removers.

10.1.1 Summary of results for free formaldehyde

Out of the 150 products purchased, 31 products were selected for quantitative analysis for free formaldehyde. Of these, there were 23 products without a formaldehyde releaser in the list of ingredients, which gave a reading above 2.5 ppm with the semi-quantitative method of analysis and eight products with a content of formaldehyde releaser according to the list of ingredients. Eight of the 12 purchased products with formaldehyde releasers were selected to represent different product types and formaldehyde releasers used.
The free formaldehyde content of all 31 products was measured to be between 0.5-637 ppm. In 24 out of the 31 products (77%), a content of free formaldehyde above 10 ppm was found. It is these 24 products that will form the basis of the following risk assessment. The concentration of free formaldehyde in the 24 products divided into products with and without formaldehyde releaser according to the list of ingredients is given in TABLE 27 below.

TABLE 27. Content of free formaldehyde in products with and without formaldehyde releaser according to the list of ingredients measured with the quantitative method of analysis. The table summarises the 24 products where the content of free formaldehyde was measured at a concentration above 10 ppm.

Product type	Total number of products	Concentration of free formaldehyde (ppm) (With formaldehyde releaser (pcs))	Concentration of free formaldehyde (ppm) (Without formaldehyde releaser (pcs))
Face cream	2	75-586 ppm (2 products)	- (0 products)
Body Lotion	3	182-637 ppm (3 products)	- (0 products)
Eye cream	3	356 ppm (1 product)	191-262 ppm (2 products)
Self-tanner	14	300 ppm (1 product)	12-507 ppm (13 products)
Make-up remover	2	421 ppm (1 product)	356 ppm (1 product)

Of these, 8 products had a formaldehyde releaser in the list of ingredients. They contained an average of 355 ppm (from 75 to 637 ppm) free formaldehyde, while the 16 products that did not have a formaldehyde releaser in the list of ingredients and for which a free formaldehyde concentration of more than 10 ppm was measured, contained an average of 150 ppm (from 12 to 507 ppm) free formaldehyde.

10.1.2 Risk assessment – sensitisation and elicitation

There were three types of products (eight products in total) that could be classified as creams assumed to be used daily: face creams, body lotions and eye creams. These are products that are not washed/cleaned off the skin. They were analysed under one, as leave-on products applied to the face and/or body (Api et al., 2020). The calculated sensitisation levels for this product type were 110-165 ppm. In the model, a value higher than this level is equal to a risk of sensitisation. The higher the value, the higher the risk of allergy.

Six of the eight creams contained a formaldehyde release, according to the list of ingredients. Five of these had higher levels of free formaldehyde than both the lower limit of 110 ppm and the upper limit of 165 ppm. In several cases, levels were more than twice the upper calculated sensitisation level, including three products (an eye cream (355 ppm), a face cream (586 ppm) and a body lotion (637 ppm)). Two eye creams did not have a formaldehyde releaser on the list of ingredients but contained 191 and 262 ppm free formaldehyde, respectively. The average level of free formaldehyde in these two products (226 ppm) was lower than the products with a formaldehyde releaser in the list of ingredients (355 ppm), but for both products it was still above the sensitisation risk level.

All eight cream products constitute a significant risk of elicitation by exceeding the 10 ppm by a factor ranging from 7.5 to 63.

Self-tanners accounted for 58% (14/24) of the products where free formaldehyde above 10 ppm was found. They contained between 12 and 507 ppm free formaldehyde. The following levels above 110 ppm (risk of sensitisation) were found in four products: 210, 300, 480 and 507 ppm, of which only one self-tanner (the one with 300 ppm free formaldehyde) contained formaldehyde releaser according to the list of ingredients. As self-tanners are unlikely to be used daily, this could argue for the use of the upper sensitisation level of 165 ppm in the assessment, as more frequent use increases the risk of sensitisation and the risk assessment model assumes repeated (daily) use. All four products also exceed this level and are therefore considered to constitute a risk of sensitisation.
Overall, the average free formaldehyde in the self-tanners that did not have a formaldehyde releaser in the list of ingredients (but contained more than 10 ppm) was 122 ppm. However, there was a wide range in concentrations (12-507 ppm).
For all 14 self-tanners (with more than 10 ppm formaldehyde) there is a risk of elicitation.

Make-up removers were the only products that were not necessarily leave-on products. However, for the two make-up removers where a content of free formaldehyde was quantified, it is recommended that they are removed/cleaned off again since higher levels of formaldehyde can be tolerated in principle before there is a significant risk of sensitisation. This is because smaller amounts of the product (and therefore formaldehyde) are left behind when cleaning/washing. The risk of sensitisation was calculated for make-up removers (which are cleaned off) to be in the range between 375 and 565 ppm. Two make-up removers contained free formaldehyde, one with a formaldehyde releaser in the list of ingredients and 421 ppm formaldehyde, and one without any formaldehyde releaser according to the list of ingredients, which contained 355 ppm. Thus, one make-up remover is above the lower sensitization level, but none above the upper one. However, it should be noted that there is not much difference in the free formaldehyde content for the two products and that 355 ppm is close to the calculated sensitisation level (375 ppm). Therefore, it cannot be ruled out that at this level, these products may also in practice constitute a risk of sensitisation, even if the level is not formally exceeded. Both products constitute a risk of elicitation.

It should be noted that for the above assessment, a conservative approach to the risk of sensitisation has been applied. Thus, it has not been possible to take into account aggregate exposure, i.e. the fact that several products containing formaldehyde may be used on the same skin area and contribute to the total exposure since there is no scientific consensus on the method.

10.1.3 Levels below 10 ppm

Six products, which in the quantitative analysis contained less than 10 ppm formaldehyde, were found. These are:

- 1 face cream (1 ppm)
- 2 body lotions (1 ppm)
- 1 eye cream (3 ppm)
- 1 self-tanner (8 ppm)
- 1 skin tonic (0.5 ppm)

These are low levels. In one study, 2.5 ppm free formaldehyde was also shown to elicit when applied to irritated eczema skin (Hauksson et al., 2015b). Only two products (3 and 8 ppm) in this group are between 2.5 and 10 ppm, where there will be a risk of elicitation, but it is considered to be low.

10.1.4 Products with and without formaldehyde releaser

The list of ingredients on cosmetic products is an important tool for people who have developed an allergy. Doctors also use the list of ingredients to identify the causes of allergic eczema in individual patients and advise them on what to avoid in order to get well. Hidden allergen content, such as formaldehyde, can have significant consequences, meaning that an allergic person may inadvertently use the product and develop allergic eczema or become persistently, covertly exposed, resulting in chronic allergic eczema on large parts of the body that will not heal.

In this report, several products were found to contain formaldehyde above 10 ppm, where no formaldehyde releaser was indicated in the list of ingredients. It regards:

- 1 make-up remover (355 ppm)
- 2 eye creams (191 and 262 ppm)
- 13 self-tanners (10 products: 12-103 ppm) (3 products: 210; 480; 507 ppm).

Thus, this is found across of product categories, although self-tanners make up a large proportion of the products concerned.

On average, the levels of free formaldehyde were higher in products that had a formaldehyde releaser in the list of ingredients (355 ppm) than in products that contained formaldehyde above 10 ppm and did not have a formaldehyde releaser in the list of ingredients (150 ppm). However, some of the products contained this so-called hidden formaldehyde, which would pose a significant risk for both sensitisation and elicitation based on the models used in this report. Thus, it is of immediate concern that hidden formaldehyde has been found in so many products. Similar findings have been seen in other scientific studies (Hauksson et al., 2015b; Malinauskinene et al., 2015; ACCC, 2010; Jairoun, 2020).

Two of the products where more than 10 ppm formaldehyde was found, one (an eye cream) stated that the product was designed for very sensitive skin (DK-152) and the other (a hand cream) stated that the product could counteract moderate to intense dryness (DK-68). A broken skin barrier with dry skin and possibly eczema poses an increased risk of sensitisation and elicitation. These factors are built into the risk assessment model used in this project and are thus considered in the estimated levels of sensitisation and elicitation.
The eye cream (DK-152) contained formaldehyde (191 ppm) without a formaldehyde releaser in the list of ingredients. The hand cream (DK-68) contained a formaldehyde releaser according to the list of ingredients. There is no consensus on the definition of 'sensitive skin', but the hidden formaldehyde in this product is considered to constitute both a risk of sensitisation and a significant risk of elicitation.

10.1.5 Comments and conclusion

A total of 12 out of the 31 products (39%) sampled for quantitative analysis contained formaldehyde at a level which, according to the calculation models, constituted a risk of sensitisation. Out of the total number of products (150), these represented 8%. Of these, seven (4.7%) had a formaldehyde releaser in the list of ingredients and five (3.3%) had no formaldehyde releaser in the list of ingredients.

Formaldehyde releasers are allowed for use in cosmetic products at levels that are estimated to release formaldehyde in the amounts measured in this project for the products that had a formaldehyde releaser in the list of ingredients (de Groot et al., 2010). This also means that

formaldehyde in cosmetic products is a known cause of allergy (Fasth et al., 2018). Thus, in a recent Danish study of patients with cosmetic-related facial eczema, 6.3% were allergic to formaldehyde (Bruusgaard-Mouritsen et al., 2021). Among all patients with formaldehyde allergy, six out of 10 cases were associated with the use of cosmetic products (Fasth et al., 2018).
In the present project, quantitative analysis identified almost equal numbers of products, with and without a formaldehyde releaser in the list of ingredients, that contained formaldehyde at a level that, based on the calculation models, constituted a risk of sensitisation. This contributes to making formaldehyde allergy a significant problem.

People with formaldehyde allergy have particular difficulty in avoiding formaldehyde, as it is not declarable when it is not added but released into the product from a formaldehyde releaser. This means that formaldehyde allergy sufferers have had to learn the names of all the known formaldehyde releasers in order to avoid formaldehyde. Studies have shown that it is very difficult for allergy sufferers to avoid formaldehyde (Noeisen et al., 2007). This is now attempted to be remedied with an adoption of a new limit value for the labelling with a warning of release of formaldehyde on cosmetic products if it is present (released) in a concentration higher than 10 ppm.
The many products in this and previous studies that contained hidden formaldehyde pose a significant problem.

10.2 Other health aspects

As described in the hazard assessment in chapter 9, allergy is considered to be the critical effect of formaldehyde in contact with skin. For effects other than allergy, inhalation will be the relevant route of exposure, given that oral exposure is not considered relevant for the products investigated in this project.

The 150 products purchased across the seven product categories were predominantly creams, liquids (skin toners and make-up removers) or mousses (for a few self-tanners). The majority of the products were thus products sold in a tube, can or bottle and are products applied by hand. The only exception is two of the 23 self-tanners purchased, which appear as sprays in metal cans with propellant added to atomise the liquid from the cans. For these two self-tanning products, it would therefore be relevant to carry out a risk assessment for inhalation of formaldehyde during use.

10.2.1 Methodology used

The risk assessment of cosmetic products is carried out according to "SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation". It is now available in its 11th edition (SCCS/1628/21, 2021). Risk assessment according to SCCS Notes of Guidance is based on a hazard assessment, an exposure assessment and finally, the risk assessment itself, where the so-called MoS value (Margin of Safety) is calculated. For local effects, the MoS is calculated according to the formula below, where the MoS value is the PoD value ("Point of Departure" for exposure) divided by the LED (the local external exposure dose). The hazard assessment for formaldehyde indicates that the substance gives rise to local effects only, and therefore only MoS values for local effects will be calculated in the present project. The PoD value is typically based on a NOAEL value (or a NOAEC value), i.e. the levels at which no adverse effects have been observed for the substance. If the margin of safety MoS for the ratio of the no adverse health effect value to the calculated exposure is calculated to be 100 or more, then the cosmetic product is considered safe for human health in its use.

$$MoS = \frac{PoD}{LED}$$

Formaldehyde is a unique substance because it is a small molecule that breaks down easily in air and reacts quickly with the site of contact, i.e. skin or mucous membranes. As described in the hazard assessment in chapter 9, this means that there is no systemic absorption either by dermal exposure, oral exposure or inhalation. The health effects of formaldehyde inhalation are first sensory irritation (in the form of irritation of the eyes and respiratory tract), and if the concentration is high enough over a long time (a number of years), there is a risk of developing nasal cancer. Thus, the critical inhalation effect is sensory irritation (where the eyes are more sensitive than the nose), and the NOAEC value for this also covers long-term effects such as cancer.

As described by the SCCS (SCCS/1628/21, 2021; SCCS/1538/14, 2014), the local external exposure dose can be calculated based on the concentration of formaldehyde in the air when using self-tanning sprays via the formula[33] below. LED is calculated as the daily exposure E, which is the amount of self-tanner used multiplied by the concentration of formaldehyde in the self-tanner (C) multiplied by the fraction of formaldehyde that will be airborne (f_{evap}), divided by the volume of the room or inhalation zone to which the formaldehyde evaporates:

$$LED\left(\frac{\mu g}{m^3}\right) = \frac{Exposure\ E\ \times C\ \times f_{evap}}{Volume\ V}$$
$$= \frac{amount\ (g) \times konc.of\ substance\ in\ the\ product\ (\mu g/g) \times\ airborne\ fraction}{Volume\ (m^3)}$$

10.2.2 Exposure calculations and risk assessment

The values used to calculate the theoretical worst-case concentration are given and justified below. The values in the calculations are as follows:

- Amount of self-tanner used per time
- Concentration of formaldehyde in the self-tanner
- The airborne fraction of formaldehyde
- Volume of the room or inhalation zone into which the self-tanner is sprayed

In SCCS Notes of Guidance (SCCS/1628/21, 2021), no value for the estimated daily **amount of self-tanner** that the consumer is assumed to apply exists. The closest value is estimated to be that for body lotion, which is given as 7.82 g/day. However, this amount is for a cream and not for a spray product. In 2010, the SCCS carried out an assessment of self-tanners, indicating values between 15 and 60 ml of self-tanner used in professional application booths. Assuming a density of 1 g/ml, this corresponds to between 15 and 60 g per application[34]. The lowest value is used in the latest generation of spray booths for self-tanning (SCCS/1347/10, 2010). However, it can be expected that a significantly higher amount of product is used in dedicated self-tanning booths than a consumer would use at home, as the product is coloured and excess product that is not applied on the skin will potentially stain surfaces that it hits. A worst-case value of 15 g is therefore used, which is approximately double the amount of body lotion that SCCS Notes of Guidance states that an adult uses per day (SCCS/1628/21, 2021).

In addition, the risk assessment will also take into account the frequency of use of the self-tanner. This does not affect the actual concentration level in use, but it is relevant in relation to the frequency of exposure. According to the SCCS, self-tanners are used once a week at most (SCCS/1347/10, 2010), which is consistent with the text on some of the self-tanners purchased, which states, among other things, that "the effect will diminish over a few days". According to various guides on the optimal use of self-tanners[35], self-tanners should be used every day for two, three or four consecutive days until the desired colour is achieved, after

[33] The formula is derived from Notes of Guidance (SCCS/1628/21) formula (7), which is modified for local effects.

[34] The same density assumption is used by SCCS in SCCS/1347/10 (2010).

[35] https://www.elle.dk/skoenhed/tips-guides/den-ultimative-guide-til-vellykket-selvbruner; https://www.matas.dk/stories-selvbruner-guide

which self-tanners should be used once or twice a week to maintain the colour. As a result, the calculations assume a frequency of self-tanning of twice a week on average.

No information has been identified on the time needed to apply a self-tanner. Therefore, an exposure time of 15 minutes is assumed in the calculations. The SCCS' assessment of self-tanners (SCCS/1347/10, 2010) states that exposure time in manual self-tanning booths is 2-3 minutes. Exposure time will be longer when consumers have to spray the product themselves, but 15 minutes is considered to be worst-case.

The analytical results of the present study are used as the **concentration of formaldehyde in the self-tanner**. Of the self-tanners purchased, two are spray products. These are EU-101 and DK-118. However, EU-101 is a self-tanner with a free formaldehyde screening result of < 2.5 ppm (the product does not contain dihydroxyacetone). The content of free formaldehyde in the product DK-118 was measured at 64 mg/kg in the quantitative analysis, corresponding to 64 µg/g. This concentration of formaldehyde is used in the calculations.

Regarding the **airborne fraction of formaldehyde**, SCCS states that there is a difference between the concentration in the liquid and the resulting concentration in the air after a spray is applied (SCCS/1628/21, 2021). Factors that come into play here include how much of the substances in the spray become airborne (evaporate) and also how quickly they react with the air or break down, as is the case with formaldehyde.

In this worst-case calculation, the airborne fraction of formaldehyde is assumed to be 100%. However, this is considered to be a significant overestimation due to, among other things, the following reasons. Formaldehyde is a volatile, small molecule, so a large proportion of the formaldehyde contained in the self-tanner that is sprayed out will probably also be available for inhalation, although formaldehyde will be broken down after some time.
The SCCS describes in their opinion on formaldehyde in nail hardeners that measurements of formaldehyde have been taken in a bathroom after the use of nail hardeners containing (up to 2%) formaldehyde. The highest measured concentration of formaldehyde was 97 µg/m^3, which peaked 5 minutes after application. The levels of formaldehyde in the bathroom decreased to background levels after 45-60 minutes (SCCS/1538/14, 2014). These measurements show that formaldehyde concentrations are expected to be high for a short time (close to the set indoor air quality limit value) but will quickly decrease again. Thus, exposure will be short-term, especially if consumers vent during use, as recommended on product DK-118.

The **volume** of air into which self-tanners are sprayed can, in the worst case, be assumed to be the inhalation zone itself, or the volume of the room in which the self-tanner is applied can be used. According to Notes of Guidance (SCCS/1628/21, 2021 – appendix 11), the following volumes are used to calculate the inhalation concentration of spray products:

- 1 m^3 corresponding to the immediate inhalation zone around the head
- 10m^3 corresponding to the volume of a bathroom

For comparison, a value for the inhalation zone of 2 m^3 is used according to REACH guidance documents for consumer exposure (ECHA, 2016). However, the worst-case inhalation zone of 1 m^3 as specified in SCCS Notes of Guidance is used.

The calculations of the theoretical concentration of formaldehyde in the inhalation zone and in a bathroom are given in TABLE 28 and TABLE 29 below compared with the NOAEC value for sensory irritation of the eyes and the NOAEC value for development of nasal cancer, respectively. The rightmost column shows the ratio of NOAEC to the theoretically calculated exposure, corresponding to MoS. The ratio is thus an expression of how many times higher the NOAEC value is in relation to the calculated exposure, i.e. how large a margin of safety (MoS) there is.

10.2.2.1 Risk of acute effects (sensory irritation)

In the TABLE 28 below, MoS for acute effects of formaldehyde are calculated.

A calculation example for the volume of 1 m^3 (inhalation zone) is inserted below:

$$LED = \frac{15\ g \times 64\ \mu g/g \times 1}{1\ m^3} = 960\ \mu g/m^3$$

In comparison, the NOAEC value for sensory irritation is 0.37 mg/m^3 or 370 µg/m^3, which means that

$$MoS = \frac{PoD}{LED} = \frac{370\ \mu g/m^3}{960\ \mu g/m^3} = 0{,}39$$

TABLE 28. Applied values and calculated theoretical concentration (exposure) when using self-tanning spray DK-118 for different volumes. Compared with the NOAEC value for sensory irritation.

Quantity (g)	Concentration in the product (µg/g)	Airborne fraction	Volume (m^3)	Calculated exposure (LED) (µg/m^3)	PoD (µg/m^3)	MoS
15	64	1	1	960	370	0.39
15	64	1	10	96	370	3.85

PoD = Point of Departure, which here is the NOAEC value for sensory irritation of the eyes (ECHA, 2020)

It can be seen from the calculations in TABLE 28, assuming that 100% of the formaldehyde in the self-tanning spray evaporates on use, and that the formaldehyde is either present directly in the inhalation zone (volume of 1 m^3) or distributed in a bathroom of 10 m^3, the calculated MoS values are 0.4 and 3.9 for sensory effects (faster eye blinking), respectively. In other words, in both situations the calculated MoS is well below 100, which means that there is a risk of effects in the form of sensory irritation (more frequent eye blinking and possible irritation of the nose).

However, these are theoretical worst-case calculations. Where the real value will actually lie will require measurement in practice. As described in the SCCS opinion for formaldehyde in nail hardeners (which had a significantly higher content concentration (20,000 ppm) than this self-tanner used in the calculations (64 ppm)), measurements resulted in a maximum concentration in a bathroom of 97 µg/m^3 corresponding to the concentration calculated for the volume of 10 m^3 in TABLE 28. For comparison, a theoretical concentration of formaldehyde in the air of 96 µg/m^3 has been calculated here for the self-tanner with a formaldehyde content of 64 ppm. This could indicate that the real resulting concentration of formaldehyde in the room/inhalation zone could be a factor 300 lower than the calculated theoretical worst-case concentration.

The above calculations are a theoretical worst-case calculation, and there are several factors that will mean that the formaldehyde concentration will be lower than the theoretical one and will decrease over time:

- Formaldehyde reacts rapidly at room temperature (photo oxidises) and, according to (WHO, 2010) has a half-life of about one hour, which means that the concentration will decrease within a short time.
- As described in SCCS Notes of Guidance, it is not the actual concentration of formaldehyde in the product (and thus the calculated theoretical concentration as used in the above calcu-

lations) that should be used in the exposure calculations but the concentration actually present in the spray mist. Thus, using a fraction of 100% in the calculations significantly overestimates the real concentration, which can only be verified by measurements in practice.
- There will be natural ventilation from cracks in doors and windows, which means a decrease in concentration over time.
- If consumers air out during or after the use of the self-tanner, as recommended on the product, the concentration will be significantly reduced.
- In addition, some consumers may move away from the area where the self-tanner is sprayed if they experience a sensory irritation.

Finally, it should be pointed out that the calculated theoretical concentration of formaldehyde in the air of a 10 m^3 bathroom is just below the WHO limit value for formaldehyde in indoor air, which is an indicative limit value for 30 minutes average exposure in indoor air. This means that the concentration of formaldehyde must be constantly above the WHO limit value for 30 minutes before it is considered to be exceeded.

The calculations show that there may be a short-term exceedance of the NOAEC value for sensory irritation, i.e. there may be irritation (faster eye blinking) when using this self-tanner in the inhalation zone. However, any discomfort is expected to be short-lived. Using this self-tanner will increase the overall indoor concentration of formaldehyde, but it is a product that is likely to be used a maximum of twice a week (except in the first week, when it can be used up to four times in one week). However, it cannot be concluded whether there will be a real risk of sensory irritation or not, as this depends on the actual concentration of formaldehyde in the spray mist, which has only been calculated theoretically in this project and not measured.

10.2.2.2 Risk of chronic effects (nasal cancer)

Sensory irritation is an acute effect, i.e. the effect depends on the actual concentration. However, the development of nasal cancer is a chronic effect that only develops over a long period of exposure. The NOAEC value used for the development of nasal cancer of 7.45 mg/m^3 is derived from sub-chronic animal studies in which animals were exposed to formaldehyde inhalation for six hours per day for five days per week. Thus, it should be corrected for the fact that the exposure from self-tanners is not applied for 30 hours per week, but instead 15 minutes per time and twice per week, corresponding to 30 minutes per week (see assumptions discussed above). I.e. The NOAEC value is corrected by a factor of 60.

In TABLE 29 below, MoS for chronic effects of formaldehyde is calculated.

TABLE 29. Applied values and calculated theoretical concentration (exposure) when using self-tanning spray DK-118 for different volumes. Compared with the NOAEC value for the development of nasal cancer.

Quantity (g)	Concentration in the product (µg/g)	Airborne fraction	Volume (m^3)	Calculated exposure (LED) (µg/m^3)	PoD (µg/m^3)	PoD corrected (µg/m^3)	MoS
15	64	1	1	960	7450	447,000	466
15	64	1	10	96	7450	447,000	4656

PoD = Point of Departure, which here is the NOAEC value for the development of nasal cancer (ECHA, 2020)

This is shown by TABLE 29 that the calculated MoS value for both the inhalation zone (1 m^3) and the bathroom (10 m^3) is above 100. A MoS value at or above 100 means that there is no health risk. Thus, it is assessed that there is no risk of nasal cancer from prolonged use of this self-tanning spray under the worst-case assumptions used:

This means that the worst-case calculations show that there is no risk of the development of nasal cancer. The worst-case calculations assume that:

- The self-tanner is used for 15 minutes twice a week over a long period
- That 100% of the formaldehyde contained in the self-tanner evaporates
- That 100% of formaldehyde is inhaled through the nose
- That the formaldehyde concentration is constant during the period of use

As discussed above, these are theoretical worst-case calculations for formaldehyde concentration, which assume a wide range of conditions listed above that are unlikely to occur in practice. For example, there will be a form of natural ventilation even with windows and doors closed, and there will be photo-oxidation of formaldehyde in the air. Moreover, the actual measurements described in the SCCS opinion for formaldehyde in nail hardeners show that the real formaldehyde concentration in a room when using a spray is probably much lower than the theoretically calculated one.

11. Conclusion

The purpose of this project was to acquire knowledge on formaldehyde in cosmetic products, including the origin of formaldehyde in products where a formaldehyde releaser is not declared. The purpose was also to assess, whether the identified levels of formaldehyde constitute a risk to the consumers, including allergic reactions in consumers.

In this project, a total of 150 cosmetic products (mainly leave-on products) were investigated for a content of free formaldehyde. Of these 150 products, 12 had a formaldehyde releaser in the list of ingredients, and eight had no legible list of ingredients, i.e. it could not be verified, whether they contained a formaldehyde releaser or not. All 150 products were analysed for a content of free formaldehyde by means of a semi-quantitative analysis (colour reaction method), after which a selection of the products was analysed quantitatively for free formaldehyde.

Quantitative analysis for free formaldehyde
The analyses carried out in this report have shown that cosmetic products with a content of free formaldehyde, but without a formaldehyde releaser in the list of ingredients, exist. In some cases, the content of free formaldehyde in these products is significant and close to or above the existing limit of 500 ppm regarding legal requirement of labelling a warning on formaldehyde content, cf. the Cosmetics Regulation.

For 23 products without a formaldehyde releaser in the list of ingredients, a content of free formaldehyde above 2.5 ppm was measured according to the semi-quantitative colour reaction method. These 23 products plus eight of 12 products containing a formaldehyde releaser were subsequently analysed quantitatively for free formaldehyde. For budgetary reasons, only eight of the 12 products containing a formaldehyde releaser were selected. Products in different product categories and with different formaldehyde releasers were selected.
As a result, the measured concentrations of free formaldehyde ranged from 75 to 637 ppm (average of 355 ppm) for the eight products with formaldehyde releasers in the list of ingredients and from 1 to 507 ppm (average of 105 ppm) for the 23 products without a formaldehyde releaser in the list of ingredients.

Ingredients and packaging studied
The analyses in this project focused, among other things, on ingredients and packaging from which an information retrieval at the start of the project identified suspected content or release of formaldehyde. These ingredients and packaging were:
- DHA (dihydroxyacetone) used exclusively in self-tanners
- Glycerine
- Polysorbate 80
- Cocamidopropyl betaine
- PEG compounds (PEG-100 stearate was specifically studied in this project)
- PET packaging (is typically used as packaging for skin tonics)

Both the semi-quantitative analyses and the quantitative analyses, conducted with the above-mentioned raw materials and packaging, showed a clear correlation between a content of free formaldehyde and DHA. In the pure raw material for DHA (i.e. 100% DHA), a content of 291 ppm free formaldehyde was measured by quantitative analysis, whereas the content of free formaldehyde decreased to 16 ppm when the raw material DHA was mixed into a cosmetic product (containing DHA, but with a content of free formaldehyde below 2.5 ppm measured with the semi-quantitative analytical method). The mixing ratio was 30% pure DHA and 70%

cosmetic product. Thus, there are indications that an interplay of ingredients in the cosmetic products may lower the content of free formaldehyde, as the drop from 291 ppm to 16 ppm is far greater than can be explained by an approximately one-third dilution. A possible explanation may be the presence of antioxidants, which may help to prevent the formation of free formaldehyde.

The analyses carried out in this project confirm the existing knowledge (SCCS/1612/19, 2020) that DHA contains free formaldehyde as an impurity, and they indicate that the content of DHA in cosmetic products may be the cause of a content of free formaldehyde in such products. Of the 31 cosmetic products that were quantitatively analysed for free formaldehyde, 14 contained DHA and all of these were self-tanners.

The results for the other raw materials and PET packaging do not suggest that these raw materials and packaging can be the cause of the presence of free formaldehyde in cosmetic products without a formaldehyde releaser in the list of ingredients. Thus, PET packaging and the other focus substances (raw materials) in this project are not considered to be the cause of the relatively high amounts of free formaldehyde identified in the quantitative analyses.

Physical/chemical conditions studied
The physical/chemical experiments carried out, where temperature and pH have been manipulated, do not provide a clear answer as to the possible reason for the identified content of free formaldehyde in products that neither contain a formaldehyde releaser nor DHA. However, the results show that an alkaline pH seems to lead to an increased release of formaldehyde. The pH of the products has not been investigated in general in this project, so it is not possible to conclude definitively on the importance of pH.

Follow-up studies on the three products with a content of formaldehyde
When products containing a formaldehyde-releaser and DHA according to the list of ingredients are disregarded, there are still in total three products that contain free formaldehyde above 10 ppm. For these products both the packaging material and ingredients were examined further.

One of the producers of the three cosmetic products shipped empty packaging material on which migration analyses were conducted in order to investigate, whether the packaging material (consisting primarily of PP) could be the cause of the measured content of free formaldehyde in the product. For the two other products, the attempt to obtain empty packaging material from the producers failed. The result of the investigation was that there is no indication of the packaging material being the cause of the measured concentration of free formaldehyde. A determination of the material of the two other products (packaging) showed that it is commonly used plastic materials (PET, PP and PE) that are used and hence, are in contact with the cosmetic product. This means that there is not any indication of the packaging material being the cause of the measured content of free formaldehyde in the three products.

A review of the ingredients on the list of ingredients for the three products showed that two raw materials (disodium EDTA and hydroxyehtyl cellulose), which are used separately in two of the three cosmetic products, can contain free formaldehyde either as an impurity in the raw material itself or because of degradation of the raw material to, among others, formaldehyde. However, these concentrations of formaldehyde are not high enough to explain the entire content of free formaldehyde measured by the quantitative analyses carried out in this project. For the third cosmetic product, the listed ingredients provided no explanation for the measured content of free formaldehyde. Consequently, other sources may be the cause of the free formaldehyde, but the sources have not been identified in this project.

No differences in free formaldehyde content in products within and outside the EU
The results of the semi-quantitative analyses showed that for products without a formaldehyde releaser in the list of ingredients there is no immediate difference in the possible content of free formaldehyde in products purchased in DK, the EU and non-EU. When taking into account that more Danish products have been purchased than products from the EU and non-EU, respectively, no significant differences are observed.

The risk of allergy
The result of the quantitative analyses for free formaldehyde was that 24 of the 31 analysed cosmetic products – i.e. products both with and without a formaldehyde releaser on the list of ingredients – had a content of free formaldehyde above 10 ppm, which is the new limit value that the EU Commission has adopted regarding labelling a warning on released formaldehyde on cosmetic products. 10 ppm is also the level of elicitation for exposure of formaldehyde from leave-on products on eczema skin. The levels of free formaldehyde ranged from 12 to 637 ppm for the 24 products with a content of free formaldehyde above 10 ppm. Thus, all of these 24 products carry a risk of elicitation in already sensitised individuals. The higher the formaldehyde content, the higher the risk is that consumers, who have already developed an allergy towards formaldehyde, will have an allergic reaction.

By use of the perfume industry's QRA methodology, the sensitisation levels were calculated with to be between 110 and 165 ppm for leave-on products (such as face creams, body lotions, eye creams and self-tanners) and between 375 and 565 ppm for make-up removers that are rinsed off after use. The risk assessment model assumes daily use, while most self-tanners are probably used less frequently. Thus, the upper sensitisation level (165 ppm) is used for the assessment of this product type. As described in Chapter 5 "Levels of elicitation and sensitisation", the perfume industry's risk assessment model is not officially accepted by the SCCS, but it is currently the only available possibility for estimating levels for sensitisation when exposed dermally to cosmetic products. Applying this risk assessment model for sensitisation, it can be concluded that:

- Seven out of eight creams with a content of free formaldehyde according to the quantitative analyses (face creams, body lotions and eye creams) exceed both the lower and upper sensitisation levels of 110 and 165 ppm, respectively, and according to the model, constitute a risk of sensitisation. Five of these contain a formaldehyde releaser according to the list of ingredients.
- Four out of 15 (27%) self-tanners contain higher levels of free formaldehyde than the upper sensitisation level of 165 ppm and the use of these products may therefore carry a risk of sensitisation. One of the self-tanners contains a formaldehyde releaser according to the list of ingredients.
- One out of two make-up removers exceeds the lower sensitisation level of 375 ppm. This make-up remover contains a formaldehyde releaser according to the list of ingredients. Neither of the two make-up removers exceed the upper sensitisation level of 565 ppm. However, the second make-up remover (without a formaldehyde releaser on the list of ingredients) contains free formaldehyde at a level (355 ppm) close to the established sensitisation level, i.e. it cannot be ruled out that there might also be a risk of sensitisation when using this product.

For 12 out of a total of 31 (39%) products analysed (with the quantitative method of analysis), a risk of sensitisation possibly exists. It should be noted that a conservative approach has been used in determining the above sensitisation levels. According to the perfume industry's risk assessment model, the listed sensitisation levels should be multiplied by a factor of 0.33 for leave-on products that are intended to be used on the face or body. This is in order to account for the risk of using several cosmetic products containing the same allergen, thus leading to a higher daily exposure. This project illustrates that there is a real risk that, for example an eye cream, face cream, body lotion and self-tanner, each with a content of free formaldehyde, are all used on the same day. In actuality, more cosmetic products than the 12 products listed above may carry a risk of sensitisation, if several products containing free formaldehyde are used on the same day.

For 16 products, free formaldehyde was found with the quantitative method of analysis, even though the products do not have a formaldehyde releaser on their list of ingredients. These products are distributed as follows:

- One make-up remover (355 ppm)
- Two eye creams (191 and 262 ppm)
- 13 self-tanners (12-76 ppm: nine products) (four products:103; 210; 480; 507 ppm)

Thus, the products are from different product categories, although self-tanners make up a large proportion of the group. For self-tanners, the survey in this project showed that the ingredient DHA (dihydroxyacetone) may contain residues or impurities of free formaldehyde, which may be a significant explanation for the overrepresentation of self-tanners in the above list. The results of the semi-quantitative analyses of all 150 cosmetic products also show a correlation between self-tanner and a content of free formaldehyde in products without a formaldehyde releaser on the list of ingredients. All 13 self-tanners with a content of free formaldehyde above 10 ppm contain DHA.

The conclusion is that except for products that contain a formaldehyde releaser according to the list of ingredients and products that contain DHA, there are still a total of three products containing free formaldehyde at levels above 10 ppm, for which there is a risk of elicitation (one make-up remover and two eye creams).

Some of the products with this so-called hidden formaldehyde, i.e. both the products containing DHA (self-tanners) and the other products, where there is no formaldehyde releasers on the list of ingredients, would, based on the models used in this report, constitute a significant risk of both sensitisation and elicitation. Thus, it is of immediate concern that hidden formaldehyde has been found in so many products. Similar findings have been seen in other scientific studies (Hauksson et al., 2015b; Malinauskinene et al., 2015; ACCC, 2010; Jairoun, 2020), which was one of the reasons for initiating this project.

Risk of other effects
The critical effect of formaldehyde when the substance is in contact with the skin is allergy. There is no absorption of formaldehyde through the skin, as formaldehyde reacts with the water content of the skin. Thus, when a risk assessment of formaldehyde for other effects is to be conducted, it only makes sense to perform this assessment for products applied via a spray, since a risk of exposure through inhalation exists for these products. This is the case for two of the purchased self-tanners, but only one of them was subjected to a quantitative analysis for free formaldehyde. The second product showed no evidence of free formaldehyde in the initial semi-quantitative analysis conducted for all of the products in the project. For this one self-tanner, a risk assessment of possible health effects from using the product has been conducted.

Formaldehyde is a carcinogen, but the carcinogenic effects of inhalation (nose cancer) are seen at higher concentrations than the so-called sensory effects of formaldehyde. The critical effect of formaldehyde through inhalation is thus sensory effects, such as irritation of the respiratory tract and irritation of the eyes, which is seen by increased blinking of the eyes. The risk assessment is based on these levels and on a worst-case assumption that all formaldehyde contained in the self-tanner evaporates in the inhalation zone (at the head). It is also assumed that no venting takes place.

Under these worst-case conditions, the calculations show that there may be a short-term exceedance of the limit value for sensory irritation, i.e. there may be discomfort (faster eye blinking) when using this self-tanner directly in the inhalation zone. However, there are strong indications that the irritation will be short-lived, partly because formaldehyde reacts/oxidises rapidly in the air, and partly because there will always be some form of natural ventilation in the room. The use of this self-tanning spray will contribute to an increase in the overall indoor concentration of formaldehyde, but it is a product that is likely to be used twice a week at most (apart from the first application, where it can be used up to four times a week until the desired colour is achieved). It cannot be concluded whether there will be a risk of sensory irritation or not, as this depends on the actual concentration of formaldehyde in the spray mist, which has only been calculated theoretically in this project and has not been measured. However, worst-case calculations show that there will be no risk of developing nasal cancer from using this self-tanning spray twice a week for a prolonged period of time.

12. References

ACCC, 2010. Australian Competition & Consumer Commission. ACCC Research survey of formaldehyde in cosmetics. Final report. November 2010. https://www.productsafety.gov.au/system/files/ACCC%20research%20survey%20of%20Formaldehyde%20in%20Cosmetics.pdf

Andersen et al., 2001. Andersen KE, Johansen JD, Bruze M, Frosch PJ, Goossens A, Lepoittevin JP, Rastogi S, White I, Menné T. The time-dose-response relationship for elicitation of contact dermatitis in isoeugenol allergic individuals. Toxicol Appl Pharmacol. 2001 Feb 1;170(3):166-71. doi: 10.1006/taap.2000.9095.

Andersen et al., 2014. Survey of Formaldehyde. Part of the LOUS review Environ-mental project No 1618, 2014. Andersen DN, Slothuus T, Larsen PB. DHI. Danish EPA. https://www2.mst.dk/Udgiv/publications/2014/11/978-87-93283-23-7.pdf

Api et al., 2008. Api AM, Basketter DA, Cadby PA, Cano MF, Ellis G, Gerberick GF, Griem P, McNamee PM, Ryan CA, Safford R. Dermal sensitization quantitative risk assessment (QRA) for fragrance ingredients. Regul Toxicol Pharmacol. 2008 Oct;52(1):3-23. doi: 10.1016/j.yrtph.2007.10.008

Api et al., 2020. Updating exposure assessment for skin sensitization quantitative risk assessment for fragrance materials. Api AM, Basketter DA, Bridges J, Cadby PA, Ellis G, Gilmour N, Greim H, Griem P, Kern P, Khaiat A, O'Brian J, Rustmeyer T, Ryan C, Safford B, Smith B, Vay M, White IR. Regulatory Toxicology and Pharmacology, Volume 118, December 2020, 104805. https://doi.org/10.1016/j.yrtph.2020.104805. https://www.sciencedirect.com/science/article/pii/S0273230020302312?via%3Dihub

Ashland, 2015. Natrosol™ FPS-HB Hydroxyethylcellulose. SDS number R0702896. Ashland, 05/21/2015. https://thinkhwi.com/datasheets/2633/sds-resale/491B-NATROSOL%20FPS%20HB_(USA).PDF

Bach et al., 2012. Chemical migration in drinking water stored in polyethylene terephthalate (PET) bottles: a source of controversy. Bach C, Dauchy X, Chagnon M-C, Etienne S. Water Research, IWA Publishing, 2012, 46 (3), pp. 571-583.

Bach et al., 2014. Effect of sunlight exposure on the release of intentionally and/or non-intentionally added substances from polyethylene terephthalate (PET) bottles into water: Chemical analysis and *in vitro* toxicity. Bach C, Dauchy X, Severin I, Munoz J-F, Etienne S, Chagnon M-C. Food Chemistry 162 (2014) 63–71.

Basketter et al., 2001. Basketter DA, Wright ZM, Warbrick EV, Dearman RJ, Kimber I, Ryan CA, Gerberick GF, White IR. Human potency predictions for aldehydes using the local lymph node assay. Contact Dermatitis. 2001 Aug;45(2):89-

Basketter et al., 2008. Basketter DA, Catherine J Clapp, Bob J Safford, Ian R Jowsey, Pauline McNamee, Cindy A Ryan, G Frank Gerberick. Preservatives and skin sensitization quantitative risk assessment. Dermatitis Jan-Feb 2008;19(1):20-7.

Bergh et al., 1998. Formation of formaldehyde and peroxides by air oxidation of high purity polyoxyethylene surfactants. Bergh M, Magnusson K, Nilsson JLG, Karlberg A-T. Department of Occupational Medicine, Dermatology Division, National Institute for Working Life, Solna, Sweden. Contact Dermatitis, 1998, 39, 14-20.

Bruusgaard-Mouritsen et al., 2021. Facial contact dermatitis caused by cosmetic-relevant allergens. Bruusgaard-Mouritsen MA, Garvey LH, Johansen JD. Contact Dermatitis. 2021 Sep 5. doi: 10.1111/cod.13966. Online ahead of print.

CIR, 2002. Final report on the safety assessment of EDTA, calcium disodium EDTA, diammonium EDTA, dipotassium EDTA, disodium EDTA. TEA-EDTA, tetrasodium EDTA, tripotassium EDTA, trisodium EDTA, HEDTA and trisodium HEDTA. Int. J. Toxicol. 21 (Suppl. 2), 95-142, 2002, Cosmetic Ingredient Review. https://journals.sagepub.com/doi/pdf/10.1080/10915810290096522

COWI, 2013. Hazardous substances in plastic materials. TA 3017, 2013. Klima- og Forurensningsdirektoratet. COWI. Danish Technological Institute. January, 2013.

Danish Allergy Research Centre, 2006. Formaldehyde and formaldehyde releasers (*in Danish*). Videncenter for allergi. Accessed September 2021. https://www.videncenterforallergi.dk/kliniske-retningslinjer/patientinformation/patientinformation-formaldehyde/

Danish Allergy Research Centre, 2013. List of formaldehyde releasers *(in Danish)*. The list was updated March 15, 2013. Videncenter for allergi. https://www.videncenterforallergi.dk/formaldehyde-frigorere676/

de Groot et al., 1988. Patch test reactivity to DMDM hydantoin. Relationship to formaldehyd allergy. de Groot AC, van Joost T, Bos JD, van der Meeren HL, Weyland JW. Contact Dermatitis. 1988 Apr;18(4):197-201

de Groot et al., 2009. Formaldehyde-releasers: relationship to formaldehyde contact allergy. Contact allergy to formaldehyde and inventory of formaldehyde-releasers. de Groot AC, Flyvholm M, Lensen G, Menne T, Coenraads P-J (2009). Contact Dermatitis, 61(2), 63-85.

de Groot et al., 2010. Formaldehyde-releasers in cosmetics: relationship to formaldehyde contact allergy. Part 2. Patch test relationship to formaldehyde contact allergy, experimental provocation tests, amount of formaldehyde released, and assessment of risk to consumers allergic to formaldehyde. De Groot A, White IR, Flyvholm M-A, Lensen G, Coenraads P-J. Contact Dermatitis 2010: 62: 18–31.

Doi et al., 2010. Survey of formaldehyde (FA) concentration in cosmetics containing FA-donor preservatives. Doi T, Kajimura K, Taguchi S. Journal of Health Science, 56(1), 116-122, 2010.

Dow Deutschland, 2021. CELLOSIZE™ Hydroxyethyl Cellulose QP-300. Revision date: 14.11.2021. https://www.chempoint.com/products/download?grade=44729&doctype=sds

Ebner et al., 2020. Releas of melamine and formaldehyde from Melamine-Formaldehyde Plastic Kitchenware. Ebner I, Haberer S, Sander S, Kappenstein O, Luch A, Bruhn T. Molecules 2020, 25, 3629.

ECHA, 2016. Guidance on Information Requirements and Chemical Safety Assessment Chapter R.15: Consumer exposure assessment. Version 3.0. July 2016. https://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

ECHA, 2017. Investigation report. Formaldehyde and formaldehyde releasers. 15 March 2017.

https://echa.europa.eu/documents/10162/13641/annex_xv_report_formalde-hyde_en.pdf/58be2f0a-7ca7-264d-a594-da5051a1c74b

ECHA, 2019. Substance Evaluation Conclusion as required by REACH article 48 and evaluation report for formaldehyde. CAS no. 50-00-0. Evaluating Member State: France (ANSES). June 7, 2019.
https://echa.europa.eu/documents/10162/cc0acabf-6e82-f2ed-5dbe-8058f48ce6c4

ECHA, 2020. RAC, SEAC Opinion on an Annex XV dossier proposing restrictions on Formaldehyde and formaldehyde releasers. Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 13 March 2020) and SEAC's opinion (adopted 17 September 2020).
https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f

ECHA, 2021. Formaldehyde Registration Dossier ECHA. https://echa.europa.eu/da/registration-dossier/-/registered-dossier/15858

ECHA C&L, 2021. ECHAs Classification & Labelling database, tilgået 2021. https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database

EFSA, 2006. Use of formaldehyde as a preservative during the manufacture and preparation of food additives. Opinion of the Scientific Panel on food additives, flavorings, processing aids and materials in contact with food (AFC). The EFSA Journal (2006) 415, 1-10.
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2007.415

EFSA, 2014. Endogenous formaldehyde turnover in humans compared with exogenous contribtion from food sources EFSA Journal 2014;12(2):3550

EU Regulation 1223, 2009. Regulation (EC) no 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (EU Regulation 1223/2009.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&qid=1618988823579&from=EN

EU Regulation no. 10, 2011. Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0010-20200923&qid=1619256684822&from=EN

EU Regulation 831, 2019. Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0831&qid=1618989164417&from=EN

EU Regulation 1181, 2022. Commission Regulation (EU) 2022/1181 of 8 July 2022 amending the preamble of Annex V to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products. https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:32022R1181&qid=1657546744104&from=en

EU Commission Recommendation no. 794, 2019. Commission Recommendation (EU) 2019/794 of 15 May 2019 on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food.

Executive Order 1426, 2021. Executive Order on threshold limit values for substances and materials. *In Danish: Bekendtgørelse om grænseværdier for stoffer og materialer. BEK nr. 1426 af 28.6.2021*. https://www.retsinformation.dk/eli/lta/2021/1426

Ezendam et al., 2018. Ezendam J, Bokkers BGH, Bil W, Delmaar JE. Skin sensitisation quantitative risk assessment (QRA) based on aggregate dermal exposure to methylisothiazolinone in personal care and household cleaning products. Food Chem Toxicol. 2018 Feb;112:242-250. doi: 10.1016/j.fct.2017.12.054.

Fasth et al., 2018. Ten-year trends in contact allergy to formaldehyde and formaldehyde-releasers. Fasth IM, Ulrich NH, Johansen JD. Contact Dermatitis. 2018 Nov;79(5):263-269. doi: 10.1111/cod.13052. Epub 2018 Aug 6.

Fischer et al., 2009. The dose-response relationship between the patch test and ROAT and the potential use for regulatory purposes. Fischer LA, Voelund A, Andersen KE, Menné T, Johansen JD. Contact Dermatitis. 2009 Oct;61(4):201-8. doi: 10.1111/j.1600-0536.2009.01607.x.

Fischer et al., 2011. Can exposure limitations for well-known contact allergens be simplified? An analysis of dose-response patch test data. Fischer LA, Menné T, Voelund A, Johansen JD. Contact Dermatitis. 2011 Jun;64(6):337-42. doi: 10.1111/j.1600-0536.2011.01876.x. Epub 2011 Apr 28.

Friedmann & Pickard, 2014. Contact hypersensitivity: quantitative aspects, susceptibility and risk factors. Friedmann PS, Pickard C. Exp Suppl. 2014;104:51-71. doi: 10.1007/978-3-0348-0726-5_5.Review

Gerberick et al. 2005. Compilation of historical local lymph node data for evaluation of skin sensitization alternative methods. Gerberick GF, Cindy A Ryan, Petra S Kern, Harald Schlatter, Rebecca J Dearman, Ian Kimber, Grace Y Patlewicz, David A Basketter. Dermatitis 2005 Dec;16(4):157-202.

Geiss et al., 2016. Correlation of volatile carbonyl yields emitted by e-cigarettes with the temperature of the heating coil and the perceived sensorial quality of the generated vapours. Geiss O, Bianchi I, Barrero-Moreno J. International Journal of Hygiene and Environmental Health. Volume 219, Issue 3, May 2016, Pages 268-277.
https://www.sciencedirect.com/science/article/pii/S1438463916000158?via%3Dihub

GE Silicones, 1999. Regarding the evolution of formaldehyde from polydimethylsiloxanes. GE Silicones, Waterford, NY 12188, September 1999. https://imageserv5.team-logic.com/mediaLibrary/99/Formaldehyde_Generation_-_GE_Silicones.pdf

Goon et al., 2003. Presence of formaldehyde in topical corticosteroid preparations available on the Swedish market. Goon AT-J, Gruvberger B, Persson L, Isaksson M, Bruze M. Contact Dermatitis 2003, 48, 199-203.

Halla et al., 2018. Cosmetics Preservation: A Review on Present Strategies. Halla N, Fernandes IP, Heleno SA,Costa P, Boucherit-Otmani Z, Boucherit K, Rodrigues AE, Ferreira ICFR, Barreiro MF. Molecules, 2018, 23, 1571.

Hauksson et al., 2015a. Formaldehyde in cosmetics in patch tested dermatitis patients with and without contact allergy to formaldehyde. Hauksson I, Pontén A, Isaksson M, Hamada H, Engfeldt M, Bruze M. Department of Occupational and Environmental Dermatology, Skåne University Hospital, Lund University, Malmö, Sweden. Contact Dermatitis, 74, 145-151. doi: 10.1111/cod.12493.

Hauksson et al., 2015b. Skincare products containing low concentrations of formaldehyde detected by the chromotropic acid method cannot be safely used in formaldehyde-allergic patients. Hauksson I, Pontén A, Gruvberger B, Isaksson M, Engfeldt M, Bruze M.Br J Dermatol. 2016 Feb;174(2):371-9. doi: 10.1111/bjd.14241. Epub 2015 Nov 30.

Heede, 2016. Epidemiology of dermatitis. A cahracterisation of genetic predisposition and personal consequences. Heede NG. PhD Thesis. University of Copenhagen 2016. ISBN nr- 978-87-92613-89-9.

Hemenway et al., 2012. Formation of reactive impurities in aqueous and neat polyethylene glycol 400 and effects of antioxidants and oxidation inducers. Hemenway JN, Carvalho TC, Rao VM, Wu Y, Levons JK, Narang AS, Paruchuri SR, Stamato HJ, Varia SA. Journal of Pharmaceutical Sciences, Vol. 101, No. 9, September 2012.

Hilton et al., 1998. Estimation of relative skin sensitizing potency using the local lymph node assay: a comparison of formaldehyd with glutaraldehyde. Hilton J, Dearman RJ, Harvey P, Evans P, Basketter DA, Kimber I. Am J Contact Dermat. 1998 Mar;9(1):29-33.

IARC, 2006. IARC Monographs on the Evaluation of Carcinogenic Risk in Humans. 2006. Formaldehyde, 2-Butoxyethanol and 1-tret-Butoxypropan-2-ol. Volume 88.

Isaksson et al., 2006. Can an imidazolidinyl urea-preserved corticosteroid cream be safely used in individuals hypersensitive to formaldehyde. Isaksson M, Gruvberger B, Goon AT, Bruze M. Contact Dermatitis. 2006 Jan;54(1):29-34.

Jairoun et al., 2020. Hidden formaldehyde content in cosmeceuticals containing preservatives that release formaldehyde and their compliance behaviors: bridging the gap between compliance and local regulation. Jairoun AA, Al-Hemyari SS-A, Shahwan M, Zyoud SH, Ashames A. Cosmetics 2020, 7, 93.

Jensen et al., 2016. Thermal Decomposition of Electronic Cigarette Liquids. Portland State University, 2016. https://pdxscholar.library.pdx.edu/cgi/viewcontent.cgi?article=4091&context=open_access_etds

Jensen et al., 2005. Methyldibromo glutaronitrile contact allergy: effect of single versus repeated daily exposure. Jensen CD, J Ohansen JD, Menné T, Andersen KE. Contact Dermatitis. 2005 Feb;52(2):88-92. doi: 10.1111/j.0105-1873.2005.00505.x.

Johansen et al., 1996. Threshold responses in cinnamic-aldehyde-sensitive subjects: results and methodological aspects. Johansen JD, K E Andersen, S C Rastogi, T Menne. Contact Dermatitis 1996 Mar;34(3):165-71. doi: 10.1111/j.1600-0536.1996.tb02167.x.

Johansen et al., 2015. European Society of Contact Dermatitis guideline for diagnostic patch testing - recommendations on best practice. Johansen JD, Aalto-Korte K, Agner T, Andersen KE, Bircher A, Bruze M, Cannavó A, Giménez-Arnau A, Gonçalo M, Goossens A, John SM, Lidén C, Lindberg M, Mahler V, Matura M, Rustemeyer T, Serup J, Spiewak R, Thyssen JP, Vigan M, White IR, Wilkinson M, Uter W. Contact Dermatitis. 2015 Oct;73(4):195-221. doi: 10.1111/cod.12432.

Jordan et al., 1979. Threshold responses in formaldehyd-sensitive subjects. Jordan WP Jr, Sherman WT, King SE. J Am Acad Dermatol. 1979 Jul;1(1):44-8. doi: 10.1016/s0190-9622(79)70003-x.

Kajimura et al., 2008. The release of formaldehyde upon decomposition of 2-bromo-2-nitropropan-1,3-diol (Bronopol). Kajimura K, Tagami T, Yamamoto T, Iwagami S. Journal of Health Scince 54(4), 488-492, 2008.

Kligman, 1966. The identification of contact allergens by human assay. 3. The maximization test: a procedure for screening and rating contact sensitizers. Kligman AM. J Invest Dermatol. 1966 Nov;47(5):393-409. doi: 10.1038/jid.1966.160

Kimyon et al., 2021. Isothiazolinone Detection in Dish Soap and Personal Care Products: Comparison of Lovibond Isothiazolinone Test Kit and Ultrahigh-Performance Liquid Chromatography–Tandem Mass Spectrometry. Kimyon RS, Zang L-Y, Siege PD, Voller LM, Schlarbaum JP, Warshaw EM. Dermatitis. 2021 Jul-Aug; 32(4): 245–250. doi: 10.1097/DER.0000000000000672. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8330411/

Larsen et al., 2021. Survey and risk assessment of chemicals in knitting yarn. Survey of chemical substances in consumer products no. 184, March 2021. Danish EPA. Larsen PB, Semark ID, Andersen ES, Andersen DN, DHI. Kolarik B, Jensen A, Eriksen JV, Medico Kemiske Laboratorium. https://www2.mst.dk/Udgiv/publications/2021/03/978-87-7038-290-8.pdf

Latorre et al., 2011. Allergic contact dermatitis caused by formaldehyde and formaldehyde releasers. Latorre N, Silvestre JF, Monteagudo AF. Actas Dermosifiliogr., 2011; 102(2); 86-97.

Lv et al., 2015. Investigation on formaldehyde release from preservatives in cosmetics. Lv C, Hou J, Xie W, Cheng H. Int. J. Cosmet. Sci. 2015, 37, 474–478. https://onlinelibrary.wiley.com/doi/abs/10.1111/ics.12212

Malinauskiene et al., 2015. Formaldehyde may be found in cosmetic products even when unlabelled. Malinauskiene L, Blaziene A, Chomiciene A, Isaksson M. Open Med. 2015; 10: 323-328. https://www.researchgate.net/publication/282459964_Formaldehyde_may_be_found_in_cosmetic_products_even_when_unlabelled

Marzulli & Maibach, 1974. The use of graded concentrations in studying skin sensitizers: experimental contact sensitization in man. Marzulli FN, Maibach HI. Food Cosmet Toxicol. 1974 Apr;12(2):219-27. doi: 10.1016/0015-6264(74)90367-8.

Moldoveanu & Chou, 2018. Pyrolysis of glycerin at different temperatures and heating rates. Moldoveanu SC, Chou C-E. 2018. https://www.coresta.org/sites/default/files/abstracts/2018_TSRC82_Moldoveanu.pdf

NASEM, 2018. National Academies of Sciences, Engineering, and Medicine. 2018. Public health consequences of e-cigarettes. Washington, DC: The National Academies Press. https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf

Noeisen et al., 2007. Difficulties in avoiding exposure to allergens in cosmetics. Noiesen E, Munk MD, Larsen K, Johansen JD, Agner T.Contact Dermatitis. 2007 Aug;57(2):105-9. doi: 10.1111/j.1600-0536.2007.01170.x. https://pubmed.ncbi.nlm.nih.gov/17627650/

Ooi et al., 2018. Influence of the E-Cigarette Emission Profile by the Ratio of Glycerol to Propylene Glycol in E-Liquid Composition. Ooi BG, Dutta D, Kazipeta K, Chong NS. ACS Omega 2019, 4, 13338−13348. https://pubs.acs.org/doi/pdf/10.1021/acsomega.9b01504

OSHA, 2011. Hair smoothing products that could release formaldehyde. Updated 9/2011. OSHA, Occupational Safety and Health Organisation. https://www.osha.gov/sites/default/files/hazard_alert.pdf

Poulsen et al., 2021. Survey and risk assessment of chemicals in textile face masks. *The report has not been published yet. Is expected to be published during 2021.* Poulsen PB, Geschke S, Gelardi RM, Borregaard C, Ostenfeldt M, Merlin C, FORCE Technology. Knudsen LE, Copenhagen University. Danish EPA.

Proksch, 2018. pH in nature, humans and skin. The Journal of Dermatology. Vol. 45, Issue 9, September 2018, pp. 1044-1052. https://onlinelibrary.wiley.com/doi/epdf/10.1111/1346-8138.14489

Robnik et al., 2020. A novel testing approach for oxidative degradation dependent incompatibility of amine moiety containing drugs with PEGs in solid-state. Robnik B, Naumoska K, Casar Z. Pharmaceutics, 2020, 12, 37.

SCCS/1347/10, 2010. Scientific Committee on Consumer Safety SCCS. Opinion on dihydroxyacetone. Adopted on 9th plenary meeting on 14 December 2010.

SCCS/1459/11, 2012. Scientific Committee on Consumer Safety SCCS. OPINION on Fragrance allergens in cosmetic products. Adopted on 26-27 June 2012. SCCS/1459/11

SCCS/1538/14, 2014. Scientific Committee on Consumer Safety, SCCS. Opnion on the safety of the use of formaldehyde in nail hardeners. SCCS/1538/14. Revision of 16 December 2014. https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_164.pdf

SCCS/1567/15, 2015. Scientific Committee on Consumer Safety, SCCS. Memorandum on use of Human Data in risk assessment of skin sensitization. Adopted on 15 December 2015. SCCS/1567/15

SCCS/1589/17, 2018. Scientific Committee on Consumer Safety, SCCS. OPINION ON Skin Sensitisation Quantitative Risk Assessment for Fragrance Ingredients (QRA2) Adopted on 30 July 2018. SCCS/1589/17

SCCS/1612/19, 2020. Scientific Committee on Consumer Safety, SCCS. Opinion on Dihydroxyacetone – DHA (1,3-Dihydroxy-2-propanone). CAS No. 96-26-4. SCCS/1612/19. Adopted on meeting 3-4 March 2020.

SCCS, 2021. Scientific Committee on Consumer Safety (SCCS). Request for a scientific advice on the threshold for the warning ‘contains formaldehyde’ in Annex V, preamble point 2 for formaldehyde-releasing substances. 12 February 2021.

SCCS/1628/21, 2021. Scientific Committee on Consumer Safety SCCS. THE SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation. 11th revision. Adopted 30-31 March 2021. SCCS/1628/21. https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_250.pdf

SCCS/1632/21, 2021. Scientific Committee on Consumer Safety. SCCS. Scientific advice on the threshold for the warning ‘contains formaldehyde’ in Annex V, preamble point 2 for formaldehyde-releasing substances. https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_254.pdf

Scott et al., 2002. Insights into the quantitative relationship between sensitization and challenge for allergic contact dermatitis reactions. Scott AE, Kashon ML, Yucesoy B, Luster MI, Tinkle SS. Toxicol Appl Pharmacol. 2002 Aug 15;183(1):66-70. doi: 10.1006/taap.2002.9469.

Songprasirt et al., 2015. Migration of formaldehyde from urea plastic bowl into cooked instant noodles. Songprasirt N, Vatanasomboon P, Sujirarat D, Singhakant C. Asia Journal of Public Healht, 2015; 6(2), 63-69.

Soroory et al., 2013. Application of PDMS-based coating in drug delivery systems using PVP as channeling agent. Soroory H, Mashak A, Rahimi A. Iran Polym J (2013) 22:791–797. https://www.researchgate.net/publication/258169000_Application_of_PDMS-based_coating_in_drug_delivery_systems_using_PVP_as_channeling_agent

Susak, 1996. The use of Methenamine as an antiperspirant for amputees. Susak Z, Minkov R, Isakov E. Prosthetics and Orthotics International, 1996, 20, 172-175.

White et al., 1986. The effect of altering area of application and dose per unit area on sensitization by DNCB. White SI, Friedmann PS, Moss C, Simpson JM. Br J Dermatol. 1986 Dec;115(6):663-8. doi: 10.1111/j.1365-2133.1986.tb06646.x.

WHO, 2000. Air Quality Guidelines for Europe. Second edition. WHO regional publications, European Series, No 91. https://www.euro.who.int/__data/assets/pdf_file/0005/74732/E71922.pdf

WHO, 2005. Formaldehyde in Drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality. WHO/SDE/WSH/05.08/48. https://www.who.int/water_sanitation_health/dwq/chemicals/formaldehyde130605.pdf

WHO, 2010. World Health Organization. WHO Guidelines for indoor air quality: Selected Pollutants. https://www.euro.who.int/__data/assets/pdf_file/0009/128169/e94535.pdf

Wolkoff & Nielsen, 2011. New WHO norm for formaldehyde. (*In Danish:* Ny WHO-norm for formaldehyd). Dansk kemi, 92, nr. 4, 2011. https://www.kemifokus.dk/wp-content/uploads/sites/7/DAK4-2011-s19-21.pdf

Zachariae et al., 2005. Experimental elicitation of contact allergy from a diazolidinyl urea-preserved cream in relation to anatomical region, exposure time and concentration. Zachariae C, Hall B, Cottin M, Cupferman S, Andersen KE, Menné T. Contact Dermatitis. 2005 Nov;53(5):268-77. doi: 10.1111/j.0105-1873.2005.00712.x.

Appendix 1. Results of the semi-quantitative analyses

This appendix contains the results of the semi-quantitative analyses for free formaldehyde by use of the CA method (colour-reaction-method).

The results are listed for each product and categorised in order according to product type. It is listed whether the product contains one or more of the five ingredients in focus, and whether the packaging of the products is made of PET. Moreover, it is listed whether the product contains a formaldehyde releaser (preservative) according the list of ingredients, and if the product is marketed for e.g. dry skin or eczematous skin.

The results of the CA method are concentrations of free formaldehyde in a given interval.

TABEL 30. Semi-quantitative results for the content of free formaldehyde by use of the CA-method for all 150 purchased products. The products are listed in order according to their product type, and thereafter by origin (where the product has been purchased, i.e. DK (Denmark), EU (EU) or NEU (outside EU/non-EU)).

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
DK-10	Face cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 61	No	PEG-12 dimethicone	No
DK-12	Face cream	Plastic	< 2.5	-	No	No	No	Polysorbate 80	No	PEG-9	No
DK-13	Face cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 60	No	No	No
DK-14	Face cream	PET	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	No	No
DK-15	Face cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	INo	No
DK-16	Face cream	Glass	< 2.5	-	No	No	Glycerine	No	No	PEG-20 PEG-30 PEG-100	No
DK-18	Face cream	Glass	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-100	No
DK-19	Face cream	PET	< 2.5	-	No	No	No	Polysorbate 80	No	PEG-18	No
DK-20	Face cream	Glass	< 2.5	-	No	No	No	No	No	PEG-100	No
DK-21	Face cream	Glass	< 2.5	-	Other	No	Glycerine	Polysorbate 80	No	PEG-40	No
DK-32	Face cream	Plastic	40 ≤ x < 100	-	Dry skin	Imidazolidinyl urea	No	No	No	PEG-10	No
EU-2	Face cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-75 stearate PEG-8	No
EU-4	Face cream	Glass	< 2.5	-	No	No	Glycerine	No	No	No	No

Lab. no.	Product type	Packaging material	Result free formalde-hyde (interval)	Discoloura-tion of fluid	For special skin	Content according to list of ingredients					
						Contains formalde-hyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-com-pound	Contains cocami-dopropylbe-taine
EU-5	Face cream	Glass	≥ 100	-	No	Diazolidinyl urea	Glycerine	No	No	PEG-40 Hy-drogenated Castor oil	No
EU-8	Face cream	Plastic	< 2.5	-	Dry skin	No	No	Polysorbate 60	No	No	No
EU-11	Face cream	Plastic	2.5 ≤ x < 5	Orange	Other	No	Glycerine	Polysorbate 80	No	PEG-100-stearat	No
NEU-6	Face cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	No	No
NEU-7	Face cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-100-stearat	
NEU-17	Face cream	Other	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	No	No
NEU-22	Face cream	Plastic	< 2.5	-	No	Not listed	No list of in-gredients	No list of in-gredients	No list of in-gredients	No list of in-gredients	No list of in-gredients
NEU-23	Face cream	Plastic	≥ 100	-	No	Not listed	No list of in-gredients	No list of in-gredients	No list of in-gredients	No list of in-gredients	No list of in-gredients
DK-34	Body lotion	Plastic	< 2.5	Yellow	Other	No	Glycerine	Polysorbate 60	No	Ingen	No
DK-36	Body lotion	Plastic	< 2.5	Yellow	Dry skin	No	Glycerine	No	No	PEG-75	No
DK-37	Body lotion	Plastic	< 2.5	Yellow	Dry skin	No	Glycerine	Polysorbate 80	No	PEG-40	No
DK-38	Body lotion	Plastic	< 2.5	Yellow	No	No	Glycerine	Polysorbate 80	No	PEG-100	No
DK-40	Body lotion	Plastic	< 2.5	-	Dry skin	No	Glycerine	No	No	No	No
DK-41	Body lotion	Plastic	≥ 100	-	No	Diazolidinyl urea	Glycerine	No	No	ingen	No
DK-42	Body lotion	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	No	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
DK-43	Body lotion	Plastic	< 2.5	-	No	No	No	Polysorbate 80	No	No	No
DK-44	Body lotion	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-18	No
DK-45	Body lotion	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-100	No
DK-46	Body lotion	Plastic	< 2.5	-	Dry skin	No	Glycerine	No	No	PEG-100	No
DK-68	Body lotion	Plastic	≥ 100	-	No	Sodium hydroxymethylglycinate	Glycerine	No	No	ingen	No
EU-1	Body lotion	Glass	< 2.5	-	Dry skin	No	No	Polysorbate 80	No	PEG-100-stearat	No
EU-3	Body lotion	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	PEG-100-stearat	No
EU-26	Body lotion	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	PEG-100-stearat	No
EU-27	Body lotion	Plastic	< 2.5	Yellow	Eczematous skin	No	Glycerine	No	No	No	No
EU-33	Body lotion	Plastic	2.5 ≤ x < 5	Dark-Orange	No	No	Glycerine	No	No	PEG-100-stearat	No
EU-35	Body lotion	Plastic	< 2.5	Yellow-Orange	Other	No	Glycerine	No	No	Ingen	No
NEU-28	Body lotion	Plastic	≥ 100	-	Dry skin	Diazolidinyl urea	Glycerine	Polysorbate 60	No	No	No
NEU-29	Body lotion	PET	2.5 ≤ x < 5	Orange	Dry skin	No	Glycerine	No	No	PEG-100-stearat	No
NEU-30	Body lotion	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	No	No
NEU-31	Body lotion	Plastic	< 2.5	Yellow-Orange	No	No	Glycerine	No	No	No	No
NEU-39	Body lotion	Plastic	≥ 100	-	No	DMDM hydantoin	No	No	No	No	No
DK-51	Hand cream	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	PEG-20	No

Lab. no.	Product type	Packaging material	Result free formalde-hyde (interval)	Discoloura-tion of fluid	For special skin	Content according to list of ingredients					
						Contains formalde-hyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-com-pound	Contains cocami-dopropylbe-taine
DK-56	Hand cream	Plastic	2.5 ≤ x < 5	-	No	No	Glycerine	Polysorbate 60	No	PEG-25	No
DK-60	Hand cream	Plastic	< 2.5	-	Dry skin	No	Glycerine	No	No	PEG-100-stearat	No
DK-61	Hand cream	Plastic	< 2.5	-	Dry skin	No	Glycerine	No	No	PEG-100-stearat	No
DK-62	Hand cream	Other	< 2.5	-	No	No	Glycerine	No	No	No	No
DK-63	Hand cream	PET	< 2.5	-	No	No	Glycerine	No	No	No	No
DK-64	Hand cream	Plastic	< 2.5	-	Dry skin	No	Glycerine	No	No	No	No
DK-65	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	No	No
DK-69	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-100	No
DK-70	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-100	No
EU-55	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-40 stea-rate	No
EU-57	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-18	No
EU-58	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-100-stearat	No
EU-59	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-100-stearat	No
EU-72	Hand cream	Plastic	20 ≤ x < 40	-	No	Imidazolidinyl urea	Glycerine	No	No	PEG-100	No
NEU-52	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	Ingen	No
NEU-53	Hand cream	Plastic	2.5 ≤ x < 5	-	No	Diazolidinyl urea	Glycerine	Polysorbate 60	No	PEG-10 phy-tosterol	No
NEU-54	Hand cream	Other	< 2.5	Yellow	Dry skin	No	Glycerine	No	No	Ingen	No
NEU-66	Hand cream	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	No	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
NEU-67	Hand cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	No	No
NEU-71	Hand cream	Plastic	40 ≤ x < 100	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients
DK-138	Make-up remover	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-10 PEG-4	No
DK-77	Make-up remover	PET	< 2.5	Yellow, Lightly discoloured	No	No	Glycerine	Polysorbate 80	No	Ingen	No
DK-78	Make-up remover	PET	< 2.5	Light Yellow	Other	No	Glycerine	Polysorbate 80	No	PEG-7 Caprylic/Capric glycerides PEG-6 Caprylic/capric glycerides	No
DK-81	Make-up remover	Plastic	< 2.5	Light Yellow	No	No	Glycerine	Polysorbate 80	No	PEG-100 Sterarate PEG-150 Distearate	Cocamidopropylbetain
DK-85	Make-up remover	Plastic	< 2.5	Perhaps lightly coloured	No	No	Glycerine	No	No	PEG-6 Caprylic/Capric Glycerides	No
DK-86	Make-up remover	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	PEG-6 Caprylic/Capric Glycerides	No
DK-89	Make-up remover	PET	≥ 100	-	No	No	Glycerine	No	No	PEG-30	Cocamidopropylbetain
DK-90	Make-up remover	PET	< 2.5	-	No	No	No	No	No	No	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
DK-91	Make-up remover	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-7	No
DK-93	Make-up remover	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	No	Cocamidopropylbetain
EU-79	Make-up remover	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-60 glyceryl stearatese PEG-8	Cocamidopropylbetain
EU-83	Make-up remover	Plastic	< 2.5	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients
EU-131	Make-up remover	PET	< 2.5	-	No	No	Glycerine	No	No	No	No
NEU-76	Make-up remover	PET	< 2.5	-	No	No	Glycerine	No	No	Ingen	No
NEU-80	Make-up remover	PET	< 2.5	-	No	No	Glycerine	No	No	Ingen	No
NEU-82	Make-up remover	Plastic	< 2.5	-	No	No	No	Polysorbate 85	No	PEG-12 Laurate	No
NEU-84	Make-up remover	PET	< 2.5	Yellow	No	No	Glycerine	No	No	Ingen	No
NEU-88	Make-up remover	PET	< 2.5	-	No	No	Glycerine	No	No	No	No
NEU-92	Make-up remover	PET	≥ 100	-	No	DMDM hydantoin	No	No	No	Ingen	No
DK-107	Self-tanner	Plastic	≥ 100	Dark red	No	No	Glycerine	No	Dihydroxyacetone	Ingen	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
DK-113	Self-tanner	Metal	20 ≤ x < 40	Light red	No	No	No	Polysorbate 20	Dihydroxyacetone	No	Cocamidopropylbetain
DK-114	Self-tanner	PET	2.5 ≤ x < 5	-	No	No	Glycerine	No	Dihydroxyacetone	No	Cocamidopropylbetain
DK-115	Self-tanner	PET	10 ≤ x < 20	-	No	No	Glycerine	No	Dihydroxyacetone	No	Cocamidopropylbetain
DK-117	Self-tanner	PET	40 ≤ x < 100	-	No	No	Glycerine	No	Dihydroxyacetone	No	Cocamidopropylbetain
DK-118	Self-tanner	Metal	10 ≤ x < 20	Purple	No	No	Glycerine	Polysorbate 20	Dihydroxyacetone	No	No
DK-119	Self-tanner	Plastic	2.5 ≤ x < 5	Reddish	No	No	Glycerine	Polysorbate 60	Dihydroxyacetone	PEG-100	No
DK-120	Self-tanner	Glass	10 ≤ x < 20	-	No	No	Glycerine	No	Dihydroxyacetone	No	No
DK-121	Self-tanner	Plastic	< 2.5	Yellow	No	No	Glycerine	Polysorbate 60	Dihydroxyacetone	PEG-6 PEG-27 PEG-40	No
DK-122	Self-tanner	Plastic	2.5 ≤ x < 5	Green/purple bottom	No	No	Glycerine	Polysorbate 60	Dihydroxyacetone	Ingen	No
DK-124	Self-tanner	Plastic	< 2.5	Yellow	No	No	No	No	Dihydroxyacetone	No	No
EU-101	Self-tanner	Metal	< 2.5	Yellow, Lightly discoloured	No	No	Glycerine	No	No	PEG-10 PEG-18	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
EU-102	Self-tanner	Plastic	5 ≤ x < 10	-	No	No	No	No	Dihydroxyacetone	Ingen	No
EU-103	Self-tanner	Plastic	10 ≤ x < 20	Discoloured	No	No	Glycerine	Polysorbate 60	Dihydroxyacetone	Ingen	No
EU-105	Self-tanner	PET	< 2.5	Yellow	No	No	No	No	Dihydroxyacetone	PEG-18	No
EU-108	Self-tanner	PET	≥ 100	-	No	DMDM hydantoin	Glycerine	Polysorbate 20	Dihydroxyacetone	PEG-7	No
EU-109	Self-tanner	PET	< 2.5	Dark yellow/brown	No	No	Glycerine	No	Dihydroxyacetone	PEG-40	Cocamidopropylbetain
NEU-104	Self-tanner	Plastic	2.5 ≤ x < 5	-	No	No	Glycerine	No	Dihydroxyacetone	PEG-2 PEG-45M	No
NEU-106	Self-tanner	Metal	< 2.5	-	No	No	Glycerine	Polysorbate 20	Dihydroxyacetone	Ingen	No
NEU-110	Self-tanner	Plastic	< 2.5	-	No	2-Bromo-2-nitropropane-1,3-diol	Glycerine	Polysorbate 20	Dihydroxyacetone	Ingen	No
NEU-111	Self-tanner	Plastic	≥ 100	-	No	No	Glycerine	No	Dihydroxyacetone	Ingen	No
NEU-112	Self-tanner	PET	< 2.5	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients
NEU-123	Self-tanner	Glass	5 ≤ x < 10	Red-Orange	No	No	Glycerine	Polysorbate 80	Dihydroxacetone	No	No
DK-116	Skin tonic	PET	< 2.5	Dark Yellow	No	No	Glycerine	Polysorbate 80	No	No	No
DK-128	Skin tonic	Plastic	< 2.5	-	No	No	Glycerine	No	No	PEG-8 PEG-60	No
DK-130	Skin tonic	Plastic	< 2.5	-	No	No	No	No	No	PEG-6	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
DK-132	Skin tonic	PET	< 2.5	-	Other	No	Glycerine	No	No	No	No
DK-139	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	No	No
DK-140	Skin tonic	Plastic	< 2.5	Yellow	No	No	Glycerine	No	No	PEG-40 PEG-7	No
DK-141	Skin tonic	PET	< 2.5	Yellow and purple dots	No	No	Glycerine	No	No	No	No
DK-142	Skin tonic	PET	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-26 PEG-40	No
DK-145	Skin tonic	Glass	< 2.5	Yellow/Orange	Other	No	Glycerine	Polysorbate 80	No	No	No
DK-146	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	PEG-40	No
DK-87	Skin tonic	Plastic	< 2.5	Yellow-Orange	Dry skin	No	No	Polysorbate 60	No	PEG-100-stearat PEG-20 Stearate	No
EU-126	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	PEG-12 PEG-40	No
EU-127	Skin tonic	PET	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	PEG-40 PEG-9	No
EU-129	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	PEG-40	No
EU-136	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	PEG-40	No
EU-137	Skin tonic	Plastic	2.5 ≤ x < 5	Orange	No	No	Glycerine	Polysorbate 20	No	Ingen	No
NEU-133	Skin tonic	Glass	< 2.5	-	No	No	No	No	No	No	No
NEU-134	Skin tonic	PET	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	No	No
NEU-135	Skin tonic	PET	< 2.5	-	No	No	Glycerine	No	No	No	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
NEU-143	Skin tonic	Plastic	< 2.5	-	No	No	No	Polysorbate 20	No	PEG-4	No
NEU-144	Skin tonic	PET	< 2.5	Yellow	No	No	Glycerine	Polysorbate 20	No	No	No
NEU-147	Skin tonic	PET	< 2.5	Yellow	No	No	Glycerine	Polysorbate 20	No	PEG-16	No
DK-151	Eye cream	Plastic	5 ≤ x < 10	-	No	No	Glycerine	Polysorbate 80	No	Ingen	No
DK-152	Eye cream	Plastic	≥ 100	-	No	No	Glycerine	Polysorbate 80	No	PEG-8	No
DK-158	Eye cream	Plastic	< 2.5	-	No	No	No	Polysorbate 80	No	No	No
DK-159	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	No	No
DK-161	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	PEG-8	No
DK-162	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 60	No	PEG-20 PEG-60	No
DK-163	Eye cream	Plastic	< 2.5	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients
DK-165	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-40	No
DK-166	Eye cream	Glass	< 2.5	-	No	No	Glycerine	Polysorbate 80	No	PEG-18	No
DK-168	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	No	No
EU-154	Eye cream	PET	< 2.5	-	No	No	Glycerine	No	No	No	No
EU-155	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	No	No
EU-156	Eye cream	PET	< 2.5	-	No	No	Glycerine	No	No	No	No

Lab. no.	Product type	Packaging material	Result free formaldehyde (interval)	Discolouration of fluid	For special skin	Content according to list of ingredients					
						Contains formaldehyde releaser	Contains glycerine	Contains Polysorbate	Contains DHA	Contains PEG-compound	Contains cocamidopropylbetaine
EU-169	Eye cream	Plastic	< 2.5	Yellow	No	No	Glycerine	Polysorbate 60	No	Dimethicone/PEG-10/15 Crosspolymer	No
EU-9	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	No	No	No	No
NEU-153	Eye cream	Other	< 2.5	Light reddish, primarily yellow	No	No	Glycerine	Polysorbate 20	No	PEG-100-stearat PEG-8	No
NEU-157	Eye cream	Plastic	40 ≤ x < 100	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients
NEU-159	Eye cream	PET	≥ 100	-	No	DMDM hydantoin	Glycerine	No	No	No	No
NEU-160	Eye cream	Plastic	≥ 100	-	No	No	Glycerine	No	No	No	No
NEU-167	Eye cream	Plastic	< 2.5	-	No	No	Glycerine	Polysorbate 20	No	No	No
NEU-170	Eye cream	Plastic	20 ≤ x < 40	-	No	Not listed	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients	No list of ingredients

Survey and risk assessment of free formaldehyde in cosmetic products

The strong allergen formaldehyde is prohibited from use as an ingredient in cosmetic products. However, certain so-called formaldehyde releasers, which are preservatives that release formaldehyde, are permitted.

Scientific studies have found free formaldehyde in cosmetic products that didn't have a formaldehyde releaser on the list of ingredients. The studies question the origin of this formaldehyde.

Therefore, the Danish Environmental Protection Agency wanted to acquire knowledge on formaldehyde in cosmetics products, and to investigate whether there can be a risk to the consumers.

In the project, a mapping of sources of free formaldehyde in cosmetic products was conducted. Based on this, a number of product types were selected for further investigation. The focus was on leave-on products, for example lotions.

150 cosmetic products were purchased and analyzed for free formaldehyde. Additionally, for chosen products, a risk assessment was performed.

By analysis, free formaldehyde was identified in 23 products that didn't have a formaldehyde releaser on the list of ingredients. The assessment was that 16 of these products could elicit an allergic reaction in formaldehyde allergic individuals with eczema skin.

Due to the magnitude of the concentration of free formaldehyde, five of the products were assessed to pose a risk of induction of formaldehyde allergy in non-allergic consumers.

It was found that the ingredient dihydroxyacetone (DHA), that are used in self tanners, can be a cause of free formaldehyde. 14 of the 23 products, which contained free formaldehyde, but didn't have a formaldehyde releaser on the list of ingredients, were self tanners.

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