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Survey and risk assessment of chemicals in textile face masks

Survey of chemical substances in consumer products No. 187

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Foreword

Survey and risk assessment of chemicals in textile face masks

This project has investigated the occurrence of certain chemicals in textile face masks.

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

The project was conducted by FORCE Technology together with the Department of Environment and Health at the University of Copenhagen's Institute for Public Health Research, which served as a subcontractor for the hazard assessment of these substances. The analyses in this project were conducted primarily by FORCE Technology. However, Medico Kemiske Laboratorium ApS conducted the analyses for PFAS compounds and chlorinated flame retardants, and Eurofins Product Testing A/S conducted the analyses for iso-cyanates.

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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 to September 2021.

Summary and conclusions

This project investigated the presence and migration of chemical substances in washable, reusable fabric masks. This project focused exclusively on chemical substances in fabric masks; that is, such factors as virus/bacteria filtration capacity and the risk of inhaling small textile particles or fibres were not studied. The project's purpose was to gain knowledge of problematic chemicals in fabric masks, focusing on chemicals which irritate the skin and respiratory tract, which are sensitisers, and which are carcinogenic. The project also studied the washout rate of substances which are hazardous to the environment.

A total of 40 unique fabric masks on the Danish market were purchased, from both physical stores in Denmark and Danish websites. The pool of purchased face masks consisted of both single-colour and patterned masks, in various colours and at various prices (from 10 DKK to 100 DKK per mask). Nearly half of the face masks were made from blended textiles (often a cotton and polyester blend, though other types were also included), while the remaining masks were made from either 100% polyester or 100% cotton. While a large majority of the face masks comprised three layers of fabric, the number of layers in the masks varied from one to five. Chemical analyses were conducted on all layers polled into one sample for each face mask.

Based on existing knowledge about problematic substances in textiles, a joint decision was reached with the Environmental Protection Agency to conduct analyses for the chemical substances listed in TABLE 1. Analyses for silver, copper, zinc, and fluorinated substances / PFAS compounds were conducted primarily due to their effects on the environment; analyses for the remaining substances were conducted due to their effects on human health.

TABLE 1. Overview of chemical substance analyses performed on fabric masks in this project

Substance	Analysis performed on	Result	Comments
Fluorine	30 out of 40 face masks	Presence identified in 13 out of 30 face masks. Quantities in 7 masks suggested possible use of PFAS compounds. Maximum concentration: 920 mg/kg.	Presence of the element F indicates the presence of fluorinated substances / PFAS compounds. Follow-up analyses were performed for certain PFAS compounds.
Certain fluorinated substances / PFAS compounds	5 out of 7 face masks containing F	Only the fluorinated compound abbreviated 6:2 FTOH was identified, in 3 out of 5 fabric masks. Maximum concentration: 3.4 mg/kg.	Wash test performed. On average, 58% of the 6:2 FTOH had been washed out after five washes in a washing machine.
Silver	30 out of 40 face masks	Identified in two out of 30 face masks. Maximum concentration: 12 mg/kg.	Typically used for antibacterial properties. Pre- and post-wash analyses performed; artificial sweat migration test performed.
Copper	30 out of 40 face masks	Identified in 10 out of 30 face masks.	Used in various colourants.

Substance	Analysis performed on	Result	Comments
		Maximum concentration: 82 mg/kg.	Pre- and post-wash analyses performed; artificial sweat migration test performed.
Zinc	30 out of 40 face masks	Identified in six out of 30 face masks. Maximum concentration: 30 mg/kg.	Used due to its antibacterial properties, as a catalyst in colourants, and in anti-wrinkle treatments. Pre- and post-wash analyses performed; artificial sweat migration test performed.
Antimony	30 out of 40 face masks	Identified in 21 out of 30 face masks. Maximum concentration: 214 mg/kg.	Used as a catalyst in polyester production. Primarily identified in face masks made partially or entirely of polyester. Pre- and post-wash analyses performed; artificial sweat migration test performed.
Bisphenol A	20 out of 40 fabric masks, plus 10 elastics	Identified in seven face masks and two elastics. Maximum concentration: 0.71 mg/kg in fabric and 0.85 mg/kg in an elastic.	
Formaldehyde	40 out of 40 face masks	Identified in six out of 40 face masks. Maximum concentration: 55 mg/kg.	All 40 face masks complied with the recently established limit value of 75 mg/kg.
Chlorinated flame retardants (TCEP, TCPP, and TDCP)	25 out of 40 face masks	Not identified in any of the fabric masks studied.	
General screening for organic substances	40 out of 40 face masks	16 substances identified at significant concentrations. These included a biocide, a phthalate (DBP), and isocyanates.	Isocyanates were assessed to be the most problematic (identified in 13 face masks), and additional analyses for them were performed. The other organic substances typically occurred in only one or two masks and were not assessed to be problematic.
Isocyanates (10 distinct compounds)	5 out of 13 face masks	Three of the 10 isocyanates were identified. Maximum total concentration of isocyanates: 0.38 mg/kg.	Isocyanates react with water, so they are unlikely to be present in washed face masks.

In summary, the purchased face masks were analysed for a broad array of problematic chemicals, though analyses for every possible problematic chemical were beyond the scope of this project. Some decisions were made based on existing knowledge of problematic chemical substances in textiles, as well as to focus on substances that may be problematic with respect to skin contact and inhalation. These exposure routes are particularly relevant in the context of fabric masks.

The substances of interest were identified only in very small quantities, and some substances were identified in only a small number of the fabric masks studied. In general, these small quantities were assessed to be unlikely to constitute a health risk. However, an additional risk assessment was performed for antimony and formaldehyde in terms of their effects on human health. These substances were assessed to be most problematic, based on the hazards they pose and the quantities at which they were identified:

- Antimony was identified in a majority of the purchased masks containing polyester. It was identified at the highest concentrations (up to 0.02%). Antimony is harmful if inhaled and a suspected carcinogen.
- Formaldehyde was identified in only six of the fabric masks studied, but it is both allergenic and carcinogenic.

The concentrations at which the other substances were identified were assessed to be so low as to be highly unlikely to constitute any health risks. Though problematic isocyanates were identified in several face masks, they were found only at low concentrations. When washed, isocyanates in the masks will react with water, meaning that isocyanates do not constitute a health risk in washed fabric masks.

The risk assessment conducted for antimony and formaldehyde shows that the identified concentrations are not expected to constitute a health risk under realistic usage conditions (wearing two face masks per day for a total of eight hours), based on available data. The presence of antimony is not unique to fabric masks; antimony is found in many textiles made partially or entirely of polyester.

The possibility of particularly sensitive individuals experiencing allergic reactions from the use of unwashed fabric masks cannot be excluded. However, only one of the 40 fabric masks analysed contained formaldehyde at a level close to (but still under) the recently established limit value for formaldehyde in textiles. This value was set specifically to preclude the occurrence of allergic reactions. This risk can be minimised by washing fabric masks before use.

The environmental assessment of the metals in the analyses (copper, zinc, silver, and antimony) shows that these metals are unlikely to impact aquatic environments in the quantities washed out of fabric masks. In any case, the release of silver, which is the most environmentally harmful of these four metals, can be avoided by not purchasing antibacterial face masks (or other antibacterial textile products). The environmental assessment of 6:2 FTOH, a polyfluorinated substance identified in some face masks, indicates that this substance may be problematic in aquatic environments. However, information about this particular compound and its environmental impact is lacking. Per- and polyfluorinated substances can be avoided by purchasing fabric masks (and other textile products) without dirt- and water-repellent properties.

Abbreviations

APEO	Alkylphenol ethoxylates
BDE	Bromodiphenylether. This is a group of several compounds. For example, penta-BDE is CAS no. 32534-81-9, and octa-BDE is CAS no. 32536-52-0.
BPA	Bisphenol A (CAS no. 80-05-7)
BPS	Bisphenol S (CAS no. 80-09-1)
CMR	Carcinogenic, mutagenic, reprotoxic
DBT	Dibutyltin compounds
DMF	Dimethyl fumarate (CAS no. 624-49-7)
DOT	Dioctyltin compounds
FTOH	Fluorotelomer alcohols
PBB	Polybrominated biphenyls
PCP	Pentachlorphenol (CAS no. 87-86-5)
PFAS	Per- and polyfluoroalkyl substances
PFOS	Perfluorooctane sulphonic acid (CAS no. 2795-39-3)
POP	Persistent organic pollutants
PPD	1,4-paraphenylenediamine (CAS no. 106-50-3)
ppm	Parts per million. 1 ppm is equivalent to 1 mg/kg.
NP	Nonylphenol
NPEO	Nonylphenol ethoxylates
TEPA	Tris(aziridinyl) phosphine oxide (CAS no. 545-55-1)
TBT	Tributyltin compounds
TPT	Triphenyltin compounds
TRIS	Tris(2,3-dibromopropyl) phosphate (CAS no. 126-72-7)

1. Introduction

In Denmark, there was in the spring of 2021 a requirement that persons ages 12 and up must wear a face mask or face shield in certain places and situations, including in trafficked public spaces, in retail establishments, and at indoor cultural and sporting events (Danish Health Authority, 2021; coronasmitte.dk). Both textile face masks (also referred to as "fabric masks" in this report) and single-use face masks can be worn to satisfy this requirement. However, the Danish Health Authority has warned that many fabric masks lack documentation of their filtration capabilities and quality (unless the fabric mask was produced according to a new standard, DS 3000:2021). Even so, the Danish Health Authority considers a good fabric mask to be better than no face mask at all (Danish Health Authority, 2021).

Due to the COVID-19 pandemic, there is high demand for fabric masks among consumers, additionally because they are reusable. The fabric mask is a new product that has arrived on the Danish market within the last year (2020). Consequently, there are many new entities selling fabric masks on the Danish market.

1.1 Background

It is known that many chemicals are used in manufacturing textiles, and that many manufacturing chemicals can be found in finished products. Additionally, textile products may be treated for various purposes, such as to give them oleophobic and hydrophobic properties (e.g., fluorinated compounds).

A fabric mask can potentially be used for many hours each day, and it is in direct contact with the skin. As a result, a consumer may be exposed to chemicals released by a fabric mask. Furthermore, when inhaling, consumers are exposed to any chemicals evaporating from the textile.

Reusable fabric masks can be washed in a washing machine and reused many times. Because of this, potentially problematic substances in fabric masks may be washed out of them and into the environment, where they could pose an environmental problem.

1.2 Purpose

The purpose of this project is to gain knowledge of the occurrence of problematic chemicals in fabric masks. There is a special focus on the occurrence of chemicals which may be skin irritants, sensitisers, respiratory irritants, or which may affect the respiratory system as a result of inhalation through the face mask. Another purpose of this project is to gain knowledge of substances that may be problematic when washed out, potentially posing an environmental problem.

The overall purpose is thus to assess whether realistically expected use of fabric masks may constitute a health risk to consumers or to the environment, when these masks are washed.

1.3 Scope

This project is limited to studying reusable (washable) face masks made of textiles; that is, face masks made of substances like neoprene have been excluded from this investigation. A decision was also made to focus on ready-sewn fabric masks, meaning those fabric masks which are sold ready to wear. Masks sold as do-it-yourself projects and fabrics sold for use in creating one's own masks are therefore not included in this investigation.

Only reusable fabric masks were studied in this project. Consequently, single-use face masks and face masks for medical use are not included. Medical equipment is the domain of the Danish Medicines Agency.

Similarly, the flexible metal strips contained in some fabric masks to allow for a better fit around the nose are not included in this investigation. This delimitation was chosen because the metal strips are typically surrounded by a layer of fabric, meaning that they do not contact the skin.

It was decided to examine the straps on fabric masks solely when these are made of elastic (i.e., the straps contain spandex/elastane). This delimitation was chosen because there may be relevant, problematic chemical substances present in this material (e.g., bisphenol A, also known as BPA), as described in the survey. Straps made from other materials are not examined in detail in this project.

Additionally, it was decided to focus on fabric masks for adults in this project. This restriction was chosen because children under the age of 12 are not required to wear face masks (Danish Health Authority, 2021; Danish Health Authority, 2020). Children (teenagers) ages 12 and older are approximately 155 cm tall on average (Sundhed.dk, 2020) and thereby close to a normal adult size. For these reasons, a focus on fabric masks for adults was chosen.

This project also focuses exclusively on chemical substances in fabric masks; that is, the filtration capacity of fabric masks was not studied, nor were such conditions as the inhalation of small textile particles, including synthetic fibres, which have been highlighted in the media with relation to fabric masks[1].

This is not a regulatory compliance project, which is to say that it focuses primarily on substances not restricted by law. Correspondingly, the project does not focus on antibacterial substances or the antibacterial properties of fabric masks. In the survey, it is noted whether each fabric mask we identified indicates the use of antibacterial substances, but this aspect of fabric masks is not a priority for this project.

1.4 The WHO's recommendations for fabric masks

Reusable fabric masks have undergone significant development over the last year, during the COVID-19 pandemic. The WHO's (World Health Organization) recommendations for fabric masks with respect to the COVID-19 pandemic are one good illustration of this (WHO, 2020a; WHO 2020b; WHO 2020d; WHO 2020e). At the beginning of the pandemic, its recommendations were general and broad, due to a lack of information about the effects of fabric masks. Later, its recommendations became much more specific, to the extent that the WHO now has specific recommendations for textiles for use in the production of fabric masks.

At the beginning of the pandemic, the recommendations were concerned more with functionality (filtration capacity, hydrophobic exterior material), while its recommendations today are concerned more with the particular materials used in the fabric. This is partially because of a lack of information regarding the effect (filtration capacity) of fabric masks and optimal materials for them, and because of the rapid development of information in this area.

[1]"Small, black worms in face masks are harmless synthetic fibres" (in Danish) (https://www.dr.dk/nyheder/seneste/smaa-sorte-orme-i-mundbind-er-ufarlige-syntetiske-fibre).

2. Description of legislation and standards

There are a variety of limitations on chemical substances in textiles. These are described below in greater detail. Additionally, a new Danish standard for reusable fabric masks was adopted in February 2021, and European guidelines for fabric masks were developed in 2020. These are described in greater detail below.

2.1 Legislation on chemical substances in textiles

A number of chemical substances are restricted in textiles (Danish EPA, 2020). These are listed in TABLE 2 below. Some chemical substances are restricted only in textiles intended to come into contact with the skin. Since all fabric masks come into contact with the skin, this was not accounted for in the table below.

TABLE 2. List of chemical substances restricted in textiles

Substance/group	CAS no.	Use	Limit value	Legislation
Tetra-, penta-, hexa-, hepta-, and deca-BDE (bromodiphenylether)	40088-47-9 32534-81-9 36483-60-0 68928-80-3 1163-19-5	Flame retardant	Total of all substances: 500 mg/kg	POP regulation (EU regulation 1021/2019)
Octa-BDE	32536-52-0	Flame retardant	1000 mg/kg	REACH Annex XVII, entry 45
TRIS and TEPA	126-72-7 545-55-1	Impregnating substances	May not be used	REACH* Annex XVII, entries 4 and 7
PBB (polybrominated biphenyls)	59536-65-1	Flame retardant	May not be used	REACH* Annex XVII, entry 8
PCP (pentachlorphenol)	87-86-5	Preservative, fungicide	5 mg/kg	BEK 854, 2009
Organic tin compounds TBT, TPT, DBT, DOT	-	Biocides	1000 mg/kg	REACH* Annex XVII, entry 20
Azo colourants	Multiple	Colourants	30 mg/kg for several aromatic amines that may be released by azo colourants	REACH* Annex XVII, entry 43
PFOS and derivatives	Multiple	Water- and dirt-repellent	1 µg/m^2	POP regulation (EU regulation 1021/2019)
NP and NPEO	Multiple	Used as a detergent in wet textile treatments	NPEO: 100 mg/kg	REACH* Annex XVII, entry 46
Nickel	-	In textiles, found primarily in metal elements (e.g., buttons and zips), but	Release rate of 0.5 µg/cm^2/week	REACH* Annex XVII, entry 27

Substance/group	CAS no.	Use	Limit value	Legislation
		may also originate from impurities in colourants		
PAHs (polyaromatic hydrocarbons)	Multiple	May originate from residues in e.g. spinning oils	1 mg/kg for BaP 10 mg/kg for the sum of all eight PAHs listed	REACH* Annex XVII, entry 50
DMF	624-49-7	Biocide	0.1 mg/kg	REACH* Annex XVII, entry 61
CMR substances** (33 substances, including lead, cadmium, chromium(VI), formaldehyde, certain phthalates, benzene, etc.)	Multiple	Various	Various	REACH* Annex XVII, entry 72
Mercury	-	-	100 mg/kg	BEK 73, 2016
Lead and lead compounds	-	Impurities from colourants	1 mg/kg	REACH* Annex XVII, entry 72
Cadmium and cadmium compounds	-	Impurities from colourants	1 mg/kg	REACH* Annex XVII, entry 72
Chromium(VI) and compounds thereof	-	Impurities from colourants	1 mg/kg	REACH* Annex XVII, entry 72
Formaldehyde	50-00-0	Biocide Colour fixation	75 mg/kg	REACH* Annex XVII, entry 72

* EU regulation 1907/2006
** Certain significant substances from among the 33 CMR substances appear as the last five rows of the table (below "CMR substances"). CMR stands for "carcinogenic, mutagenic, or toxic to reproduction".

In general, this project is not intended to be a regulatory compliance project; that is, the presence of substances listed above which are restricted in textiles and textile products by law was not investigated or analysed. However, the Danish Environmental Protection Agency (Danish EPA) requested analyses for formaldehyde, based on the introduction of a relatively new restriction (as of 1 November 2020) and on a proposed EU regulation that would further reduce the limit value to 30 ppm (ECHA, 2020a).

2.2 Relevant standards

This section contains descriptions of standards relevant to fabric masks: the DS 3000:2021 standard; the European guidelines on fabric masks, DS/CWA 17553:2020; and standards concerning the migration of chemical substances into artificial sweat.

2.2.1 DS 3000:2021

The DS 3000:2021 standard, titled "Washable face masks for repeated use in public spaces - Requirements and testing methods" establishes requirements and testing methods for washable face masks designed for repeated use by persons over the age of 5 in public spaces. Face masks specified in this standard are not intended for medical use, for use as personal protective equipment, or for children ages 5 and under. DS 3000:2021 contains a number of requirements and guidelines for manufacturing face masks. Those most significant to this project are described below.

2.2.1.1 Requirements on the presence and documentation of chemical substances

The standard contains the following general requirements on the presence and documentation of chemical substances:

- Any material which may come into contact with the skin during use must be documented as not causing irritation, allergic reactions, or other toxicological reactions in the user; e.g., by reference to the substances' classifications.
- At no time may chemical substances listed on the REACH candidate list (SVHC substances) be used in manufacturing processes, whether during or after fibre production.
- It must be documented that no water-, stain-, or oil-resistant treatments/impregnations containing fluorine have been used, such as those containing perfluorinated or polyfluorinated compounds.
- It must be documented that no biocides have been applied. For instance, chemical substances with an antimicrobial function may not be integrated or applied later as a treatment.
- The use of inks should be limited.

2.2.1.2 Washing test

The face mask must be washed and dried five times (as specified in DS/EN ISO 6330), and the following procedures must be used:

- Washing machine type A (front-loading, horizontal axis)
- Wash procedure $6N^h$ (60°C, normal)
- Tumble dryer type A2 (condenser) with tumble dry cycle 1 (dry cotton)
- Ballast type I (100% cotton ballast) together with one or more face masks
- Reference detergent 3 - ECE reference detergent 98 without optical brightener

The face mask must be marked with the fabric care symbol indicating 60°C machine washing, or with the symbol for 70°C or 95°C machine washing if the mask has been tested at one of these temperatures.

2.2.2 DS/CWA 17553:2020

DS/CWA 17553:2020, titled "Community face coverings - Guide to minimum requirements, methods of testing and use", is a common European guideline on the production of fabric masks, developed due to the COVID-19 pandemic. DS/CWA 17553:2020 specifies minimal performance requirements and establishes filtration levels for face masks for use in public spaces. Face masks specified in the guidelines are for use as neither medical equipment nor personal protective equipment.

Most requirements in DS/CWA 17553:2020 have also been adopted in the latest standard, DS 3000:2021. However, DS/CWA 17553:2020 also includes requirements for face mask measurements and sizes for children and adults alike. As far as requirements for chemical substances / ingredients in fabric masks, the standard states only that materials in contact with the skin may not cause skin irritation, have allergenic effects, or have other toxic effects.

3. Survey

This chapter describes the results of the survey performed in this project. The whole project (survey, chemical analyses, and risk assessment) was performed in five months. The scope of the survey was therefore limited. The survey was based on existing knowledge regarding problematic chemical substances in textiles, as well as a literature review for tests and investigations of chemical substances in fabric masks.

The following activities were carried out during the survey:
- Contacting selected relevant organisations
- Searching for specific product samples on the Danish market
- Contacting selected face mask vendors
- Literature review / internet searches

3.1 Contacting selected relevant organisations

Selected relevant organisations were contacted to request information on problematic chemical substances in fabric masks, as well as on any relevant investigations of this topic. The following organisations were contacted:
- The Danish Consumer Council (Forbrugerrådet Tænk)
- Dansk Fashion & Textile, an industry organisation for the fashion and textile industry
- WEAR, under the Danish Chamber of Commerce - an industry organisation for textile, clothing, and other businesses
- EURATEX (the European Apparel and Textile Confederation) - the European textile industry association

Overall, the institutions contacted were limited in what information on fabric masks they were able to supply. Fabric masks are relatively new products, so knowledge of them is not disseminated yet. Information received from the industry is supplied below. The European textile industry association could not be contacted by telephone. It was contacted solely by email, but it did not respond to requests.

The Danish Consumer Council (Forbrugerrådet Tænk) conducted face mask testing in October 2020, but this test focused on particle filtration, breathing resistance, and consumer testing (Danish Consumer Council, 2020). The Danish Consumer Council did not test masks for the presence of chemical substances, but it has offered advice on chemical substances in face masks. The Danish Consumer Council has no information on other European consumer organisations that have conducted chemical substance testing. Its primary focus has been the filtration capacity of fabric masks; specifically, it has studied how effective they are in comparison to e.g., disposable (medical) face masks.
The Danish Consumer Council mentioned that there are fabric masks on the Danish market that have been treated with fluorinated compounds, as well as fabric masks with antibacterial effects, achieved e.g., through the use of silver or copper. The Danish Consumer Council also supplied references to various articles and other sources of information that were used in the survey.

Dansk Fashion & Textile had no specific information on chemical substances used in fabric masks, but it agreed to contact some of its members in an attempt to find specific information about the production of fabric masks in Denmark. In general, Dansk Fashion & Textile advises its members to produce textiles according to an RSL (Restricted Substances List), such as that from AFIRM (Apparel and Footwear International RSL Management) (AFIRM, 2021).

AFIRM is an international industry organisation for clothing and footwear, and it maintains an annually updated list of substances that are either restricted (by law) in textiles worldwide, as well as substances that are generally undesirable in textiles. The RSL document from AFIRM and the requirements related to the presence of chemical substances are thus described in section 3.4.1.4 "AFIRM, 2021".
Dansk Fashion & Textile advises against the use of fluorinated compounds in textiles but notes that these are primarily used in outerwear. Dansk Fashion & Textile had no information about whether fluorinated compounds are used in manufacturing fabric masks. Regarding bisphenol A (BPA), Dansk Fashion & Textile has found that this substance is primarily present in elastic materials (such as elastic bands), but it can also occur in textiles made from recycled plastic.

3.2 Survey of products on the Danish market

A survey of fabric masks on the Danish market was conducted. Altogether, 92 fabric masks were identified on a variety of Danish online shops, 40 of which were chosen to be purchased for chemical analyses. The purpose of choosing a variety of face masks was partially to investigate the products on the market and partially to have a sufficiently broad selection of fabric mask types (across such properties as colour, printed/unprinted, material, manufacturer, etc.).

Due to the COVID-19 situation and the limited time available to conduct the survey, face masks were primarily identified in online shops, and to a limited extent, in physical shops. It did not prove difficult to find about 90 online shops selling face masks. No more than 1-2 online shops appear more than once in the survey (meaning that a maximum of two different face masks were selected from the same online shop). This demonstrates that the market for fabric mask sales is currently large, with many retailers/sellers.

Very few online shops indicated the name of the manufacturer that produced each mask offered. This information was missing from the vast majority of shops, making it impossible to know who produced each mask and where. Consequently, during the selection process, it was not possible to ensure that masks from different manufacturers were purchased.

The 92 face masks identified are distributed as shown in TABLE 3.

TABLE 3. Distribution of the 92 face masks across various categories

Colour	Quantity	Material	Quantity
Single colour	17	Cotton	33
Single colour with print	8	Primarily polyester	10
Pattern	26	Blended textile	33
White	15	Not indicated	16
Black	26		
Type of elastic/strap	**Quantity**	**No. of textile layers**	**Quantity**
Elastic-like (elastane)	72	One layer	3
Fabric-like	16	Two layers	14
Mesh	1	Three layers	51
Rubber band	1	Four or five layers	2
Not visible / not specified	2	Not indicated	22
Environmental/health marking	**Quantity**	**Standard***	**Quantity**
Oeko-Tex 100	11	CE marked[1]	5
GOTS	4	EN 6330:2012[2]	1
Cradle to Cradle	1	CWA 17553:2020[3]	1

No marking	76	AFNOR Spec S76-001[4]	1
		EN 14683:2019[5]	3
		No standard	83
Antibacterial	**Quantity**	**Price range per unit**	**Quantity**
Yes	11	10.00 – 25.00 DKK	19
No	81	25.50 – 50.00 DKK	42
		50.50 – 100.00 DKK	26
		More than 100 DKK	5

* Note that several fabric masks indicated that they conform to multiple standards, causing the sum here to exceed 92.
1. Typically, medical face masks and face shields are CE marked to indicate that they conform to EN 14683:2019, a standard for single-use medical face masks (surgical masks)
2. EN 6330:2012 Textiles - Domestic washing and drying procedures for textile testing
3. CWA 17553:2020 Community face coverings - Guide to minimum requirements, methods of testing and use. This is a new, common European standard for fabric masks.
4. AFNOR Spec S76-001 Barrier Masks. These are French guidelines that establish minimum requirements for ordinary (non-medical) fabric masks.
5. EN 14683:2019 is a standard for single-use medical face masks (surgical masks).

3.2.1 Description of surveyed face masks

The distribution of the 92 surveyed face masks is presented in TABLE 3 above. Individual aspects of the masks are described in greater detail below.

3.2.1.1 Material type and number of layers

The survey showed that the 92 fabric masks were made of various materials, including 100% cotton, 100% polyester, and blends of various fabric types. A total of 16 fabric masks did not indicate the materials they were made from. About one-third of the face masks were made from 100% cotton, one-third were made from blended fabrics (mostly blends of cotton and polyester), and 10 masks were made wholly or primarily from polyester (e.g., 95% polyester and 5% elastane). The use of cotton and polyester as the primary fabrics is in line with the WHO's recommendations for fabric masks as of last summer (WHO, 2020c), and it does not deviate significantly from the recommendations most recently issued in December. These include a recommendation for a middle layer made from a non-woven material like polypropylene; it may also be made of polyester (WHO, 2020e).

Some variation was also present in terms of the number of layers used in each mask, though a large majority (51) of the masks consisted of three layers, as the WHO recommends. There were 22 masks that offered no indication of how many layers they comprised. A small share of the masks (14) had two layers, and three masks consisted of only a single layer of fabric. One fabric mask comprised four layers, and another fabric mask comprised five layers of fabric.

3.2.1.2 Elastic bands / straps

All of the 92 face masks surveyed were equipped with elastic bands or straps to be placed behind the ears. However, only two masks specifically indicated what these straps were made of (one used mesh and the other used rubber). For the remaining face masks, there was no indication of what the straps were made of; consequently, photos of the masks were used to sort them into approximate categories of "elastic-like" and "fabric-like". A clear majority (72) appeared to be equipped with elastic bands for fastening behind the ears, and 16 masks appeared to have straps made of the same material as the masks themselves. For the remaining masks, it was not possible to see what the straps were made of.

3.2.1.3 Price range per unit

The 92 surveyed face masks are distributed evenly across price ranges (see TABLE 3), specified here as up to 25 DKK, over 25 DKK and up to 50 DKK, over 50 DKK and up to 100 DKK, and over 100 DKK per face mask. Prices were calculated per face mask, though not all fabric masks can be purchased individually. Slightly less than half of the face masks (42) fell within the 25.50 – 50 DKK price range. The cheapest price range (up to 25 DKK per unit) contained 19 face masks, many of which were sold in packs of 5 or 10 masks. A total of 31 face masks fell into the two most expensive price ranges, five of which sold for more than 100 DKK each. The cheapest fabric mask costed 10 DKK, while the most expensive fabric mask identified costed 160 DKK. The average price for the 92 surveyed products was 51.77 DKK.

The masks were relatively evenly distributed across colours, numbers of layers, etc. In other words, there is no immediate correlation between the number of layers in a fabric mask and its price.

3.2.1.4 Antibacterial face masks

Out of the 92 masks surveyed, 11 indicated that they had antibacterial properties, corresponding to 12% of the face masks. When searching for masks, we did not specifically search for masks with antibacterial properties, so this proportion of fabric masks with antibacterial properties can be considered reasonably representative of the Danish market.

3.2.1.5 Environmental/health certification marking

Some kind of environmental or health-related certification mark was present on 16 masks (17%), the most common of which was the Oeko-Tex Standard 100 mark. This certification primarily imposes health-related requirements related to the presence of chemical substances. There were 11 masks with the Oeko-Tex 100 mark. Additionally, four face masks bore the Global Organic Textile Standard (GOTS) environmental certification mark, and one face mask was certified by Cradle to Cradle, a circular economy certification that includes chemical substance requirements.

3.2.1.6 Standards

Eight of the face masks either indicated that they conformed to a particular standard or were CE marked (5 masks), indicating that the masks conform to regulatory requirements for masks used as medical equipment (see EN 14683:2019 below). Five of the masks where a particular standard is specified conformed to the following standards/guidelines:

- DS/CWA 17553:2020 (1 mask) - Community face coverings - Guide to minimum requirements, methods of testing and use. This new, common European guideline specifies minimum requirements for reusable fabric masks.
- AFNOR Spec S76-001 (1 mask) - Barrier Masks. These are French guidelines that establish minimum requirements for ordinary (non-medical) fabric masks (AFNOR, 2020).
- EN 14683:2019 (3 masks) - Medical face masks - Requirements and test methods. This standard describes requirements for single-use, disposable face masks, which are broken down into Type I, Type II, and Type IIR according to their filtration capacities[2]. When a product meets this standard's requirements, it should be CE marked. One of these three masks indicated that it met Type I requirements.

None of the 92 face masks in the survey indicated that they conformed to DS 3000:2021, the latest standard for fabric masks.

[2]Type I face masks must provide 95% filtration, Type II must provide 98% filtration, and Type IIR must provide 98% filtration along with an extra protective layer (https://www.sst.dk/da/nyheder/2020/krav-om-mundbind-i-den-kollektive-trafik-og-saerlige-anbefalinger-til-personer-i-oeget-risiko; https://www.apotekets.dk/raad-og-vejledning/mundbind/hvad-er-forskellen-paa-type-1-og-type-2-mundbind/).

3.3 Contacting selected fabric mask vendors

Using the results of the fabric mask survey, individual fabric masks were selected and their vendors were contacted. The resulting overall impression was that vendors lack knowledge of the chemical substances in fabric masks. Although only five vendors were contacted, there was significant variance in how they produced or procured the masks. One vendor bought face masks manufactured in China and resold them; another vendor sewed its own face masks primarily from recycled materials in a one-person sewing shop; and others sewed their masks in larger sewing shops, either in Denmark or in foreign countries. Three of the vendors contacted indicated that they sewed masks from recycled fabric.

The market for face masks was generally described as declining at the time of writing (spring 2021) relative to the significant growth and sales of fabric masks in spring 2020 and through winter 2020/2021. The search for 90 fabric masks samples showed that it was relatively easy to find about 90 different face mask vendors. This demonstrates the large number of vendors on the market, many of whom wished to join this growing market in spring 2020. This market thus consists of a mix of larger and smaller companies, including many small, one-person businesses.

3.4 Literature review / internet searches

A literature was conducted to find general information on chemical substances in textiles, given that information and research on chemical substances in fabric masks specifically is very limited. Additionally, a search was conducted for fabric mask tests, but here, too, there was a limited number of tests concerning chemicals in fabric masks. Lastly, a literature search was conducted for specific substances and substance groups in textiles in general.

The literature search for specific substances / substance groups relevant to textiles was based on the list of substances/groups provided by the Danish EPA in its specification of requirements for this project, but other substances considered problematic in textiles were also investigated. The substance groups that the Danish EPA wished to focus on in this project were:

- Bisphenol A (BPA), as the presence of this substance in certain textiles has recently been spotlighted. BPA is considered an endocrine disruptor[3] and has a harmonised classification as toxic to reproduction and allergenic.
- Formaldehyde, because it was recently restricted in textiles and because there is a pending EU proposal to further decrease the limit value (ECHA, 2020a). Formaldehyde has a harmonised classification as carcinogenic, allergenic, and toxic if inhaled; this is problematic, given the volatile nature of the substance.
- Fluorinated/PFAS compounds, presumed to be used in order to provide water- and dirt-repellent properties. A long list of fluorinated/PFAS compounds are considered to be poorly degradable in the environment (Danish EPA, 2013).
- Metals / metal compounds, which may be used to provide antimicrobial properties, or which may originate from impurities in colourants. Numerous metal compounds can be toxic to aquatic environments or have alarming health-related properties, depending on the particular metal or metal compound (Larsen et al., 2000).

3.4.1 General information on chemical substances in textiles

Textiles are subjected to a long list of processes during manufacturing, and a variety of chemicals are used at each step. Textile manufacturing can be divided into the following main phases (Larsen et al., 2000; KEMI, 2013): fibre production, spinning, yarn production, knitting, weaving, pre-treatment, weaving, colouring, printing, and post-treatment. For instance, various

[3] It has been added to the REACH candidate list because it is toxic to reproduction and an endocrine disruptor (https://echa.europa.eu/da/candidate-list-table/-/dislist/details/0b0236e180e22414).

chemicals are used to assist the fibre production process, spinning oils are used to reduce friction and fibre wear during the spinning process, and a variety of chemicals are used during pre-treatment to prepare textiles for the subsequent colouring, printing, and post-treatment processes. For white textiles, bleaching may also occur. Many colourants and pigments may be employed during the colouring and printing processes, alongside a wide range of auxiliary substances that include binders, softeners, and detergents. Lastly, textiles may be subjected to a wide range of post-treatments (finishes), such as to give textiles a softer or stiffer feel, facilitate fabric care (e.g., wrinkle-free), or to provide textiles with particular functionality (water-repellent, dirt-repellent, flame retardant, antibacterial treatments) (Larsen et al., 2000).

Various studies exist on chemical substances in textiles in general. As described in chapter 2 "Description of legislation and standards", a number of chemical substances are currently restricted in textiles. A thorough study of all chemicals used in textiles is beyond the scope of this report, but the report does focus on specific, significant substances and substance groups which (based on this survey) are expected to be relevant within the context of fabric masks. For this reason, the project's focus has been on those substances and substance groups which the Danish EPA listed in its specification of requirements for this project (see above, section 3.4), as well as on certain other substances which the literature review in this survey revealed to be of interest.

Some of the most significant oversight reports identified, which describe and assess chemical substances relevant to textiles in general, are described below.

3.4.1.1 Chemicals in textiles (Larsen et al., 2000)

An environmental project titled "Chemicals in textiles" studied various textiles (clothing and household textiles) on the Danish market, including conducting a hazard assessment of 190 chemical substances which occur as auxiliary substances in textiles. Simulated wash experiments (in which textiles were stirred about in warm water) were also performed in order to measure the extent to which metals, in particular, may be washed out of textiles and released into the environment when using a washing machine.

The result of the hazard assessment was a list of 27 chemical substances to be avoided in textiles, including the softener DEHP, nonylphenol ethoxylates (NPEO), and a variety of substances originating from impurities in colourants (such as anilines and heavy metals). Based on the levels detected in the wash tests conducted and the hazards posed by these substances, the heavy metals identified as risks to aquatic environments were cadmium, chromium, lead, and zinc. The results of the wash tests for metals demonstrated that the metals listed above are the primary metals released during washing (Larsen et al., 2000):

- Cobalt: washout rate of about 4%
- Chromium: washout rate of about 2%
- Copper: washout rate of about 1-4%
- Mercury: washout rate less than 8% (not detected; washout rate based on limit of detection)
- Nickel: washout rate higher than 60%
- Arsenic: very limited washout rate (could not be determined)
- Cadmium: washout rate of about 60%, but no significant washout from cadmium in PVC printing
- Lead: washout rate of about 100%, but no significant washout from lead in PVC printing
- Tin: washout rate between 38% and 55%, but no significant washout from tin in PVC printing
- Zinc: average washout rate of about 60%, but up to 100% for some textiles
- Barium: washout rate of 65%

3.4.1.2 The Swedish Chemicals Agency (KEMI, 2013)

In 2013, the Swedish Chemicals Agency conducted a review of harmful chemical substances that may be present in finished textiles and textile products. This work was performed in preparation for potential new EU regulations. The result was a list of chemical substances that ought to be regulated in textiles, based on the hazards they pose and on a qualitative risk assessment for human exposure and release into the environment. This project focused on chemical substances classified as CMR in categories 1A and 1B, substances classified as harmful to the environment, and substances classified as allergenic. The result was a list comprising 165 chemical substances, all of which can be found in finished textile products and which pose significant hazards (CMR, allergenic, or harmful to the environment).

This work served as a foundation for the existing ban on certain CMR substances, and for a proposed ban on certain allergenic substances in textiles which is currently under consideration[4].

3.4.1.3 ANSES (2018)

In 2018, the French Agency for Food, Environmental, and Occupational Health and Safety (ANSES) conducted an assessment of chemical substances found in footwear and textiles which are skin irritants or skin sensitisers (ANSES, 2018). As part of the project, a long list of chemical substances with alarming properties was developed and subsequently selected textiles were screened for these substances. The use of chemical substances with CMR effects in textiles was also assessed. During the project, 25 newly purchased textiles which come into prolonged contact with the skin, such as undergarments, leggings, and similar articles of clothing. Wash tests were also performed in order to ascertain the degree to which certain chemical substances can be washed out of textiles. Altogether, the textiles were screened for the presence of 20 groups of chemical substances, including aromatic amines, APEOs, allergenic colourants, formaldehyde, PAHs, metals, organotin compounds, and phthalates.

The results of chemical analyses of the 25 textiles are provided in TABLE 4 below.

TABLE 4. Result of screening analyses performed on 25 textile products

Substance name/group	% of products detected in	Comments
1,4-paraphenylenediamine (PPD)	20%	Allergenic colourant (also used in hair dyes and other products) Did not wash out in wash test
Allergenic colourants, including a variety of disperse dyes	Generally not detected	Of the 36 colourants screened for, only CI Disperse Yellow 23 was detected
Azo colourants	Generally not detected	Examined for 23 aromatic amines restricted by REACH
Heavy metals	16%	Cobalt, copper, antimony, lead, cadmium, and mercury were detected
Chromium	20%	
Nickel	16%	
NP and NPEO	20%	High degree of washout in wash test
Organotin compounds	4%	Two distinct organotin compounds were detected in one product
Formaldehyde	Not detected	
PAHs	Not detected	

[4] https://echa.europa.eu/da/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

The results of the screening analyses were compared with actual reports of allergic reactions in humans to certain chemical substances in textiles. Based on this comparison, the following list of chemical substances that ought to be restricted in textiles was developed (chemical substances already restricted by law are not included):

- Aniline
- PPD
- CI Disperse Yellow 23

The report describes that aniline was detected in three textile products at concentrations between 10 and 65 mg/kg. According to ANSES (2018), aniline primarily originates form the breakdown of colourants, as a number of colourants are based on aniline[5].

3.4.1.4 AFIRM, 2021

AFIRM (Apparel and Footwear International RSL Management) is an international industry organisation for clothing and footwear. AFIRM has developed a list of substances that are restricted (by law) in textiles globally, as well as substances that are generally undesirable in textiles. This RSL (Restricted Substances List) is used by a great number of textile manufacturers around the world, who may also add their own undesirable chemical substances or more stringent limit values to the list. Dansk Fashion & Textile generally advises its members to produce textiles in accordance with AFIRM's RSL (AFIRM, 2021).

AFIRM's RSL is a document comprising 21 pages with lists of chemical substances that are undesirable in textiles. The introductory section of the document provides a testing matrix with recommendations for chemical substances to test for in specific materials used in clothing and footwear. Excerpts from AFIRM's RSL are presented below for the textile materials typically identified in fabric masks.

TABLE 5. Excerpts from AFIRM's RSL (2021), focusing on the materials identified in fabric masks. A green background indicates that, according to AFIRM, there is a high risk of detecting the substance or substance group in the specified textiles. Similarly, a white background indicates that there is a lower risk of detecting the substance or substance group in the specified textiles (e.g., depending on whether the substance is added deliberately). A dash (-) indicates that AFIRM does not believe the substance group is used in the specified type of textile. AFIRM's recommended limit values are given in parentheses.

<table>
<tr><th>Substance/group</th><th>Natural fibres (e.g., cotton)</th><th>Synthetic fibres (e.g., polyester)</th><th>Natural and synthetic blends</th></tr>
<tr><td>Acids and bases (pH)</td><td colspan="3">Acetophenone (50 ppm)
2-phenyl-2-propanol (50 ppm)</td></tr>
<tr><td>AP and APEOs</td><td colspan="3">AP and OP (sum 100 ppm)
NPEOs and OPEOs (sum 100 ppm)</td></tr>
<tr><td>Azo-amines and arylamine salts</td><td colspan="3">Beyond the aromatic amines restricted by REACH Annex VII, item 43, addition 8, six substances are listed:
2,4-Xylidine; 2,6-Xylidine; 4-4-Chloro-o-toluidinium chloride; 2-Naphthylammonium acetate; 4-Methoxy-m-phenylene diammonium sulphate; 2,4,5-Trimethylaniline hydrochloride (all 20 ppm individually)</td></tr>
<tr><td>Chlorophenols</td><td colspan="3">A number of tri- and tetrachlorophenols with a limit value of 0.5 ppm each (currently, only pentachlorophenol is restricted by law)</td></tr>
<tr><td>Chlorinated benzenes and toluenes</td><td>-</td><td colspan="2">A long list of chlorobenzenes and chlorotoluenes, restricted with a limit value of 1 ppm each</td></tr>
</table>

[5] https://www.pysanky.info/Chemical_Dyes/History.html

Substance/group	Natural fibres (e.g., cotton)	Synthetic fibres (e.g., polyester)	Natural and synthetic blends
Colourants (prohibited and disperse dyes)	-	A long list of colourants, restricted with a limit value of 50 ppm each	
Flame retardants	-	A number of flame retardants, restricted with a limit value of 10 ppm each	
Formaldehyde	A limit value of 75 ppm (corresponding to applicable legislation) is given for textiles for adults; for textiles for babies, the limit value is 16 ppm		
Chromium(VI)	Limit value of 1 ppm in textiles		-
Extractable heavy metals	Antimony (30 ppm); arsenic (0.2 ppm), barium (1000 ppm); cadmium (0.1 ppm); chromium (2 ppm); cobalt (adults: 4 ppm and children/babies: 1 ppm); copper (adults: 50 ppm and children/babies: 25 ppm); lead (1 ppm); mercury (0.02 ppm); nickel (1 ppm); selenium (500 ppm)		
Totals of heavy metals	Arsenic (100 ppm) cadmium (40 ppm); mercury (0.5 ppm)	-	Arsenic (100 ppm) cadmium (40 ppm); mercury (0.5 ppm)
Organotin compounds	-	Selected organotin compounds (including organotin compounds not restricted by law) with a limit value of 1 ppm each	
Ortho-phenylphenol	Limit value of 1000 ppm		
Perfluorinated and polyfluorinated compounds	A list comprising 24 PFOS-related substances, PFOA salts, and PFOA-related substances, restricted with limit values of 25 ppb or 1000 ppb, depending on type		

It should be noted that AFIRM does list BPA (as well as bisphenols S, F, and AF) in its requirements, but it considers it unlikely that these substances will occur in the types of textiles listed above. It is, however, likely for them to occur in polymer materials, such as polycarbonate, PVC, PU, ABS, and rubber.

3.4.1.5 Oeko-Tex Standard 100

Oeko-Tex Standard 100 is a product certification mark for textiles. It ensures that a textile conforms to certain limit values for a long list of chemical substances. The certification requirements are updated regularly, at least once per year.

Oeko-Tex Standard 100 imposes different limit values, depending on whether a textile is for babies, for use in prolonged contact with the skin, or e.g. for use in the home.

The many restricted chemical substances and their limit values are given in Appendix 1. Regarding the chemical substances that this project focuses on, the following limit values set by Oeko-Tex Standard 100 for product type II (i.e., textiles with skin contact) are noteworthy:

- Formaldehyde has a limit value of 75 mg/kg, as in the new regulation on CMR substances (REACH Annex XVII, entry 72)
- Aniline has a limit value of 50 mg/kg
- BPA has a limit value of 100 mg/kg
- Limit values between 0.025 and 0.1 mg/kg are set for numerous per- and polyfluorinated compounds
- Bioactive chemicals may not be used
- Limit values are set for both the total content and the extractable content of various metals
- In general, flame retardants are not allowed. However, certain exceptions can be made, but in such cases, the flame retardants must be specifically approved.

3.4.2 Fabric mask testing

A search for fabric mask tests was performed, but only a limited number of tests could be identified, and essentially all of them concerned themselves with the efficiency (filtration capacity) of fabric masks. A single German test was the only test identified that addressed the presence of chemical substances in fabric masks. This is due to the fact that fabric masks are relatively new products on the market, and in the context of the COVID-19 pandemic, the focus is on the effectiveness of fabric masks at filtering out viruses.

The German test was conducted by DAAB, the German Allergy and Asthma Association [German: *Deutscher Allergie- und Asthmabund*] and presented on ZDF WISO, a German television programme that covers consumer issues. A total of 15 black fabric masks were tested. The masks were investigated for the presence of aniline (an aromatic amine), which is used in black dyes and other dyes. Aniline was detected in one of the 15 fabric masks. Concentrations were not specified (DAAB, 2021).

Beyond this German test, no other tests of fabric masks focusing on chemicals in the masks were identified. Other tests have focused exclusively on other topics, such as filtration capacity, fit, and comfort, as exemplified by the tests listed below:

- The Danish Consumer Council (Forbrugerrådet Tænk), October 2020 - 10 masks tested for parameters including material quality, fit, ease of breathing, comfort, and overall satisfaction (The Danish Consumer Council, 2020). Several of the fabric masks that received a "good" rating in the tests conducted by the Danish Consumer Council were purchased for chemical analyses in this project, as numerous consumers may have purchased them after seeing these test results.
- Politiken, August 2020 - Six face masks tested for particle filtration capacity. The fabric masks were specified as made of either cotton or polyester (Hansen, 2020).
- Which?, the British consumer organisation, October 2020 - 15 fabric masks tested for filtration capacity and other properties, as well as performance after many washes. An interesting conclusion from this study was that the filtration capacity improved after five washes because the material shrank (i.e., became denser), leading to better particle filtration (Which?, 2020).
- UFC-Que Choisir, the French consumer organisation - 18 home-made fabric masks made from various textiles were tested solely for filtration capacity and ease of breathing. Information about textile materials was provided; the masks were primarily made of cotton and polyester, with some masks also containing elastane, viscose rayon, or polyamides (Que Choisir, 2020).

3.4.3 Information on specific chemical substances / substance groups

Studies and information on specific chemical substances / substance groups that may be of interest in the context of testing for chemical substances in fabric masks are listed below. Given the lack of information on chemical substances in fabric masks specifically, a general description of specific chemical substances in textiles was developed. These substances / substance groups were selected based on the Danish EPA's list of focus chemicals for this project, with the addition of certain other substances considered problematic based on the descriptions above (e.g., aniline).

3.4.3.1 Bisphenols in textiles

Freire et al. (2019) analysed 96 pairs of children's socks from Spain to determine whether they contained BPA. BPA was detected in 91% of all of the children's socks. The quantities of BPA detected were low, ranging from 4 ng/g to 3739 ng/g (equivalent to 3.7 mg/kg).

Based on this study, 21 textile products were purchased and analysed for a survey on endocrine disruptors (Poulsen et al., 2020), comprising nine pairs of children's socks, six pairs of adult socks, and six pairs of underpants. These products were analysed for the presence of BPA. BPA was only detected in socks (two pairs of children's socks and one pair of adult socks). The concentrations were low, at 19, 34, and 244 ng/g. The highest value was detected in children's socks. Products purchased for this study were made from cotton in varying proportions (between 24% and 95%), since Freire et al. (2019) indicated that the highest BPA content was detected in socks with a high cotton content. Whether the detected quantity of the endocrine disruptor was sufficient to constitute a health risk was not addressed in the survey.

A previous study conducted by Xue et al. (2017), however, reported a higher concentration of BPA in synthetic materials (such as polyester) than in cotton. Xue et al (2017) analysed 77 textiles for babies (socks, fabric nappies, blankets, and bodysuits), detecting BPA levels between 2.2 and 13,285 ng/g. Xue et al. (2017) also analysed textiles for the presence of bisphenol S (BPS), which was detected at lower concentrations (between 0.7 and 394 ng/g). Xue et al. (2017) reported some intriguing differences in the article's supplementary material (also illustrated in FIGURE 1 below):

- The concentration of BPA was generally higher than that of BPS (see sub-figure a in FIGURE 1)
- The concentration of BPA and BPS was highest in articles of clothing (as opposed to cloths, nappies, and blankets) (see sub-figure a in FIGURE 1)
- The concentration of BPA and BPS was much higher in socks than in bodysuits (see sub-figure d in FIGURE 1)
- The concentration of BPA and BPS was much higher in synthetic materials (with high polyester content) than in products made from 100% cotton (see sub-figure b in FIGURE 1)
- The concentration of BPA and BPS was higher in coloured textiles than in white textiles (see sub-figure c in FIGURE 1)

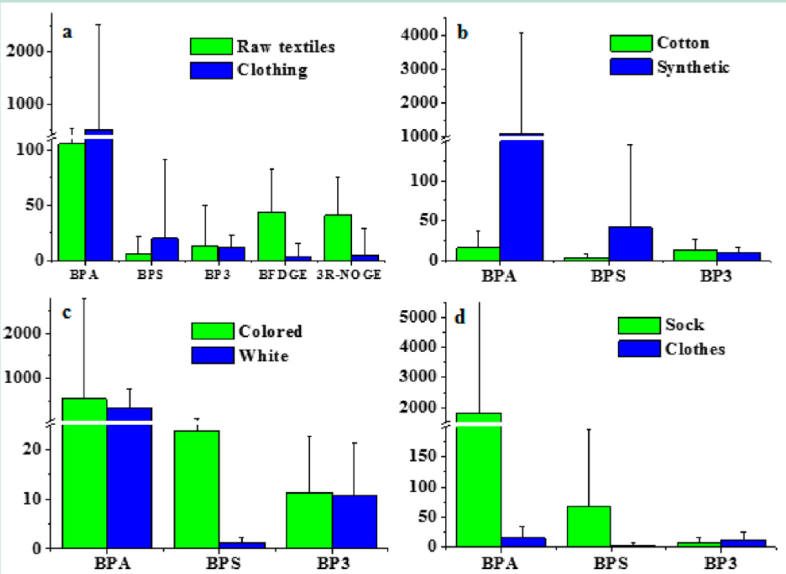

FIGURE 1. Levels of BPA and BPS (and other substances) in textiles for babies. The illustration is taken from Xue et al. (2017). Note the use of logarithmic and broken scales (indicated by two strokes crossing the y-axis).

According to Xue et al. (2017), BPA is not presumed to be used directly in textile manufacturing. Instead, they suggest that several process chemicals used, including colourants, are likely sources of the BPA detected.

The SCCS (Scientific Committee on Consumer Safety) was asked for its opinion on the risk posed by BPA occurring in clothing/textiles[6] as a result of its detection in textiles, as described above. In its opinion (dated March 2021), the SCCS stated that the concentrations of BPA detected in clothing as insufficient to constitute a risk of effects on health (SCCS, 2021a). The SCCS indicated that BPA appears to be primarily detected in products made from polyester or spandex (also known as elastane, a highly elastic polyurethane fibre). BPA is used as a process chemical in the production of colourants and antioxidants that are used in the finishing process within textile manufacturing. A number of BPA-based antioxidants are used to confer particular anti-static and water-absorbing properties to polyester in a manner that persists after washing. Given these uses of BPA, these are thought to be the reason for the occurrence of BPA in textiles (SCCS, 2021a).

The SCCS (2021a) suggests a limit value of 0.8 mg/kg for BPA in textiles, equivalent to 800 ng/g. Individual analysis results in both Xue et al. (2017) and Freire et al. (2019) did exceed this limit value. None of the children's socks investigated in the survey from last year (Poulsen et al., 2020) exceeded this limit value.

3.4.3.2 Fluorinated compounds in textiles

The results from survey may indicate that some manufacturers use fluorinated compounds to give fabric masks hydrophobic properties. This is based partly on reports from the WHO regarding hydrophobic properties for the outermost layers of fabric masks (see section 1.4) and partly on the fact that certain manufacturers of auxiliary chemicals for textiles advertise chemicals that can be used to confer hydrophobic properties on fabric masks. For example, German companies Dr. Petry[7] and CHT[8] both produce auxiliary chemicals with hydrophobic properties for textiles, and both specifically advertise the use of these auxiliary chemicals in the context of fabric mask production. In both cases, the chemicals advertised are hydrophobic auxiliary chemicals based on fluorocarbons (PFAS). This may be related to the fact that alternatives to fluorinated compounds, such as waxes, would reduce the ease of breathing through fabric masks (note, for example, that the WHO does not recommend the use of waxes (WHO, 2020b)).

Dr. Petry states that applying a hydrophobic finish to fabric masks can prevent them from becoming dampened (such as by exhaled air), improving the durability of the masks and ensuring that they retain their protective properties (namely, the filtration capacity) for a longer period of time. Both Dr. Petry and CHT recommend hydrophobic textile finishing chemicals that are based on fluorocarbons (C6 compounds) as a surface treatment for face masks. Note that CHT indicates that its hydrophobic auxiliary chemicals based on C6 fluorinated compounds do not preclude Oeko-Tex 100 certification, since C6 fluorinated compounds are permitted in textiles for adult use that come into contact with the skin (Oeko-Tex 100, 2021).

The Danish Consumer Council[9] reports that it has encountered numerous face mask manufacturers that explicitly advertise or describe the fact that their face masks are treated with fluorinated compounds (PFASs) to confer hydrophobic properties on the outer surfaces of their fabric masks. When searching for fabric mask samples for this project, we did not specifically en-

[6] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs2016_q_035.pdf

[7] https://drpetry.de/en/textile-news/hydrophobic-finishing-of-textile-fabric-for-face-masks.html

[8] https://www.cht.com/cht/medien.nsf/gfx/med_MJOS-BN9GJM_4395D1/$file/CHT-Group-textile-face-masks.pdf; https://www.cht.com/cht/web.nsf/id/pa_en_productdetail.html?Open&pID=PDE-TUEB-9MQGQF-EN

[9] Telephone conversation with the Danish Consumer Council, April 2021

counter fabric masks indicating that they contained fluorinated compounds (or PFASs). However, about 10% of the fabric masks did advertise the presence of a water-repellent outer layer. Even so, all of these masks had an exterior surface made of polyester or a polyester blend. Whether this is because of polyester's own water-repellent properties or because the material was treated with hydrophobic fluorinated compounds (PFASs) is unknown.

In an investigative article, Beesoon et al. (2020) describe in detail how the safety of fabric mask use can be maximized; that is, how the masks can best be made to protect against the virus that causes COVID-19. The article reports that the use of fluorinated compounds on the surface of the outermost fabric layer enhances the protective effect of a fabric mask. It also states that water vapour in exhaled air can cause the innermost layer of fabric to become wet, reducing both the filtration capacity and breathability of the fabric mask. Consequently, the article states, a hydrophobic inner layer would be desirable because it would cause droplets of moisture to run off of the fabric, preserving the mask's filtration capacity for a longer period of time.

The survey similarly found that at one point, the WHO recommended the use of a water-repellent material for the outermost layer of fabric masks. Today, this recommendation has been made more precise, offering polyester as an example of a water-repellent material. Producers of auxiliary chemicals for the textile industry exist that explicitly recommend the use of surface treatments containing fluorinated compounds (noting that Oeko-Tex 100 and other standards regard this as acceptable). Fabric masks which explicitly indicate that they contain fluorinated compounds are not commonly sold, but how widespread the use of these compounds is is unknown. Analyses for the presence of fluorinated compounds / PFASs should be conducted in order to better understand how widespread their use is in fabric masks on the Danish market.

According to Bringewatt et al. (2013), these hydrophobic PFASs are released into the environment when textiles treated with them are washed in washing machines. If fabric masks contain hydrophobic fluorinated compounds / PFASs, they can be presumed to have a negative impact on the environment, as fabric masks should be washed after each use.

3.4.3.3 Aniline in textiles

Aniline is an aromatic amine that is used as a precursor to a wide variety of colourants, including azo colourants (among which a number of red colourants are primarily used for dyeing cotton), colourants with anthraquinone structures (as many blue colourants are based on such structures), and triphenylmethane structures (in many yellow and green colourants)[10]. A black colourant known as "aniline black" is also produced from aniline[11], and disperse dyes can also be prepared from aniline (chlorinated anilines)[12].

In its risk assessment of aniline (EU RAR, 2004), the EU writes that there may be a risk of dermal exposure from textiles due to residual concentrations of aniline in textiles. Numerous studies have indicated that aniline can be detected in various types of textiles. Some of these studies are listed below:

- Exposure of two-year-olds to chemical substances (Tønning et al., 2009)
    - Identified in bedclothes (in two products out of five) at concentrations between 0.4 and 24 mg/kg
- KEMI (2013) indicated that aniline was detected at concentrations between 24 and 157 mg/kg

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[10] https://www.pysanky.info/Chemical_Dyes/History.html

[11] https://textilesgreen.in/aniline-black/

[12] https://www.researchgate.net/publication/221925641_Textile_Finishing_Industry_as_an_Important_Source_of_Organic_Pollutants

- Survey of chemical substances in car seats (Kjølholt et al., 2015a)
  - Identified in baby slings (in three products out of six) at concentrations between 1 and 8 mg/kg
  - Identified in car seats (in one product out of six) at a concentration of 0.57 mg/kg
  - Identified in a baby mattress (in one product out of ten) at a concentration of 210 mg/kg
- ANSES (2018) found aniline in 3 out of 25 articles of clothing at concentrations between 10 and 65 mg/kg, concluding that the use of aniline in textiles should be restricted or banned.

As described earlier, a German study detected aniline in 1 out of 15 black fabric masks studied (DAAB, 2021).

For comparison, Oeko-Tex 100 sets the limit value for aniline at 50 mg/kg, while AFIRM does not set a limit value for aniline in its RSL document.

Aniline is suspected of causing both cancer and genetic defects. Furthermore, aniline is allergenic and toxic if inhaled. From a health perspective, aniline is intriguing, as it breaks down into paracetamol. Studies suggest that paracetamol may be an endocrine disruptor, based on reduced testosterone levels (Guiloski et al., 2017) and effects on male genitalia (Mazaud-Guittot et al., 2013). However, no final assessment or consensus on the substance exists. According to bio-monitoring studies[13], small quantities of paracetamol are present in the entire European population (Holm et al., 2015). Nielsen et al. (2014), who studied the occurrence of paracetamol in selected Danes, reported that paracetamol was detectable in adults and children alike who had no paracetamol intake. Both sources indicate that aniline is a source of paracetamol in humans (Holm et al., 2015; Nielsen et al., 2014).

3.4.3.4 Antibacterial agents

The use of antibacterial agents in face masks (including in medical face masks) was studied by Chua et al. (2020). Chua et al. (2020) discuss how the quality and efficiency of various face masks can be optimised, including how face masks can better be made to protect against a variety of bacteria and viruses (such as the virus that causes COVID-19).

Chua et al. (2020) analysed various types of face masks, finding that antibacterial agents may be applied to the outermost or innermost layer of a face mask, and in some cases, to both the outermost and innermost layers of a single face mask. The antibacterial agents they detected in face masks were:

- Silver copper zeolite
- Silver nanoparticles
- Silver oxide nanoparticles
- Copper and zinc nanoparticles
- Copper oxide nanoparticles
- Zinc oxide nanoparticles
- Citric acid

The use of silver and copper as antibacterial agents is in line with the fact that a small number of fabric masks identified in this survey indicated the use of silver or copper, possibly in combination (see section 3.2.1 "Description of surveyed face masks").

Silver, copper, and zinc, which are antibacterial elements, are all considered harmful to the environment (with corresponding harmonised classifications). From an environmental perspective, the presence of these substances in fabric masks is intriguing because it is expected that these compounds will be washed out when fabric masks are washed in washing machines.

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[13] i.e., measurements of chemicals in the human body

Studies have demonstrated that silver nanoparticles in textiles can be washed out[14], while copper nanoparticles may not be washed out to such a high degree[15].

3.4.3.5 Metals (elements)

As previously described, metals in may be used in textiles for such purposes as conferring antimicrobial properties. However, they may also originate from impurities in colourants. The more recent restriction of CMR substances in textiles forbids the use of cadmium, cadmium compounds, chromium(VI) compounds, arsenic compounds, lead, and lead compounds in textiles at concentrations above 1 mg/kg. Generally speaking, various metals occur in small quantities in textiles/clothing, as illustrated in numerous studies (Larsen et al., 2000; KEMI, 2013; ANSES, 2018; Tønning et al., 2009; Kjølholt et al., 2015a). The (elemental) metals that have been detected are antimony (Sb), arsenic (As), barium (Ba), cadmium (Cd), chromium (Cr), cobalt (Co), copper (Cu), silver (Ag), lead (Pb), vanadium (V), and zinc (Zn).

AFIRM (2021) has established several requirements (limit values) on both the total content and the extractable content of various metals (see section 3.4.1.4 "AFIRM, 2021") which they recommend textile manufacturers to follow.

Antimony (Sb) is often detected in polyester textiles, as antimony is used as a catalyst in the production of polyester (Biver, 2021). Also, higher concentrations of antimony are detected in textiles than of any other metal (KEMI, 2013). As many fabric masks are made from polyester (which the WHO recommends as a water-repellent exterior material), antimony is of particular interest in the context of fabric masks made from this material. Antimony is interesting from health and environmental perspectives alike, since this substance is suspected to cause cancer, harmful if inhaled, and damaging to the environment, based on its harmonised classification.

As described earlier, there are both health-related and environmental reasons for studying fabric masks. Water-soluble metallic compounds - in other words, metals that can be washed out - may be of health-related significance (migration into sweat) and of environmental significance (release into aquatic environments via washing machines). Thus, the metals which are of greatest interest are not only those associated with human health and environmental concerns, but also those which can be washed out to a high degree: barium, cadmium, nickel, lead, tin, zinc (Larsen et al., 2000) and antimony (Biver, 2021; BfR, 2012).

3.4.3.6 Flame retardants

Some studies on the use and presence of flame retardants in textiles exists. Larsen et al. (2000) do not describe the use of flame retardants in textiles, but they do indicate that GC-MS analyses for the presence of brominated flame retardants performed in their study did not identify these chemicals. KEMI (2013) indicated that the use of both brominated and chlorinated flame retardants has been observed in textiles. Antimony trioxide can also be used in textiles as a flame retardant. The specific brominated and chlorinated flame retardants which KEMI (2013) listed as used in textiles are:

- Brominated flame retardants: TBBP-A (tetrabromobisphenol A), decaBDE (decabromodiphenyl ether), pentaBDE (pentabromodiphenyl ether), octaBDE (octabromodiphenyl ether), and HBCD (hexabromocyclododecane)
- Chlorinated flame retardants: TCEP (tris(2-chloroethyl)phosphate), TCPP (tris(-2-chloro-1-methylethyl)phosphate), and TDCP (tris(-2-chloro-1-chloromethylethyl)phosphate)

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[14] https://theconversation.com/silver-nanoparticles-in-clothing-wash-out-and-may-threaten-human-health-and-the-environment-90309

[15] https://www.hindawi.com/journals/jnm/2018/6546193/

Previous Danish EPA survey projects (Kjølholt et al., 2015a; Andersen et al., 2014a) identified chlorinated flame retardants in upholstery fabrics (TCPP, TDCP) and car seats (TCEP, TCPP, TDCP). They also identified brominated flame retardants at low concentrations in car seats (triBDE, HBCD). Flame retardants were identified in either upholstery foam or mixed samples of foam with textiles (from car seats).
As described in section 2.1 of this report, "Legislation on chemical substances in textiles", the use of several brominated flame retardants in textiles is currently restricted (e.g., several diphenyl ethers (BDEs)). HBCD is also on the REACH Candidate List. Chlorinated flame retardants are not currently restricted in textiles (though they are restricted in toys for children under three years of age and in toys intended to be placed in the mouth).

4. Prioritisation of substances

Substances were prioritised for the chemical analyses of face masks based on the survey. From the outset, the Danish EPA wished to focus on the following substances:
- BPA, as the presence of this substance in certain textiles has recently been spotlighted
- Formaldehyde, because it was recently restricted in textiles and because there is a pending EU proposal to further decrease the limit value
- Fluorinated/PFAS compounds, presumed to be used in order to provide water- and dirt-repellent properties
- Metals / metal compounds, which may be used to provide antimicrobial properties, or which may originate from impurities in colourants

These substances were selected primarily because they are not already restricted in textiles by law, and because of their characteristics related to human health and/or the environment. This chapter contains a hazard assessment and a discussion of the substances to be prioritised in the chemical analyses, considering particularly those substances not already restricted in textiles by law.

4.1 Initial hazard assessment of substances

An initial hazard assessment was conducted based on the classifications of the substances identified. Where available, the harmonised classification is listed; otherwise, the most common notified classification in the ECHA's C&L Database is listed.

In the case of fluorinated substances / PFASs, the exact compounds used are generally not disclosed. Instead, phrases like "fluorine technology" typically appear. The substances in fabric masks that were named are based on C6 fluorine technology; consequently, some of the most common C6 perfluorinated compounds are listed in the table below. These are also compounds that can be detected by chemical analyses.

The metals included in the initial hazard assessment are those metals which are washed out of textiles to the greatest extent (see section 3.4.3.5 "Metals (elements)"); that is, those metals which are of greatest interest from an exposure perspective, in terms of both health and the environment. Metals already restricted in textiles by law are not included.

TABLE 6. Classifications of selected identified substances. Harmonised classifications are shown in boldface. Relevant H-statements are listed in the comments.

Substance	CAS no.	Classification	Comments
Aniline	62-53-3	**Acute Tox. 3 *, H301** **STOT RE 1, H372** **STOT RE 2, H373** **Acute Tox. 3 *, H311** **Eye Dam. 1, H318** **Skin Sens. 1, H317** **Acute Tox. 3 *, H331** **Muta. 2, H341** **Carc. 2, H351** **STOT RE 1, H372** **Aquatic Acute 1, H400**	Relevant H-statements: H317 May cause an allergic skin reaction H331 Toxic if inhaled H341 Suspected of causing genetic defects H351 Suspected of causing cancer H400 Very toxic to aquatic life

Substance	CAS no.	Classification	Comments
BPA	80-05-7	**Eye Dam. 1, H318** **Skin Sens. 1, H317** **STOT SE 3, H335** **Repr. 1B, H360F**	Appears on the REACH Candidate List because of reprotoxic and endocrine disruptive effects[16] Appears on the CoRAP list Relevant H-statements: H317 May cause an allergic skin reaction H335 May cause respiratory irritation H360 May damage fertility or the unborn child
BPS	80-09-1	Proposed classification: Repr. 1B, H360FD	Appears on the CoRAP list Raised for discussion in the ECHA's ED Expert Group, which specialises in endocrine disruptive effects; no assessment available[17] Relevant H-statements: H360 May damage fertility or the unborn child
Formaldehyde	50-00-0	**Acute Tox. 3 *, H301** **Eye Irrit. 2; H319** **STOT SE 3; H335** **Skin Corr. 1B; H314** **Skin Irrit. 2; H315** **Skin Sens. 1; H317** **Acute Tox. 3 *, H311** **Skin Corr. 1B, H314** **Skin Sens. 1, H317** **Acute Tox. 3 *, H331** **Muta. 2, H341** **Carc. 1B, H350**	Appears on the CoRAP list Recently restricted in textiles; an EU proposal to further decrease the limit value is under consideration[18] Relevant H-statements: H317 May cause an allergic skin reaction H335 May cause respiratory irritation H331 Toxic if inhaled H341 Suspected of causing genetic defects H350 May cause cancer
Antimony	7440-36-0	Acute Tox. 4, H302 Acute Tox. 4, H332 Aquatic Chronic 2, H411 Carc. 2, H351	Appears on the CoRAP list Relevant H-statements: H332 Harmful if inhaled H351 Suspected of causing cancer H411 Toxic to aquatic life with long-lasting effects
Silver	7440-22-4	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Appears on the CoRAP list Approved as an active biocide Relevant H-statements: H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long-lasting effects

[16] https://echa.europa.eu/da/candidate-list-table/-/dislist/details/0b0236e180e22414

[17] https://echa.europa.eu/da/ed-assessment/-/dislist/details/0b0236e180764fc5

[18] https://echa.europa.eu/da/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

Substance	CAS no.	Classification	Comments
Copper	7440-50-8	**Aquatic Chronic 2, H411**	Approved as an active biocide Raised for discussion in the ECHA's ED Expert Group, which specialises in endocrine disruptive effects; no assessment available [19] <u>Relevant H-statements:</u> H411 Toxic to aquatic life with long-lasting effects
Zinc	7440-66-6	**Pyr. Sol. 1, H250** **Water-react. 1, H260** **Aquatic Acute 1, H400** **Aquatic Chronic 1, H410**	<u>Relevant H-statements:</u> H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long-lasting effects
Nickel	7440-02-0	**Skin Sens. 1, H317** **Carc. 2, H351** **STOT RE 1, H372** **Aquatic Chronic 3, H412**	<u>Relevant H-statements:</u> H317 May cause an allergic skin reaction H351 Suspected of causing cancer H412 Harmful to aquatic life with long-lasting effects
Barium	7440-39-3	Water-react. 2, H261 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3	-
Tin	7440-31-5	-	-
PFHxA	307-24-4	Skin Corr. 1B	Considered PBT** Suspected to cause a wide range of negative health effects, including endocrine disruption, immune system effects, etc. [20]
PFHxS	82382-12-5 355-46-4	Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Corr. 1B, H314 Acute Tox. 4, H332	On the REACH Candidate List Considered vPvB*** Suspected to cause a wide range of negative health effects, including endocrine disruption, immune system effects, etc. [21] <u>Relevant H-statements:</u> H332 Harmful if inhaled
6:2 FTOH	647-42-7	Acute Tox. 4, H302 STOT RE 2, H373 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	<u>Relevant H-statements:</u> H335 May cause respiratory irritation

* Indicates that manufacturers must use at least this classification, but may choose another, stricter classification
** PBT = persistent, bioaccumulative, and toxic
*** vPvB = very persistent, very bioaccumulative

[19] https://echa.europa.eu/da/ed-assessment/-/dislist/details/0b0236e18564ffda

[20] https://mst.dk/media/177442/datablad-pfas-2019.pdf

[21] https://mst.dk/media/177442/datablad-pfas-2019.pdf

From the initial hazard assessment presented above, we can see that both aniline and formaldehyde have alarming health-related properties; namely, carcinogenic and allergenic properties. Both substances are also classified as toxic if inhaled. Furthermore, aniline is classified as harmful to the environment.

Both BPA and bisphenol S (BPS) are on the CoRAP list because they are suspected endocrine disruptors. At this time, however, only BPA is on the candidate list due to its endocrine disruptive effects. BPS is being evaluated for endocrine disruptive effects, but no assessment of it is currently available. BPA is additionally classified as a respiratory irritant.

As far as metals are concerned, it makes the most sense to proceed with analyses for antimony (harmful environmental effects, suspected carcinogen, toxic if inhaled), as well as silver, copper, and zinc (all of which are harmful to the environment). Copper is also being evaluated for endocrine disruptive effects. Antimony is often detected in polyester (because it is used in the production of polyester), and since a number of fabric masks are made from polyester, analysis for antimony is relevant to this project.

Regarding fluorinated substances / PFASs, many of these substances have been either classified or recommended to be classified as PBT or vPvB, as they essentially do not break down in the environment. Out of the C6 compounds listed, PFHxS is classified as toxic if inhaled, and 6:2 FTOH is classified as a respiratory irritant. Based on the survey alone, it is impossible to determine whether fluorinated substances / PFASs are used for fabric mask surface treatments, or which compounds, if any, would be used for this purpose. We have observed only indications that these substances may be used in individual fabric masks (via information from the Danish Consumer Council and websites belonging to companies that sell surface treatments for use on face masks).

4.2 Selection of substances for chemical analyses

Based on the above information, a joint decision was made with the Danish EPA to focus on the following substances in the chemical analyses:

- Formaldehyde
- Bisphenol A
- Metals (silver, zinc, copper, and antimony)
- Fluorinated substances (initially, in the form of a total fluorine content analysis)

Additionally, it was decided to conduct a general screening analysis for volatile organic compounds in order to investigate the possibility of other relevant chemical substances occurring in fabric masks (from a health perspective), including such substances as aniline.

5. Product purchased for chemical analysis

Based on the survey and the 92 fabric masks identified, a total of 40 fabric masks were purchased for the chemical analyses. The 40 fabric masks were chosen using the following criteria:

- Fabric masks selected should ideally reflect their distribution with respect to material, number of layers, colour, price range, and elastic band type identified for the 92 fabric masks
- To the greatest extent possible, fabric masks should be purchased from different manufacturers, for a total of 40 unique face masks.
- Face masks sewn from recycled materials at smaller workshops were deliberately avoided, because these masks are considered to all be unique (i.e., they are not mass-produced). Consequently, it would not be possible to purchase the same mask again at a later date. Because this project requires the purchase of several uniform fabric masks for chemical analyses, these kinds of masks were excluded.
- Fabric masks with antibacterial properties were not specially selected, as this project is not focused on antibacterial fabric masks.

During the order process, branding or manufacturer information was not provided for some of the fabric masks purchased. As a result, it was discovered upon delivery that some of the face masks purchased were identical. Subsequently, new face masks were purchased to arrive at a total of 40 unique face masks for the analyses. This did, however, make it impossible to achieve a uniform distribution across all of the purchased face masks, compared to that of the 92 face masks in the survey.

In several cases, there were discrepancies between the information provided on the websites and the information found in the instructions, packaging, and markings that accompanied the purchased face masks. In particular, information provided on the websites about materials in the masks differed from the information that accompanied the actual products. This also impacted the distribution of the purchased fabric masks, compared with the 92 fabric masks in the survey. Furthermore, upon delivery, it was discovered that some fabric masks had antibacterial properties, even though this information was not provided on their respective websites. Some masks were delivered loose, with no packaging; thus, there was no additional information available for these masks beyond what was listed on the corresponding websites.

The 40 purchased face masks are listed in TABLE 7 below. The 40 face masks are distributed as follows:

- Colour: 12 black, 5 white, 11 patterned, 7 single-colour, and 5 single-colour with print
- Material: 13 made from cotton (including 3 made of organic cotton), 8 from polyester, 19 from blended fabrics
- Layers: 3 single-ply face masks, 9 double-ply face masks, 22 triple-ply face masks, a single quadruple-ply mask, a single quintuple-ply mask, and 4 masks with no information as to the number of layers
- Environmental/health marking: 9 face masks with Oeko-Tex 100 certification, 2 masks with GOTS[22] certification (and thus made of organic cotton), and 29 uncertified masks

[22] GOTS stands for Global Organic Textile Standard, an international certification programme for organic textiles

- Price: 7 face masks with prices up to 25 DKK/unit, 19 fabric masks with prices above 25 DKK and up to 50 DKK/unit, 14 fabric masks with prices above 50 DKK and up to 100 DKK/unit, and no fabric masks with prices above 100 DKK (as many of these were antibacterial) The 40 purchased face masks had an average price of 50.48 DKK per mask, which is about 1.30 DKK below the average price of all the masks in the survey.

TABLE 7. Overview of the 40 fabric masks purchased for chemical analysis. Under lab no.,[23] BLA indicates a blended fabric, BOM indicates cotton, and POL indicates polyester.

Lab no.	Colour	Material	Origin	No. of layers
BLA1	White	65% polyester and 35% cotton 65% polyester and 35% cotton 100% polyester	Non-EU	3
BLA2	Black	Polyester and cotton	Non-EU	5
BLA3	Single colour	Bamboo fibre, viscose rayon, and polyester	Non-EU	3
BLA4	Single colour	Mesh, 100% polyester Single jersey, 100% cotton Isoli, 65% cotton / 35% polyester	DK	3
BLA5	Single colour w/ print	Polyester Cotton	DK	2
BLA6	Pattern	Cotton 20% cotton, 80% polyester	Non-EU	2
BLA7	Black	65% polypropylene, 35% polyamide 70% polyester and 30% polyamide 65% polypropylene, 35% polyamide	EU	3
BLA8	Pattern	65% cotton and 35% polyester (all layers)	Non-EU	3
BLA9	Black	100% cotton 100% polyester 95% polyester, 5% elastane	Non-EU	3
BLA10	Single colour	100% polyester Viscose bamboo blend (60%) and cotton (40%) Viscose bamboo blend (60%) and cotton (40%)	Non-EU	3
BLA11	Black	100% certified organic cotton Melt-blown antibacterial polypropylene material 100% certified organic cotton	Non-EU	3
BLA13	Black	100% cotton 100% polyester	Non-EU	2
BLA14	Single colour w/ print	100% polyester Melt-blown (filter) 100% cotton	Non-EU	3
BLA15	Pattern	100% cotton 100% polyester	Non-EU	2
BLA16	Single colour	100% cotton 96% polyester and 4% elastane	EU	2
BLA17	White	50% polyester / 50% Tencel	DK	2

[23] There are a few gaps in the lab number series, due to the fact that some fabric masks were not actually made of the materials listed on the websites from which they were purchased.

Lab no.	Colour	Material	Origin	No. of layers
		50% polyester / 50% Tencel		
BLA18	Pattern	100% cotton Polypropylene 100% polyester	Non-EU	2 layers + disposable filter
BLA19	Pattern	Cotton Polyester	EU	2
BLA20	Black	Not indicated	DK	not indicated
BOM1	Black	100% cotton 100% cotton 100% cotton	EU	3
BOM2	White	Cotton	DK	3
BOM3	Single colour	Cotton	EU	3
BOM4	Pattern	Cotton	DK	2
BOM5	Pattern	Cotton	Non-EU	4
BOM6	White	Not indicated	Not indicated	3
BOM7	Single colour w/ print	Cotton (organic)	DK	3
BOM9	Pattern	100% organic cotton	Non-EU	not indicated
BOM10	Pattern	Cotton (organic)	DK	not indicated
BOM11	Black	Cotton (all layers)	Non-EU	3
BOM12	White	Cotton	DK	3
BOM13	Black	100% cotton Replaceable non-woven filter textile 100% cotton	Non-EU	3
BOM14	Black	100% cotton Not indicated Not indicated	DK	3
POL1	Pattern	88% polyester and 12% spandex Filter of unknown material 100% polyester	Non-EU	3
POL2	Single colour w/ print	SMS filtering layer Polyester	Non-EU	1
POL3	Single colour	95% polyester / 5% elastane	Non-EU	1
POL4	Single colour w/ print	Polyester (all layers)	DK	3
POL5	Black	95.7% polyester / 4.3% spandex	Non-EU	not indicated
POL6	Single colour	93% recycled polyester and 7% elastane 92% recycled polyester and 8% elastane	Non-EU	2
POL7	Pattern	95% polyester and 5% elastane	Non-EU	1
POL8	Black	Not indicated	DK	3

Lab no.	Colour	Material	Origin	No. of layers
		100% polyester 100% polyester, satin weave		

6. Exposure scenarios

Exposure to chemical substances in face masks can occur in several ways:

- through skin contact, when chemical substances may migrate from a fabric mask into sweat and possibly be absorbed through the skin
- through inhalation, when chemical substances released from a face mask are breathed in
- through oral intake, when small fibres break free from a face mask and are subsequently swallowed

The intake of small textile fibres was not studied in this project, whose focus is on the presence of chemical substances in fabric masks. Oral intake was therefore not considered in the exposure scenarios.

The general exposure scenario used for the risk assessment in this project is one based on a realistic worst-case scenario: a consumer wearing a face mask for several hours per day, such as when working, travelling to and from the workplace using public transportation, and shopping in stores. The exposure calculations consider exposure through skin contact and inhalation individually, with the total exposure calculated as their sum.

In this project, however, the focus is primarily on exposure through skin contact, because migration analyses using e.g. artificial sweat make it possible to simulate this type of exposure in a relatively realistic manner.

It is difficult to create a realistic scenario for exposure via inhalation, since consumers both inhale and exhale through a fabric mask. The small quantities of chemical substances that may be released from a fabric mask will be inhaled when a consumer inhales through the fabric mask, but some proportion of them may be expelled again when the consumer exhales through the fabric mask. Other physical conditions, such as temperature and ambient humidity, also affect the release of these gases. Therefore, the creation of an experimental scenario that realistically simulates the quantity of substances a consumer is exposed to when wearing a fabric mask was ruled impossible. For this reason, a worst-case approach was selected for this project, in which the total content of selected (volatile) organic compounds is extracted from the fabric masks. In the risk assessment, this total content will be used for a worst-case calculation for exposure via inhalation. In doing so, the study is restricted to drawing specific conclusions only about the worst-case scenario in which the total amount of a particular substance present is inhaled in a single day.

The values used for the exposure scenario are listed in TABLE 8 below, and discussed in greater detail below the table.

TABLE 8. Values used for the face mask exposure scenario

Parameter	Value used in this project	Comments
Body weight	Adults: 60 kg Children, age 12: 42 kg	Per REACH guideline R.15 Per sundhed.dk
Exposure time	Adults: 8 hours/day Children, age 12: 2 hours/day	Based on an estimate
No. of face masks per day	Adults: 2 masks Children, age 12: 1 mask	Based on recommendations from the Danish Health Authority

Parameter	Value used in this project	Comments
Skin area	Face mask area	Applies to both 12-year-olds and adults
Inhalation volume	Adults: 3.08 m^3/hour for 4 hours and 1.49 m^3/hour for 4 hours Children, age 12: 1.13 m^3/hour for 2 hours	Based on RIVM (2014) and a mix of heavy and light exercise for adults; for children, light exercise only

6.1 Body weight

As specified in the ECHA's REACH guideline document, R.15, a standard female body weight of 60 kg was used for adults (ECHA, 2016). While 12-year-olds have an average height of about 155 cm and are close to adult size, their average body weight is somewhat less than that of adult women. According to Sundhed.dk, the average weight of a 12-year-old girl is 42 kg, and the average weight of a 12-year-old boy is 43 kg (Sundhed.dk, 2020). Consequently, a weight of 42 kg was selected as a realistic worst case for 12-year-old children.

6.2 Exposure time

Adults may be required to wear face masks (such as fabric masks) in the workplace. For this reason, a realistic worst-case exposure time of eight hours per day was selected. This does not account for possible face mask use during travel to and from the workplace, as well as possible face mask use when making personal purchases in shops, etc. However, it can also be expected that there will be breaks throughout the work day when a face mask is not worn. Thus, the total exposure time for adults was set at a total of 8 hours per day.

For children (over the age of 12), face masks are not required at school, but they are required on public transportation and in shops, just as they are for adults. For this reason, an exposure time of two hours per day was chosen (as for adults outside the workplace).

6.3 Number of face masks per day

According to the WHO, face masks must be replaced when they become damp (WHO, 2020e). The Danish Health Authority (2021) recommends not wearing the same face mask for more than four hours per day. For this reason, it was assumed that adults wearing a face mask for a total of 8 hours in one day would need to use two face masks per day.

6.4 Skin area

For 12-year-old children and adults alike, it was assumed that the skin area in contact with the face mask would be equal to the area of the fabric mask itself. It is likely that there will be places around the nose and cheeks where there is air between the face mask and the skin, but how tightly and how well a fabric mask fits varies from person to person. Thus, the entire area of the face mask was used as a worst-case value.

6.5 Inhalation volume

The ECHA (2016) references RIVM (2014), which specifies an inhalation volume of 1.49 m^3/hour for adults engaged in light exercise, and 3.07 m^3/hour for heavy physical exercise. It was assumed that an adult's workday involves a mix of heavy exercise and light exercise, and that face mask usage outside of the workplace falls under light exercise (travel and shopping).

Only light exercise was assumed for children, since children over the age of 12 are only required to wear face masks when on public transportation and in shops. According to RIVM (2014), the inhalation volume for children ages 11 to 16 is 1.13 m^3/hour for light exercise.

In summary, the following inhalation volumes were used:

- Adults: Four hours of heavy physical exercise (3.07 m^3/hour) and four hours of light exercise (1.49 m^3/hour)
- 12-year-old children: Two hours of light exercise (1.13 m^3/hour)

7. Chemical analyses

This chapter describes the chemical analyses performed on the 40 unique fabric masks purchased. The chemical analyses were divided into two stages. The first stage consisted of initial analyses used to identify the masks with highest content of selected chemical substances. These masks were then subjected to follow-up analyses, including migration analyses and wash tests.

7.1 Initial chemical analyses

In consultation with the Danish EPA, it was decided to perform the following initial chemical analyses on the fabric masks purchased:

- 30 fabric masks out of 40 were subjected to a quantitative total fluorine content analysis (single determination) in order to gather data on the possible use of fluorine-based treatments (fluorinated substances / PFASs)
- 30 fabric masks out of 40 were subjected to a quantitative content analysis for selected metals (silver, copper, zinc, and antimony) (duplicate determination)
- All 40 fabric masks were subjected to a screening analysis to identify the presence of any other relevant volatile organic chemical substances (single determination)
- All 40 fabric masks were subjected to a quantitative formaldehyde content analysis (duplicate determination)
- 30 fabric masks out of 40 were subjected to a semi-quantitative BPA analysis, involving 20 analyses performed on the fabric material of selected face masks and 10 analyses performed on selected elastics (duplicate determination)

The analyses for total fluorine content, selected metals, and BPA were not performed on all 40 of the fabric masks purchased. This is partially due to budget limitations that precluded performing every analysis for every product purchased, and partially due to prioritisation based on the results of the survey. For instance, the literature (see section 3.4.3.1 "Bisphenols in textiles") shows that the highest concentrations of BPA likely occur in synthetic materials as opposed to cotton, and in coloured fabrics as opposed to white fabrics. It also shows that metals primarily occur in coloured textiles (especially in polyester, in the case of antimony) (see section 3.4.3.5 "Metals (elements)"). Consequently, fabric masks were selected to be analysed for these chemical substances based on the following criteria and considerations:

- Total fluorine content analysis: All face masks indicating some kind of resistance to water or dirt (three), as well as masks with dust-resistant properties (four); thereafter, random masks from those remaining, up to a total of 30.
- Metal content analysis: Seven of the eight polyester masks were selected for this analysis; thereafter, random masks from the remaining coloured masks, up to a total of 30. The eighth 100% polyester face mask (POL 4) was not selected because the wrong quantity of this mask had been shipped. As a result, there were not enough units of this mask available when the analyses began. The five white fabric masks were not selected for metal content analyses because metals are assumed to originate primarily in colourants.
- BPA analysis: Seven polyester face masks were selected for this analysis, as well as 13 coloured fabric masks with either high polyester content or a single polyester layer. Additionally, ear loops were selected from 10 face masks whose ear loops consisted of an elastic material, as opposed to e.g. woven fabric, which was the case for many of the masks.

The results of the analyses are presented below. Naturally, some "holes" are present in the index numbers, since not all 40 face masks were selected for the fluorine, metal, and BPA content analyses. Some "holes" also appear in the index numbers under the screening and formaldehyde analyses, as some of the purchased fabric masks turned out to be identical upon receipt. Consequently, some fabric masks were not included for chemical analyses in the project.

7.1.1 Quantitative total fluorine content analysis

Out of 40 fabric masks, 30 were selected and subjected to a quantitative total fluorine content determination. To perform this analysis, a sample of each mask weighing approximately 1 g was burnt in a bomb calorimeter. The water in the bomb calorimeter captures the fluorine emitted; thereafter, fluoride in the water can be measured by ion chromatography (IC). This method is a combination of DS/EN ISO 18125 (2017) (combustion) and DS/EN ISO 10304-1 (2009) (measurement by IC). The limit of detection is 1 mg/kg. It has an uncertainty of 10%, though this value increases near the 1 mg/kg limit of detection.

The analysis was performed as a single determination, though the results for certain samples (six in all), primarily those containing high levels of fluorine, were verified by duplicate determination. The results are presented below in TABLE 9.

TABLE 9. Determination of the total fluorine content in 30 selected masks out of the 40 fabric masks purchased. If (for example) the packaging of a fabric mask indicated that it was dirt-repellent, water-repellent, etc., this is noted in the Comments column. The number of layers is also noted in the Comments column.

Fabric mask	Fluorine content (mg/kg)	Comments	Fabric mask	Fluorine content (mg/kg)	Comments
Fabric masks made of cotton (BOM)					
BOM 1	< 1	Three layers	**BOM 7**	< 1	Three layers
BOM 2	< 1	Three layers	**BOM 10**	< 1	Dupl. determ. No. of layers not stated
BOM 3	< 1	Three layers	**BOM 11**	< 1	Dust protection Three layers
BOM 5	< 1	Dirt-resistant Four layers	**BOM 12**	< 1	Anti-dust Three layers
BOM 6	< 1	Three layers	**BOM 14**	< 1	Anti-dust Three layers
Fabric masks made from blended fabrics (BLA)					
BLA 1	91	Dupl. determ. Water-resistant Three layers	**BLA 10**	530	Three layers
BLA 3	150	Three layers	**BLA 13**	14	Two layers
BLA 5	2.8	Two layers	**BLA 15**	920	Dupl. determ. Two layers
BLA 6	< 1.0	Two layers	**BLA 17**	< 1.0	Dupl. determ. Two layers
BLA 7	< 1.0	Three layers	**BLA 18**	4.4	Two layers + single use filter
BLA 8	< 1.0	Three layers	**BLA 19**	1.7	Two layers
BLA 9	< 1.0	Three layers	**BLA 20**	< 1.0	No. of layers not stated

Fabric masks made from polyester (POL)					
POL 1	< 1.0	Dupl. determ. Three layers	**POL 6**	7.3	Two layers
POL 2	630	Dupl. determ. One layer	**POL 7**	250	Dirt-resistant One layer
POL 5	110	Dust-resistant No. of layers not stated	**POL 8**	9.1	Three layers

Dupl. determ. = Duplicate determination performed to verify results for certain samples

As shown in TABLE 9, fluorine above the 1 mg/kg limit of detection was found in 13 of the 30 fabric masks. Fluorine was detected only in fabric masks made of polyester and blended fabrics. The table notes whether each fabric mask indicated that it had e.g. water-repellent or dirt-repellent properties, as these may indicate the presence of fluorinated substances / PFAS compounds. Indications of water-repellent or dirt-repellent properties were presented on the websites or packaging of seven out of 30 fabric masks. However, the claimed properties of these seven fabric masks do not immediately appear to align with the levels of fluorine detected in these masks, assuming that a direct correlation exists between levels of fluorinated substances / PFAS compounds and water- or dirt-repellent properties.

The highest total fluorine concentration detected was 920 mg/kg, while the lowest was 1.7 mg/kg. It should be noted that all layers of each mask were analysed; that is, regardless of whether a mask comprised one, two, three, or four layers of fabric, each sample was of the same weight, no matter if it contained one layer or several. The two polyester face masks in which the highest concentrations of fluorine were detected comprised only one layer of fabric, while BLA 15, which consisted of a blend of multiple fabrics, comprised two layers. Therefore, it is possible that the concentration of fluorine in a given mask was diluted during the analysis process, as fluorine may have only been present in its outermost layer. Even so, this approach was chosen to make it possible to detect fluorine present in any layer of the selected fabric masks.

According to Knepper et al. (2014), PFAS compounds are typically used at concentrations of 0.2 to 0.5% of a textile's mass, corresponding to a total fluorine concentration between 400 and 2500 mg/kg. However, the majority of the fabrics in EPA Survey Project no. 136, regarding PFASs in fabrics for children (Lassen et al., 2015), had fluorine concentrations between 100 and 400 mg/kg. This project identified a variety of PFAS compounds. This is in line with the results of EPA Survey Project no. 147, regarding chemical substances in floor rugs for children (Klinke et al., 2016). Total fluorine concentrations between 100 and 150 mg/kg were found in this project, resulting in the detection of PFAS compounds.

Given the above results concerning the total fluorine content in the 30 selected fabric masks, a joint decision was made with the Danish EPA to subject the five masks below to a quantitative analysis for fluorinated substances / PFAS compounds:
- BLA 3
- BLA 10
- BLA 15
- POL 2
- POL 7

These fabric masks are the five masks in which the highest concentrations of fluorine were detected using single-determination analyses. The results of the follow-up analyses are presented in section 7.2 "Follow-up chemical analyses".

7.1.2 Quantitative content analysis for selected metals (Ag, Cu, Zn, Sb)

The total content of the four selected metals (silver, copper, zinc, and antimony) was determined using digestion followed by ICP-OES (inductively coupled plasma–optical emission spectroscopy) for detection. Samples of about 0.2 g were used for the analyses. These analyses followed accredited method M1.167 for the determination of metals in plastics. This method is in accordance with EPA 3052, DS/EN ISO 11885, and CPSC-CH-E-1002-08.3 (2012). However, the accreditation of this method encompasses only regulated metals, not the metals of interest for this analysis; all the same, this method is very well-suited to our purposes, as the same technique of digestion and analysis is used for accredited testing in a variety of fields.

The limit of detection and analytical uncertainty vary from one metal to the next:
- Ag: limit of detection at 2 mg/kg, 10% analytical uncertainty
- Cu: limit of detection at 1 mg/kg, 10% analytical uncertainty
- Zn: limit of detection at 5 mg/kg, 20% analytical uncertainty
- Sb: limit of detection at 10 mg/kg, 20% analytical uncertainty

All determinations were performed as duplicate determinations. The results are presented as the average of the two determinations. The results of the individual determinations are presented in Annex 2.

TABLE 10. Quantitative determinations of the concentrations of silver (Ag), copper (Cu), zinc (Zn), and antimony (Sb) in 30 selected masks out of the 40 fabric masks purchased.

Fabric mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)	Layers in mask	Information on product or website
Fabric masks made of cotton (BOM)						
BOM 1	≤ 2	≤ 1	≤ 5	≤ 10	3	Oeko-Tex 100
BOM 3	≤ 2	59	≤ 5	≤ 10	3	Oeko-Tex 100
BOM 4	≤ 2	21	≤ 5	22	2	
BOM 5	≤ 2	8.3	≤ 5	≤ 10	4	
BOM 9	≤ 2	≤ 1	7.3	≤ 10	Not indicated	Organic cotton
BOM 11	≤ 2	1.0	≤ 5	≤ 10	3	
BOM 14	12.1	≤ 1	5.8	17	3	Antibacterial
Fabric masks made from blended fabrics (BLA)						
BLA 2	9.3	≤1	30	45	5	Antibacterial
BLA 3	≤ 2	≤1	≤ 5	53	3	Oeko-Tex 100
BLA 4	≤ 2	≤1	≤ 5	66	3	
BLA 5	≤ 2	1.7	≤ 5	89	2	
BLA 6	≤ 2	82	≤ 5	104	2	
BLA 7	≤ 2	≤1	≤ 5	≤ 10	3	
BLA 8	≤ 2	≤1	≤ 5	214	3	
BLA 9	≤ 2	≤1	≤ 5	74	3	
BLA 11	≤ 2	24	20	≤ 10	3	Oeko-Tex 100 Organic cotton
BLA 13	≤ 2	≤1	≤ 5	≤ 10	2	Oeko-Tex 100
BLA 14	≤ 2	≤1	≤ 5	194	3	

Fabric mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)	Layers in mask	Information on product or website
BLA 15	≤ 2	1.2	≤ 5	160	2	
BLA 16	≤ 2	≤1	≤ 5	102	2	
BLA 18	≤ 2	≤1	10.3	94	2 + disposable filter	
BLA 19	≤ 2	19	≤ 5	129	2	
Fabric masks made from polyester (POL)						
POL 1	≤ 2	≤1	≤ 5	210	3	
POL 2	≤ 2	≤1	≤ 5	99	1	
POL 3	≤ 2	1.7	≤ 5	129	1	
POL 5	≤ 2	≤ 1	≤ 5	135	Not indicated	
POL 6	≤ 2	≤ 1	≤ 5	115	2	
POL 7	≤ 2	≤ 1	14	173	1	
POL 8	≤ 2	≤ 1	≤ 5	131	3	

As shown in TABLE 10, **silver** was found in only two of the 30 fabric masks analysed, at concentrations of 9 and 12 mg/kg. The presence of silver may be explained by its addition in order to confer antibacterial properties on the masks. Both BOM 14 and BLA 2 indicated on their packaging that their material had antibacterial properties. However, this information was not presented on the websites from which the products were purchased.

Similarly, **copper** can be used for its antibacterial properties, but copper is also used in a variety of colourants. Copper was found in 10 of the 30 fabric masks analysed, at concentrations between 1 and 82 mg/kg. None of the information supplied for these face masks suggests that copper was used in order to confer antibacterial properties on the masks. However, several of the fabric masks in the study were supplied without any accompanying usage instructions, information, or other text. For reference, the Oeko-Tex 100 standard (see Annex 1) permits no more than 50 mg/kg of extractable copper in textiles which come into direct contact with the skin. The analysis used here indicates the total copper content, which is higher than the portion that may be extracted from the material.

Zinc may also be used for its antibacterial properties, although zinc compounds are used for many other purposes in textiles. For instance, they may be used as dyeing catalysts and in anti-wrinkle treatments (Larsen et al., 2000). Zinc was identified in six of the 30 face masks analysed at concentrations between 6 and 30 mg/kg. Only BLA 2 (the mask with the highest concentration of zinc) was labelled as being antibacterial. None of the information supplied for the remaining face masks suggests that zinc was used in order to confer antibacterial properties on the masks.

Antimony is used as a catalyst in the production of polyester (Biver, 2021). As shown in TABLE 10, the concentration of antimony is also highest in fabric masks consisting either entirely of polyester (POL 1 through POL 8) or of blended fabrics (BLA). The masks' packaging and the websites from which they were purchased indicated that these fabric masks consisted of blended fabrics, with polyester as a component of one or more layers. However, according to the information provided, BLA 11 did not contain polyester. Antimony was found in 21 of the 30 fabric masks analysed, but only in two of the seven fabric masks made entirely of cotton. The concentrations found in the cotton face masks were low (between 17 and 22 mg/kg), while higher concentrations were found in fabric masks made from blended fabrics (including polyester) and in 100% polyester masks. The concentrations in these masks ranged from 45 to 214 mg/kg. Antimony was found in all of the polyester fabric masks, and only three of the 15 blended fabric masks analysed did not contain antimony above the limit of detection. For comparison, the EU Ecolabel programme[24] sets the maximum concentration of antimony in certified fabrics at 260 mg/kg.

Based on the above results regarding the presence of silver, copper, zinc, and antimony in the 30 selected fabric masks, a joint decision was made with the Danish EPA to subject the following five face masks to a quantitative analysis for the presence of the same metals in a washed mask:

- BLA 2, due to high levels of silver and zinc
- BLA 6, due to high levels of copper and antimony
- BLA 11, due to high levels of copper and zinc
- BOM 14, due to a high level of silver, as well as the presence of both zinc and antimony
- POL 7, due to high levels of zinc and antimony

It was also decided to perform migration analyses with artificial sweat for the following five masks in which the highest concentrations of antimony were detected. Antimony is one of the four metals of interest with health-related effects, so its migration into artificial sweat is relevant in this context.

- POL 1
- POL 7
- BLA 6
- BLA 8
- BLA 14

The results of the follow-up analyses are presented in section 7.2 "Follow-up chemical analyses".

7.1.3 GC-MS screening for volatile organic compounds

All 40 of the purchased fabric masks were subjected to a screening analysis to test for the presence of volatile or semi-volatile organic compounds that consumers could inhale when wearing fabric masks.

To perform the screening analysis, 0.75 g of fabric mask (equal portions of all layers) were extracted using organic solvents. The resulting extract was then concentrated before analysis by gas chromatography with mass spectrometry (GC-MS). This analysis makes it possible to identify volatile, semi-volatile, and other organic substances extracted from the fabric. Only single determinations were performed, as this is a screening analysis. The most relevant substances by mass from each fabric mask (those with the highest signals or semi-quantitative content) were identified using the NIST Mass Spectral Library. The limit of detection varies for each substance, ranging from about 1 to 50 mg/kg.

TABLE 11. GC-MS screening analyses performed on the 40 fabric masks purchased

Fabric mask	CAS no.	Substance name	Quantity
Fabric masks made of cotton (BOM)			
BOM 1	-	*No substances identified in significant quantities*	
BOM 2	a) 4098-71-9	a) likely isophorone diisocyanate b) possibly carboxylic acids, such as stearic acid	a) +
BOM 3	-	*No substances identified in significant quantities*	
BOM 4	83690-72-6	Likely N-methyl-N-benzyltetradecanamine	+

[24] https://www.ecolabel.dk/-/criteriadoc/3211

Fabric mask	CAS no.	Substance name	Quantity
BOM 5	105-60-2	Likely caprolactam	+
BOM 6	-	*No substances identified in significant quantities*	
BOM 7	-	*No substances identified in significant quantities*	
BOM 9	-	*No substances identified in significant quantities*	
BOM 10	-	*No substances identified in significant quantities*	
BOM 11	-	*No substances identified in significant quantities*	
BOM 12	a) 56-81-5 b) 84-74-2	a) Glycerine b) Dibutyl phthalate (DBP)	a) ++ b) +++
BOM 13	-	*No substances identified in significant quantities*	
BOM 14	a) 56-81-5 b) 84-74-2	a) Glycerine b) Dibutyl phthalate (DBP)	a) ++ b) ++
Fabric masks made from blended fabrics (BLA)			
BLA 1	141-02-6	Bis(2-ethylhexyl) fumarate	++
BLA 2	-	*No substances identified in significant quantities*	
BLA 3	101-68-8	1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	+
BLA 4	-	*No substances identified in significant quantities*	
BLA 5	-	*No substances identified in significant quantities*	
BLA 6	a) 56-81-5 b) 88-99-3 c) 584-84-9	a) glycerine b) likely phthalic acid c) 2,4-diisocyanato-1-methylbenzene	a) +++ b) ++ c) ++
BLA 7	-	*No substances identified in significant quantities*	
BLA 8	101-68-8	1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	+
BLA 9	a) 3531-19-9 b) 141-02-6	a) likely 2-chloro-4,6-dinitrobenzenamine b) Bis(2-ethylhexyl)fumarate	a) ++ b) +
BLA 10	-	*No substances identified in significant quantities*	
BLA 11	-	*No substances identified in significant quantities*	
BLA 13	a) 126-30-7 b) 110-63-4 c) 101-68-8	a) neopentyl glycol b) butanediol c) 1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	a) ++ b) ++ c) +++
BLA 14	a) 142-16-5 b) 141-02-6	a) Bis(2-ethylhexyl)maleate b) Bis(2-ethylhexyl)fumarate	a) + b) +++
BLA 15	a) 88-99-3 b) 584-84-9	a) likely phthalic acid b) 2,4-diisocyanato-1-methylbenzene	a) ++ b) ++
BLA 16	141-02-6	Bis(2-ethylhexyl) fumarate	+
BLA 17	-	*No substances identified in significant quantities*	
BLA 18	-	*No substances identified in significant quantities*	
BLA 19	101-68-8	1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	+
BLA 20	-	*No substances identified in significant quantities*	
Fabric masks made from polyester (POL)			
POL 1	a) 101-68-8 b) 141-02-6	a) 1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI) b) Bis(2-ethylhexyl)fumarate	a) + b) ++

Fabric mask	CAS no.	Substance name	Quantity
POL 2	a) 126-30-7 b) 584-84-9 c) 409-71-9 d) 120-55-8	a) neopentyl glycol b) 2,4-diisocyanato-1-methylbenzene c) Likely isophorone diisocyanate d) Diethylene glycol dibenzoate	a) +++ b) +++ c) +++ (two isomers) d) ++
POL 3	a) 101-68-8 b) 141-02-6	a) 1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI) b) Bis(2-ethylhexyl)fumarate	a) + b) ++
POL 4	-	*No substances identified in significant quantities*	
POL 5	a) 101-68-8 b) 141-02-6	a) 1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI) b) Bis(2-ethylhexyl)fumarate	a) + b) +
POL 6	a) 4098-71-9 b) 120-51-4 c) 101-68-8	a) Likely isophorone diisocyanate b) Benzyl benzoate c) 1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	a) ++ (two isomers) b) ++ c) +
POL 7	101-68-8	1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	+
POL 8	-	*No substances identified in significant quantities*	

+: Up to 2 times average area of internal standard in tests
++: 2–10 times average area of internal standard in tests
+++: At least 10 times average area of internal standard in tests

In TABLE 12 below, the substances identified in the GC-MS screening are presented in a summary table. The classifications of the substances are also listed. Only the most relevant health-related and environmental classifications are listed here. This means that classifications for physical conditions, such as flammability, are not listed.

In the table, the identified substances are sorted by quantity (indicated by + symbols), frequency, and classification. The most significant substances are listed first. For this table, significance was considered in terms of skin contact, inhalation, and environmental hazards. However, the quantities detected and the number of products each substance was detected in were also taken into account.

TABLE 12. The substances identified in the 40 purchased face masks using a GC-MS screening. Harmonised classifications are shown in boldface. An asterisk (*) next to a classification means that only a small number of notified classifications (fewer than 10%) classify the substance as indicated. Substances are prioritised according to quantity, frequency, and classification; the most significant substances are listed first. The most important classifications from health and environmental perspectives are listed with keywords in the Notes column. More weight was given to classifications related to toxicity when inhaled and in contact with the skin, as well as to classifications related to serious health effects, such as carcinogenic, mutagenic, and reprotoxic properties. Allergenicity was also considered here.

Substance name	CAS no.	Identified in sample	Classification	Notes
1,1'-methylenebis(4-isocyanatobenzene) (4,4'-MDI)	101-68-8	BLA 3 (+) BLA 8 (+) BLA 13 (+++) BLA 19 (+) POL 1 (+)	**Skin Irrit. 2 H315** **Eye Irrit. 2 H319** **Skin Sens. 1 H317** **Acute Tox. 4 H332** **STOT SE 3 H335**	 Allergenic Harmful if inhaled Respiratory irritation

Substance name	CAS no.	Identified in sample	Classification	Notes
		POL 3 (+) POL 5 (+) POL 6 (+) POL 7 (+)	**Resp. Sens. 1 H334** **Carc. 2 H351** **STOT RE 2 H373**	Breathing difficulties Poss. carcinogenic Damage to organs
2,4-diisocyanato-1-methylbenzene	584-84-9	BLA 6 (++) BLA 15 (++) POL 2 (+++)	**Eye Irrit. 2 H319** **Skin Sens. 1 H317** **Acute Tox. 2 H330** **STOT SE 3 H335** **Resp. Sens. 1 H334** **Carc. 2 H351** **Aquatic Chronic 3 H412**	 Allergenic Fatal if inhaled Respiratory irritation Breathing difficulties Poss. carcinogenic Harmful to the environment
Dibutyl phthalate (DBP)	84-74-2	BOM 12 (+++) BOM 14 (++)	**Aquatic Acute 1 H400** **Repr. 1B H360Df**	Toxic to the environment Damages fertility On the REACH Candidate List
Isophorone diisocyanate (likely)	4098-71-9	BOM 2 (+) POL 2 (+++) POL 6 (++)	**Skin Irrit. 2 H315** **Resp. Sens. 1 H334** **Skin Sens. 1 H317** **Eye Irrit. 2 H319** **Acute Tox. 3 H331** **STOT SE 3 H335** **Aquatic Chronic 2 H411**	 Breathing difficulties Allergenic Toxic if inhaled Respiratory irritation Harmful to the environment
2-chloro-4,6-dinitrobenzenamine (likely)	3531-19-9	BLA 9 (++)	Acute Tox. 3 H300 Acute Tox. 1 H310 Acute Tox. 2 H330 STOT RE 2 H373 Muta. 2 H341* Aquatic Chronic 2 H411	Fatal if swallowed Fatal in contact with skin Fatal if inhaled Damage to organs Poss. genetic defects Harmful to the environment
Phthalic acid (likely)	88-99-3	BLA 6 (++) BLA 15 (++)	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3, H335 Acute Tox. 4 H302	 Respiratory irritation
Bis(2-ethylhexyl)-fumarate	141-02-6	BLA 1 (++) BLA 9 (+) BLA 14 (+++) BLA 16 (+) POL 1 (++) POL 3 (++) POL 5 (+)	Aquatic Chronic 2, H411 Skin Irrit. 2 H315	Harmful to the environment
Neopentyl glycol	126-30-7	BLA 13 (++) POL 2 (+++)	Eye Dam. 1, H318 STOT SE 3, H335*	
Caprolactam (likely)	105-60-2	BOM 5 (+)	**Acute Tox. 4 H302** **Skin Irrit. 2 H315** **Eye Irrit. 2 H319** **Acute Tox. 4 H332** **STOT SE 3, H335**	 Harmful if inhaled Respiratory irritation
Benzyl benzoate	120-51-4	POL 6 (++)	**Acute Tox. 4 H302**	

Substance name	CAS no.	Identified in sample	Classification	Notes
			Aquatic Chronic 2 H411	Harmful to the environment
Butanediol	110-63-4	BLA 13 (++)	Acute Tox. 4 H302 STOT SE 3 H336 Skin Irrit. 2 H315*	 Drowsiness
Bis(2-ethylhexyl)maleate	142-16-5	BLA 14 (+)	STOT RE 2 H373 Aquatic Chronic 1, H410 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Acute H400*	Damage to organs Toxic to the environment Toxic to the environment
Glycerine	56-81-5	BLA 6 (+++) BOM 12 (++) BOM 14 (++)	Not classified Eye Irrit. 2 H319* Skin Irrit. 2 H315* STOT RE 2 H373*	
Diethylene glycol dibenzoate	120-55-8	POL 2 (++)	Not classified Aquatic Chronic 2 H411*	 Harmful to the environment
Isophorone diisocyanate (likely)	409-71-9	POL 2 (+++)	*Not in the C&L database*	
N-methyl-N-benzyltetradecanamine	83690-72-6	BOM 4 (+)	*Not in the C&L database*	

* Indicates that only a small number of businesses (fewer than 10%) have notified this classification
H300 = Fatal if swallowed; H302 = Harmful if swallowed; H310 = Fatal in contact with skin; H330 = Fatal if inhaled; H331 = Toxic if inhaled; H332 = Harmful if inhaled;
H315 = Causes skin irritation; H317 = May cause an allergic skin reaction; H318 = Causes serious eye damage; H319 = Causes serious eye irritation
H334 = May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 = May cause respiratory irritation; H336 = May cause drowsiness or dizziness
H341 = Suspected of causing genetic defects
H351 = Suspected of causing cancer
H360 = May damage fertility or the unborn child; H361 = Suspected of damaging fertility or the unborn child
H373 = May cause damage to organs through prolonged or repeated exposure
H400 = Very toxic to aquatic life; H410 = Very toxic to aquatic life with long-lasting effects; H411 = Toxic to aquatic life with long-lasting effects; H412 = Harmful to aquatic life with long-lasting effects

Three **isocyanates** were identified during the screening analyses, all of which are allergenic, harmful, or toxic if inhaled and capable of causing breathing difficulties. The presence of isocyanates may be explained by the use of adhesives to glue individual layers of fabric together in a face mask.

Dibutyl phthalate (DBP) was found in two of the single-colour, unprinted cotton masks. The presence of DBP may be explained by the use of adhesives to glue individual layers of fabric together.

Additionally, **2-chloro-4,6-dinitrobenzenamine** was detected. This substance is classified as fatal if inhaled or in contact with the skin. This substance was found in only one face mask, and the identification was not unequivocal.

Lastly, **bis(2-ethylhexyl) fumarate** (a biocide) was found in seven face masks. This substance is harmful to the environment.

From a health perspective, isocyanates and possibly DBP are of interest for further investigation. A joint decision was reached with the Danish EPA to examine five face masks for the presence of a variety of isocyanates, including the three isocyanates whose presence in fabric masks was indicated by the screening results. The five face masks selected were:

- BLA 6
- BLA 13
- BLA 15
- POL 2
- POL 6

The results of the follow-up analyses are presented in section 7.2 "Follow-up chemical analyses".

7.1.4 Quantitative formaldehyde content analysis

The 40 purchased fabric masks were analysed for the presence of formaldehyde according to DS/EN ISO 14184-1, *Textiles: Determination of formaldehyde, Part 1: Free and hydrolysed formaldehyde (water extraction method)*. A fabric sample of about 2.5 g was extracted using water at 40°C, and the concentration of formaldehyde was determined using a colorimetric method with acetylacetone as a reagent. The measurement range indicated for this standard is from 16 mg/kg to 3500 mg/kg, but for these experiments, the sensitivity was increased by using 2.5 times more material. (The standard specifies extraction of 1 g, or 2.5 g for low concentrations of formaldehyde). Duplicate determinations were performed; the results are presented as the average of each single determination. Analysis results are given in mg/kg of sample. The limit of detection given the quantity used is 6 mg/kg. The uncertainty ranges from 5% to 25% depending on the concentration of formaldehyde in the sample.

The results of the quantitative formaldehyde content determination for the 40 fabric masks are presented below in TABLE 13. The results of the individual determinations are presented in Annex 3.

TABLE 13. Quantitative formaldehyde determination for the 40 purchased fabric masks

Fabric mask	Formaldehyde content (mg/kg)	Fabric mask	Formaldehyde content (mg/kg)
Fabric masks made of cotton (BOM)			
BOM 1	< 6	BOM 9	< 6
BOM 2	< 6	BOM 10	< 6
BOM 3	< 6	BOM 11	< 6
BOM 4	53	BOM 12	< 6
BOM 5	< 6	BOM 13	6
BOM 6	< 6	BOM 14	6
BOM 7	< 6		
Fabric masks made from blended fabrics (BLA)			
BLA 1	< 6	BLA 11	< 6
BLA 2	22	BLA 13	< 6
BLA 3	< 6	BLA 14	7
BLA 4	< 6	BLA 15	< 6
BLA 5	< 6	BLA 16	< 6
BLA 6	< 6	BLA 17	6
BLA 7	< 6	BLA 18	< 6
BLA 8	< 6	BLA 19	< 6
BLA 9	< 6	BLA 20	< 6

Fabric mask	Formaldehyde content (mg/kg)	Fabric mask	Formaldehyde content (mg/kg)
BLA 10	< 6		
Fabric masks made from polyester (POL)			
POL 1	< 6	**POL 5**	< 6
POL 2	< 6	**POL 6**	< 6
POL 3	< 6	**POL 7**	< 6
POL 4	< 6	**POL 8**	< 6

The results show that formaldehyde was only detected at (significant) concentrations above the limit of detection in two of the fabric masks analysed. These masks contained concentrations of 22 and 53 mg of formaldehyde per kg of fabric. Low concentrations of formaldehyde (6 or 7 ppm) near the limit of detection were identified in four more fabric masks.

Thus, none of the 40 fabric masks analysed have any issues with the new restriction on formaldehyde in fabrics which entered into force on 1 November 2020, establishing a maximum concentration of 75 mg/kg (see section 2.1 "Legislation on chemical substances in textiles"). There is a proposal to further decrease the limit value to 30 ppm (ECHA, 2020a). If adopted, BOM 4 would exceed the new limit value.

Face masks were not selected for migration analyses or wash tests based on formaldehyde content, as formaldehyde is highly soluble in water[25]. In light of how formaldehyde reacts with water, the results of such analyses would likely be irrelevant. This is one reason that consumers are recommended to wash fabrics before use.

7.1.5 Semi-quantitative bisphenol A content analysis in selected face masks / elastics

The semi-quantitative content analysis for bisphenol A (BPA) in fabrics was performed by adding acetone and dichloromethane to small pieces of fabric masks. Samples were extracted using a combination of ultrasonic cavitation and physical agitation, followed by filtration and concentration by evaporation. The concentrated samples were then dissolved in methanol and water for subsequent analysis using liquid chromatography with tandem mass spectrometry (LC-MS^2). True duplicate determinations were performed.

The results of the semi-quantitative determination of BPA content for the 20 selected fabric masks and the 10 selected elastics are presented below in TABLE 14. The limit of quantification in this semi-quantitative analysis was 0.05 mg/kg.

TABLE 14. Semi-quantitative results for BPA in the 20 selected fabric masks and 10 selected elastics

Fabric mask	BPA content (mg/kg)	Comments
Fabric masks made of cotton (BOM)		
BOM 1 - elastic	< 0.05	Only the elastic from this face mask was analysed
BOM 4 - elastic	< 0.05	Only the elastic from this face mask was analysed
BOM 7 - elastic	< 0.05	Only the elastic from this face mask was analysed

[25] According to the ECHA's database of registered substances, the solubility of formaldehyde in water is 550 g/litre. High solubility in water is typically defined as a value above 1 g/litre (http://npic.orst.edu/envir/watersol.html).

Fabric masks made from blended fabrics (BLA)		
BLA 3	< 0.05*	
BLA 4	< 0.05	
BLA 5	< 0.05	
BLA 6	**> 0.5**	Level above the highest standard, 0.4 mg/kg
BLA 8	< 0.05*	
BLA 9	< 0.05	Both the fabric and elastic from this face mask were analysed
BLA 9 - elastic	< 0.05	Both the fabric and elastic from this face mask were analysed
BLA 10	< 0.05*	Both the fabric and elastic from this face mask were analysed
BLA 10 - elastic	< 0.05	Both the fabric and elastic from this face mask were analysed
BLA 13	< 0.05*	
BLA 14	< 0.05	Both the fabric and elastic from this face mask were analysed
BLA 14 - elastic	< 0.05	Both the fabric and elastic from this face mask were analysed
BLA 15	< 0.05	
BLA 16	< 0.05	
BLA 18	< 0.05	
BLA 20 - elastic	< 0.05	Only the elastic from this face mask was analysed
Fabric masks made from polyester (POL)		
POL 1	< 0.05*	Both the fabric and elastic from this face mask were analysed
POL 1 - elastic	< 0.05*	Both the fabric and elastic from this face mask were analysed
POL 2	< 0.05	
POL 3	**> 0.5**	One of the two determinations contained BPA at a level above the highest standard, 0.4 mg/kg
POL 4	< 0.05	Both the fabric and elastic from this face mask were analysed
POL 4 - elastic	< 0.05	Both the fabric and elastic from this face mask were analysed
POL 5	< 0.05	
POL 6	< 0.05	Both the fabric and elastic from this face mask were analysed
POL 6 - elastic	**About 0.3**	Both the fabric and elastic from this face mask were analysed
POL 7	< 0.05	
POL 8	< 0.05	Both the fabric and elastic from this face mask were analysed
POL 8 - elastic	< 0.05	Both the fabric and elastic from this face mask were analysed

* Results indicated possible presence of BPA at levels below the limit of quantification.

As shown in TABLE 14, BPA concentrations above the 0.05 mg/kg limit of quantification (i.e., 50 ng/g) were found in only three samples. Two of the samples were taken from the actual fabric portion of fabric masks, while one was taken from the elastic of a fabric mask. The fabric samples from BLA 6 and POL 3, in which BPA was detected, consisted of a 100% cotton layer plus an 80% polyester / 20% cotton layer, and a single 95% polyester / 5% elastane layer, respectively. All of the elastics selected for analysis were chosen because they were suspected of containing elastane, but no information on their material compositions was provided.

It is suspected that BPA is present at low concentrations in BLA 3, BLA 8, BLA 10, BLA 13, and POL 1, but this was not possible to confirm using this semi-quantitative analysis due to a lack of an internal standard and a relatively high limit of quantification. The results indicated that BLA 8 and POL 1 contained BPA at levels closest to the limit of quantification.

Relatively large differences occurred between duplicate determinations for some of the samples analysed. Such samples include POL 3, for which only one determination was above the limit of quantification; the elastic from POL 6; and several face masks for which results indicated the presence of BPA at levels below the limit of quantification.

Based on the results of the semi-quantitative BPA analyses, a joint decision was reached with the Danish EPA to proceed with quantitative analyses for BPA content in both unwashed and washed masks using the following five face masks:
- BLA 6
- BLA 8
- POL 1
- POL 3
- POL 6 - elastic

7.1.6 Selection of products for follow-up analyses
Based on the results of the initial chemical analyses, a joint decision was reached with the Danish EPA to proceed with the follow-up analyses listed below:
- Quantitative determination of fluorinated substances / PFAS compounds in washed and unwashed face masks
- Quantitative determination of the four metals of interest in washed face masks
- Migration analyses for the four metals of interest in unwashed face masks
- Quantitative determination of certain isocyanates in unwashed face masks
- Quantitative determination of BPA in washed face masks

In general, the masks chosen were the five face masks found to contain the highest concentrations of these substances in the initial chemical analyses. The specific face masks analysed are described in the subsections for each follow-up analysis below.

It was decided not to perform quantitative determinations and migration analyses for formaldehyde and isocyanates because formaldehyde is highly soluble in water, and because isocyanates react with water (by hydrolysis) to form carbon dioxide and urea compounds. It is thus expected that the concentrations of formaldehyde and isocyanates in washed face masks would be quite low, given the reactions of these substances with water.

Finally, it was decided to test for the presence of TCEP, TCPP, and TDCP, chlorinated flame retardants which have previously been identified in textiles. These flame retardants are not currently restricted in textiles, but they are restricted in toys for children under three years of age, as well as in other toys designed to be placed in the mouth.

7.2 Follow-up chemical analyses
Several of the follow-up chemical analyses were performed on washed fabric masks. The method used to wash the fabric masks is described below.

7.2.1 Wash test

The purpose of performing wash tests on the selected face masks is to determine which substances of interest are washed out into the environment and in what quantities, as well as to determine the quantities of these substances that remain in the face masks after washing.

To simulate the washing process as performed by a consumer, the fabric masks were washed in a washing machine at 60°C according to paragraph 5.4 of DS 3000:2021, "Washable face masks for repeated use in public spaces - Requirements and testing methods". In practical terms, this means the face masks were washed five times, as specified in both DS 3000:2021 and in DS/EN ISO 6330, "Textiles - Domestic washing and drying procedures for textile testing". A standardised washing machine, tumble dryer, and detergent were used as specified in both DS/EN ISO 6330 and DS 3000:2021.

All of the selected face masks were washed together, as this best simulates realistic washing conditions. The standard prescribes the use of ballast, if necessary ("neutral" textiles, such as pre-washed towels) and tumble drying after washing. In this particular case, a "neutral" textile was not used, since the face masks themselves served as ballast by being washed together.

A normal machine washing cycle uses about 50 to 60 litres of water, which would result in wash water that contains only very small quantities of the substances of interest. Advanced analysis methods would be required to detect the washed-out substances in the wash water at such low concentrations. Instead, the substances were measured in the washed face masks, with the difference between analysis results before and after washing taken to be the quantity washed out.

There is a drawback to this method: It was not possible to perform every chemical analysis on the exact same mask before and after washing. This is also a result of the relatively small size of a fabric mask. None of the fabric masks were of especially high weight (typically between just 7 and 15 g), making it necessary to use multiple fabric masks of the same kind for these analyses. Therefore, pre- and post-wash chemical analyses were performed on different units of the same face masks. Whether all of the units received for a given mask were actually produced from the same piece of fabric is unknown.

7.2.2 Quantitative determination of fluorinated substances / PFAS compounds

The five fabric masks with the highest fluorine concentrations were selected to be analysed for concentrations of selected fluorinated substances / PFAS compounds. The analyses for fluorinated substances / PFAS compounds were performed by Medico Kemiske Laboratorium ApS. The analyses targeted the fluorinated substances below (listed in TABLE 15), covering a number of the most well-known and studied PFAS compounds, as well as certain fluorotelomer alcohols (FTOHs).

TABLE 15. Limits of detection (LOD) and analytical uncertainties for PFAS compounds

PFAS compound	LOD (mg/kg)	Uncertainty (%)
Perfluoro-n-butanoic acid (PFBA)	0.1	20
Perfluoro-n-pentanoic acid (PFPeA)	0.1	20
Perfluoro-n-hexanoic acid (PFHxA)	0.1	20
Perfluoro-n-heptanoic acid (PFHpA)	0.1	20
Perfluoro-n-octanoic acid (PFOA)	0.1	20
Perfluoro-n-nonanoic acid (PFNA)	0.1	20

PFAS compound	LOD (mg/kg)	Uncertainty (%)
Perfluoro-n-decanoic acid (PFDA)	0.1	20
Potassium perfluoro-1-butane sulphonate (PFBS)	0.02	20
Sodium perfluoro-1-hexane sulphonate (PFHxS)	0.02	20
Sodium perfluoro-1-octane sulphonate (PFOS)	0.02	20
N-Methyl perfluorooctane sulfonamidoethanol (N-Me-FOSE)	0.02	20
N-Ethyl perfluorooctane sulfonamidoethanol (N-Et-FOSE)	0.02	20
1H,1H,2H,2H-Perfluoro-1-octanol (6:2-FTOH)	0.1	20
1H,1H,2H,2H-Perfluoro-1-decanol (8:2-FTOH)	0.1	20
1H,1H,2H,2H-Perfluoro-1-dodecanol (10:2-FTOH)	0.1	20

7.2.2.1 Method of analysis - fluorinated substances / PFAS compounds

The method used for PFOS determination was based on DS/CEN/TS 15968, "Determination of extractable perfluorooctane sulphonate (PFOS) in coated and impregnated solid articles, liquids, and fire-fighting foams - Methods for sampling, extraction, and analysis by LC-qMS or LC-tandem/MS". Small modifications were made to the reference method, but these modifications have been validated.

Medico Kemiske Laboratorium ApS is accredited to perform PFOS analyses on textiles according to the method listed above. Analyses for the other PFASs were conducted according to the same principles.

The following method of analysis was used: The sample was extracted for 2 hours in methanol at or above 60°C. Then, LC/MS analysis was performed. Fluorotelomer alcohols were instead determined using GC/MS.

True duplicate determination was performed for all samples. Uncertainties and limits of detection (LODs) are listed in TABLE 15.

Analysis for fluorinated substances / PFAS compounds was carried out by Medico Kemiske Laboratorium ApS.

7.2.2.2 Analysis results - fluorinated substances / PFAS compounds

The results of the quantitative content analyses for the five selected fabric masks are presented below in TABLE 16. These analyses were performed on unwashed and washed fabric masks. The results are presented as the average of the two determinations performed. Results are presented the identified quantity both per unit weight and per unit surface area of the face masks. The results of the individual determinations are presented in Annex 4.

TABLE 16. Quantitative content determination of selected fluorinated substances / PFAS compounds in washed and unwashed face masks. The pre-wash results for the same face mask are italicised and given in parentheses.

Fabric mask	6:2 FTOH	All 14 other compounds listed above
BLA 3	2.0* mg/kg 1024 µg/m^2 *(3.4 mg/kg* *1741 µg/m2)*	n.d. *(n.d.)*
BLA 10	0.8 mg/kg	n.d.

	337 µg/m2 *(2.3 mg/kg 959 µg/m^2)*	*(n.d.)*
BLA 15	n.d. *(n.d.)*	n.d. *(n.d.)*
POL 2	0.9 mg/kg 237 µg/m2 *(2.9 mg/kg 763 µg/m^2)*	n.d. *(n.d.)*
POL 7	n.d. *(n.d.)*	n.d. *(n.d.)*

n.d. = not detected above the limit of detection
* = relatively large difference between duplicate determinations (0.9 and 3 mg/kg)

As indicated by the results, only 6:2 FTOH, a fluorotelomer alcohol, was detected in the fabric masks analysed. None of the other fluorinated substances / PFAS compounds targeted in the analyses were identified above the listed limits of detection.

Only the 14 listed fluorinated substances / PFAS compounds were targeted. These are considered the most frequently used fluorinated substances / PFAS compounds. However, this means that other PFAS compounds not targeted in the analyses could have been used in the fabric masks.

A portion of the fluorinated substances would be expected to be washed out of the masks during washing, but these results show the opposite: 6:2 FTOH was measured at higher levels in washed masks than in unwashed masks. There are several possible reasons for this:
- The values identified are relatively low (about 10 times the limit of detection). Uncertainties are often higher for low concentrations, near the limit of detection.
- The analyses were performed on different units of the same face mask. Since each mask consists of such a small amount of material (typically between just 7 and 15 g), it was not possible to perform pre- and post-wash analyses on the exact same masks. The manufacturing process for a mask may result in variances between individual masks. There is no guarantee that the two face masks analysed were produced from the same fabric.
- Additionally, a large gap was observed between the duplicate determinations for BLA 3. This is in line with similar observations from other quantitative analyses in the section below, as well as from the semi-quantitative BPA analyses in section 7.1.5. This indicates that the substances of interest are distributed highly unevenly in some of the face masks studied. Consequently, the analysis results depend in large part on the size of each sample and the location from which each sample is taken. It is thus possible that the elevated levels detected in the washed face masks are the result of these substances being distributed more evenly after washing. The barrels of the washing machine and tumble dryer may have also affected the results, along with the detergent used. However, it seems more likely that these differences are caused by the substances of interest being distributed unevenly throughout the fabric masks.

7.2.3 Quantitative post-wash determination of metals

The five face masks with the highest concentrations of copper (Cu), silver (Ag), and zinc (Zn) were selected for a quantitative post-wash analysis for the four metals of interest. Copper, silver, and zinc are harmful to the environment, meaning that the extent to which these metals can be washed out is of interest to this project.

7.2.3.1 Method of analysis - quantitative determination of selected metals

This analysis was performed in the same manner as for the unwashed face masks; that is, using digestion followed by ICP-OES (see section 7.1.2 "Quantitative content analysis for selected metals (Ag, Cu, Zn, Sb)").

7.2.3.2 Analysis results - quantitative determination of selected metals

All determinations were performed as duplicate determinations. The results are presented below in TABLE 17 as the average of the two determinations.

TABLE 17. Quantitative determination of Ag, Cu, Zn, and Sb concentrations in five selected face masks after washing. The pre-wash results for the same face mask (from TABLE 10) are italicised and given in parentheses.

Fabric mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)	Comments
BLA 2	6.7 *(9.3)*	8.3 *(≤1)*	26.8 *(30)*	28 *(45)*	Solid black mask
BLA 6	≤ 2 *(≤ 2)*	69 *(82)*	14 *(≤ 5)*	70 *(104)*	Flower pattern Multiple colours
BLA 11	≤ 2 *(≤ 2)*	29 *(24)*	50 *(20)*	≤ 10 *(≤ 10)*	Solid black mask
BOM 14	9.4 *(12.1)*	9.1 *(≤ 1)*	13 *(5.8)*	30 *(17)*	Solid black mask
POL 7	≤ 2 *(≤ 2)*	≤ 1 *(≤ 1)*	≤ 5 *(14)*	195 *(173)*	Patterned Multiple colours

A green background indicates cases for which the post-wash content was higher than the pre-wash content.

As shown by the results in TABLE 17, the concentrations of metals measured before and after washing appear to be mismatched in some instances. One might assume that the concentrations of these metals ought to decline; as described in section 3.4.1.1 regarding chemicals in textiles, zinc is specifically mentioned as a metal which washes out in significant quantities. Meanwhile, copper would not be expected to wash out significantly. The results show that the concentrations of copper, zinc, and antimony in some masks were higher after washing than before. There are several possible reasons for this:

- General analytical uncertainties.
- Because analyses were performed on distinct units of each face mask, there may have been some variance in the concentrations of metals in the fabric used for each mask analysed. There is no guarantee that the two face masks analysed were produced from the same fabric, though in principle, the masks should be uniform.
- Variations in masks with prints and patterns, such as BLA 6 and POL 7, may be caused by differences in the precise quantities of each colour present in the analysed samples. The use of colourants contributes to concentrations of metals.
- Copper present in the wash water (from the plumbing) may have added copper to the washed face masks, though it may be more likely that the heightened levels in the washed masks are the product of a more even post-wash distribution of the substances of interest.
- An uneven pre-wash distribution (due to such factors as colour variation in face masks) may have been equalised to a certain extent during washing.
- The specific sites from which samples were taken for each face mask may also account for some differences. For example, if the fabric in the middle of a face mask is thicker or stronger than the fabric on the sides, this may have impacted the results.

7.2.4 Migration analyses for metals

Five fabric masks were selected for migration analyses with artificial sweat and a subsequent quantitative determination of the four metals of interest in the migration liquid. The purpose of the migration analyses was to assess the migration of metals which pose health-related concerns (in this case, antimony) to the skin while wearing a fabric mask. The chosen method and migration liquid are presented below, along with the results.

7.2.4.1 Research into methods for determining migration from textiles

We conducted a search for standardised methods for determining the migration of chemical substances from textiles. The purpose was to investigate whether a migration analysis into water or into artificial sweat should be used.

In a report from the Joint Research Centre (2007) about the release of formaldehyde from textiles, the release (migration) for formaldehyde was studied using ordinary water (per DS/EN ISO 14184-1:2011, a standard for determining formaldehyde in textiles through aqueous extraction). Formaldehyde migration was also measured using the same method, but with the aqueous medium replaced by an artificial sweat solution. The results were ambiguous, as they depended on specific samples and likely on the particular textile finish used in each. However, there was a general trend for higher extraction into simulated sweat than into water.

Biver (2021) analysed the migration of antimony from polyester textiles, including some analysis of different migration liquids (various artificial sweat solutions) and different experimental conditions. For instance, the temperature and pH of the solution were varied. The two standards studied were EN ISO 105-E04 and EN 1811. EN ISO 105-E04 is the method recommended in the Oeko-Tex 100 standard for determining the migration of metals from textiles (Oeko-Tex, 2018). EN 1811 is a method for determining the release of nickel from ear studs. There is some variation in the composition of the migration liquids used in the two methods (see below).
Based on the results of the experiments, the recommendation in Biver (2021) was to use EN ISO 105-E04 to determine the migration of antimony from textiles, as the simulated sweat which the standard specifies has a pH value closer to that of actual sweat. This recommendation was based on the study's conclusions; namely, that the total migration of antimony from textiles depends on the following parameters:

- Time - Reducing the migration time from 24 hours to 12 hours produced a drop in the migration of antimony from the textile to the migration liquid
- Temperature - Reducing the temperature from 37°C to 20°C or 4°C produced a drop in the migration of antimony
- pH - Increasing the pH from 5.5 to 7 produced a drop in the migration of antimony from the textile

Differences in sweat simulations

- Previous survey projects[26] from the Danish EPA used EN ISO 105-E04 (test solution II) to measure the migration of chemical substances from textiles. In this method, migration is determined using an artificial sweat solution consisting of 1-histidine-monohydrochloride-1-hydrate, sodium chloride, sodium dihydrogen phosphate, and sodium hydroxide, with the pH adjusted to 5.5.

[26] Survey of chemical substances in car seats (survey no. 135, 2015); Exposure of two-year-olds to chemical substances (survey no. 102, 2009)

- Another artificial sweat solution that has been used with textiles in previous EPA survey projects[27] is prepared according to JRC Report 20001 EUR 19826 EN, which specifies simulated sweat made from deionised water, calcium chloride, magnesium chloride, potassium carbonate, potassium chloride, potassium phosphate, sodium chloride, and hydrochloric acid, with the pH adjusted to 6.8.
- The simulant in EN 1811 consists of sodium chloride, lactic acid, urea, and sodium hydroxide, with the pH adjusted to 6.5.

Based on this information, we decided to use the sweat simulation described in EN ISO 105-E04, which is also recommended by Oeko-Tex 100. This solution has the lowest pH value, and it is also closest to the pH of actual skin (about 5.5[28]).

7.2.4.2 Method of analysis - migration of selected metals

A sample weighing about 1.25 g was taken from each fabric mask. The mass and area of each sample were measured carefully to ensure that an equal proportion of each layer was included. Each sample was then placed in the artificial sweat solution described above (test solution II in EN ISO 105-E04) and held in a heated cabinet at 37°C for eight hours. Migration analyses were performed on the unwashed face masks.

After eight hours, the samples were removed from the migration liquid, and the liquid was analysed for the presence of the four metals of interest using the same method as for the unwashed face masks; that is, by digestion and subsequent ICP-OES determination (see section 7.1.2 "Quantitative content analysis for selected metals (Ag, Cu, Zn, Sb)").

7.2.4.3 Analysis results - migration of selected metals

All determinations were performed as duplicate determinations. The results are presented below in TABLE 18 as the average of the two duplicate determinations. The results are listed in mg/kg face mask or in μg/cm^2 face mask based on the weight and the surface area of the cut samples of the face masks for the analysis.

TABLE 18. Quantitative determination of concentrations of Ag, Cu, Zn, and Sb in migration liquid (artificial sweat) for the five selected, unwashed face masks. Given in mg/kg and μg/cm^2 in parenthesis and italic below.

Fabric mask	Ag (mg/kg) *(μg/cm^2)*	Cu (mg/kg) *(μg/cm^2)*	Zn (mg/kg) *(μg/cm^2)*	Sb (mg/kg) *(μg/cm^2)*	Comments
BLA 6	≤ 0.2 *(≤ 0.01)*	1.21 *(0.062)*	0.48 *(0.026)*	≤ 2 *(≤ 0.1)*	Flower pattern Multiple colours
BLA 8	≤ 0.2 *(≤ 0.01)*	0.33 *(0.013)*	0.65 *(0.025)*	2.9 *(0.11)*	Pattern Multiple colours
BLA 14	≤ 0.2 *(≤ 0.01)*	0.44 *(0.015)*	0.51 *(0.018)*	≤ 2 *(≤ 0.1)*	Single colour with large print
POL 1	≤ 0.2 *(≤ 0.01)*	0.69 *(0.037)*	0.28 *(0.015)*	3.5 *(0.18)*	Pattern Few colours
POL 7	≤ 0.2 *(≤ 0.01)*	0.89 *(0.028)*	0.86 *(0.027)*	7.2 *(0.22)*	Pattern Multiple colours

[27] Polyfluoroalkyl substances (PFASs) in textiles for children (survey no. 136, 2015)

[28] https://pubmed.ncbi.nlm.nih.gov/3700100/

As shown in the results, copper, zinc, and antimony migrated into artificial sweat. Migration of silver above the indicated limit of detection was not found. Silver may not have been detected because it reacted with chloride in the migration liquid to produce silver chloride.

In terms of health effects, antimony is of particular interest to this analysis. Comparing these results to those presented in TABLE 10 and TABLE 17 shows that a small amount of antimony has apparently migrated from the analysed face masks into the migration liquid (artificial sweat).

7.2.5 Quantitative determination of isocyanates

In the screening, three isocyanates were identified in several of the 40 fabric masks studied. The isocyanates were identified based solely on the NIST Mass Spectral Library after analysis by GC-MS. While the hit rate for these substances was high, these identifications were not confirmed using reference substances. For this reason, five fabric masks were selected to undergo a quantitative analysis in order to determine the concentrations of ten isocyanates present in the masks. The masks chosen were the five fabric masks which appeared to contain the highest quantities of isocyanates, according to the screening results.

7.2.5.1 Method of analysis - isocyanates

A 1 g sample was taken from each mask and added to 10 mL of DBA derivatisation liquid (10 mM in toluene) and an internal standard. The samples were extracted for two hours on a vibration table, after which the toluene phase was drained off. Subsequently, 3 mL of pure toluene were added. The toluene phase was dehydrated using a rotary evaporator at 60°C, and the samples were then dissolved again in 2000 µL of acetonitrile. Samples were filtered if cloudy. 200 µL of the extract were then mixed with 500 µL of a 50:50 solution of methanol and water. The mixture was then analysed via HPLC-MS, together with a standard and controls. The quantitative analysis of the components was performed with an internal standard and based on calibration standards.

All five of the selected fabric masks were analysed for all ten of the listed isocyanates. The analytical uncertainty is 20%, and the limit of detection is 0.02 mg/kg. The ten isocyanates targeted were:

- 2,4-TDI (2,4-toluendiisocyanate) - CAS no. 584-84-9
- 2,6-TDI (2,6-toluendiisocyanate) - CAS no. 91-08-7
- Ethylisocyanate (EIC) - CAS no. 109-90-0
- Methylisocyanate (MIS) - CAS no. 624-83-9
- Phenylisocyanate - CAS no. 103-71-9
- Propylisocyanate (PIC) - CAS no. 110-78-1
- Hexamethylene diisocyanate (HDI) - CAS no. 822-06-0
- Hydromethylene diphenyl-4,4'-diisocyanate (HMDI) - CAS no. 5124-30-1
- Methylene diphenyl diisocyanate (MDI) - CAS no. 101-68-6
- Isophorone diisocyanate - CAS no. 4098-71-9

The chemical analyses for isocyanates were carried out by Eurofins Product Testing A/S.

7.2.5.2 Analysis results - isocyanates

All determinations were performed as duplicate determinations. The results are presented below in TABLE 19 as the average of the two determinations. The results of the individual determinations are presented in Annex 5.

TABLE 19. Quantitative concentrations of isocyanates in five selected, unwashed fabric masks

Fabric mask (unwashed)	BLA 6 (mg/kg)	BLA 13 (mg/kg)	BLA 15 (mg/kg)	POL 2 (mg/kg)	POL 6 (mg/kg)
Ethylisocyanate (EIC)	0.044	0.060	0.037	0.048*	0.040
MDI	0.030	< 0.02	< 0.02	< 0.02	0.34
Isophorone diisocya-nate	0.15	< 0.02	0.17	< 0.02	< 0.02
All other compounds listed above	< 0.02	< 0.02	< 0.02	< 0.02	< 0.02

* = relatively large difference between duplicate determinations (0.025 and 0.071 mg/kg)

The content analyses of the five selected fabric masks identified three isocyanates: EIC (ethyl-isocyanate), MDI (methylene diphenyldiisocyanat) and isophorone diisocyanate. EIC was identified in all five face masks, but it was not identified during the screening analyses. MDI was identified in two of the five selected face masks, but it was only identified in one of these masks during the screening analyses. Of the isocyanates identified, MDI was identified in the highest quantities, with the highest concentration occurring in POL 6. Isophorone diisocynate was identified in two of the five selected face masks, but not in the same masks as in the screening analyses. None of the other isocyanates listed were identified in the selected fabric masks.

This discrepancy between the results of the screening analyses and the quantitative content analyses occurred because during screening, isocyanates were identified based solely on the NIST Mass Spectral Library after GC-MS, without the use of reference substances for confirmation. The lack of confirmation via reference substances makes it possible to mistake one isocyanate compound for another. Quantitative analyses conducted with an internal standard are far more reliable.

7.2.6 Quantitative determination of BPA

The five fabric masks in which the highest concentrations of BPA were detected during the initial analyses were selected for this analysis. The initial analyses for BPA (see section 7.1.5 "Semi-quantitative bisphenol A content analysis in selected face masks / elastics") showed that BPA was present in three face masks and indicated that it may be present in several other masks below the limit of quantification. Accordingly, two of these other masks were also subjected to a quantitative BPA content analysis.

The quantitative BPA content analysis was performed on the five selected face masks both before and after washing.

7.2.6.1 Method of analysis - BPA

This analysis was performed in the same manner as described in section 7.1.5 "Semi-quantitative bisphenol A content analysis in selected face masks / elastics"; that is, by extraction with acetone and dichloromethane, followed by LC-MS^2 determination. However, isotope-labelled BPA was used as an internal standard. The limit of detection was measured at 8 µg/kg (equivalent to 8 ppb). The expanded uncertainty was measured at 25% for this method. Additionally, the expanded uncertainty for the matrix was measured for a single sample (in which a high degree of variation was observed) to be a relative 380%. However, it should be noted that this high uncertainty is for the matrix of a single sample with a high degree of variation in BPA content. It does not apply to the method in general.

7.2.6.2 Analysis results - BPA

The results of the quantitative content analyses for the five selected fabric masks are presented below in TABLE 20. These analyses were performed on unwashed and washed fabric masks. The results are presented as the average of all determinations performed. In some cases, additional determinations were performed beyond duplicate determinations (two separate determinations), as a large gap was observed between the duplicate determinations. Where the number of determinations exceeds duplicate determination, this is noted in the table.

Note that the analyses for POL 6 were performed only on the elastic from this mask, not on the mask itself (the fabric portion). The results of the individual determinations are presented in Annex 6.

TABLE 20. Results of the quantitative BPA content determination for unwashed and washed face masks.

Fabric mask - unwashed	BLA 6 (mg/kg)	BLA 8 (mg/kg)	POL 1 (mg/kg)	POL 3 (mg/kg)	POL 6, elastic (mg/kg)
BPA	0.71	0.11*	0.096*	0.040	0.85
Fabric mask - washed	**BLA 6 (mg/kg)**	**BLA 8 (mg/kg)**	**POL 1 (mg/kg)**	**POL 3 (mg/kg)**	**POL 6, elastic (mg/kg)**
BPA	0.63	0.040	0.059	0.083*	1.3

* = a large gap between determinations was observed, so six or more determinations were performed:
Ten determinations were performed with BLA 8, five of which were ≤ 0,025 mg/kg, with a maximum value of 0.63 mg/kg. The median was 0,033 mg/kg.
Six determinations were performed with POL 1, four of which were ≤ 25 µg/kg, with a maximum value of 0.41 mg/kg. The median was 0,019 mg/kg.
Six determinations were performed with POL 3 after washing, three of which were ≤ 0,025 mg/kg, with a maximum value of 0.35 mg/kg. The median was 28 µg/kg.

As these results show, BPA was identified in four of the selected face masks and in the elastic from one fabric mask at concentrations between 0.040 and 0.85 mg/kg before washing. For three samples, the concentration of BPA declined after washing; for POL 3 and the elastic from POL 6, however, the concentration of BPA was higher after washing. As mentioned previously, the reason for this may be that two distinct units (of the same kind of mask) were used for the analyses.

High variation was observed in the values measured for certain samples, and additional analyses were performed to confirm the measurements. A similar phenomenon was observed in the semi-quantitative BPA analyses, as well as in the quantitative fluorinated compound analyses in section 7.2.2. These variations may be due to the product variations in the actual fabrics used for one or more layers of the fabric masks studied. It is also possible that the higher post-wash values are the result of a more even distribution of the BPA content in the samples.

7.2.7 Quantitative determination of chlorinated flame retardants

A subset of 25 fabric masks was selected to undergo a quantitative determination of chlorinated flame retardants (TCEP, TCPP, and TDCP) before washing. Only masks made partially or entirely of cotton were selected for this analysis, since cotton is generally regarded as being more flammable than polyester. Consequently, cotton face masks were judged to be more likely to contain flame retardants than polyester face masks.

The 25 fabric masks selected to undergo a quantitative determination of the three chlorinated flame retardants consisted of 12 cotton masks (out of 13) and 13 blended textile masks (out of 19). The masks were selected randomly.

7.2.7.1 Method of analysis - chlorinated flame retardants (TCEP, TCPP, and TDCP)

The method of analysis for the determination of chlorinated flame retardants (TCEP, TCPP, and TDCP) is based on the method described in the Danish EPA's survey report on flame retardants in textiles (Andersen et al., 2014a). Equal portions of all layers of each mask were used. If a mask also included a filter, both the fabric and filter layers were included in the samples analysed, still in equal portions. If a mask had a plastic filter attached to its exterior, the plastic was not analysed. Only the actual fabric in the mask was analysed.

Samples of approximately 1 g were cut into smaller pieces, weighed, and then extracted in a solution of cyclohexane and acetone. This solution contained 4,4'-dibromooctafluorobiphenyl as an internal standard. Each sample was extracted for two hours in an ultrasonic bath. Thereafter, it was analysed by GC-MS in SIM (selected ion monitoring) mode. True duplicate determinations were performed for all samples. The analytical uncertainty was 20%, and the limit of detection (LOD) was 0.1 mg/kg for all three flame retardants.

The analyses for the three chlorinated flame retardants were performed by Medico Kemiske Laboratorium ApS.

7.2.7.2 Analysis results - chlorinated flame retardants

The results of the quantitative content analyses for the 25 selected fabric masks are presented below in TABLE 21. The analyses were performed on unwashed fabric masks.

TABLE 21. Quantitative content of TCEP, TCPP, and TDCP in the 25 selected unwashed fabric masks

Fabric mask (unwashed)	Cotton mask (mg/kg)	Blended textile mask (mg/kg)
Face masks analysed	BOM 1, BOM 2, BOM 3, BOM 4, BOM 5, BOM 6, BOM 7, BOM 9, BOM 10, BOM 11, BOM 13, BOM 14	BLA 1, BLA 2, BLA 3, BLA 5, BLA 6, BLA 9, BLA 10, BLA 11, BLA 13, BLA 14, BLA 15, BLA 17, BLA 19
TCEP CAS no. 115-96-8	Not identified	Not identified
TCPP CAS no. 13674-84-5 (sum of isomers)	Not identified	Not identified
TDCP CAS no. 13674-87-8	Not identified	Not identified

As shown in TABLE 21, neither TCEP nor TCPP nor TDCP was identified above the limit of detection in any of the single determinations of the 25 fabric masks studied.

7.3 Substances of interest for risk assessment

Based on the analysis results, substances of interest for a risk assessment from health-related and environmental perspectives were considered.

7.3.1 Substances of interest for health-related reasons

The following list provides an overview of substances quantitatively identified during the chemical analyses which are of potential interest for a subsequent hazard assessment and risk assessment for health-related reasons:

- 6:2 FTOH - identified in 3 out of 5 fabric masks (both before and after washing)

- Formaldehyde - identified in 6 out of 40 fabric masks before washing; neither wash tests nor migration analyses were performed
- Antimony - identified in 21 out of 30 fabric masks; migration into artificial sweat observed for 3 out of 5 masks
- Ethylisocyanate (EIC) - identified in 5 out of 5 fabric masks before washing
- Methylene diphenyl diisocyanate (MDI) - identified in 2 out of 5 fabric masks before washing
- Isophorone diisocyanate - identified in 2 out of 5 fabric masks before washing
- BPA - identified during screening in 2 out of 20 fabric masks and in 1 out of 10 elastics; indication of presence of BPA observed in five additional samples. Five samples were subjected to follow-up analyses; BPA was quantified in 4 out of 5 fabric masks and in 1 out of 1 elastic, both before and after washing. Migration analyses were not performed.

The three isocyanate compounds, 6:2 FTOH, and BPA were identified in only a small number of the fabric masks studied, and at very low concentrations: either below 1 mg/kg or no more than 2–3 mg/kg, corresponding to 0.0003%. Because of these low concentrations, a joint decision was reached with the Danish EPA to discontinue further hazard assessments and risk assessments for these substances.

Additionally, the maximum total concentration identified of the three isocyanates was 0.4 mg/kg of face mask. Even if we assume in exposure calculations that the entire content of all identified isocyanates is released from a new, unwashed face mask within four hours, the maximum inhaled concentration of isocyanates would be 0.35 µg/m^3. This calculation is based on the following data and assumptions for a realistic worst-case exposure scenario:

- the actual data for the face masks in which isocyanates were identified; that is, the weights of these masks;
- the assumption of a 100% evaporation rate over four hours (distributed equally across all four hours), which is obviously a worst-case consideration;
- the use of two brand new face masks in one day, as described in the exposure scenarios;
- the assumption that half of the evaporated isocyanates are inhaled (the other half is exhaled); and
- an inhalation volume for adults of 1.49 m^3/hour during light exercise for eight hours, as described in the exposure scenarios (see section 6 “Exposure scenarios").

For comparison, the RAC has proposed a limit value of 0.025 µg/m^3 for diisocyanates in workplace environments (ECHA, 2020b). The scenario described would exceed the proposed limit value by a factor of 14. Of the three isocyanates identified, two are diisocyanates. However, this is based on a workplace environment limit value. This limit value accounts for the need to reduce the risk of eight hours of exposure per workday over the course of one's entire professional life. Finally, diisocyanates and isocyanates react with water (Kapp Jr., 2014; WebKemi, 2014) and are thus assumed not to be present in washed fabric masks. In view of these considerations, it was decided not to include isocyanates in hazard assessments for this project.

Thus, the only substances selected for a hazard assessment and subsequent risk assessment were formaldehyde and antimony. The presence of formaldehyde is already restricted in textiles via a limit value. This restriction is relatively new (as it came into effect on 1 November 2020). There is an EU proposal to further decrease the limit value (ECHA, 2020a). Formaldehyde also has a harmonised classification as an allergen; consequently, an assessment of the risk posed by the identified formaldehyde in contact with the skin is of interest to this project. Formaldehyde was thus selected for a hazard assessment and subsequent risk assessment due not only to the proposed reduction of the limit value, but also because of the direct skin contact that occurs when fabric masks are in use, as well as the potential inhalation of formaldehyde released from a mask while in use.

Antimony is not currently restricted by law in textiles, but it was selected for a hazard assessment and subsequent risk assessment due to its classification as a suspected carcinogen and as harmful when inhaled.

7.3.2 Substances of interest for environmental reasons

Based on the substances identified, the following substances are of interest for further evaluation in an environmental context (due to the washout of substances from fabric masks):

- 6:2 FTOH
- Copper (Cu)
- Zinc (Zn)
- Silver (Ag)
- Antimony (Sb)

The environmental assessment for this project was conducted on a general level only, as no clear conclusions could be drawn from the wash test results.

8. Hazard assessment

This chapter contains a hazard assessment of the two selected substances: antimony and formaldehyde. Hazard assessments are summaries of the most significant hazards, based on existing assessments of the substances in question.

8.1 Antimony

A comprehensive toxicological assessment performed by The Agency for Toxic Substances and Disease Registry (ATSDR) (ATSDR, 2019), the ECHA's records for antimony (ECHA, 2021a), and several other sources were used as the foundation for the hazard assessment of antimony.

Antimony is a metalloid from the same group of chemicals as arsenic and phosphorus (group VB). It typically occurs with valences of +3 (Sb(III)) or +5 (Sb(V)). Metallic antimony has a flaky, crystalline texture with a blue-white colour and a metallic lustre. Typical compounds are sulphide, hydroxide, and oxide compounds (ATSDR, 2019).

Antimony forms very hard, technically interesting alloys with copper, lead, and tin. Antimony trioxide is used as a flame retardant, as a primer in white enamel, and as an initiator or additive in the production of polyethylene terephthalate (also known as PET and as polyester, in textile form). Furthermore, antimony is used as a catalyst in the production of polyester for textiles (Biver, 2021). As a result, antimony can be identified in finished textile products.

Soluble pentavalent antimony (antimony(V)) compounds are used as treatments for some forms of leishmaniasis and schistosomiasis (parasitic infections). They have also been used to induce vomiting in cases of poisoning (ATSDR, 2019). Due to their long-standing use as medicines, the possible effects of these antimony(V) compounds are well known.

Antimony in its metallic form is used in alloys; otherwise, it is used in the form of various salts.

The toxic effects of antimony (including inflammation of the intestinal tract) have been known for centuries, thanks to its use as a treatment for sand fly bites (which can transmit the parasite responsible for leishmaniasis). Drugs based on antimony have been used against leishmaniasis for over 80 years and are still used today (ATSDR, 2019), but they are no longer registered in Denmark and the EU.

8.1.1 Identification, classification, and physiochemical parameters

Antimony does not have a harmonised classification, but the following classifications are notified and can be found in the ECHA's C&L database (2021):

- Acute Tox. 4, H302 "Harmful if swallowed"
- Acute Tox. 4, H332 "Harmful if inhaled"
- Carc. 2, H351 "Suspected of causing cancer", with inhalation listed as a relevant exposure vector
- Repr. 1A, H340 "May cause genetic defects"
- STOT RE 2, H373 "May cause damage to organs", with the lungs listed as the organ affected by inhalation

Antimony trioxide has a harmonised classification as Carc. 2, H351. Antimony oxide has a notified classification as Acute Tox. 4, H302 and H332 (harmful if swallowed or inhaled).

Antimony is on the CoRAP (Community Rolling Action Plan[29]) list after Germany requested its addition, with particular emphasis on testing for carcinogenic effects. Its deadline has been set at the end of 2021.

In fabric masks, antimony is expected to occur as a salt or an oxide compound. It is most likely to occur as antimony trioxide, as mentioned above. The most significant antimony compounds are listed in TABLE 22 below.

TABLE 22. Physiochemical parameters of antimony and its salts which may be relevant in the context of face masks (ATSDR, 2019; ECHA, 2021a). Substances which exist in two forms are denoted by the letters A and B.

Chemical name	Antimony	Antimony trioxide A: Senarmontite B: Valentinite	Antimony trisulphide A: Stibnite B: Amorphous	Antimony trichloride	2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane
Synonyms	Stibium	ATO	ATS	ATC	ATEG
CAS no. / EC no.	7440-36-0 / 231-146-5	1309-64-4 / 2t5-I7 5-0	1345-04-6 / 215-7I3-4	10025-91-9 / 233-047-2	29736-75-2 / 249-820-2
Molecular formula	Sb	O_3Sb_2	S_3Sb_2	Cl_3Sb	$Sb_2(C2H_4O_2)_3$
Molar mass	121.75 g/mol	291.52 g/mol	339.72 g/mol	228.11 g/mol	423.68 g/mol
Physical form (at 20°C)	Crisp, silvery-white metal	A: Hard, white substance B: Hard, colourless substance	A: Hard, black substance B: hard, yellowish-red substance	Hard, colourless substance	Hard, colourless substance
Density (at 20°C)	6.684 g/cm^3	A: 5.2 g/cm^3 B: 5.67 g/cm^3	A: 4.64 g/cm^3 B: 4.12 g/cm^3	3.140 g/cm^3 (at 25°C)	No data
Melting point	630°C	656°C	550°C	73.4°C	68.4°C
Boiling point (at 1013 hPa)	1637°C	A: 1.550°C B: 1.425°C	1.150°C	283°C	267.3°C
Vapour pressure	1 mmHg (at 886°C)	1 mmHg (at 574°C)	No data	1 mmHg (at 49.2°C)	No data
Octanol/water partition coefficient (log-KOW)	No data	No data	No data	No data	No data
Solubility in water (at 20°C)	Metallic antimony is insoluble in water.	Very low solubility	1.75 mg/L	6.016 g/L (at 0°C)	0.4–1.2 µg/L
Solubility in ethanol (at 30°C)	No data	No data	Soluble	Soluble	No data

The limit value for antimony in workplace environments is 5 mg/m^3, while the gas stibine (H_3Sb) has a lower limit value of 0.25 mg/m^3 (0.05 ppm) (AT, 2021). Stibine is formed when

[29] The CoRAP (Community Rolling Action Plan) is a shared plan of action for substances to be evaluated for REACH-related purposes. The list is a rolling list of substances to be evaluated for a period of three years each. The purpose of such evaluations is to clarify any concerns as to whether the production and/or use of a substance may constitute a risk to human health and the environment. (https://echa.europa.eu/da/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan)

acids react with antimony compounds. Gaseous stibine reacts with water to form antimony trioxide and water (ATSDR, 2019). Consequently, stibine is judged unlikely to occur in face masks.

8.1.2 Background levels

Belzile et al. (2011) provide background levels of these substances in air measured down to a few pg/m^3 in remote regions like the South Pole, down to < 20 ng/m3 in urban areas, and in unusually high-exposure situations, such as in active mines. They also note that antimony can bind to particles in the air, resulting in significantly higher exposure values. Little data on indoor exposure, such as that following release from fabrics and rugs, is available. Corresponding data for background levels of antimony in Denmark was not found.

Background levels in groundwater are indicated as being quite low in the US. In Canada, the daily intake is estimated at 2.8 µg, based on an average of 1.87 µg Sb / litre and daily water consumption of 1.5 L. In groundwater, antimony primarily occurs in an oxidised form, $(Sb(OH)_6)^-$. Micro-organisms in water can reduce or methylate antimony.

The Danish database of substances in groundwater from GEUS JUPITER[30], "Inorganic trace elements in ground water monitoring surveys, 1993-2002", reports that antimony was found in groundwater at concentrations of up to 5.6 µg/L in 30% of 879 groundwater samples, and up to 8 µg/L in 67% of 12 groundwater wells. These values exceed the quality requirement of 2 µg Sb / litre in one drinking water quality survey (GEUS, 2003).

As mentioned previously, antimony, including antimony trioxide (Sb_2O_3), is used as a catalyst in the production of polyester for textiles, but it is also used to produce PET (polyethylene terephthalate), which is used in water bottles. PET and polyester have the same chemical formula, so traces of antimony can be found in both.

Ferdinand et al. (2003) and Laursen et al. (2003) found antimony in polyester fibres in toys at concentrations ranging from 160 to 240 µg Sb/g, where antimony may migrate from textiles into tissue fluids. They concluded that the measured concentrations of 0.1 µg/kg bodyweight are below the acceptable daily dose (ADD).

Antimony is found in such foods as vegetables, dairy products, mushrooms, fish, and others at concentrations below 1.0 µg/g dry weight. Belzile et al. (2011) indicate that antimony consumed in foods does not exceed the TDI (total daily intake) of 0.6 µg/kg bodyweight recommended by the WHO (2003).

8.1.3 Absorption, distribution, and excretion

Exposure to antimony occurs through the inhalation of gases and particles, the ingestion of foods, migration from food packaging, and the consumption of drinking water from the tap or from bottles. Exposure may also occur through contact with materials impregnated with antimony compounds for flame retardant purposes, such as textiles, rugs, ceramics, and plastics. A certain level of intake is possible from breathing indoor air.

Antimony is absorbed through the lungs, the digestive tract, and the skin. The degree of absorption depends on the particular form of antimony. According to the ATSDR (2019), insoluble compounds, such as antimony and antimony trioxide, are excreted more slowly from the lungs (over weeks) than are more soluble compounds, such as antimony trichloride. Gastrointestinal absorption is reported at 1% for antimony trioxide and 10% for antimony potassium tartrate. In general, information on the dermal uptake of antimony compounds is lacking. The only

[30] Jupiter is GEUS's nationwide database of groundwater, drinking water, raw material, environmental, and geotechnical data. GEUS is the National and Geological Studies of Denmark and Greenland.

information found was on the dermal uptake of antimony trioxide (ATO); at 0.25%, this is considered negligible (EU RAR, 2008).

The ATSDR (2019) states that antimony is not metabolised. Pentavalent antimony does undergo a certain rearrangement to trivalent antimony; the ECHA (2020d) and others have requested more information on this.

Antimony is distributed throughout the body, with the highest concentrations found in the lungs, gastrointestinal tract, red blood cells, liver, kidneys, bones, spleen, and pancreas (ATSDR, 2019).

Antimony is excreted in urine and faeces; trivalent compounds are primarily excreted in faeces, while the more water-soluble pentavalent compounds are excreted in urine (ATSDR, 2019).

Several studies cited by the ATSDR (2019) observed transport across the placenta in rodents. This exposure was verified through biological measurements of antimony concentrations in blood and urine. Data from the US National Health and Nutrition Examination Survey (NHANES), conducted by the Centers for Disease Control (CDC), report median urinary concentrations of 0.132 µg Sb/L for 1999-2000, which in 2015-2016 fell to 0.047 µg Sb/L; this is attributed to reduced exposure or methodological differences (CDC, 2019). No more recent European data was found.

A recent Iranian study of pregnant women found antimony concentrations in the blood ranging from 0.5 to 11.4 µg Sb/L (Vigeh et al., 2020).

8.1.4 Acute and chronic effects

Antimony's acute toxicity is known from workplace environments and from the use of antimony compounds as medicines, including as an emetic, with an effect down to 0.5 mg/kg (Sundar 2010). The toxic effects of antimony have been known for centuries in connection with its use as a means of controlling sand fly bites, which can transmit the parasite that causes leishmaniasis. The side effects of antimony in humans include inflammation of the gastrointestinal tract, changes in electrocardiogram signals (ECG), vomiting, diarrhoea, joint pain, and muscle pain at doses above 1 mg/kg/day. At lower doses below the acute MRL (minimum risk level) of 1 mg/kg/day, effects on blood glucose levels in humans are observed, as is reduced growth in the foetuses of experimental animals. The intermediate MRL is set at 0.0006 mg/kg/day (ATSDR, 2019).

The ATSDR (2019) references skin conditions and eye irritation in workers exposed to airborne antimony; effects on the eyes have been seen in experimental animals, though skin conditions have not. Dissolution in sweat is supplied as a possible reason for the skin conditions. Furthermore, inhalation impacts the respiratory system, including such effects such as inflammation, fibrosis, and cancer. Acute and intermediate MRLs are 0.001 mg/m^3, and for chronic effects, 0.0003 mg/m^3 (ATSDR, 2019).

The National Toxicology Program (NTP) in the USA conducted long-term studies in rats and mice with inhalation of antimony trioxide for 2 years. The conclusion was that some evidence existed for carcinogenicity in rats, down to the lowest concentration of 10 mg/m^3, and clear evidence existed in mice down to concentrations of 10 mg/m^3. The lowest dose was 3 mg/m^3. Based on this background and on mechanistic studies, antimony trioxide is classified as "reasonably anticipated to be a human carcinogen" by the NTP, with the IARC classifying antimony trioxide as possibly carcinogenic (2B) in 1989, but with no subsequent updates. The IARC has listed antimony trioxide as a medium priority for reassessment (IARC, 2019). In the assessment of antimony trioxide for RoHS legislation, its suspected carcinogenic effect was assessed to be a product of the physical particles, not the substance itself. It was further stated that antimony trioxide is considered to be a carcinogen with a threshold effect, with a NOEL of 0.5 mg/m^3 (Öeko-Institut, 2019).

As mentioned previously, antimony is on the CoRAP list, with particular emphasis on testing for carcinogenic effects (ECHA, 2020d). The studies which found a basis for classification as possibly carcinogenic are based on the aforementioned long-term animal experiments on inhalation in mice and rats. A number of producers also highlighted reprotoxicity.

The CoRAP substance evaluation (ECHA, 2020d) indicates that there is evidence that following exposure to compounds containing antimony, unidentified antimony compounds are found (e.g., Sb^{3+}, Sb^{5+} or methylated antimony (Me-Sb)) which become systemically available and produce effects regardless of the exposure vector. The ECHA has determined that it is therefore necessary to carry out an assessment of these compounds in parallel with the assessment of diantimony trioxide (ATO, CAS no 1309-64-4), metallic antimony (Sb metal, CAS no 7440-36-0), antimony sulphide (ATS, CAS no 1345-04-6) and antimony trichloride (ATC, CAS no 10025-91-9), where there are also conditions of immediate concern which merit further investigation.

Genotoxicity has been reported in mice, but not rats in the NTP study. The ATSDR (2019) lists a number of positive in vitro studies, while one in vivo study is positive.

Reprotoxicity is described in a Russian study from 1967, where menstrual disorders and miscarriages were reported at higher rates in female employees exposed to metallic antimony, antimony pentasulfide and antimony trioxide compared to controls. The weight of their children was also reduced. There is no exposure level information. Furthermore, reduced litter size in rats dosed at 209 mg/m^3 is mentioned, but with no effect on foetal weight (Belyaeva 1967, quoted by the ATSDR).

Rossi et al. (1987), quoted by the ATSDR, found effects on growth 10-22 days after birth in rats dosed with 0.7 mg Sb/kg/day in the form of antimony trichloride. Dilation of blood vessels has been reported after birth, though without changes in arterial blood pressure.

Studies of the drug meglumine antimoniate at subcutaneous doses of 0, 150 and 300 mg Sb/kg/day showed embryotoxic effects at the two highest doses. Transport across the placenta was verified by measurements of antimony in foetuses (Miranda et al., 2006).

8.1.5 Summary and discussion of antimony

The ATSDR has summarised the hazard assessment in the list of effects below:

- Proven effects:
    - Effects in the form of e.g. irritation and pulmonary fibrosis of the respiratory tract following inhalation
    - Effects on the gastrointestinal tract in the form of irritation, nausea and vomiting following oral exposure
- Suspected effects:
    - Cardiovascular - myocardial and ECG changes following ingestion of soluble antimony compounds
    - Decreased serum glucose metabolism
    - Damage to reproduction

In addition, antimony and antimony trioxide are suspected to have carcinogenic effects, which must now be investigated further via CoRaP (ECHA 2020d).

There are clearly deficiencies in the data for a number of antimony compounds. In connection with its reassessment of antimony and antimony compounds, cf. article 46(1) of the REACH regulation (EU Regulation no. 1907/2006), the ECHA has requested the following:

- For antimony: Further studies on genotoxicity with a deadline in mid 2021[31]
- For antimony sulphide: Additional studies of subchronic toxicity after inhalation, focusing on pulmonary toxicity, cardiotoxicity and toxicokinetics with a deadline in late 2021[32]
- For the antimony compound known as ATEG[33] which is used as a catalyst for the production of PET and polyester: Peroral subchronic test, as well as toxicokinetic studies, with a deadline in late 2021[34]. These requests include a request to perform toxicokinetic studies, including determination of ATEG (the primary antimony compound), and possibly transformation into the trivalent (Sb(III)), pentavalent (Sb(V)) and alkylated (e.g., methylated) Sb compounds that may be produced from the primary antimony compound.

As described, antimony is often used in the form of antimony trioxide. The dermal uptake of antimony trioxide is considered negligible (0.26%). Oral uptake is assumed not to occur when wearing a fabric mask. Inhalation is not considered relevant for antimony or antimony trioxide as well. Among other factors, both antimony and antimony trioxide have melting points above 600°C; according to Karlsson et al. (2018), evaporation does not occur below this temperature.

8.1.6 Critical effect and DNEL/DMEL

The critical effect of antimony is the suspected carcinogenic properties of the substance, both for antimony and antimony trioxide.

DNEL values (derived no effect level) are provided for antimony (Sb) in the ECHA's records for antimony (see TABLE 23). For comparison, MRLs (minimum risk levels) established by the ATSDR (2019) for antimony are also provided. As antimony is likely to occur as antimony trioxide, the DNEL values for inhalation of and dermal exposure to antimony trioxide are also presented in the table below for comparison.

TABLE 23. DNELs and MRLs set for antimony and antimony trioxide (ECHA, 2021a; ATSDR, 2019)

Exposure	Endpoint(s)	NOAEC/NOAEL	Uncertainty factor	DNEL/MRL*
Antimony				
Inhalation	Chronic lung inflammation	0.155 mg/m3	Interspecies variations (10), uncertainty (0.2)[35]	DNEL: 0.08 mg/m^3 (ECHA, 2021a)
	Chronic lung inflammation	0.008 mg/m^3	Interspecies variations (3), intra-individual variations (10)	MRL: 0.0003 mg/m^3 (ATSDR, 2019)
Dermal	Systemic effects	1409 mg/kg/day	Based on oral intake and corrected, interspecies variations (10)	DNEL: 28 mg/kg/day (ECHA, 2021a)

[31] https://echa.europa.eu/documents/10162/694bf6f6-4a24-6e99-1933-1f5b85ad4353

[32] https://echa.europa.eu/documents/10162/bffa9141-4f7e-1ff6-9981-7184e44aad5d

[33] 2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane Justification for the selection of a candidate CoRAP substance (europa.eu)

[34] https://echa.europa.eu/documents/10162/ffb07233-ac9a-e513-ebd3-6ff901ae23df

[35] An uncertainty factor of 0.2 is used to account for the respirable proportion of antimony

Exposure	Endpoint(s)	NOAEC/NOAEL	Uncertainty factor	DNEL/MRL*
Oral	Increased liver weight	1409 mg/kg/day	Interspecies variations (10), toxicokinetics (2.5), sub-chronic to chronic (2)	DNEL: 28 mg/kg/day (ECHA, 2021a)
	Decrease in glucose serum levels	0.064 mg/kg/day	Interspecies variations (10), intra-individual variations (10)	MRL: 0.0006 mg/kg/day (ATSDR, 2019)
Antimony trioxide				
Inhalation	Lung inflammation	0.155 mg/m3	Intra-individual variations (10), uncertainty (0.2)	DNEL: 0.095 mg/m^3 (ECHA, 2021b)
Dermal	Systemic effects	1409 mg/kg/day	Based on oral intake and corrected, interspecies variations (10), exposure duration (2), toxicokinetics (2.5)	DNEL: 33.5 mg/kg/day (ECHA, 2021b)

* DNEL values are set by the ECHA; MRLs are set by the ATSDR

A significant difference can be seen between the DNEL values specified in the ECHA's records and those in the ATSDR's assessment of antimony. The DNEL values from the ECHA's records for antimony and antimony trioxide do not seem to differ particularly much. For the risk assessment, DNEL values used for antimony are those for dermal exposure, both because this is the lowest DNEL value and because dermal exposure is considered a relevant exposure vector for antimony, due to the physiochemical properties of antimony and antimony compounds.

8.2 Formaldehyde

Larsen et al. (2021) conducted a project entitled “Survey and risk assessment of chemicals in knitting yarn" which included a hazard assessment of formaldehyde. The EFSA's assessment of formaldehyde as a preservative for food (EFSA, 2006), the Danish EPA’s LOUS report on formaldehyde (Andersen et al., 2014b), the SCCS's opinion on formaldehyde (SCCS, 2014), and a number of other sources were used as the basis of the hazard assessment for formaldehyde. This project uses the assessment in Larsen et al. (2021) as a foundation.

Uses of formaldehyde vary widely, from use in consumer products to use as an intermediate in the chemical industry; use in the production of condensed resins for the wood, paper, and textile processing industries; and in chemical synthesis (Andersen et al., 2014b). Formaldehyde is also used to produce formaldehyde plastics, a common name for a wide variety of plastic materials formed by the reaction of formaldehyde with e.g. urea, melamine, phenol, or furfuryl alcohol (Andersen et al., 2014b). In addition, formaldehyde is used as a preservative (in the form of "formaldehyde releasers") in a large number of consumer products, such as cosmetic products and household cleaners (Andersen et al., 2014b). Formaldehyde can be found in impregnating treatments used to make fabrics wrinkle-free, shrink-free, and colour-fast (Danish Allergy Research Centre, 2006).

Denmark produces relatively large volumes of chipboard, and formaldehyde is used in this production. In Denmark, there has been a decrease in the number of products containing formaldehyde (Andersen et al., 2014b).

8.2.1 Identification, classification, and physiochemical parameters

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 inhaled"
- Skin Corr. 1B H314 "Causes severe skin burns and eye damage"
- Skin Sens 1 H317 (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 workplace environments is set at 0.28 ppm or 0.437 mg/m^3. Formaldehyde has the remark LEK, meaning that there is a ceiling value (L), that the substance is EU classified (E), and that the substance is carcinogenic (K). Furthermore, there is a remark about skin sensitisation (BEK 1426, 2021).

TABLE 24. Physiochemical parameters of formaldehyde (ECHA, 2021c)

Chemical name	Formaldehyde
Synonyms	Methyl aldehyde, formalin, methanal
CAS no. / EC no.	50-00-0 / 200-001-8
Density	815 kg/m³
Molecular formula	CH_2O
Molar mass	30.031 g/mol
Physical form (at 20°C)	Colourless gas
Density	0.62 g/cm^3
Melting point	-118.3°C
Boiling point (at 1013 hPa)	-21°C
Vapour pressure (at 20°C)	12.6 hPa
Octanol/water partition coefficient (log-KOW) (at 25°C)	0.35
Solubility in water (at 20°C)	Highly soluble in water 550 g/litre
Solubility in ethanol (at 30°C)	Soluble

8.2.2 Background levels

The general population is exposed to formaldehyde from many sources, formaldehyde has applications in many different areas, making exposure to the substance very complex. One of the most important sources for background exposure for the average consumer is formaldehyde in indoor air, from sources including such building materials as pressed wood products, insulation, and carpets (Andersen et al., 2014b).

Sensitive people can perceive formaldehyde at concentrations down to 0.03 mg/m^3. Concentrations of formaldehyde above 0.1 mg/m^3 for an average of 30 minutes' exposure in indoor air can irritate the eyes and nose (WHO, 2000). This is the guiding limit value set by the WHO for an average of 30 minutes' exposure in indoor air. The formaldehyde concentration in outdoor air is usually below 0.001 mg/m^3 in rural areas, and below 0.02 mg/m^3 in cities (IARC, 2006).

Formaldehyde exposure also occurs through one's diet, and indirectly, via food contact materials (FCMs), which may contain formaldehyde. The regulation on food contact plastics (EU regulation 10/2011) sets a limit value of 15 mg/kg for the migration of formaldehyde into foods. The natural content of formaldehyde in foods is on the order of 1.6 mg/kg bodywt./day (1.4

from food and 0.2 from FCMs). This contribution to formaldehyde exposure from food is considered safe, as it is at least 600 times lower than the endogenous turnover of formaldehyde (EFSA, 2014).

Other exposures originate from consumer products like cleaning products and textiles, where allergy is the highest risk because of dermal exposure. Exposure to formaldehyde while using these consumer products may constitute an allergy risk to consumers (Andersen et al., 2014b).

8.2.3 Absorption and distribution

Formaldehyde reacts with the point of contact, so systemic absorption does not occur following dermal exposure, oral exposure, or inhalation. There is no evidence of systemic toxicity or a systemic target organ after prolonged exposure to formaldehyde. Formaldehyde is classified as Carc. 1B and Muta. 2 due to changes at the point of contact (i.e., during inhalation). These changes are typically seen in the nose, in the form of nasal cancer.
Formaldehyde is an endogenous metabolite (meaning that formaldehyde forms naturally in the body), and it can be found at considerable concentrations. The EFSA (2014) has estimated the endogenous turnover of formaldehyde to be approx. 0.6-0.91 mg/kg bodywt./min and 878-1310 mg/kg bodywt./day, assuming a half-life of 1-1.5 min. Compared to formaldehyde conversion and background levels of formaldehyde from food sources (1.4-1.7 mg/kg bodywt./day for a person weighing 60-70 kg), including from methanol in the diet, the relative contribution of exogenous formaldehyde from consumption of animal products (milk, meat) from animals exposed to formaldehyde-treated feed is negligible (< 0.001%).

8.2.4 Acute and chronic effects

Formaldehyde's allergenic effect is considered the most critical effect of skin contact, and it is estimated that about 0.5% of the European population exhibits an allergic reaction to skin contact with formaldehyde (Larsen et al., 2021).

Formaldehyde has been found to be a skin sensitiser in a number of animal experiments, including in LLNA testing in mice, for exposure to a 0.29% formaldehyde solution (Larsen et al., 2021).

In humans, skin sensitization has been observed in connection with exposure to 1% formaldehyde, while those already sensitised may react (elicitation) when exposed to 0.003% formaldehyde in an aqueous solution or to 0.006% in products containing formaldehyde (SCCS, 2014). Based on provocation experiments with allergy sufferers, the ECHA (2020a) indicates that exposure at a concentration of 20.1 μg/cm^2 causes an allergic reaction in the 10% most sensitive formaldehyde allergy sufferers (the so-called ED_{10} (eliciting dose)). It is this value of 20.1 μg/cm^2, used in the opinion of the RAC and SEAC, which is behind the 75 mg/kg restriction on formaldehyde in textiles listed in Annex XVII of REACH, entry 72, on CMR substances in textiles (ECHA, 2020a). Along with an assumption of 10% migration of formaldehyde from textiles and a general weight for textiles of 0.2 kg/m^2 a concentration limit of 3350 mg formaldehyde/kg of textile can be calculated. Based on this calculated limit value, the RAC and SEAC set the current limit value at 75 mg/kg. There was some discussion about lowering the limit value to 30 mg/kg of textile, which is already the limit value for toys, but in view of costs to the textile industry and the uncertainty about the additional health benefits of lowering the limit value, the value of 75 mg/kg was allowed to stand (ECHA, 2020a). The limit value for formaldehyde in cosmetic products has recently been re-evaluated by the SCCS (2021b), which indicates that the ED_{10} value of 20.1 μg/cm^2 ought to be 2 μg/cm^2 and 0.41 μg/cm^2 for ED_5 corresponding to allergic reactions in the 5% most sensitive individuals, based on modelling of data from a repeated open application test (ROAT).

Formaldehyde can be found in impregnating treatments used to make fabrics wrinkle-free, shrink-free, and colour-fast. According to the Danish Allergy Research Centre (2006), most people with formaldehyde allergies will be able to use all textiles freely without any problems. However, some may react with eczema when wearing wrinkle-free clothing, typically where the clothing is close to the body.

Since eye irritation is one of the more sensitive effects, outbreaks of eye irritation are thought to provide a safety margin for the onset of irritation-induced cytotoxicity and cell proliferation. A maximum formaldehyde concentration of 100 µg/m^3 (0.1 mg/m^3) in indoor air was established by the WHO in 2010, based also on NOELs for eye irritation as a sensitive and preventive parameter for the more serious effects of formaldehyde.

Whether systemic absorption of formaldehyde and systemic effects (such as cancer) are likely to occur following dermal exposure has not been reported. During exposure, formaldehyde reacts quickly with the surface of the mucous membranes, making it unavailable for systemic uptake (Andersen et al., 2014b; ECHA, 2020c).

Based on animal experimental data, the WHO (2004) and EFSA (2006) determined a NOAEL of 15 mg/kg bodywt./day based on a long-term rat trial with dosing via drinking water, as higher exposure levels led to effects in the gastric mucosa. Based on this, the WHO (2004) and EFSA (2006) determined a TDI value of 0.15 mg/kg bodywt./day using an uncertainty factor of 100 for intra-individual and interspecies variation. The WHO has concluded 2.6 mg formaldehyde/litres to be an acceptable concentration in drinking water.

The SCCS (2014) further considers that respiratory irritation and carcinogenic effects are the most important effects of inhalation. In its substance evaluation report for formaldehyde, the ECHA (2019) specifies that the substance has been shown to be carcinogenic if inhaled once the exposure exceeds a certain threshold value. Here, 0.1 mg/m^3 is set as a tolerable exposure level for humans without risk with regard to carcinogenic effects and irritation of the eyes and respiratory tract. This value was originally set by the WHO in 2010 as a WHO guideline limit value for indoor air, as indicated above.
The NOAEL for sensory irritation was a vapour concentration of 0.5 ppm (0.6 mg/m^3) (Nielsen et al., 2013). A DNEL value for workers of 0.5 mg/m^3 for prolonged exposure via inhalation and 1 mg/m^3 for short-term exposure via inhalation was listed in formaldehyde's REACH dossier (Andersen et al., 2014b). A reduction to this value has been proposed in connection with the updated assessment published by the ECHA in 2020 (ECHA, 2020c) (and also described in ECHA (2019), to 0.37 mg/m^3 (0.3 ppm) and 0.74 mg/m^3 (0.6 ppm)). The corresponding value for consumers for long-term exposure via inhalation is listed as 0.1 mg/m^3 (0.083 ppm) (ECHA, 2019). The DNEL of 0.1 mg/m^3 for consumers covers long-term local effects in the form of respiratory irritation, sensory irritation, and cancer (ECHA, 2019). However, in an ECHA publication (2020c), the RAC (Risk Assessment Committee) concludes that the original studies on which this DNEL value is based contain too few observations and too much variation in the data. Instead, they suggest the use of other studies, arriving at a DNEL value of 0.05 mg/m^3.

8.2.5 Critical effect and calculation of DNEL

An overview of DNEL values set for formaldehyde in various sources are listed in TABLE 25 below.

TABLE 25. DNEL-values set for formaldehyde in various sources

Exposure	Endpoint	NOAEC/NOAEL	Uncertainty factors	DNEL
Dermal	Allergy		Not used	20 µg/cm^2* (ECHA, 2020a)

Exposure	Endpoint	NOAEC/NOAEL	Uncertainty factors	DNEL
		ED_{10}-value; i.e., reaction in the 10% most sensitive		30 µg/cm²* (SCCS, 2014)
				2 µg/cm²* (SCCS, 2021b)
Dermal	Systemic effects	-	-	Systemic effects cannot be calculated for skin contact, as formaldehyde is not absorbed systemically through the skin
Oral	Effects on the gastric mucosa	15 mg/kg bodywt./day	Safety factor of 100 (no reason given)	TDI: 0.15 mg/kg bodywt./day (EFSA, 2006)
		82 mg/kg bodywt./day	Allometric scaling (4), intra-individual variations (5)	4.1 mg/kg bodywt./day (ECHA, 2021c)
Inhalation	Sensory irritation of mucous membranes (blinking the eyes)	0.37 mg/m³	None	0.37 mg/m³ (ECHA, 2020c)
Inhalation	Sensory irritation of mucous membranes	0.63 mg/m³	WHO standard factor for sensory irritation (5)	0.100 mg/m³ (WHO, 2010)
Inhalation	Cell changes in the nose	1.25 mg/m³ (LOAEC)	Intra-individual variations (3.16), interspecies variations (2.5) from LOAEC to NOAEC (3)	0.05 mg/m³ (ECHA, 2020c)

* This value refers to a reaction in the 10% most sensitive formaldehyde allergy sufferers in a provocation trial.

For the risk assessment, the lowest DNEL value proposed by the SCCS (2021b) of 0.41 µg/cm² was used for the elicitation of allergic reactions (in already sensitised individuals) via dermal exposure. The value is based on ED_5 corresponding to allergic reactions in the 5% most sensitive individuals. The lowest DNEL value for inhalation listed in ECHA (2020c) established by the RAC and SEAC was also used for the risk assessment. Oral exposure is assumed to be irrelevant for fabric masks.

9. Risk assessment

This chapter presents exposure calculations and a risk assessment from a health perspective for the two selected substances: antimony and formaldehyde.

As described in the hazard assessment no assessment has been made of risk in relation to oral intake, as it is not expected that consumers will swallow pieces of fabric masks. Conditions such as inhalation of small textile particles (e.g., synthetic fibres) have neither been investigated in this project, as any possible effects due to this are likely not due to the chemical content of a fabric mask, but to inhalation of the physical textile particles.
Therefore, the risk assessment focuses on dermal exposure and exposure via inhalation. Formaldehyde is a small molecule, which is volatile and allergenic. Recently (1 November 2020), a law came into effect which limits the concentration of formaldehyde in textiles due to its allergenic properties (REACH Annex XVII, entry 72). However, there is an EU proposal to further reduce the limit value to 30 ppm (ECHA, 2020a). Therefore, the risk assessment of formaldehyde concentrations in the studied face masks was performed to account for both skin contact and inhalation.

The analysis results in this project for the concentration of antimony in the fabric masks studied show a clear correlation between polyester content and antimony concentration. Fabric masks made of polyester have the highest concentrations of antimony, followed by fabric masks made from blended fabrics (primarily consisting of both cotton and polyester). Fabric masks made entirely of cotton contain the lowest levels of antimony, if even identified above limit of detection. This indicates that the antimony in the fabric masks comes from antimony used as a catalyst in the production of polyester; specifically, this is antimony trioxide, also described in the hazard assessment for antimony.

Only one risk assessment was conducted here, for dermal exposure to antimony. This is because antimony and antimony compounds, including antimony trioxide, are solids which do not melt until reaching temperatures in excess of 600°C. Evaporation first takes place above this temperature (Karlsson et al., 2018). Consequently, inhalation of antimony is assessed unlikely and irrelevant to this risk assessment.

9.1 Method used

The method used here is the method for risk assessments of consumer products described in the ECHA's guidelines (ECHA, 2016). Exposure is calculated from realistic worst-case scenarios using the values described in Chapter 6 “Exposure scenarios”.

Dermal exposure is calculated for antimony based on the values for the analyses of migration of antimony into artificial sweat (see section 7.2.4 “Migration analyses for metals”). A value for the quantity of migrated antimony per cm^2 of fabric mask is given here. The actual exposure will thus be the migration volume multiplied by the area of the individual fabric mask in contact with the skin, multiplied by the proportion of the antimony compound which is actually absorbed through the skin (presented in the hazard assessment).

Migration analyses were not performed for formaldehyde because it is soluble in water. If the substance were placed in an aqueous liquid, complete migration would be expected. The exposure calculations thus use the analysed content value identified in the fabric masks, calculated per unit area of the fabric masks studied.

No analyses showing the quantity of formaldehyde which evaporates from fabric masks were performed. One reason for this is that such analyses are difficult to conduct in a way that realistically simulates inhalation. For the exposure calculations, the worst case is thus assumed to be that the entire measured content of formaldehyde in a fabric mask evaporates during use. As described in chapter 6 “Exposure scenarios”, realistic values are used for inhalation volume for consumers while wearing fabric masks. The exposure used is thus the measured quantity of formaldehyde in the fabric masks divided by the inhaled quantity of air during the period in which the fabric masks are worn.

In the risk assessment, the values for exposure, whether dermal exposure or exposure via inhalation, are compared with the DNEL values; that is, those values are not considered to result in health effects. The RCR (risk characterisation ratio) is then calculated as follows.

$$RCR = \frac{Exposure}{DNEL}$$

RCR values higher than or equal to 1 indicate that the exposure is equal to or exceeds the DNEL value, meaning that the protection level for the consumer is too low. A health risk may therefore be present.

9.2 Exposure calculations and assessment of risk

The exposure calculations for the established exposure scenarios have been performed for the two substances below. The exposure scenarios considered in the risk assessment (see also Chapter 6 “Exposure scenarios") which account for both inhalation and dermal exposure are as follows:

- For adults: Use of fabric masks for 8 hours per day (four hours of heavy physical exercise and four hours of light exercise). The face mask is changed once during the day; i.e., a total of two masks are used per day.
- For children over 12 years: Use of a fabric mask for two hours per day with light exercise. One fabric mask is used per day.
- Children under 12 are not expected to wear face masks, so no exposure calculations have been performed for them.

9.2.1 Antimony

The values used for dermal **exposure** to antimony are listed in TABLE 26 below, where the calculated exposure, DNEL value used, and calculated RCR value are also presented. These calculations were performed for the three fabric masks for which migration of antimony into artificial sweat was measured above the limit of detection. Calculations are made by multiplying the listed values together and dividing by the body weight (bodywt.) to get exposure in mg of substance per kg of body weight per day. The following is a calculation example for face mask BLA 8:

$$Exposure = \frac{Migration \times area\, mask \times dermal\, uptake \times no.of\; masks\, per\, day}{Body\, weight}$$

$$= \frac{0.11\, {}^{\mu g}/_{cm^2} \times 218.5\, cm^2 \times 0.0026 \times 2\, masks\, per\, day}{60\, kg \times 1000\, {}^{\mu g}/_{mg}} = 2.08 \frac{mg}{kg} bodywt./day$$

The RCR value is subsequently calculated for BLA 8 as:

$$RCR = \frac{Expsoure}{DNEL} = \frac{2.08\, mg/kg\; bodywt./day}{28\, mg/kg\; bodywt./day} = 0.07$$

In calculating the risk (RCR value), the DNEL value of 28 mg/kg bodywt./day for antimony was used (see section 8.1.6 of the hazard assessment). The corresponding DNEL value for antimony trioxide, which is expected to occur in fabric masks, is 33.5 mg/kg bodywt./day. The lowest value is used as the worst case.

It should be noted that the exposure calculations for children use the surface area of the face masks purchased here, which are designed for adults. Thus, it is expected that the actual exposure will be less for children over the age of 12, since their masks will be smaller, provided that the composition and migration qualities of these masks are in line with those purchased for children over the age of 12.

TABLE 26. Values used, calculated exposure, and risk for antimony (antimony trioxide) for dermal exposure

Face mask	Migration into artificial sweat (µg/cm²)	Surface area of face mask (cm²)	Dermal uptake	No. of face masks per day (pcs./day)	Body weight (kg)	Amount absorbed in the body (mg/kg/day)	DNEL (mg/kg/day)	RCR
For adults								
BLA 8	0.11	218.5	0.0026	2	60	2.08	28	0.07
POL 1	0.18	201.25	0.0026	2	60	3.14	28	0.11
POL 7	0.22	199.5	0.0026	2	60	3.80	28	0.14
For children over 12 years								
BLA 8	0.11	218.5	0.0026	1	42	1.49	28	0.05
POL 1	0.18	201.25	0.0026	1	42	2.24	28	0.08
POL 7	0.22	199.5	0.0026	1	42	2.72	28	0.10

As the exposure calculations show, the RCR values for all masks, whether for children or for adults, are below 1, meaning that no health effects can be expected from the presence and migration of antimony in these fabric masks. The exposure calculations are based on the use of new, unwashed fabric masks every day for a long period of time. A test for migration into artificial sweat was performed for unwashed fabric masks. It can thus be expected that the antimony will eventually be washed out of a fabric mask, and that the calculated exposure thus will decrease with repeated washing. The expected real exposure will thus be less when a fabric mask is washed and reused over and over.

For comparison, BfR (2012) indicates that the WHO calculates an exposure of 6 µg/kg bodywt./day for antimony trioxide by wearing ordinary polyester clothing. This calculated exposure is about 1/500 of the worst-case calculations performed above in TABLE 26.

In this project, content analyses were performed on four of the fabric masks that contained antimony after five washes in a washing machine. No clear conclusion could be made from this. For two of the masks, the concentration of antimony declined after the five times washing, but for two other fabric masks the concentration increased. However, according to the literature (Biver, 2021), the antimony content of textiles is expected to decrease after washing for synthetic textiles such as polyester, whereby the migration of antimony for artificial sweat is expected to decrease over time when using the textiles.

Exposure via **inhalation,** as previously mentioned is not expected to be realistic for antimony due to the fact that antimony and antimony compounds are solid at room temperature, and are expected to evaporate only when reaching their melting points above 600°C.

9.2.2 Formaldehyde

The values used for **dermal exposure** for formaldehyde are listed inTABLE 27 below, where the calculated exposure, DNEL value used and calculated RCR value are also indicated. The calculations have been made for the six fabric masks in which formaldehyde was measured above the limit of detection in the chemical analyses. For formaldehyde, the critical effect of dermal exposure is allergy. The exposure is therefore calculated by multiplying the listed values together and dividing by the area of the face mask to get the exposure in µg of fabric per cm^2 skin area. The following is a calculation example for face mask BOM 4:

$$Exposure =$$

$$\frac{Content\ concentration\ \times weigth\ of\ mask\ \times fraction\ migration\ \times no.of\ masks\ per\ day}{Area\ of\ mask}$$

$$= \frac{53\ {}^{\mu g}/_{g}\ \times 12.07\ g\ \times 0.1\ \times 2\ masks\ per\ day}{240.5\ cm^2} = 0.53\ \mu g/cm^2$$

RCR value calculated subsequently for BOM 4 as:

$$RCR = \frac{Exposure}{DNEL} = \frac{0.536\ \ \mu g/cm^2}{0.41\ \ \mu g/cm^2}\ =\ 1.30$$

In the calculation of risk (RCR value) the lowest is used DNEL value for formaldehyde for risk for allergies as suggested in the reassessment of SCCS (2021b) at 0.41 µg/cm^2 (see section8.2 in hazard assessment). This value is based on ED_5 (elicitation dose 5) corresponding to allergic reaction in the 5% most sensitive individuals in this exposure. The corresponding DNEL value used to determine the current limit value for formaldehyde content in textiles is by comparison 20 µg/cm^2 (based on ED_{10}) and is thus almost 50 times higher. However, the lowest value is used as the worst case.

The dermal exposure is the same for adults and children above the age of 12, as it is the same quantity formaldehyde per skin area, both consumer groups are exposed to.

For dermal exposure, it is the total exposure per skin area per day that must be taken into account. In the exposure scenario, it is assumed that two new, unwashed fabric masks are used per day; that is, the exposure must be multiplied by two. The six masks listed consist of a minimum of two layers of fabric and a maximum of five layers of fabric. The identified content of formaldehyde in the analysis covers the contents of all layers of fabric together, but the consumer has only direct skin contact with the innermost layer of fabric. To what extent the consumer is exposed to formaldehyde from the other layers is unknown.

TABLE 27. Values used, calculated exposure, and risk of formaldehyde for dermal exposure

Face mask	Measured content in face mask ((µg/g)	Weight of face mask	Percentage migrating	No. of face masks per day (pcs./day)	Area of face mask (cm^2)	Amount of formaldehyde per unit skin area ($\mu g/cm^2$)	DNEL ($\mu g/cm^2$)	RCR
For adults and children over 12 years								
BOM 4*	53	12.07	0.1	2	240.5	0.532	0.41	**1.30**
BOM 13	6	13.37	0.1	2	279.5	0.057	0.41	0.14
BOM 14	6	13.37	0.1	2	240	0.067	0.41	0.16
BLA 2**	22	16.95	0.1	2	228	0.327	0.41	0.80
BLA 14	7	12.93	0.1	2	187	0.097	0.41	0.24
BLA 17*	6	23.81	0.1	2	333	0.086	0.41	0.21

* Face mask consists of two layers fabric. The remaining face masks (except BLA 2) consist of three layers of fabric.

** Face mask consists of five layers of fabric. The remaining face masks (except BOM 4 and BLA 17) consist of three layers of fabric.

The exposure calculations show that the RCR value for five of the six face masks, and for both children and adults, is less than 1, which means that no health effects in the form of allergic reactions are expected due to the content and migration of formaldehyde in the five face masks studied. For BOM 4, which has the highest measured content of formaldehyde (but still below the allowable value according to the current legislation), an RCR value of 1.3 was calculated. This means that particularly sensitive consumers who are already sensitised to formaldehyde may experience an allergic reaction if they wear two new, unwashed fabric masks of the same type in one day.

Formaldehyde was not identified in the remaining 34 fabric masks above the limit of detection of 6 µg/g. It should be noted, however, that although the RCR values for the majority of face masks are below 1, and therefore there is no immediate risk of allergic reactions, it cannot be ruled out that people who are particularly sensitive to formaldehyde may experience an allergic reaction when wearing a face mask. However, this will not be the case with the majority of the population. This is because the RCR value is calculated based on a so-called ED5 value, where it is the 5% most sensitive individuals who will still be able to experience allergic reactions at the concentration used in the calculation. Thus, there may be few individuals, which are more sensitive and resact at a lower concentration.

No migration analyses have been performed for artificial sweat; consequently, the calculations are made using the total content of formaldehyde in each mask. The proportion of formaldehyde migrating out of the fabric mask during the period in which the consumer wears the fabric mask has been assumed to be 10%, corresponding to a proportion of 0.1. This share covers, that though formaldehyde has a high water solubility, the face masks do not become totally soaked, when wearing it. It gets at most slightly moist from sweat and due to the exhaled air, which is why it is not expected that all of the contained formaldehyde would dissolve into sweat on the skin. In addition, formaldehyde is a volatile substance that will also evaporate from the outer layer and thus away from the skin, whereby the full amount does not come in contact with the skin. Finally, the measured content of formaldehyde is for all layers of fabric, but only the innermost layer is in direct contact with the skin. These conditions mean that it will most likely only be a few particularly sensitive individuals who may experience allergic reactions, while the majority of the population will not experience health effects.

The exposure calculations are based on the use of new, unwashed fabric masks. As formaldehyde is highly soluble in water, the contents will be washed out when the fabric masks are washed. If fabric masks are washed before their first use, the risk of allergic reactions will thus be minimal, including for BOM 4.

Exposure via inhalation is listed inTABLE 28 below, where the calculated exposure, DNEL value used, and calculated RCR value are also presented for both adults and children over 12 years of age. The calculations have been made for the six fabric masks in which formaldehyde was measured above the limit of detection in the chemical analyses. For formaldehyde, the critical effect of inhalation is respiratory irritation and sensory irritation. Exposure is therefore calculated by multiplying the listed values together and dividing by the volume of the amount of air inhaled during the hours in which a fabric mask is worn during the day.

The calculations used an inhaled proportion of 0.5 x 0.5, corresponding to 0.25 altogether, which covers an assumption that only half of the substance will be inhaled while the other half is exhaled, and that only half of the face mask actually covers the mouth and nose where direct inhalation occurs. For adults, the volume inhaled through a face mask is considered to come from heavy physical exercise half the time, and light physical exercise the other half of the time (based on the data provided in Chapter 6 “Exposure scenarios”).

The following is a sample calculation for BOM 4:

$$Exposure = \frac{Content \times weight\ of\ mask \times fraction\ inhaled \times no.of\ masks\ per\ day}{Volume\ inhaled\ through\ mask}$$

$$= \frac{53\ {}^{mg}/_{kg} \times 12.07\ g \times (0.5 \times 0.5) \times 2\ masks\ per\ day}{\left(\left(4\ hours \times 3.07\ {}^{m^3}/_{hour}\right) + \left(4\ hours \times 1{,}49\ {}^{m^3}/_{hours}\right)\right) \times 1000\ {}^{g}/_{kg}} = 0.018\ mg/m^3$$

The RCR value is calculated subsequently for BOM 4 as:

$$RCR = \frac{Exposure}{DNEL} = \frac{0.018\ mg/m^3}{0.05\ mg/m^3} = 0.35$$

TABLE 28. Values used, calculated exposure, and risk of formaldehyde by inhalation

Face mask	Measured content in face mask	Weight of face mask (g)	Percentage inhaled*	No. of face masks per day (pcs./day)	Volume inhaled through face mask ** (m^3)	Concentration inhaled (mg/m^3)	DNEL (mg/m^3)	RCR
For adults								
BOM 4	53	12.07	0.5 x 0.5	2	18.24	0.018	0.05	0.35
BOM 13	6	13.37	0.5 x 0.5	2	18.24	0.002	0.05	0.04
BOM 14	6	13.37	0.5 x 0.5	2	18.24	0.002	0.05	0.04
BLA 2	22	16.95	0.5 x 0.5	2	18.24	0.010	0.05	0.20
BLA 14	7	12.93	0.5 x 0.5	2	18.24	0.002	0.05	0.05
BLA 17	6	23.81	0.5 x 0.5	2	18.24	0.004	0.05	0.08
For children over 12 years								
BOM 4	53	12.07	0.5 x 0.5	1	2.26	0.071	0.05	**1.42**
BOM 13	6	13.37	0.5 x 0.5	1	2.26	0.009	0.05	0.18
BOM 14	6	13.37	0.5 x 0.5	1	2.26	0.009	0.05	0.18

Face mask	Measured content in face mask	Weight of face mask (g)	Percentage inhaled*	No. of face masks per day (pcs./day)	Volume inhaled through face mask ** (m^3)	Concentration inhaled (mg/m^3)	DNEL (mg/m^3)	RCR
BLA 2	22	16.95	0.5 x 0.5	1	2.26	0.041	0.05	0.83
BLA 14	7	12.93	0.5 x 0.5	1	2.26	0.010	0.05	0.20
BLA 17	6	23.81	0.5 x 0.5	1	2.26	0.016	0.05	0.32

* This value covers an assumption that only half of the substance will be inhaled, as the other half is exhaled, and that it is only the half of the face mask which actually covers the mouth and nose where direct inhalation occurs.
** The volume inhaled is calculated as the sum of four hours of heavy physical exercise (3.07 m^3/hour) and four hours of light exercise (1.49 m^3/hour) for adults, and two hours of light exercise (1.13 m^3/hour) for children over 12 years.

In the calculation of risk (RCR value) the lowest DNEL value of 0.05 mg/m^3 for formaldehyde is used, which takes into account long-term effects in the form of respiratory irritation and sensory irritation as suggested by the RAC (ECHA, 2020c) (see section 8.2 in the hazard assessment). This value of 0.05 mg/m^3 is also proposed as a new limit value for the release of formaldehyde from consumer products in general, where this concentration may maximally off-gas from a consumer product measured in an emission chamber after a maximum of 28 days (ECHA, 2020c - Annex X).

The exposure calculations show that the RCR value for all face masks for adults is less than 1, which means that no health effects in the form of respiratory irritation and sensory irritation are expected, which the DNEL value used covers. For children, the RCR value for face mask BOM 4, which had the highest concentration of formaldehyde, is above higher than 1. The calculated RCR values for the remaining face masks are all below 1. Formaldehyde was not identified in the remaining 34 fabric masks above the limit of detection of 6 µg/g. Thus, only one of the 40 face masks had an RCR value higher than 1, and only for a child.

This means that under the presumptions used here, there may be a risk of respiratory irritation and sensory irritation in children due to the content of formaldehyde in a brand new, unwashed face mask (BOM 4). However, it should be noted that these calculations assume that 100% of the measured content of formaldehyde evaporates from the face mask, while the mask is worn. For the calculations for adults, it is assumed that this happens during the four hours a face mask is worn, while for children over 12 years of age, it is assumed that the entire measured content of formaldehyde evaporates during the two hours the face mask is worn in the course of a day. In practice, the formaldehyde content will probably evaporate more slowly, whereby the exposure will be lower and a real risk of health effects in the form of respiratory irritation and sensory irritation will probably not be present.

In addition, the risk of respiratory irritation and sensory irritation will only be present if a new, unwashed face mask is used. The formaldehyde content will have dropped significantly as soon as the face mask is washed. This is one of the reasons for which the new Danish standard, DS 3000:2021, for washable face masks requires that face masks be washed before being packaged and sold.

In principle, both the dermal exposure and the inhalation exposure should be added together to assess the overall risk of formaldehyde exposure when using a fabric mask. However, this is done only when the effect (endpoint) and mechanism of action are the same, which is not the case here. The critical effect of skin contact is allergy, whereas the critical effect of inhalation is respiratory irritation and sensory irritation.

9.3 Exposure from other indirect sources

The above risk calculations cover exclusively risk for exposure of the two substances from fabric mask. However, consumers may be exposed to both substances from other sources as well, which is discussed in more detail below.

9.3.1 Antimony

According to the Danish EPA's database of chemical substances in consumer products (Danish EPA, 2021), antimony was previously identified in the following types of consumer products:

- Sex toys (maximum 0.6 mg/kg)
- Earplugs (35-28000 mg/kg)
- Textile dyes (maximum 84 mg/kg)
- Various textile products (jackets, gloves) (maximum 200 mg/kg)
- Textile fabrics (maximum 200 mg/kg)
- Pram covers (maximum 130 mg/kg)
- Glitter glue (maximum 220 mg/kg)
- Wire (maximum 570 mg/kg)
- 3D printing materials (maximum 370 mg/kg; migration analyses performed - no migration)
- Lamination materials (maximum 180 mg/kg)
- Metal jewellery (6-72600 mg/kg)
- Nature toys (maximum 260 mg/kg)
- Rolling mattress (maximum 150 mg/kg)
- Tattoo colours (henna and kohl products) (maximum 0.15 mg/kg)
- Slime toys (maximum 3.8 mg/kg)
- Wicks for scented candles (maximum 3500 mg/kg)
- Knitting yarn (maximum 0.9 mg/kg)

Antimony is thus identified in small amounts in a wide range of consumer products, with the exception of earplugs, metal jewellery, and wicks for scented candles, where the content is high (up to a few percent). For the remaining consumer products, antimony is maximally identified at a concentration of approx. 200 mg/kg, which is the maximum content in a fabric mask identified in this project. For 3D print materials and wires, the levels are approx. double those identified as the maximum in fabric masks. However, these are consumer products which consumers are not necessarily often in contact with.

Common to all the above findings is that in these projects, only content analyses have been performed, but no migration analyses, and no assessment has been made of the health risk for any of the above findings in consumer products. It is only in the project on 3D print materials and in foam plastic toys for which migration of antimony has been carried out, but no content of antimony in the migration fluid was detected above the detection limit.

Thus, an assessment of the risk of health effects has not been made before for antimony in consumer products. This is either because it has been assessed that the risk of antimony in consumer products will not constitute a significant health risk due to the low concentrations, or because other substances in the above projects have proven to be more alarming.

Thus, it is not possible in this project to make an overall risk assessment for the total exposure to antimony from other consumer products as well. The highest risk is considered to occur from polyester textiles, as antimony also occurs in clothing containing polyester. Moreover, there is a daily prolonged exposure. However, BfR (2012) states that the WHO has calculated this exposure to be low (6 µg/kg bodywt./day for antimony trioxide); that is, a calculated exposure that is approx. 500 times less than the worst-case calculations made in this project (TABLE 26).

However, as described, the expected exposure will be highest in unwashed clothing, as antimony is expected to wash out as the laundry is washed again and again (Biver, 2021).

The hazard assessment for antimony indicates (in section 8.1.2 ”Background levels”) that antimony is present in small amounts in both food and drinking water. Intake from food is not estimated to be higher than 0.6 µg/kg bodywt./day (Belzile et al., 2011), and concentrations of antimony in groundwater are stated to be a maximum of 8 µg Sb / litre (GEUS, 2003), which will result in a daily intake of 0.3 µg/kg bodywt./day for adults (60 kg) and 0.4 µg / kg bw / day for children over 12 years of age by consuming 2 litres of water per day. When using a DNEL value of 28 mg/kg bodywt./day, as used in the exposure calculations above (TABLE 26), the additional exposure from food and drinking water will thus at most constitute an additional contribution to the RCR of 0.00004 (0.4 + 0.6 µg/kg bodywt./day divided by DNEL at 28,000 µg/kg bodywt./day). The exposure contribution from food and drinking water is therefore considered insignificant and will not change the above conclusions.

9.3.2 Formaldehyde

According Danish EPA database of chemical substances in consumer products (Danish EPA, 2021 has been previously identified formaldehyde in the following types of consumer products:
- 3D-print materials (no migration)
- Mica glue and gel pen (maximum 63 mg/kg)
- Rugs (maximum 13 mg/kg)
- Different textiles (undershirt, petticoat, of five, gloves, shirt) (maximum 180 mg/kg) – health assessment performed here
- Textile fabrics (maximum 82 mg/kg)
- Indoor climate (calculated concentration based on measurements degassed from various electrical consumer products) (maximum 19.5 /g/m^3) – health assessment has been carried out here
- Indoor climate (calculated concentration based on theoretical assessments from various consumer products, contributions to, incense mm.) (theoretical maximum 235 /g/m^3) – health assessment has been made here
- Hobby glue (content found, but not quantified)
- Do-it-yourself products for the home (paint, finish, sealant, putty, wood oil, glue for glass fabric) (maximum 120 /g/m^3)
- Stickers (maximum 8.4 mg/kg)
- Tents for children (maximum 163 /g/m^3) – measured exposure
- Modelling clay (maximum 1220 mg/kg)
- Soap bubble fluid (maximum 40.5 mg/kg)
- Incense
- Changing pads (maximum 100 mg/kg)
- Knitting yarn (maximum 21.5 mg/kg)
- Products made in exotic woods (parquet flooring, furniture, blinds, dining table, mm.)

Formaldehyde is thus identified in a wide range of consumer products, both as content and as degassed from products, as textiles, furniture, wood products and electrical products. In a number of the projects, a health assessment has been made of formaldehyde, but several of the projects are of older date, why the risk assessment approach in REACH was not used in the calculation of RCR value. For some consumer products, it has been assessed, that the content or emission of formaldehyde could have health effects. This is valid for:
- Children using modelling clay and slime
- Adults' use of do-it-yourself products for the home using acid-curing floor varnish

For many of the above products apply, that they all to some degree contribute to the concentration of formaldehyde in indoor climate. There is therefore no doubt that the total exposure to formaldehyde may be high, if consumer products are used, which contributes to release of formaldehyde in indoor climate (e.g. wooden furniture, craft glue, paint, floor rugs, electronic products, etc.). In an older survey project from 2006 (Jensen & Knudsen, 2006) the overall health assessment is calculated by chemical substances in indoor climate from a wide range of selected consumer products. The project by Jensen & Knudsen (2006) calculates the maximum concentration of formaldehyde in indoor air to be about 500 µg/m^3, but it indicates that under ordinary circumstances, it will fall below 50 µg/m^3, corresponding to 0.05 mg/m^3. The concentration of 0.05 mg/m^3 is the same DNEL value used in the exposure calculations in this project, and the limit value, as proposed by the RAC to ECHA (2020c), is to apply as the maximum released concentration for consumer products in the future (concentration measured in an emission chamber after a maximum of 28 days). Based on this older survey project, the concentration of formaldehyde in the indoor air alone may exceed the DNEL value if spaces are not sufficiently ventilated on a day-to-day basis. Inhalation of formaldehyde from fabric mask thus is an additional exposure, why it is important to remember to wash fabric mask before use, which is also a requirement in the new Danish standard DS 3000:2021 for washable face mask, where fabric mask must be washed, before being packaged and sold.

9.4 Discussion and conclusion

In this project, a health risk assessment has been made of the content and migration/release of antimony and formaldehyde from 40 purchased fabric masks.

Antimony was identified in 21 of the 30 analysed fabric masks at a maximum concentration of 210 mg/kg, after which a migration test into artificial sweat was performed for the five fabric masks with the highest content of antimony. Three out of those five masks showed migration of antimony above the limit of detection of 0.1 µg/cm^2.

The presence of formaldehyde was identified in six out of 40 fabric masks above the limit of detection at 6 mg/kg, of which only two of the 40 fabric masks had formaldehyde concentration significantly above the limit of detection, but still below the regulatory limit value of 75 mg/kg.

The exposure and risk assessment of the two substances show that there is no expected health risk from wearing fabric masks for eight hours daily as an adult, or for two hours daily as a child over 12 years of age, using the maximum measured content values or migration values for the substances. This is especially true when considering that antimony and formaldehyde are expected to be washed out of masks, and considering that the risk assessment is based on the use of a new, unwashed mask every four hours. This can only be considered an absolute worst-case scenario. The washing-out of formaldehyde from fabric masks is expected to proceed somewhat faster than for antimony. The new Danish standard for washable face masks (DS 3000:2021) also requires fabric masks to be washed before being packaged and sold.
It should be noted, however, that ECHA has requested toxicokinetic data for antimony, such as data on the dermal uptake of antimony and antimony compounds, as there is generally very little data in this area.

10. Environmental assessment

In this chapter, an assessment of the environmental effects was performed on the basis of the results of wash tests carried out on the analysed fabric masks. The assessment of environmental effects was performed on a general level, as health-related assessments of the use of fabric masks were the primary purpose of this project. An environmental impact assessment was conducted for the following substances:

- Copper (Cu)
- Zinc (Zn)
- Silver (Ag)
- Antimony (Sb)
- 6:2 FTOH

For the above substances, the environmental effects are described on the basis of a listing of relevant values in ECHA's database of registered substances. In addition, a calculation of the expected maximum concentration of the substances in wash water was made based on the analysis results in this project. These values are compared with the existing established environmental quality requirements for wastewater.

10.1 Environmental effects

The classifications of the five selected substances, as well as relevant environmental parameters, are presented in TABLE 29 below. Data are based on ECHA's database of registered substances.

According to TABLE 29, the metals copper, zinc and silver all meet the CLP criteria for category 1 acute danger to the aquatic environment with LC_{50}-values for fish (96h) below 1 mg/litre, as well as the criteria for long-term danger (chronic danger) for the aquatic environment with NOEC values below 0.1 mg/litre. These three metals are thus the most environmentally hazardous, which is also apparent from the listed PNEC values (Predicted No Effect Concentration) for fresh water (as specified in ECHA's database of registered substances).

The values for the fluorotelomer alcohol 6:2 FTOH are limited because of lack of data, but the group of per- and polyfluorinated substances is generally considered to be of concern to the environment, which is also apparent from an RMOA (Regulatory Management Option Analysis) ECHA's conclusion to prepare an Annex XV restriction proposal for PFAS connections in general (ECHA, 2021d). Work is thus underway to develop a proposal to restrict a wide variety of PFAS compounds at the EU level. The Annex XV restriction proposal is expected to be ready in July 2022.

Data on bioaccumulation are limited, which i.a. is due to the fact that bioaccumulation is not normally performed for inorganic substances. Only BCF values for sediment are available and no log K_{ow}-values. Normally, substances are considered to be able to bioconcentrate at BCF values above 500 or log K_{ow}-values above 4. Per- and polyfluorinated substances such as 6:2 FTOH are usually perceived as difficult to degrade and with potential for bioaccumulation in the environment.

Danish executive order no. 1625 of 19/12/2017 on the determination of environmental targets for streams, lakes, transitional waters, coastal waters, and groundwater (BEK 1625, 2017) establishes environmental quality requirements for fresh water, which can also be used as an indicator of the environmental hazard posed by various substances. Silver, copper and zinc have the lowest set environmental quality requirements (in the order mentioned) and are therefore considered the three most environmentally hazardous metals. A Danish environmental quality requirement for 6:2 FTOH has not been set. The EU environmental quality requirements for PFOSs and their derivatives are presented here for lack of an existing quality requirement for 6:2 FTOH.

TABLE 29. Classifications and relevant environmental parameters for the five selected substances

Substance	Copper	Zinc	Silver	Antimony	6:2 FTOH
CAS no.	7440-50-8	7440-66-6	7440-22-4	7440-36-0	647-42-7
Classified[1] (only environment)	**Aquatic Chronic 2, H411**	**Aquatic Acute 1, H400** **Aquatic Chr. 1, H410**	Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Aquatic Chronic 2, H411	Aquatic Chronic 1, H410
LC_{50} (fish, 96h)	38.4 µg/litre	169 µg/litre	1,2 µg/litre	14.400 µg/litre	4840 µg/litre
NOEC chronic	2.2 µg/litre	25 µg/litre	5.9 µg/litre	1130 µg/litre	> 10 /g/litre[2]
log K_{OW}	-	-	-	-	- (log K_{OC} 2.43)
BCF[3]	-	-	70	40	46
PBT / vPvB assessment	Not used for inorganic substances	Not used for inorganic substances	Not used for inorganic substances	Not used for inorganic substances	Not rated
PNEC[4] fresh water	7.8 µg/litre	20.6 µg/litre	0.04 µg/litre	113 µg/litre	Not rated
Environmental quality-requirements for fresh water[5]	1 µg/litre	7.8 µg/litre	0.017 µg/litre	113 µg/litre	0,00065 µg/litre (for PFOS)

1. Harmonised classifications are shown in boldface. Otherwise, notified classified are listed.
2. No NOEC could be set for 6:2 FTOH, no deaths were observed at the concentrations used
3. BCF = Bio Concentration Factor for sediment, as no other data is available.
4. PNEC = Predicted No Effect Concentration, as specified in ECHA's database above registered substances
5. According to Executive Order no. 1625 of 19/12/2017 on the determination of environmental objectives for watercourses, Lakes, transitional waters, coastal waters and groundwater.
H400 = Very toxic to aquatic life; H410 = Very toxic to aquatic life with long-lasting effects; H411 = Toxic to aquatic life with long-lasting effects.

10.2 Concentrations in wash water

A simple calculation has been made of the concentration of the leached substances from fabric mask in the washing water from a washing machine in an ordinary household. The calculation is based on the maximum leached amounts identified by the analyses in this project. It should be noted, that estimates of the washed-out amounts are based on content analyses of fabric masks before and after washing. The difference is assumed to be the amount washed out. This approach is therefore uncertain and is only an estimate. It must also be pointed out, that there are no clear conclusions on the leaching results, as in some cases higher concentrations of the metals in the masks have been seen after washing than measured before washing. All of the face masks were washed together, so there is a possibility of some masks having absorbed substances from the other masks. The most likely cause, however, is probably differences in the fabric itself in the samples, used for the analyses. Many of the fabric masks were patterned, making their colouring uneven. Due to the sizes of the face masks, different masks were used for pre- and post-wash analyses.

In addition, the following assumptions have been used in the calculations:

- It is assumed that 10 fabric masks are purchased, two of which are used each day. The masks are washed together in a washing machine (with other clothing).
- A washing machine uses 55 litres of water for a wash at 60°C. This is based on information from HOFOR[36], indicating that older washing machines use 100 litres per wash, while newer machines use as little as 40 litres per wash. A volume of 55 litres is thus assumed to correspond to the water consumption in a washing machine that is a few years old.
- One fabric mask weighs an average of 15 g, which is the average of the 40 purchased fabric masks in this project.
- The washout rate is calculated as an average over five machine washes, as it is the number of washes, made in this project, where the content of metals and 6:2 FTOH is analysed again after washing.

The resulting concentration in the wastewater from the washing machine after the five washes off 10 fabric mask is subsequently compared with the environmental quality requirements for inland water (fresh water) according to the Danish executive order no. 1625 of 19/12/2017 on the determination of environmental objectives for watercourses, Lakes, transitional waters, coastal waters and groundwater (BEK 1625, 2017) which is also listed in the bottom row of TABLE 29. The results are also given in the table below. The calculations are in practice made by taking the maximum difference between the content values in fabric mask multiplied by the weight of one fabric mask and multiplied by 10 fabric mask and divided by the total consumption of water in the five machine washes. A calculation example is given below for silver.

$$Concentration\ in\ washing\ water =$$

$$\frac{Amount\ washed\ out\ per\ 5\ washes\ \times weight\ of\ mask\ \times no.of\ masks}{litre\ water\ per\ wash\ \times\ no.of\ washes}$$

$$= \frac{2.7\ \mu g/g\ \times 15\ g\ \times 10}{55\ liter\ \times 5} = 1.47\ \mu g/litre$$

The ratio of the concentration in washing water (C) and Environmental Quality Requirements (EQR) calculated as follows:

$$\frac{C}{EQR} = \frac{1.47\ \mu g/liter}{0.017\ \mu g/liter} = 86.6$$

For the four metals, Danish environmental quality requirements for fresh water have been set (inland water). The general quality requirements for inland water and not the maximum quality requirements have been used for the calculations. For 6:2 FTOH, no Danish environmental quality requirement has been set. In the Danish statutory order (BEK 1625, 2017), a reference to the EU-environmental quality requirements for PFOS and derivatives has been made. No data exists for fluorotelomer alcohols or 6:2 FTOH. The provisions have been used for the calculations here EU-environmental quality requirements for PFOS despite the fact that 6:2 FTOH is not included in this group of perfluorinated compounds, but is a polyfluorinated compound.

[36] https://www.hofor.dk/privat/spar-penge/spareraad-til-vand/spar-vand-ved-toejvask/

TABLE 30. Concentrations of the five substances in washing water on average for five machine washes

Substance	Quantity washed out from face mask in 5 washes (µg/g)	Weight of face mask (g)	Number of face masks	Number of washes	Litres of water per wash (litres)	Concentration in wash water (C) (µg/litre)	Environmental quality requirements (EQR) (µg/litre)	Factor C / EQR
Silver	2.7	15	10	5	55	1.47	0.017	86.6
Zinc	9	15	10	5	55	4.91	7.8	0.6
Copper	13	15	10	5	55	7.09	1	7.1
Antimony	34	15	10	5	55	18.55	113	0.2
6:2 FTOH	2	15	10	5	55	1.09	0.00065	1678.3

As shown in TABLE 30, when 10 fabric masks are washed five times, the calculated concentration in the wash water is below the established environmental quality requirement for fresh water for zinc and antimony. For these two substances, the wash water could thus, in principle, be discharged directly to fresh water, as the environmental quality requirement is already met. Zinc and antimony washed out from use of fabric masks are thus assumed not to significantly affect aquatic environments.

The concentrations of copper and silver in wash water are 7 and 97 times higher, respectively, than the environmental quality requirements for thse substances. However, it should be noted that only estimates of concentrations of these substances in wash water are presented here. The wash water was not analysed directly; instead, it was assumed that the amount of a chemical that disappeared from a face mask had been washed out in the wash water. It should also be noted that the wash water from the washing machine is not the only wastewater from a household. Consequently, the wash water will be diluted many times by the rest of the water consumption in the household. In addition, there will be wastewater treatment before the water is discharged to the environment.

For 6:2 FTOH, where the calculations are made on the basis of the environmental quality requirement for PFOS and similar compounds, it can be seen that the concentration in the wash water exceeds the environmental quality requirement almost 1700 times. Although there is a significant dilution, and possibly subsequent wastewater treatment, per- and polyfluorinated substances are generally undesirable in the aquatic environment, because they are persistent in the environment, accumulates in the food chain and has a number of undesirable effects, such as being carcinogenic and endocrine disrupting (Danish EPA, 2019). The calculations indicate, that the substance 6:2 FTOH is potentially problematic for aquatic environments, but more detailed calculations and specific assessments of the environmental effects of 6:2 FTOH are needed in order to produce a final assessment of the substance's impact on aquatic environments. Here, it is important to note the unknown factors in this simple calculation:

- The environmental quality requirement used is that of PFOS and similar perfluorinated compounds, as no environmental quality requirement has been set specifically for fluorotelomer alcohols such as 6:2 FTOH. It should be noted that this fluorotelomer compound not only has a shorter carbon chain (C6 rather than C8) than PFOS, but it is also not fully fluorinated (a polyfluorinated compound). Both of these factors are significant in terms of the expected environmental effects (degradability, toxicity, and bioaccumulability). 6:2 FTOH is thus expected to be less environmentally harmful to the aquatic environment compared to PFOS, including the fact that it is less water soluble than PFOS (Kjølholt et al., 2015b; VMR, 2018).

- There will be a significant dilution of the wash water discharged from a washing machine with the household's remaining water consumption, combined with further dilution when the water reaches an aquatic environment.
- There will be some form of wastewater treatment, but whether wastewater treatment is carried out or how effective it is for these substances has not been assessed.

10.3 Discussion and conclusion

Based on the listed data and simple calculations made for concentrations of the substances in wash water from washing fabric masks in a washing machine, the four metals are generally not considered to pose a significant environmental problem, as the wash water is expected to be diluted and subsequently purified to such an extent as to comply with the established environmental quality requirements for discharges to fresh water. However, the assessment does not include whether wastewater treatment is carried out in all cases and how effective the treatment is for these substances. It must also be pointed out, that the concentration of the leached substances is expected to continually decrease until either the total amount has been washed out, or no more can be washed out.

Silver seems to be the most problematic of the four metals for the aquatic environment, but is in return not identified in particular many of those surveyed fabric mask. Only two of the total of 30 analysed fabric mask had a content of silver, and both fabric mask had antibacterial properties. It is thus possible to avoid a silver content in fabric masks by avoiding fabric masks with antibacterial properties.

For 6:2 FTOH, however, where the calculations are made on the basis of the environmental quality requirement for PFOS and similar compounds, no final conclusion can be drawn, other than that per- and polyfluorinated substances are generally undesirable in the environment, as they are persistent in the environment, they accumulate in the food chain, and they have a number of undesirable effects, such as being carcinogens and endocrine disruptors. Simple calculations indicate that 6:2 FTOH is potentially problematic in aquatic environments. A forthcoming restriction proposal for PFAS connections in general is being prepared and is expected to be ready during summer 2022 (ECHA, 2021d). Work is thus underway on a general ban on this type of substance. Until then, per- and polyfluorinated substances can be avoided by avoiding the use of fabric mask (or other textiles) with dirt-repellent properties. The new Danish standard for washable face masks (DS 3000:2021) imposes the requirement that water-, stain-, and oil-resistant treatments containing fluorine may not be used on fabric masks. These requirements encompass both perfluoro-containing and polyfluoro-containing treatment agents.

11. Discussion and conclusion

This project has researched the content and migration of chemical substances in washable reusable fabric mask. This project focused exclusively on chemical substances in fabric masks; that is, such factors as virus/bacteria filtration capacity and the risk of inhaling small textile particles or fibres were not studied. The project's purpose was to gain knowledge of problematic chemicals in fabric masks, focusing on chemicals which irritate the skin and respiratory tract, which are sensitisers, and which are carcinogenic.

It has been researched for the following chemical substances in fabric mask. Based on the survey results as well as budgetary reasons there was not analysed for all substances in all purchased face mask. For example, antimony was primarily expected in face mask of polyester, silver primarily in face mask with antibacterial properties, and BPA primarily in coloured face mask or in elastics. For all listed results applies that the number of fabric mask with an identified content above the detection limit is stated:

- The element fluorine indicates the content of fluorinated compounds / PFAS compounds in 30 of 40 selected fabric masks. Fluorine was identified in 13 of the 30 fabric masks, and for seven of these in quantities, which could indicate fluorine / PFAS content. Of these 5 fabric masks were analysed for content of certain fluorinated substances/PFAS compound, of which the fluorine compound 6:2 FTOH was identified in 3 of the 5 fabric masks. There is a myriad of different fluorine / PFAS compounds, meaning, that there may have been other compounds present, which were not analysed for.
- The metals silver, copper, zinc and antimony due to their harmful effects on the environment, and antimony are also due to potentially harmful effects on health. Chemical analyses were carried out for 30 of 40 purchased fabric masks.
  - Silver, typically added to achieve antibacterial properties, was only identified in two of the 30 fabric masks in small quantities.
  - Copper, used in a wide variety colourant, was identified in 10 of 30 fabric masks in small quantities.
  - Zinc used due to its antibacterial properties, as a catalyst in colourants, and in anti-wrinkle treatments, was identified in six of 30 fabric masks in small quantities.
  - Antimony, which is used as a catalyst in the production of polyester, was identified in virtually all face mask containing polyester (in 21 of 30 fabric mask) and in the highest amounts of the four metals.
  - For selected face masks content analysis of metals both before and after washing was carried out, as well as migration of metals to artificial sweat. These results were used in the subsequent health and environmental assessment.
- Analyses for bisphenol A, which is an endocrine disruptor, were performed on 20 out of 40 face masks, as well as 10 of the fabric masks' elastics. Small amounts of bisphenol A were identified in nine samples, two of which were elastics.
- All 40 fabric masks were analysed for formaldehyde. Formaldehyde was identified in six fabric masks, only two of which contained it at levels significantly above the limit of detection.
- Analyses for three specific chlorinated flame retardants were performed on 25 of the 40 fabric masks, but none of the masks contained these flame retardants.
- Finally, a general screening analysis was performed in all 40 fabric masks to investigate the occurrence of possible problematic organic substances. A biocide was identified in some fabric masks, as well as a single phthalate in two of the face masks. In addition, a few organic substances with alarming health properties were identified, but only in some fabric masks. The discovery of isocyanates, which are both allergenic and carcinogenic, appeared to be the primary problem with several fabric masks (13 out of 40 masks studied). Therefore, follow-up quantitative analyses were performed on five selected fabric masks to quantify the

concentrations. However, the low content (< 1 mg/kg, corresponding to 0.0001%) is not considered to constitute a health problem.

While the fabric masks purchased were analysed for a wide range of problematic chemicals, it was not possible to carry out chemical analyses for all possible problematic chemicals in this project. Some decisions were made based on existing knowledge of problematic chemical substances in textiles, as well as to focus on substances that may be problematic with respect to skin contact and inhalation. These exposure routes are particularly relevant in the context of fabric masks.

The substances of interest were identified only in small quantities, and some substances were identified in only a small number of the fabric masks studied. It was therefore decided that in the risk assessment, as far as health is concerned, the focus would be solely on antimony, which was identified in the majority of the purchased fabric masks containing polyester, and occasionally at higher concentrations (up to 0.02%); and on formaldehyde (identified at a maximum concentration of 0.005%), which is both allergenic and carcinogenic. The concentrations at which the other substances were identified were assessed to be so low as to be highly unlikely to constitute any health risks. Though problematic isocyanates were identified in several face masks, they were found only at low concentrations (< 0.0001%). When washed, the isocyanates in the masks will react with water, meaning that isocyanates do not constitute a health risk in washed fabric masks.

The risk assessment conducted for antimony and formaldehyde shows that the identified concentrations are not expected to constitute a health risk under realistic usage conditions (wearing two face masks per day for a total of eight hours), based on available data. Antimony is, however, in the ECHA's spotlight, and a more detailed assessment of antimony has been requested under the CoRAP program, especially in terms of toxicokinetics, as the skin uptake of antimony is poorly understood. In addition, antimony's long-term effects in the form of potential carcinogenic effects must be further investigated.

Formaldehyde is a volatile, allergenic, carcinogenic substance and is therefore problematic in itself. Consumers are also exposed to formaldehyde from indoor air, as the substance evaporates from a wide range of products, such as electrical/electronic products, as well as from natural products (e.g., those made of wood). Consumer exposure to formaldehyde must therefore be minimised where possible. The possibility of particularly sensitive individuals experiencing allergic reactions from the use of unwashed fabric masks cannot be excluded. However, only one of the 40 fabric masks analysed contained formaldehyde at a level close to (but still under) the recently established limit value for formaldehyde in textiles (which took effect in November 2020). This value was set specifically to preclude the occurrence of allergic reactions. This risk can be minimised by washing fabric masks before use. This is one of the requirements in the new Danish standard for washable face masks (DS 3000:2021), which requires that fabric masks be washed before being packaged and sold. This will eliminate the risk to people who buy face masks for immediate use.

The environmental assessment of the metals in the analyses (copper, zinc, silver, and antimony) shows that these metals are unlikely to impact aquatic environments in the quantities washed out of fabric masks. In any case, the release of silver, which is the most environmentally harmful of these four metals, can be avoided by not purchasing antibacterial face masks (or other antibacterial textile products). The environmental assessment of 6:2 FTOH, a polyfluorinated substance identified in some face masks, indicates that this substance may be problematic in aquatic environments. However, information about this particular compound and its environmental impact is lacking. An upcoming restriction proposal for PFAS compounds is being prepared and is expected to be completed in summer 2022. Work is thus underway on a general ban on this type of substance. Until then, per- and polyfluorinated substances can be avoided by not using fabric masks (and other textiles) with dirt- and water repellent properties. The new Danish standard for washable face masks (DS 3000:2021) imposes the requirement that water-, stain-, and oil-resistant treatments containing fluorine may not be used on fabric masks. These requirements encompass both perfluoro-containing and polyfluoro-containing treatment agents.

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Appendix 1. Oeko-Tex 100

The chemical substance content, extraction, and migration requirements for the Oeko-Tex Standard 100 certification are listed in this appendix. Images of the requirements were taken directly from Oeko-Tex Standard 100, Annex4 (Oeko-Tex 100, 2021) and inserted in the following pages.

Fabric masks are to meet the requirements of product class II, with direct skin contact.

Annex 4: Limit values table
Anhang 4: Tabelle der Grenzwerte

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Annex 4 / Anhang 4

Limit values table / Tabelle der Grenzwerte

Any value measured in the laboratory (which is measured in mg/kg, µg/m² or w-%) must be below the specified limit to obtain the certificate.

Jeder im Labor gemessene Wert (welcher in mg/kg, µg/m² oder w-% gemessen wird) muss unter dem angegebenen Grenzwert liegen, um das Zertifikat zu erhalten.

Limit values and fastness, part 1 / Grenzwerte und Echtheiten, Teil 1

(The testing procedures are described in a separate document / Die Prüfverfahren sind in einem separaten Dokument beschrieben)

Product Class / Produktklasse	I Baby	II in direct contact with skin / mit Hautkontakt	III with no direct contact with skin / ohne Hautkontakt	IV Decoration material / Ausstattungsmaterialien
pH value / pH-Wert[1]				
	4.0 - 7.5	4.0 - 7.5	4.0 - 9.0	4.0 - 9.0
Formaldehyde, free and partially releasable / Formaldehyd, freies und teilweise abspaltbares [mg/kg]				
Law 112	n.d.[2]	75	150	300
Extractable (heavy) metals / Extrahierbare (Schwer-)metalle [mg/kg]				
Sb (Antimony / Antimon)	30.0	30.0	30.0	
As (Arsenic / Arsen)	0.2	1.0	1.0	1.0
Pb (Lead / Blei)	0.2	1.0[3]	1.0[3]	1.0[3]
Cd (Cadmium)	0.1	0.1	0.1	0.1
Cr (Chromium / Chrom)	1.0	2.0	2.0	2.0
Cr(VI)	0.5			
Co (Cobalt)	1.0	4.0	4.0	4.0
Cu (Copper / Kupfer)	25.0[4]	50.0[4]	50.0[4]	50.0[4]
Ni (Nickel)[5]	1.0[6]	4.0[7]	4.0[7]	4.0[7]
Hg (Mercury / Quecksilber)	0.02	0.02	0.02	0.02
Ba (Barium)	1000	1000	1000	1000
Se (Selenium / Selen)	100	100	100	100
Heavy metals total content / Schwermetalle Totalgehalt [mg/kg]				
As (Arsenic / Arsen)	100	100	100	100
Cd (Cadmium)	40.0	40.0[3]	40.0[3]	40.0[3]
Hg (Mercury / Quecksilber)	0.5	0.5	0.5	0.5
Pb (Lead / Blei)	90.0	90.0[3]	90.0[3]	90.0[3]
Pesticides / Pestizide [mg/kg][8,9]				
Sum / Summe[9]	0.5	1.0	1.0	1.0
Glyphosate and salts for conventional cotton / Glyphosat und Salze für gewöhnliche Baumwolle	5	5	5	5
Pesticides under observation / Pestizide unter Beobachtung[9]	u.o. / u.B.[10]			

FIGURE 2. Limit values for chemical substances in Oeko-Tex Standard 100 (part 1)

Annex 4: Limit values and fastness, part 2
Anhang 4: Grenzwerte und Echtheiten, Teil 2

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Annex 4 / Anhang 4

Limit values and fastness, part 2 / Grenzwerte und Echtheiten, Teil 2

(The testing procedures are described in a separate document / Die Prüfverfahren sind in einem separaten Dokument beschrieben)

Product Class / Produktklasse	I Baby	II in direct contact with skin / mit Hautkontakt	III with no direct contact with skin / ohne Hautkontakt	IV Decoration material / Ausstattungsmaterialien
Chlorinated phenols / Chlorierte Phenole [mg/kg][9]				
Pentachlorophenol / Pentachlorphenol (PCP)	0.05	0.5	0.5	0.5
Tetrachlorophenols / Tetrachlorphenole (TeCP), Sum / Summe	0.05	0.5	0.5	0.5
Trichlorophenols / Trichlorphenole (TrCP), Sum / Summe	0.2	2.0	2.0	2.0
Dichlorophenols / Dichlorphenole (DCP), Sum / Summe	0.5	3.0	3.0	3.0
Monochlorophenols / Monochlorphenole (MCP), Sum / Summe	0.5	3.0	3.0	3.0
Phthalates / Phthalate [w-%][11]				
Sum / Summe[9]	0.05	0.05	0.05	
Sum without DINP / Summe ohne DINP[9]				0.1
Organic tin compounds / Zinnorganische Verbindungen [mg/kg][9]				
TBT, TPhT	0.5	1.0	1.0	1.0
DBT, DMT, DOT, DPhT, DPT, MBT, MOT, MMT, MPhT, TeBT, TeET, TCyHT, TMT, TOT, TPT	1.0	2.0	2.0	2.0
Other chemical residues / Andere Rückstandschemikalien				
Carcinogenic Arylamines / Krebserregende Arylamine [mg/kg][9,12,13]	20	20	20	20
Arylamines under observation / Arylamine unter Beobachtung[9]	u.o. / u.B.[10]			
Aniline / Anilin [mg/kg][9,14]	20	50	50	50
Benzene / Benzol [mg/kg][9]	5.0	5.0	5.0	5.0
Bisphenol A [mg/kg][9]	100	100	100	100
Diazene-1,2-dicarboxamide / Azodicarboxamid (ADCA) [w%][9]	0.1	0.1	0.1	0.1
DMFu [mg/kg][9]	0.1	0.1	0.1	0.1
OPP [mg/kg][9]	10	25	25	25
Phenol [mg/kg][9]	20	50	50	50
Quinoline / Quinolin [mg/kg][9]	50	50	50	50
TCEP [mg/kg][9]	10	10	10	10
Chemical residues under observation / Rückstandschemikalien unter Beobachtung[9]	u.o. / u.B.[10]			
Colorants / Farbmittel [mg/kg]				
Cleavable carcinogenic arylamines / Abspaltbare krebserregende Arylamine[9,13]	20	20	20	20
Cleavable arylamines under observation / Abspaltbare Arylamine unter Beobachtung[9,13]	u.o. / u.B.[10]			
Cleavable Aniline / abspaltbares Anilin[9,14]	20	50	50	50
Carcinogens / Krebserregende[9]	50			
Allergens / Allergisierende[9]	50			
Others / Andere[9]	50			
Navy Blue[9]	not used / nicht verwendet			
C.I. Basic Yellow 2 (C.I. Solvent Yellow 34; Auramine hydrochloride)	u.o. / u.B.[10]			

FIGURE 3. Limit values for chemical substances in Oeko-Tex Standard 100 (part 2)

Annex 4: Limit values and fastness, part 3
Anhang 4: Grenzwerte und Echtheiten, Teil 3

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Annex 4 / Anhang 4

Limit values and fastness, part 3 / Grenzwerte und Echtheiten, Teil 3

(The testing procedures are described in a separate document / Die Prüfverfahren sind in einem separaten Dokument beschrieben)

Product Class / Produktklasse	I Baby	II in direct contact with skin / mit Hautkontakt	III with no direct contact with skin / ohne Hautkontakt	IV Decoration material / Ausstattungsmaterialien
Chlorinated benzenes and toluenes / Chlorierte Benzole und Toluole [mg/kg][9]				
Sum / Summe	1.0	1.0	1.0	1.0
Polycyclic aromatic hydrocarbons (PAHs) / Polycyclische aromatische Kohlenwasserstoffe (PAKs) [mg/kg][15]				
Benzo[a]pyrene / Benzo[a]pyren	0.5	1.0	1.0	1.0
Benzo[e]pyrene / Benzo[e]pyren	0.5	1.0	1.0	1.0
Benzo[a]anthracene / Benzo[a]anthracen	0.5	1.0	1.0	1.0
Chrysene / Chrysen	0.5	1.0	1.0	1.0
Benzo[b]fluoranthene / Benzo[b]fluoranthen	0.5	1.0	1.0	1.0
Benzo[j]fluoranthene / Benzo[j]fluoranthen	0.5	1.0	1.0	1.0
Benzo[k]fluoranthene / Benzo[k]fluoranthen	0.5	1.0	1.0	1.0
Dibenzo[a,h]anthracene / Dibenzo[a,h]anthracen	0.5	1.0	1.0	1.0
Sum 24 PAHs / Summe 24 PAKs[9]	5.0	10.0	10.0	10.0
Biological active products / Biologisch aktive Produkte				
	none / keine[16]			
Flame retardant products / Flammhemmende Produkte				
General / Generell	none / keine (10 mg/kg; each / je; for sum SCCP + MCCP / für Summe SCCP + MCCP 50 mg/kg)[16,17] Sum of all / Summe von allen 50 mg/kg			
Solvent residues / Lösemittelrückstände [w-%][9,18]				
NMP[19]	0.05 0.10[20]			
DMAc[19]	0.05 0.10[20]			
DMF[19]	0.05 0.10[20]			
Formamide / Formamid	0.02	0.02	0.02	0.02
Surfactant, wetting agent residues / Tensid-, Netzmittelrückstände [mg/kg][9]				
NP, OP, HpP, PeP; / Sum / Summe	10.0	10.0	10.0	10.0
NP, OP, HpP, PeP, NP(EO), OP(EO); / Sum / Summe	100.0	100.0	100.0	100.0
4-tert-butylphenol	u.o. / u.B.[10]			

FIGURE 4. Limit values for chemical substances in Oeko-Tex Standard 100 (part 3)

Annex 4: Limit values and fastness, part 4
Anhang 4: Grenzwerte und Echtheiten, Teil 4

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Annex 4 / Anhang 4

Limit values and fastness, part 4 / Grenzwerte und Echtheiten, Teil 4

(The testing procedures are described in a separate document / Die Prüfverfahren sind in einem separaten Dokument beschrieben)

Product Class / Produktklasse	I Baby	II in direct contact with skin / mit Hautkontakt	III with no direct contact with skin / ohne Hautkontakt	IV Decoration material / Ausstattungsmaterialien
PFCs, Per- and polyfluorinated compounds / Per- und polyfluorierte Verbindungen[9,21]				
PFOS, PFOSA, PFOSF, N-Me-FOSA, N-Et-FOSA, N-Me-FOSE, N-Et-FOSE; / Sum / Summe [µg/m2]	1.0	1.0	1.0	1.0
PFOA and salts Sum / PFOA und Salze Summe [mg/kg]	0.025	0.025	0.025	0.025
PFHpA [mg/kg]	0.05	0.1	0.1	0.5
PFNA [mg/kg]	0.05	0.1	0.1	0.5
PFDA [mg/kg]	0.05	0.1	0.1	0.5
PFUdA [mg/kg]	0.05	0.1	0.1	0.5
PFDoA [mg/kg]	0.05	0.1	0.1	0.5
PFTrDA [mg/kg]	0.05	0.1	0.1	0.5
PFTeDA [mg/kg]	0.05	0.1	0.1	0.5
Further Perfluorinated carboxylic acids, each; according to Annex 5 / je; gemäß Anhang 5 [mg/kg]	0.05			
Perfluorinated sulfonic acids, each; according to Annex 5 / je; gemäß Anhang 5 [mg/kg]	0.05			
Partially fluorinated carboxylic / sulfonic acids, each; according to Annex 5 / je; gemäß Anhang 5 [mg/kg]	0.05			
Partially fluorinated carboxylic / sulfonic acids, under observation / unter Beobachtung	u.o. / u.B.[10]			
Partially fluorinated linear alcohols, each; according to Annex 5 / je; gemäß Anhang 5 [mg/kg]	0.50			
Esters of fluorinated alcohols with acrylic acid, each; according to Annex 5 / je; gemäß Anhang 5 [mg/kg]	0.50			
PFOA related Substances Sum / PFOA-bezogene Stoffe Summe [mg/kg][22]	1.0	1.0	1.0	1.0
UV stabilizers / UV Stabilisatoren [w-%][9]				
UV 320	0.1	0.1	0.1	0.1
UV 327	0.1	0.1	0.1	0.1
UV 328	0.1	0.1	0.1	0.1
UV 350	0.1	0.1	0.1	0.1
Chlorinated paraffins / Chlorparaffine[9]				
Sum of SCCP and MCCP [mg/kg]	50	50	50	50
Siloxanes / Siloxane [w-%][9]				
Octamethylcyclotetrasiloxane (D4)	0.1	0.1	0.1	0.1
Decamethylcyclopentasiloxane (D5)	0.1	0.1	0.1	0.1
Dodecamethylcyclohexasiloxane (D6)	0.1	0.1	0.1	0.1
N-Nitrosamines / N-Nitrosamine; each / je[9] [mg/kg]	0.5	0.5	0.5	0.5
N-nitrosatable substances / N-nitrosierbare Substanzen; Sum / Summe [mg/kg]	5	5	5	5

FIGURE 5. Limit values for chemical substances in Oeko-Tex Standard 100 (part 4)

Annex 4: Limit values and fastness, part 5
Anhang 4: Grenzwerte und Echtheiten, Teil 5

Annex 4 / Anhang 4

Limit values and fastness, part 5 / Grenzwerte und Echtheiten, Teil 5

(The testing procedures are described in a separate document / Die Prüfverfahren sind in einem separaten Dokument beschrieben)

Product Class / Produktklasse	I Baby	II in direct contact with skin / mit Hautkontakt	III with no direct contact with skin / ohne Hautkontakt	IV Decoration material / Ausstattungsmaterialien
Colour fastness (staining) / Farbechtheiten (Anbluten)				
To water / Wasserechtheit	3 - 4	3	3	3
To acidic perspiration / Schweissechtheit, sauer	3 - 4	3 - 4	3 - 4	3 - 4
To alkaline perspiration / Schweissechtheit, alkalisch	3 - 4	3 - 4	3 - 4	3 - 4
To rubbing, dry / Reibechtheit, trocken[23,24]	4	4	4	4
To saliva and perspiration / Speichel- und Schweissechtheit	fast / echt			
Emission of volatiles / Emission leichtflüchtiger Komponenten [mg/m3][25]				
Formaldehyde / Formaldehyd [50-00-0]	0.1	0.1	0.1	0.1
Toluene / Toluol [108-88-3]	0.1	0.1	0.1	0.1
Styrene / Styrol [100-42-5]	0.005	0.005	0.005	0.005
4-Vinylcyclohexene / 4-Vinylcyclohexen [100-40-3]	0.002	0.002	0.002	0.002
4-Phenylcyclohexene / 4-Phenylcyclohexen [4994-16-5]	0.03	0.03	0.03	0.03
Butadiene / Butadien [106-99-0]	0.002	0.002	0.002	0.002
Vinylchloride / Vinylchlorid [75-01-4]	0.002	0.002	0.002	0.002
Aromatic hydrocarbons / Aromatische Kohlenwasserstoffe	0.3	0.3	0.3	0.3
Organic volatiles / Flüchtige organische Stoffe	0.5	0.5	0.5	0.5
Organic cotton fibres and materials / Bio-Baumwoll Fasern und Materialien[26]				
Glyphosate and salts for organic cotton / Glyphosat und Salze für organische Baumwolle	0.5	1.0	1.0	1.0
Genetically modified organisms (GMO) / Gentechnisch veränderte Organismen (GMO)	not detectable / nicht nachweisbar			
Determination of odours / Geruchsprüfung				
General / Generell	no abnormal odour / kein aussergewöhnlicher Geruch[27]			
SNV 195 651 (Modified / Modifiziert)[25]	3	3	3	3
Banned fibres / Verbotene Fasern				
Asbestos / Asbest	not used / nicht verwendet			

FIGURE 6. Limit values for chemical substances in Oeko-Tex Standard 100 (part 5)

Appendix 2. Results of metal analyses

This appendix contains the detailed results (single determinations) of all chemical analyses of metals carried out for the selected face masks. The chemical analyses have been carried out by FORCE Technology. The method used for the analyses, detection limit (LOD) and uncertainties are described in section 7.1.2 "Quantitative content analysis for selected metals (Ag, Cu, Zn, Sb)".

TABLE 31. Quantitative determination of the content of silver (Ag), cupper (Cu), zinc (Zn) and antimony (Sb) in 30 selected of the 40 purchased textile face masks **before** wash. The unit used is mg/kg face mask. The two single determinations carried out for each face mask are listed as "x-1" and "x-2", respectively.

Face mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)
Face mask of cotton (BOM)				
BOM 1-1	≤ 2	≤1	≤ 5	≤ 10
BOM 1-2	≤ 2	≤1	≤ 5	≤ 10
BOM 3-1	≤ 2	58.8	≤ 5	≤ 10
BOM 3-2	≤ 2	58.8	≤ 5	≤ 10
BOM 4-1	≤ 2	20.4	≤ 5	16
BOM 4-2	≤ 2	20.7	≤ 5	27
BOM 5-1	≤ 2	13.8	≤ 5	≤ 10
BOM 5-2	≤ 2	2.8	≤ 5	≤ 10
BOM 9-1	≤ 2	≤1	7.1	≤ 10
BOM 9-2	≤ 2	≤1	7.6	≤ 10
BOM 11-1	≤ 2	≤1	≤ 5	≤ 10
BOM 11-2	≤ 2	≤1	≤ 5	≤ 10
BOM 14-1	10.6	≤1	7.8	24
BOM 14-2	12.6	≤1	≤ 5	≤ 10
Face mask of mixed textiles (BLA)				
BLA 2-1	12.5	≤1	29.8	43
BLA 2-2	7.4	≤1	29.0	44
BLA 3-1	≤ 2	≤1	≤ 5	63
BLA 3-2	≤ 2	≤1	≤ 5	40
BLA 4-1	≤ 2	≤1	≤ 5	62
BLA 4-2	≤ 2	≤1	≤ 5	66
BLA 5-1	≤ 2	≤1	≤ 5	87
BLA 5-2	≤ 2	3.2	≤ 5	86
BLA 6-1	≤ 2	65.1	≤ 5	95
BLA 6-2	≤ 2	93.2	≤ 5	106
BLA 7-1	≤ 2	≤1	≤ 5	≤ 10
BLA 7-2	≤ 2	≤1	≤ 5	≤ 10

Face mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)
BLA 8-1	≤ 2	≤1	≤ 5	199
BLA 8-2	≤ 2	≤1	≤ 5	211
BLA 9-1	≤ 2	≤1	≤ 5	75
BLA 9-2	≤ 2	≤1	≤ 5	66
BLA 11-1	≤ 2	21.5	18.4	≤ 10
BLA 11-2	≤ 2	23.3	20.0	≤ 10
BLA 13-1	≤ 2	≤1	≤ 5	≤ 10
BLA 13-2	≤ 2	≤1	≤ 5	≤ 10
BLA 14-1	≤ 2	≤1	≤ 5	163
BLA 14-2	≤ 2	≤1	≤ 5	199
BLA 15-1	≤ 2	≤1	≤ 5	150
BLA 15-2	≤ 2	≤1	≤ 5	145
BLA 16-1	≤ 2	≤1	≤ 5	99
BLA 16-2	≤ 2	≤1	≤ 5	87
BLA 18-1	≤ 2	≤1	7.7	77
BLA 18-2	≤ 2	≤1	11.4	94
BLA 19-1	≤ 2	17.9	≤ 5	110
BLA 19-2	≤ 2	16.1	≤ 5	126
BLA 20-1	≤ 2	1.7	≤ 5	≤ 10
BLA 20-2	≤ 2	1.7	≤ 5	≤ 10
Face mask of polyester (POL)				
POL 1-1	≤ 2	≤1	≤ 5	194
POL 1-2	≤ 2	≤1	≤ 5	188
POL 2-1	≤ 2	≤1	≤ 5	87
POL 2-2	3.2	≤1	≤ 5	92
POL 3-1	≤ 2	1.7	≤ 5	128
POL 3-2	≤ 2	1.7	≤ 5	131
POL 5-1	≤ 2	≤1	≤ 5	137
POL 5-2	≤ 2	≤1	≤ 5	134
POL 6-1	≤ 2	≤1	≤ 5	116
POL 6-2	≤ 2	≤1	≤ 5	115
POL 7-1	≤ 2	≤1	15.7	172
POL 7-2	≤ 2	≤1	13.0	174
POL 8-1	≤ 2	≤1	≤ 5	129
POL 8-2	≤ 2	≤1	≤ 5	133

TABLE 32. Quantitative determination of the content of silver (Ag), cupper (Cu), zinc (Zn) and antimony (Sb) in five selected of the 40 purchased textile face masks **after** wash. The unit used is mg/kg face mask. The two single determinations carried out for each face mask are listed as ”x-1” and ”x-2”, respectively.

Face mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)
BLA 2-1	6.3	3.6	24.1	28
BLA 2-2	7.1	12.9	29.5	27
BLA 6-1	≤ 2	73.5	13.0	75
BLA 6-2	≤ 2	63.5	14.2	65
BLA 11-1	≤ 2	23.2	35.0	≤ 10
BLA 11-2	≤ 2	34.2	64.8	≤ 10
BOM 14-1	9.0	8.6	12.4	31
BOM 14-2	9.8	9.6	13.1	29
POL 7-1	≤ 2	≤ 1	≤ 5	195
POL 7-2	≤ 2	≤ 1	≤ 5	195

TABLE 33. Quantitative determination of the content of silver (Ag), cupper (Cu), zinc (Zn) and antimony (Sb) in **migration fluid** (artificial sweat) of five selected of the 40 purchased un-washed textile face masks. The unit used is mg/kg face mask. The two single determinations carried out for each face mask are listed as ”x-1” and ”x-2”, respectively.

Face mask	Ag (mg/kg)	Cu (mg/kg)	Zn (mg/kg)	Sb (mg/kg)
BLA 6-1	≤ 0.2	1.74	0.50	≤ 2
BLA 6-2	≤ 0.2	0.69	0.45	≤ 2
BLA 8-1	≤ 0.2	0.29	0.62	2.8
BLA 8-2	≤ 0.2	0.37	0.68	3.1
BLA 14-1	≤ 0.2	0.38	0.48	≤ 2
BLA 14-2	≤ 0.2	0.50	0.54	2.0
POL 1-1	≤ 0.2	1.02	0.23	3.6
POL 1-1	≤ 0.2	0.37	0.33	3.4
POL 7-1	≤ 0.2	1.39	0.85	7.3
POL 7-2	≤ 0.2	0.40	0.87	7.1

Appendix 3. Results of analyses for formaldehyde

This appendix contains the detailed results (single determinations) of all chemical analyses for formaldehyde carried out for the 40 purchased textile face masks. The chemical analyses have been carried out by FORCE Technology. The method used for the analyses, detection limit (LOD) and uncertainties are described in section 7.1.4 “Quantitative formaldehyde content analysis”.

TABLE 34. Quantitative determination of the content of formaldehyde the 40 purchased unwashed textile face masks. The unit used is mg/kg face mask. The two single determinations carried out for each face mask are listed as ”x-1” and ”x-2”, respectively.

Face mask	Content of formaldehyde (mg/kg)
BOM 1-1	< 6
BOM 1-2	< 6
BOM 2-1	< 6
BOM 2-2	< 6
BOM 3-1	< 6
BOM 3-2	< 6
BOM 4-1	48
BOM 4-2	58
BOM 5-1	< 6
BOM 5-2	< 6
BOM 6-1	< 6
BOM 6-2	< 6
BOM 7-1	< 6
BOM 7-2	< 6
BOM 9-1	< 6
BOM 9-2	< 6
BOM 10-1	< 6
BOM 10-2	< 6
BOM 11-1	< 6
BOM 11-2	< 6
BOM 12-1	< 6
BOM 12-2	< 6
BOM 13-1	< 6
BOM 13-2	6
BOM 14-1	< 6
BOM 14-2	6
BLA 1-1	< 6

Face mask	Content of formaldehyde (mg/kg)
BLA 1-2	< 6
BLA 2-1	21
BLA 2-2	23
BLA 3-1	< 6
BLA 3-2	< 6
BLA 4-1	< 6
BLA 4-2	< 6
BLA 5-1	< 6
BLA 5-2	< 6
BLA 6-1	< 6
BLA 6-2	< 6
BLA 7-1	< 6
BLA 7-2	6
BLA 8-1	< 6
BLA 8-2	< 6
BLA 9-1	< 6
BLA 9-2	< 6
BLA 10-1	< 6
BLA 10-2	< 6
BLA 11-1	< 6
BLA 11-2	< 6
BLA 13-1	< 6
BLA 13-2	< 6
BLA 14-1	7
BLA 14-2	6
BLA 15-1	< 6
BLA 15-2	< 6
BLA 16-1	< 6
BLA 16-2	< 6
BLA 17-1	7
BLA 17-2	6
BLA 18-1	< 6
BLA 18-2	< 6
BLA 19-1	< 6
BLA 19-2	< 6
BLA 20-1	< 6
BLA 20-2	< 6
POL 1-1	< 6
POL 1-2	< 6
POL 2-1	< 6
POL 2-2	< 6
POL 3-1	< 6
POL 3-2	< 6

Face mask	Content of formaldehyde (mg/kg)
POL 4-1	< 6
POL 4-2	< 6
POL 5-1	< 6
POL 5-2	< 6
POL 6-1	< 6
POL 6-2	< 6
POL 7-1	< 6
POL 7-2	< 6
POL 8-1	< 6
POL 8-2	< 6

Appendix 4. Analyses results for PFAS

This appendix contains the detailed results (single determinations) of all chemical analyses for PFAS/fluorinated substances in selected textile face masks. The chemical analyses have been carried out by Medico Kemiske Laboratorium ApS. The method used for the analyses, detection limit (LOD) and uncertainties are described in section 7.2.2 “Quantitative determination of fluorinated substances / PFAS compounds”.

TABLE 35. Quantitative determination of the content of selected fluorinated substances/PFAS compounds in **unwashed** textile face masks. The unit is mg/kg face mask. A and B are the two single determinations.

Substance name	LOD	Uncertainty	BLA 3		BLA 10		BLA 15		POL 2		POL 7	
	(mg/kg)	(%)	A	B	A	B	A	B	A	B	A	B
Perfluoro-n-butanoic acid (PFBA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-pentanoic acid (PFPeA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-hexanoic acid (PFHxA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-heptanoic acid (PFHpA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-octanoic acid (PFOA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-nonanoic acid (PFNA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-decanoic acid (PFDA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Potassium perfluoro-1-butanesulfonate (PFBS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Sodium perfluoro-1-hexanesulfonate (PFHxS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Sodium perfluoro-1-octanesulfonate (PFOS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
N-Methylperfluorooctanesulfonamidoethanol (N- Me-FOSE)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
N-Ethylperfluorooctanesulfonamidoethanol (N-Et- FOSE)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
1H,1H,2H,2H-Perfluoro-1-octanol (6:2-FTOH)	0.1	20	**0.9**	**3**	**0.7**	**0.8**	ND	ND	**0.9**	**0.8**	ND	ND
1H,1H,2H,2H-Perfluoro-1-decanol (8:2-FTOH)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
1H,1H,2H,2H-Perfluoro-1-dodecanol (10:2-FTOH)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

ND = Not detected

TABLE 36. Quantitative determination of the content of selected fluorinated substances/PFAS compounds in textile face masks **after wash**. The unit is mg/kg face mask. A and B are the two single determinations

Substance name	LOD	Uncertainty	BLA 3		BLA 10		BLA 15		POL 2		POL 7	
	(mg/kg)	(%)	A	B	A	B	A	B	A	B	A	B
Perfluoro-n-butanoic acid (PFBA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-pentanoic acid (PFPeA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-hexanoic acid (PFHxA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-heptanoic acid (PFHpA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-octanoic acid (PFOA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-nonanoic acid (PFNA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Perfluoro-n-decanoic acid (PFDA)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Potassium perfluoro-1-butanesulfonate (PFBS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Sodium perfluoro-1-hexanesulfonate (PFHxS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Sodium perfluoro-1-octanesulfonate (PFOS)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
N-Methylperfluorooctanesulfonamidoethanol (N- Me-FOSE)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
N-Ethylperfluorooctanesulfonamidoethanol (N-Et- FOSE)	0.02	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
1H,1H,2H,2H-Perfluoro-1-octanol (6:2-FTOH)	0.1	20	**1.8**	**4.9**	**2.3**	**2.2**	ND	ND	**3.1**	**2.6**	ND	ND
1H,1H,2H,2H-Perfluoro-1-decanol (8:2-FTOH)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
1H,1H,2H,2H-Perfluoro-1-dodecanol (10:2-FTOH)	0.1	20	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND

ND = Not detected

Appendix 5. Analysis results for isocyanates

This appendix contains the detailed results (single determinations) of all chemical analyses for isocyanates in selected textile face masks. The chemical analyses have been carried out by Eurofins Product Testing A/S. The method used for the analyses, detection limit (LOD) and uncertainties are described in section 7.2.5 “Quantitative determination of isocyanates”.

TABLE 37. Quantitative determination of the content of selected isocyanates in **unwashed** textile face masks. The unit is mg/kg face mask. A and B are the two single determinations.

Substance name	LOD	Uncertainty	BLA 6		BLA 13		BLA 15		POL 2		POL 6	
	(mg/kg)	(%)	A	B	A	B	A	B	A	B	A	B
2.4-TDI (2.4-toluendiisocyanat)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
2.6-TDI (2.6-toluendiisocyanat)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Ethylisocyanat (EIC)	0.02	20	**0.050**	**0.037**	**0.047**	**0.073**	**0.033**	**0.041**	**0.025**	**0.071**	**0.034**	**0.046**
Methylisocyanat (MIC)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Phenylisocyanat	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Propylisocyanat (PIC)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
HDI(hexamethylendiisocyanat)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
Hydromethylendiphenyl-4,4'- diisocyanat (HMDI)	0.02	20	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02
MDI (diphenylmethandiisocyanat)	0.02	20	**0.030**	**0.030**	<0.02	<0.02	<0.02	<0.02	<0.02	<0.02	**0.29**	**0.39**
Isophorondiisocyanat	0.02	20	**0.17**	**0.12**	<0.02	<0.02	**0.20**	**0.13**	<0.02	<0.02	<0.02	<0.02

Appendix 6. Analysis results for BPA

This appendix contains the detailed results (single determinations) of all the quantitative analyses carried out for BPA in selected textile face masks. The chemical analyses have been carried out by FORCE Technology.

In some cases, more than two single determinations (duplicate determinations) were carried out because of an observation of a large dispersion between the results of the single determinations. The detection limit (LOD) was determined at 0.008 mg/kg and the limit of quantification (LOQ) was determined at 0.025 mg/kg. The uncertainty is listed in section 7.2.6.

TABLE 38. Results of the quantitative determination of the content of BPA in selected textile face masks **before** wash. The unit used is mg/kg face mask. The single determinations carried out for each face mask are listed as ”x-1” and ”x-2”, respectively.

Face mask	Content of BPA (mg/kg)
BLA 6-1	0.77
BLA 6-2	0.64
BLA 8-1	0.043
BLA 8-2	0.63
BLA 8-3	0.023*
BLA 8-4	0.013*
BLA 8-5	0.073
BLA 8-6	0.016*
BLA 8-7	0.019*
BLA 8-8	0.012*
BLA 8-9	0.095
BLA 8-10	0.21
POL 1-1	0.41
POL 1-2	0.11
POL 1-3	0.021*
POL 1-4	0.009*
POL 1-5	0.014*
POL 1-6	0.017*
POL 3-1	0.049
POL 3-2	0.030
POL 6 elastic-1	0.74
POL 6 elastic-2	0.96

* These values are under the quantification limit of 0.025 mg/kg and are therefore uncertain.

TABLE 39. Results of the quantitative determination of the content of BPA in selected textile face masks **after** wash. The unit used is mg/kg face mask. The single determinations carried out for each face mask are listed as ”x-1” and ”x-2”, respectively.

Face mask	Content of BPA (mg/kg)
BLA 6-1	0.66
BLA 6-2	0.59
BLA 8-1	0.040
BLA 8-2	0.040
POL 1-1	0.054
POL 1-2	0.063
POL 3-1	0.36
POL 3-2	0.054
POL 3-3	0.017*
POL 3-4	0.014*
POL 3-5	0.025
POL 3-6	0.031
POL 6 elastik-1	1.97
POL 6 elastik-2	0.63

* These values are under the quantification limit of 0.025 mg/kg and are therefore uncertain.

Survey and risk assessment of chemicals in textile face masks

Due to the increased use of face masks in relation to the COVID-19 pandemic, the Danish EPA have chosen to investigate 40 different textile face masks of different material for problematic chemicals. The projects primary focus was chemicals, which irritate the skin and respiratory tract, which are sensitisers, and which are carcinogenic. Additionally, the washout rate of substances, which are hazardous to the environment have also been studied. The study investigated the chemicals: fluorine (PFAS-compounds), heavy metals, bisphenol A, formaldehyde, isocyanates and chlorinated flame retardants. The substances were identified in very small quantities, and some only in a small number of fabric masks. In general, these small quantities were assessed to be unlikely to constitute a health risk. Antimony and formaldehyde, which were seen as the most problematic substances concerning danger and identified amount, were investigated further in a risk assessment. The risk assessment indicated that the identified concentrations of antimony and formaldehyde are not expected to pose any health risk during realistic conditions of use. It cannot be excluded that formaldehyde in unwashed fabric masks may cause allergic reactions in particularly sensitive individuals.

The environmental assessment of the metals in the analyses (copper, zinc, silver, and antimony) shows that these metals are unlikely to affect aquatic environments in the quantities washed out of fabric masks. Concentrations of 6:2 FTOH in few face masks indicates that the compound potentially is problematic for the aquatic environment, but there is a lack in knowledge regarding this specific compound and its environmental impact.

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