Superior Health Council

THE POTENTIAL IMPACT OF FACE MASKS ON BELGIAN PUBLIC HEALTH AND THE ENVIRONMENT: EVALUATION AND POLICY RECOMMENDATIONS

JANUARY 2024
SHC № 9565

.be

Federal Public Service Health, Food Chain Safety
and Environment

Superior Health Council
Avenue Galilée, 5 bte 2
B-1210 Brussels

Tel.: 02/524 97 97
E-mail: info.hgr-css@health.fgov.be

Please cite this document as follows:
Superior Health Council. The potential impact of face masks on Belgian public health and the environment: evaluation and policy recommendations. Brussels: SHC; 2024. Report 9765.

Public advisory reports as well as booklets may be consulted in full on the Superior Health Council website:
www.shc-belgium.be

Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9765

The potential impact of face masks on Belgian public health and the environment: evaluation and policy recommendations

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium evaluates the possible risks associated with the long-term use of face masks treated with silver-based biocides and TiO_2 by the general population and healthcare professionals. A ban is proposed on TiO_2 in face masks intended for single use. This report is an update to the earlier advisory report SHC 9654 (July 2021).

This version was validated by the Board on
10/01/2024[1]

I INTRODUCTION AND ISSUE

On March 22nd 2023, the Superior Health Council (SHC) received a request for advice from the Federal Minister of Climate, Environment, Sustainable Development and the Green Deal concerning the prolonged use of face masks in Belgium during and after the global COVID-19 pandemic. Recent studies and reports (e.g. SHC 9654; Sciensano AgMask and TiO_2Mask studies) did not exclude that exposure to silver-based biocides and TiO_2 in face masks with fibres made of polyester, polyamide or non-woven synthetic materials may potentially cause adverse health effects. In addition, the Minister also highlighted the potential release of (micro)plastics.

Three questions were addressed to the Superior Health Council:

(1) What are the safety and potential impact of face masks on the environment?
(2) What are the safety and potential impact of face masks on public health?
(3) What are the appropriate policy recommendations in order to avoid any negative impact of face masks on the environment and on public health?

This takes into account the possible need to wear face masks in certain circumstances (e.g. occupation-related) or to prevent the transmission of respiratory diseases.

In July 2021, the SHC published its advisory report 9654 on face masks entitled "*Gezondheidsrisico's van stoffen mondmaskers behandeld met biocide op basis van zilver ter bescherming tegen COVID-19 infectie*". In that report, a number of uncertainties were indicated, particularly related to the lack of solid scientific information on the release of toxic

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

substances from the masks and inhalation by the users. It was expected that Sciensano would be able to deliver new data allowing more firm conclusions.

Since the publication of the previous advisory report in 2021 (hence only containing literature data published before 2020), several new studies have been published, including the AgMask and TiO_2 Mask studies of Sciensano. A review of this new data was deemed necessary. Therefore, the SHC has decided to review and expand the previous advisory report SHC 9654. The result is the current report.

II SUMMARY

During the COVID-19 pandemic, different types of face masks were massively used to prevent the spread of the virus and protect one's health. However, questions were raised on the potential negative effects of intensive and prolonged use of these masks. During the manufacturing process, multiple chemicals are used to obtain certain antimicrobial and quality properties. In addition, unintended contamination also occurs. In a previous advisory report published in 2021 (SHC 9654), the Superior Health Council conducted a first conservative risk assessment. It was concluded that it could not be ruled out that toxicological thresholds may be exceeded when using certain brands of face masks. Still, this risk was put into perspective given the many uncertainties regarding exposure levels and the conservative toxicological approach.

The current advisory report is a follow-up to SHC 9654. It extends the risk assessment, by also taking into account the results of new experimental studies and scientific literature published since 2021. The following conclusions are drawn:

- Although this report identified some risks based on conservative risk estimates, it is clear that the **protective benefit of the face masks during the pandemic strongly outweighed any theoretical risks.** The use of face masks saved many lives, especially at the beginning of the pandemic.

- Several studies found traces in various masks (mostly surgical masks or FFP2/N95) of substances of concern (e.g. polycyclic aromatic hydrocarbons, volatile organic compounds, organophosphate esters, phthalates). However, a “risk” is the product of both "hazard" and "exposure". **Fortunately, the estimated daily intake levels from wearing face masks during 4 or 8 hours generally do not exceed the health-based limit values**.

- Wearing commercially available face masks results in **an additional bodily burden of micro/nanoplastics on top of the existing background levels**. However, undisputable extrapolation to a distortion of human health is not possible at the moment due to the lack of trustable experimental data.

- Although valuable new data was published on the release of chemicals, no convincing and conclusive evidence was generated on the release of these substances. Hence, a **conservative exposure estimate** remains appropriate.

- Silver (ionic, metallic, nanoparticles) is often added to face masks for its biocidal effects. From a worst-case exposure scenario, it was found that **the amount of silver inhaled by users is generally below critical values for adverse health effects**, although exceptions remain possible depending on the type/brand of masks. Given the excellent physical filtering capacity of many masks, using masks containing silver might be beneficial for healthcare workers who are heavily exposed to pathogens, but the additional benefit of the silver is probably small for the general public.

- Titanium dioxide is added to face masks mostly for cosmetical properties (whitening). Using a conservative risk assessment, it was found that health risks cannot be ruled out in certain cases of intensive use and strong mask-specific TiO_2 release. **Since there is some evidence for the possible carcinogenicity of TiO_2 to humans, TiO_2 should be banned from face masks based on the precautionary principle, in particular in the disposable masks that are carried during 4 - 8 h. The**

predominantly cosmetic benefits and the limited antibacterial and antiviral capacity of TiO_2 in this short period do not outweigh avoidable health risks.

- **Face masks heavily polluted the environment during the COVID-pandemic**. The demand for biodegradability of masks may be an important parameter in future mask purchases. We could emphasize that **revalorizing** these masks could be also a viable option as an end-life scenario.

- Some **legal restrictions** on the use of chemicals in face masks should be further clarified, to avoid different interpretations. The government needs to require manufacturers to be more **transparent** about the chemical composition and safety of their masks. Besides, the Superior Health Council supports the suggestion of Sciensano to invest in an **independent research lab** for further research, although the subject should be broadened to the various aspects of nanomaterials in general.

III METHODOLOGY

After analyzing the request, the Board and the co-Chairs of the Chemical Environmental Factors group identified the necessary fields of expertise. An *ad hoc* working group was set up which included experts in chemistry, toxicology, pharmacy, environmental health, human exposure, pneumology, allergology, occupational health, prevention, textile engineering, and human ecology. The experts of this working group provided a general and an *ad hoc* declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

This advisory report is based on a review of the peer-reviewed scientific literature published in both scientific journals and reports from national and international organizations competent in this field, as well as on the expert opinion of the working group members. The scientific literature was collected using search engines such as Google Scholar and databases such as PubMed, Web of Science and Scopus.

Once the advisory report was endorsed by the working group, it was ultimately validated by the Board.

<u>Keywords and MeSH descriptor terms[2]</u>

MeSH terms*	**Keywords**	***Sleutelwoorden***	***Mots clés***	***Schlüsselwörter***
“Covid-19”	Covid-19	*Covid-19*	*Covid-19*	*Covid-19*
“pandemics	pandemic	*pandemie*	*pandémie*	*Pandemie*
“nanoparticles”	nanoparticles	*nanodeeltjes*	*nanoparticules*	*Nanopartikel*
“silver”	silver	*zilver*	*argent*	*Silber*
“titanium dioxide”	titanium dioxide	*titaniumdioxide*	*dioxyde de titane*	*Titandioxid*
“textiles”	textile	*textiel*	*textile*	*Textilwaren*
“masks”	face mask	*mondmasker*	*masque buccal*	*Gesichtsmaske*
-	human exposure	*humane blootstelling*	*exposition humaine*	*menschliche Exposition*
“toxicity”	toxicity	*toxiciteit*	*toxicité*	*Toxizität*
-	biocide	*biocide*	*biocide*	*Biozid-Produkt*

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed: http://www.ncbi.nlm.nih.gov/mesh.

[2] The Council wishes to clarify that the MeSH terms and keywords are used for referencing purposes as well as to provide an easy definition of the scope of the advisory report. For more information, see the section entitled "methodology".

List of abbreviations used

ACGIH	American Conference of Governmental Industrial Hygienists
ADI	Acceptable Daily Intake
AEL	Acceptable Exposure Level
AMPA	α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid
ANSES	*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*
AOX	Adsorbable Organically bound Halogens
CDC	Centers for Disease Control and Prevention
COV	*Composé organique volatil*
DNEL	Derived No-Effect Level
HAP	*Hydrocarbure aromatique polycyclique*
INRS	*Institut national de la recherche scientifique*
OEL	Occupational Exposure Limit
OPE	Organophosphate Ester
OSHA	Occupational Safety and Health Administration
NIOSH	National Institute for Occupational Safety & Health
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
PAH	Polycyclic Aromatic Hydrocarbon
PCB-DL	Dioxin-like Polychlorinated Biphenyls
PFAS	Per- and Polyfluoralkyl Substances
PT	Product Type
R_0	Reproductive Number
RD	Royal Decree
REL	Recommended Exposure Limit
RIVM	*Rijksinstituut voor Volksgezondheid en Milieu*
SHC	Superior Health Council
TWA	Time Weighted Average
VOC	Volatile Organic Compound

IV ELABORATION AND ARGUMENTATION

1 Introduction

The use of face masks has saved many lives during the COVID-19 pandemic (Das et al, 2021; Peeples, 2020; Pullangott et al, 2021; Wang et al, 2020). Billions of masks were used by the general population and temporarily became the “new normal”. However, questions were raised on the potential negative effects for users while carrying the masks. Besides, also the environmental burden was questioned since a considerable part of the masks were thrown away after a single use. In the manufacturing of some parts of the masks, various chemicals are used to obtain key properties (including the overall quality and antimicrobial effects). Besides, unintended chemical contamination can also occur. Traces of chemicals such as Volatile Organic Compounds (VOCs) (Xie et al, 2021), phthalates (Wang et al, 2022; Xie et al, 2022), organophosphate esters (OPEs) (Fernández-Arribas et al, 2021), heavy metals such as lead (Pb) and zinc (Zn) (Bussan et al, 2022) and some per- and polyfluoroalkyl substances (PFAS) (Muensterman et al, 2022) were detected in face masks. In addition, some brands of masks are treated with chemical additives known for being toxic to humans: graphene for antimicrobial properties, metals such as copper, silver, iron and gold as ions or micro/nanoparticles also for antimicrobial properties and titanium dioxide as whitening and tissue reinforcement additive, to name a few. Some other treatments such as polyphenols and different polymers with antiviral properties are still in development (Chua et al, 2020; Kusumoputro et al, 2020; Mallakpour et al, 2021). An additional issue is that most of these masks are produced outside the EU and their composition is not always clearly defined.

All this leads to the concern that the use of face masks may pose health risks. **Decisions on using face masks depend on the balance between beneficial protective effects and negative toxic effects for users and bystanders.** This balance is in favor of wearing a mask for the individual and for society in general during pandemics, but this is not necessarily the case during normal activities (e.g. protection against dust or preventively during non-pandemic times).

If we accept the existence of this balance, then the questions are:

1) Can we decide whether the toxicity for the user surpasses the beneficial effects?
2) If we accept this possibility, how to define and apply the criteria needed to judge whether the risks are larger than the benefits?

The answer to the first question was straightforward during the COVID-19 crisis. There was a constant flow to hospitals of infected patients needing specialized medical care and this number was extraordinarily high during the exponential increase of infections (initial high reproductive number R_0, representing the average number of new infections generated by an infectious person in a naïve population; Liu et al, 2020). Hence, the protection of healthcare employees and the population at large was needed.

Although it is tempting to keep the focus on the pandemic, masks are also carried during several daily activities, in industrial setups as protection against dust and in non-pandemic medical contexts for protecting vulnerable patients. In these situations, the answer is not straightforward and the second question should be considered. Therefore, the available information from research institutes (including Sciensano), scientific literature, and occasionally from the media will be described hereafter. When sufficient information is gathered, a risk assessment will be performed.

The information used in this document is obtained through a literature search of papers mostly published after 2020 (i.e. after the publication of the previous advisory report, SHC 9654). Besides, an expert meeting was organized (August 2, 2023) with an extensive presentation and discussion of the recent Sciensano studies. The environmental burden due to the massive use of single-use face masks during the COVID-19 pandemic is discussed in a separate chapter.

2 Face mask types

Essentially, a face mask consists of three layers or more. The outer layer is (mostly) hydrophobic and the inner layer is (mostly) a tender skin-friendly layer. The middle layer is the filtering layer and this material is produced through a series of chemical reactions leading to a polymer preparation (mostly polypropylene) which is transformed into a fine-meshed netting with a fibre diameter of 1 - 5 µm which is sufficient to repel amongst others bacteria and viruses. The production step from polymer melt into the high-density fibre construct is known as “melt spinning” which is a combination of extrusion of the stream of polymer melt through a very fine-mazed grid forming ultra-fine fibres. These fibres are captured on a drum as a layer that can be used in the masks. Several variations on this general layout are possible. This includes the four (and five) layer mask with two (or three) inner filtering layers or one filtering and one supporting layer.

In previous advices, different brands of commercially available face masks were compared. In the present document, the distinction is no longer among commercial brands but among types of masks. In short, the following types of masks are in use (largely based on Das et al, 2021; see also Lee et al, 2016).

- Cloth face masks (non-medical use) (Fig. 1a)
  Home-made masks made of everyday cotton fabric, worn over mouth and nose.

- Medical or surgical masks (Fig. 1b & Fig. 2)
  Worn by healthcare providers to protect against infection and by COVID-19 patients to prevent spreading droplets with a virus load. The masks are mostly three-ply (three layers; hydrophobic external layer, polypropylene filter as the middle layer, and a tender absorbent sheet as inner layer) and four-ply (2 filtering layers). These masks are certified according to the European EN 14 683:2019 standard (see Appendix 1). Types I and II have a bacterial filtering effectiveness of > 95 and 98 % respectively, while types IR and IIR are also splash-resistant.

- Respirator masks. These masks are used by healthcare workers who directly come into contact with patients (Fig. 1c)

  - Filtering Facepiece respirators (FFP1, FFP2, FFP3)

    High-performance masks used against vapors, dust particles and infectious agents. These masks effectively prevent inhalation of dust particles, droplets, and aerosols. Filtration is executed by complex polypropylene microfibers and electrostatic rates. Three different categories of protection exist: FFP1, FFP2 and FFP3 have minimum filtration efficiencies of 80 %, 94 % and 99 % respectively, according to the European Standard EN 149:2001. However, in practice, Lee et al (2016) showed that some FFP respirators may not achieve the required protection levels (product-specific).

- N95 and KN95

  In the United States, N95 respirators hurdle at least 95 % of strong and watery aerosol trial components under experimental circumstances approved by NIOSH and CDC. N designates that these masks are not resistant to oils. The American N95 mask is therefore similar to the European FFP2. Masks with the same characteristics are approved as KN95 in the People's Republic of China. KN95 filters at least 95 % of particles up to 0.3 µm. The N95 or KN95 consists of 4 layers, with a smooth inner layer, a hydrophobic outer layer, a support layer and a filtering layer in the middle.

Of note is that in medical/surgical masks and masks with respirators, chemical reactions are needed in order to produce the filtering fabric. The importance of chemical substances is treated hereafter.

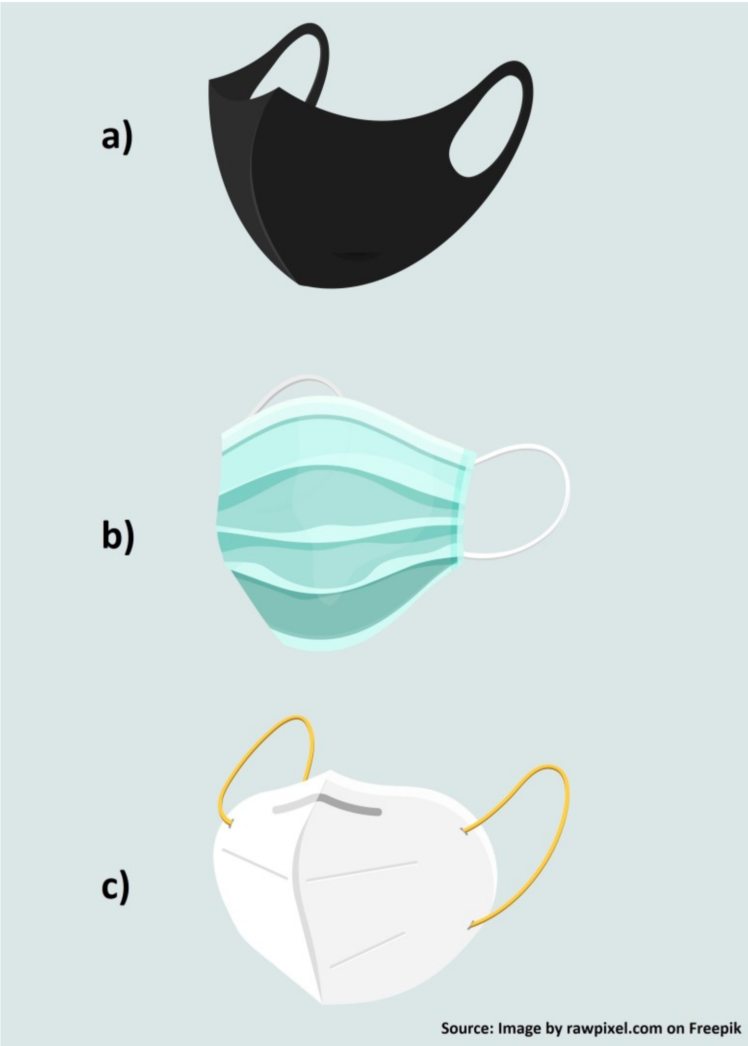

Figure 1. *Different types of face masks: a) cloth face mask, b) surgical mask, c) FFP2/N95 mask.*[3]

[3] Image modified after freepik.com.

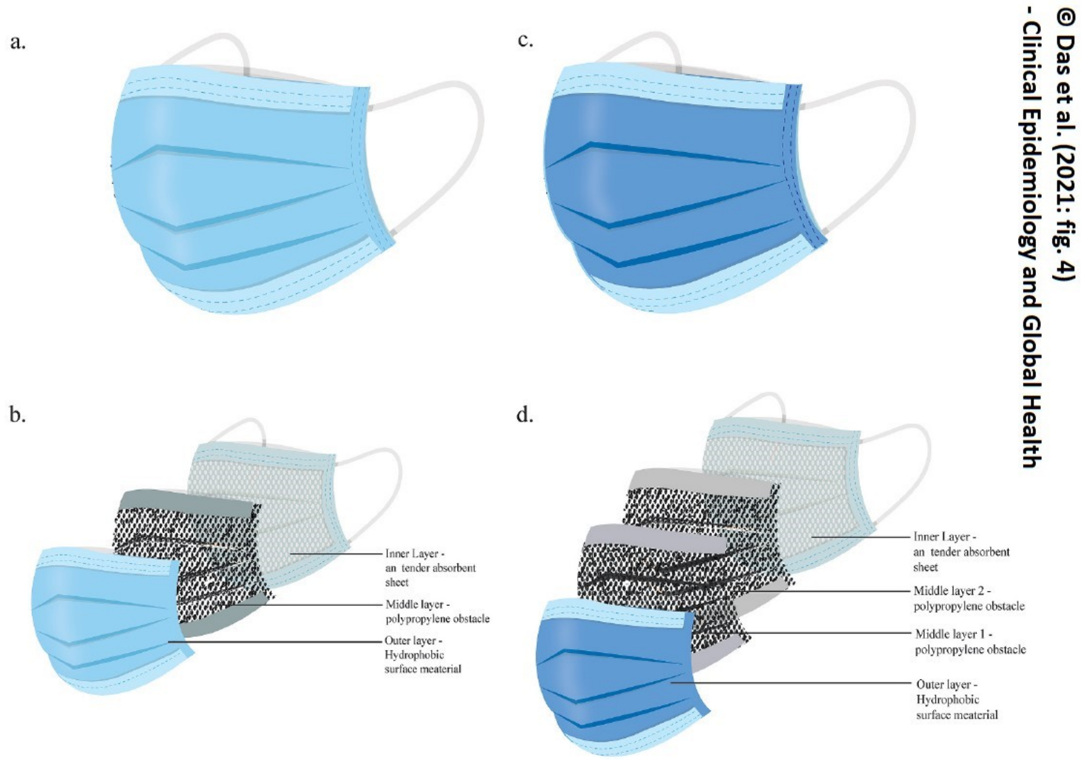

Figure 2*. Different types of surgical masks and their layering pattern. a. 3-ply surgical mask; b. layering pattern of 3-ply surgical mask; c. 4-ply surgical mask; d. different layering pattern of 4-ply surgical mask. Source: Das et al (2021: fig. 4).*

3 Government reports

A number of reports from different institutes are summarized hereafter.

3.1 ANSES (France)

ANSES published multiple documents on face masks before and during the COVID-pandemic.

- "*Évaluation du bénéfice sanitaire attendu de dispositifs respiratoires dits antipollution*."

  Type: Advisory report
  Published: May 2018
  Hyperlink: https://www.anses.fr/fr/system/files/AIR2015SA0218Ra.pdf

- "*Avis de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'évaluation des risques sanitaires liés à l'usage de masques contenant du graphène*."

  Type: Advisory report
  Published: October 28, 2021
  Hyperlink: https://www.anses.fr/fr/system/files/CONSO2021SA0089.pdf
  This report followed on the Canadian decision to withdraw graphene containing masks from the market.

- "*Avis de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail relatif à l'évaluation des risques sanitaires liés à la présence de substances chimiques dans des masques chirurgicaux mis à la disposition du grand public*."

  Type: Advisory report
  Published: October 27, 2021
  Hyperlink: https://www.anses.fr/fr/system/files/CONSO2021SA0087.pdf

The most relevant document of ANSES on this subject is the advisory report published on 27 October 2021, examining 23 surgical face masks of 3 different types: type I: filtration capacity ≥ 95 %, type II: filtration capacity ≥ 98 % and type IIR: filtration capacity ≥ 98 % and resistant to moist. The presence of several chemicals was tested including allergens in fragrance substances, formaldehyde, dioxins, phthalates, aromatic hydrocarbons, glyphosate and its metabolite AMPA, other pesticides, and adsorbable and extractable organohalogens.

The results of 2021 were compared to those obtained during a similar analysis in 2020 of 17 commercial face mask brands. The conclusion was:

> *"Les substances quantifiées dans des masques chirurgicaux vendus sur le marché français sont des dioxines, furanes, PCB-DL, HAP et COV dont l'origine exacte n'a pu être identifiée. D'autres substances sont probablement présentes (AOX : révélateurs possibles de composés organiques halogénés). Les autres substances recherchées (phtalates, formaldéhyde, 24 substances allergènes - principalement des parfums, plus de 500 résidus de pesticides, colophane et colorants dispersés) n'ont été ni détectées, ni quantifiées dans ce travail. Ces essais complètent le travail effectué par l'INRS en 2020, axé sur les COV, qui a révélé des niveaux d'émissions très faibles ne représentant pas de risques toxicologiques pour les utilisateurs (INRS, 2020)."*

3.2 RIVM (The Netherlands)

The RIVM published in 2021 an advisory report on the use of non-medical face masks in public.

- "*Chemische veiligheid mondkapjes. Voortgangsrapportage*."

  Type: Advisory report (Wijnhoven et al, 2021)
  Published: November 2, 2021
  Hyperlink: https://www.rivm.nl/publicaties/chemische-veiligheid-mondkapjes

An important conclusion was given in the abstract:

> *"There is still too little information available to assess whether face masks with claims such as "antibacterial" or "antiviral" are safe. Substances such as (nano)silver, (nano)copper, titanium dioxide and/or graphene are often added to these face masks. Face masks without additives are, as far as known, safe to use from a chemical point of view. The use of sprays and essential oils seems to have no added value for the protective function of the face mask. However, it can cause unwanted (allergic) reactions."*

3.3 Sciensano (Belgium)

Sciensano published a number of documents on face masks during the COVID-pandemic.

- "Identification, physicochemical characterization and preliminary risk analysis of titanium dioxide particles in face masks. Intermediate report TiO2-Mask COVID-19 project."

  Type: Report (Mast et al, 2021)
  Published: September 2021
  Hyperlink: https://www.sciensano.be/en/biblio/identification-physicochemical-characterisation-and-preliminary-risk-analysis-titanium-dioxide-0

- "Study on the presence of titanium dioxide in face masks: initial findings."

  Type: Press-release
  Published: October 28, 2021 (press-release)
  Hyperlink:
  https://www.sciensano.be/en/press-corner/study-presence-titanium-dioxide-face-masks-initial-findings

- “TEM analysis of “community masker M-VYG-A1” mouth masks.”

  Type: Report
  Published: Unknown (2022?)
  Hyperlink: https://www.sciensano.be/sites/default/files/em_analysis_report_community_masker_m-vyg-a1_-_sciensano.pdf

- “Titanium dioxide particles frequently present in face masks intended for general use require regulatory control.”

  Type: Peer-reviewed scientific publication (Verleysen et al, 2022)
  Published: February 15, 2022
  Hyperlink: https://doi.org/10.1038/s41598-022-06605-w

- “Identification and characterization of TiO2 nanoparticles in face masks by TEM.”

  Type: Non-peer reviewed scientific publication (Wouters et al, 2022)
  Published: June 27, 2022
  Hyperlink: https://www.sciensano.be/nl/biblio/identification-and-characterization-tio2-nanoparticles-face-masks-tem

- “AgMask - Evaluation of the types, efficient use and health risks of application of silver-based biocides to provide antimicrobial properties to face masks applied during the COVID-19 crisis. Intermediate report AgMask COVID-19 project 2022.”

  Type: Intermediate project report (Mast et al, 2022)
  Published: 2022
  Hyperlink: https://www.sciensano.be/en/biblio/evaluation-types-efficient-use-and-health-risks-application-silver-based-biocides-provide

- “Application of silver-based biocides in face masks intended for general use requires regulatory control.”

  Type: Peer-reviewed scientific publication (Mast et al, 2023)
  Published: January 31, 2023
  Hyperlink: https://doi.org/10.1016/j.scitotenv.2023.161889

- “Silver-based biocides and titanium dioxide particles in face masks for general use. Final report of the TiO2Mask and AgMask COVID-19 projects.”

  Type: Final project report (Montalvo et al, 2023)
  Published: February 2023
  Hyperlink: https://www.sciensano.be/en/biblio/silver-based-biocides-and-titanium-dioxide-particles-face-masks-general-use-final-report-tio2mask-0

The conclusions drawn in the final report of Sciensano were (Montalvo et al, 2023: p. 34 - 35):

> *“For all examined face masks, the amount of TiO_2 particles at the surface of the textile fibres notably exceeds the safety limit. This systematic exceedance indicates that applying an approach relying on conservative assumptions while uncertainties regarding hazard and exposure remain, does not allow for a definitive conclusion about the safety (intrinsic safety) of intensively used face masks containing polyester, polyamide, thermo-bonded non-woven and bi-component fibres that include these substances.*
>
> *More than half of the analysed face masks that contain detectable amounts of silver, contain levels well below the relevant limit values and can be considered intrinsically safe, independent of the availability of more detailed information on actual exposure. Several face masks contain, however, levels of silver which exceeded one or both of the limit values used in this study, and a definitive conclusion about their (intrinsic) safety could not be drawn.”*

The experimental set-up of Sciensano included both an approach of the real-life situation through breathing experiments and of the worst case situation through harsh leaching experiments. Although no definite conclusions could be drawn from both the real-life and leaching experiments, the measured amount of TiO_2 in the masks and the amount of silver in some masks exceeded limit values. Hence, the claim for further study is granted but for the time being, a cautious approach is needed.

Unfortunately, as mentioned by the authors, the validity of these leaching experiments can be doubted since the extreme experimental conditions are not representative for the real-life situation. However, since the breathing experiments yielded no valid results, the results of the leaching experiments might be considered as the extreme worst case scenario. As pointed out, this is not the equivalent of a valid, more realistic risk analysis (e.g. Tier 2 Risk Assessment). Sciensano stresses the need for further research, eventually through setting up regulatory standards for quality checking, expanding the analysis of similar types of masks and perform Life Cycle Analysis on face masks. Sciensano suggests setting up a centre of expertise and reference laboratory for further research.

3.4 Superior Health Council (Belgium)

- "*Gezondheidsrisico's van stoffen mondmaskers behandeld met biocide op basis van zilver ter bescherming tegen COVID-19 infectie.*"

  Type: Advisory report
  Published: July 7, 2021
  Hyperlink: https://www.health.belgium.be/nl/advies-9654-gezondheidsrisicos-van-mondmaskers-behandeld-met-zilverbiocide

The SHC published its advisory report upon at the request of the Federal Government. The conclusion of this advice was:

> *"Het is niet uitgesloten dat bij gebruik van de Avrox-mondmaskers toxicologische drempelwaarden kunnen overschreden worden maar dit risico moet gerelativeerd worden gezien de vele onzekerheden met betrekking tot de blootstellingsgraad en de conservatieve toxicologische benadering. Alhoewel dit eerder een opinie is dan een wetenschappelijke vaststelling is het duidelijk dat het potentieel nadelig gezondheidsrisico van het gebruik van mondmaskers niet opweegt tegen het voordeel van hun gebruik ter preventie van een COVID-19 besmetting. Het gebruik van maskers die aanleiding zouden kunnen geven tot het inademen van titaniumdioxide is tegenaangewezen, behalve wanneer ze het enige voorhanden zijnde middel zijn om COVID-19 te voorkomen."*

3.5 Summary of the available reports

In spite of many efforts, such as the attempts to develop new methods by Sciensano, few solid conclusions are drawn. The authors of the Sciensano report do not want to take a position on the toxicological burden of mask users because the data is not available. The method for measuring the release of TiO_2 and Ag from the masks is flawed, making it unsuitable for realistic predictions. The main point of the report is that further research needs to be done. Similarly, the RIVM also concludes that more research is needed; again, no conclusion is drawn. The authors of the ANSES report take a firm stance on some chemicals, but there is no information on TiO_2 and Ag in their report. Despite this drawback, in general, it can be concluded that there is little concern about toxic effects for the user. Finally, the SHC's earlier advisory report is consistent with the assessment that few, if any, solid conclusions are possible at the moment. At the time, it was expected that Sciensano would conduct new research in the field. In conclusion, there is no convincing new evidence generated in the different international reports published since SHC 9654. This jeopardizes further conclusions.

4 Current state of knowledge on chemicals and plastic particles in face masks

4.1 Chemicals in different face masks

The presence of a series of chemicals in face masks has been described by Chua et al (2020), Xie et al (2021) and the above-mentioned ANSES report of 27 October 2021, the most important are discussed hereafter.

Formaldehyde, a known carcinogen (IARC group 1, it may cause nasopharyngeal cancer in humans) was found in many types of masks since it is an ubiquitously used chemical in textile industry, occasionally leading to allergic contact dermatitis in clothes, but also in face masks (Clawson & Pariser, 2021; Liccardi et al, 2023). It was even suggested that the aggravation of lung diseases following COVID-19 infection might be due to the presence of formaldehyde. Although the possibility of toxic effects of formaldehyde present in face masks, the risk of health problems i.e. contact dermatitis may be considered as low, as demonstrated in a Japanese study (Kawakami et al, 2022). Pronounced effects at the level of the lungs are probably low.

The presence of **phthalates** in face masks has also been documented (De-la-Torre et al, 2022; Wang et al, 2022; Xie et al, 2022). Wang et al conclude from their study on 16 commercially available face masks that the estimated daily intake of individual members of the phthalate group was at least 80 times lower compared to the Acceptable Daily Intake (ADI) level (Wang et al, 2022). The estimated daily intake of individual compounds was not higher than 20 ng/kg/day for adults and 120 ng/kg/day for toddlers. A trial with volunteers wearing a mask for 4 h showed no increase in the urinary concentration of phthalate metabolites.

Hydrophobic layers within some face masks may have been treated with **per- and polyfluoroalkyl substances (PFAS),** in order to be water-repellant (e.g. body fluids). However, such treated face masks can act as a source of human exposure to these substances by dermal absorption of PFAS, inhalation of gas-phase PFAS and ingestion of particulate PFAS. Four types of face masks (a single-use surgical mask, an N95 mask, 6 reusable cloth masks and a special mask for firefighters) were studied by Muensterman et al (2022). Nonvolatile PFAS were found in all 9 facemasks, while volatile PFAS were found in 5 facemasks in variable concentrations. Inhalation was estimated to be the dominant exposure route (40 % – 50 %), followed by incidental ingestion (15 % – 40 %) and dermal (11 % – 20 %). Using an exposure model setup up by RIVM (2017), Muensterman et al (2022) concluded that the risk for adverse health effects in humans cannot be excluded for face masks with a high PFAS load which are used for long periods (at least 10 hours/day),

As reported by Xie et al (2021), **Volatile Organic Compounds (VOCs)** were found in nearly all of the 53 commercially available masks they investigated. Besides, they found **Polycyclic Aromatic Hydrocarbons (PAHs), organophosphate flame retardants and UV filtering chemicals**. Although the authors did not draw any conclusion on the possible toxic consequences for the user, they claim that the risks of wearing the masks might be underestimated. Chang et al (2022) performed an analysis on 7 surgical and 4 N95 commercial brands of masks and equally concluded on the presence of these compounds. However, they found that the volatile compounds disappeared within 1 hour from the tissue, when exposed to air. They suggested a simple but effective precautionary measure: "*people should expose their new surgical masks to ambient air before wearing them*".

The presence of **metals other than silver and titanium** has been described although the authors conclude that for most of the masks, the level was below detection limits (Bussan et al, 2022). Traces of copper (Cu) were found in almost all masks. The KN95 type of masks contained the lowest level of all metals tested.

Organophosphate esters (OPEs), ubiquitously used as **plasticizers or flame retardants** are also detected in face masks by Fernández-Arribas et al (2021). The levels measured varied widely, with the highest mean concentrations obtained for KN95 masks (11.6 µg/mask) and the lowest for surgical masks (0.24 µg/mask). However, according to these authors, the potential inhalation toxicity of these compounds is orders of magnitude below critical values.

It is clear that during the manufacturing of the different components of face masks, the masks are contaminated and hazardous chemicals are used. It is obvious that part of these substances remain in the masks, possibly exposing the user. Furthermore, many of these processes and constituents are not described and possibly considered as trade secrets; hence, it is likely that the list of chemicals mentioned here does not cover the whole spectrum of hazardous chemicals in face masks. From the available data it appears that the health risks, although small, are not always zero (e.g. Muensterman et al, 2022).

Preliminary conclusion on chemicals in face masks

Based on the current knowledge of the presence of hazardous chemicals in face masks and based on some worst case exposure scenarios, the estimated daily intake levels from wearing face masks generally do not exceed the health based limit values for most chemicals. However, wearing the face masks gives an additional exposure to hazardous chemicals and hence contributes to the total daily intake of different substances, which predominantly comes from others sources (e.g. food).

4.2 Plastic particles in face masks

Plastic nanoparticles are formed during synthesis of the polymers and during the melt-process. The particles are in variable amounts present in the masks and are released from the masks' fabric, causing effects in humans and in the environment (Bhangare et al, 2023; De-la-Torre et al, 2021, 2022; Fernández-Arribas et al, 2021; Jiang et al, 2023; Li et al, 2021; Li et al, 2022). Hence, the toxicity of plastic particles that emerge from the regular use of face masks should be considered (Sharifi et al, 2012). The combination of silver or titanium with nanoparticles is discussed separately.

How can we assess the exposure of the mask wearer to plastic nano- and microparticles?

In general, the uptake of micro- and nanoplastics in humans has been estimated both from direct exposure (Krishnan, 2023; Kumah et al, 2023; Zhu et al, 2023) or indirect exposure through the consumption of food (Schoonjans et al, 2023; Ziani et al, 2023).

The analysis starts with the estimation of background levels of inhaled plastic micro- and nanoparticles. Some literature data is available (Table 1). Besides, according to the commercial organization *Statista*, we consume between 78 000 and 211 000 microplastic particles/year from various sources, but these values are considered as under-estimates (Statista 2022). Comparable values were published before by Cox et al (2019) (Table 2). **Altogether, a rough estimate of the number of inhaled particles averages about 50 000 particles/year with a window between 0 and 120 000 particles.** This estimate has a wide range, taking into account large local variations and atmospheric conditions.

Table 1. *Occurrence of microplastics in the atmosphere (adapted from Vercauteren et al, 2023: table S2.3). *Particles/year are own calculations: particles/m³ x 24 hours/day x 365 days/year. The inhalation rate is set at 1 m³/hour.*

Author/reference	Origin - Location	particles/m³	Particles/year*
Bergmann et al, 2019	Outdoor – Arctic	0 – 14.4	0 – 126,144
Liu, Wang et al, 2019	Outdoor – Shangai	0 – 4.18	0 – 36,616
Liu, Wu et al, 2019	Outdoor – Pacific Ocean	0 – 1.37	0 – 12,001
Abbasi et al, 2019	Outdoor – Asaluyeh (Iran)	0.3 – 1.1	2.628 – 9.636
Gonzalez-Pleiter et al, 2020	Outdoor – urban (Spain)	13.9	121,764
Gonzalez-Pleiter et al, 2020	Outdoor – rural (Spain)	1.5	13,140
Dris et al, 2017	Indoor – France	1.64 – 4.8	13,366 – 42,048
Tunahan Kaya et al, 2018	Outdoor – bus terminal	1.64 – 4.1	13,366 – 35,916

Table 2. *Daily and annual consumption and inhalation of microplastic particles for female and male, children and adults by Cox et al (2019, corrected in 2020). The values have been rounded to the nearest 1 000. Consumed = peroral intake. For the calculation of the annual exposure, Cox et al used the inhalation rates as accepted by the EPA (Exposure Factors Handbook. The values from their table are slightly different from ours: female and male adults, moderate intensive activity: 17.28 m³/day).*

	Daily		Annual		Total	
	Consumed	Inhaled	Consumed	Inhaled	Daily	Annually
Male children	113	110	41,000 ± 7000	40,000 ± 45,000	223	81,000
Male adults	142	170	52,000 ± 8000	62,000 ± 69,000	312	114,000
Female children	106	97	39,000 ± 7000	35,000 ± 39,000	203	74,000
Female adults	126	132	46,000 ± 8000	48,000 ± 54,000	258	94,000

How can we assess the exposure of the mask wearer to nanoparticles from face masks ?

Limited literature data are available. There is no doubt that the user inhales fragments of plastics originating from the mask (De-la-Torre et al, 2021). Bhangare et al (2023), using 5 commercially available face masks, collected microplastics from the masks through a collection chamber under constant aspiration of air. They found a total particle number for surgical masks between about 5 000 particles / 8 hours for first use masks and 15 000 particles/8 hours for reused masks, the other masks gave intermediate values. The authors described the presence of three types of particles according to different coloring with Nile red. The difference in staining is due to the chemical composition (low- and high-density polyethylene, polypropylene, polystyrene, polyvinylchloride, polyamide) and not due to the dimensions of the particles.

- Comparing these data with the data from Table 1:

Assuming that the face masks are used for 4 hours per day, the number of particles inhaled during these 4 hours for first use mask is 2 500 (Bhangare et al, 2023), then this amounts to ca 500 000 particles during one year with 200 working days (2 500 particles/day x 200 days). If the masks are carried for 8 hours/day, the amount ingested particles would be around 1 million. The background number of particles ingested and inhaled is about 50 000 each year. **The ingestion of microplastic particles by wearing face masks for 4 hours per day or 8 hours per day would be 10 times respectively 20 higher than the number of particles ingested from food/ drinks and inhaled from air per year. Similarly, during short periods (4 hours) the number of inhaled particles with first use masks exceeds the number of inhaled particles without mask according to the data of Cox et al (2019).**

- Comparing these data with the estimates from *Statistica*:

Assuming the intake of about 500 000* and 1 000 000** particles per year from first use face masks compared to background values between 78 000 – 211 000 particles/year, **the intake of plastic particles due to face masks would represent an additional burden of**

microplastic particles equal between 2.3 - 6.4 fold* or 5.6 - 12.8 fold the background values (for a daily mask use of 4 and 8 hours respectively).**

Taken together, this indicates that even in the most conservative estimates and irrespective of the time window (e.g. mask use during 4 – 8 h per day), the number of plastic particles inhaled through face masks is significantly higher that the inhalation of airborne particles in the air during the same time period. These estimations are only indicative and need cautious interpretation in particular related to the accuracy of the figures. It suffices to refer to Sciensano's experiments to understand how difficult it is to obtain reliable figures. As far as we know, these are the most reliable values available in the literature. More data are available on the intake of particles expressed as µg/m³ (inhalation) or µg/g (food). However, similar data for particles from face masks are lacking and the conversion of particle numbers to weight is impossible when the chemical properties of the particles are not known (de Jesus et al, 2019). Similarly, the dimensions of the particles are not described, while it is known that the smaller particles are more of concern than the larger particles.

How is this related to human health ?

Based on the information discussed above, caution must be used when drawing conclusions. Many questions remain on the toxicity of microplastic particles. Plastic particles have been found in blood (Leslie et al, 2022), affecting many human physiological systems (Thangavel et al, 2022) and underlying mechanisms of toxicity have been suggested (Park, Park, Schauer, Yi, & Heo, 2018).

Most conclusions about human health require knowledge of the properties of the polluting particles, not only about their quantity (number and/or weight), but also about the distribution of their dimensions (e.g. nanoparticles are more toxic than microparticles) and composition. Furthermore, plastic particles in the environment often carry chemicals with potential toxic effects on humans such as nitrogen oxides, metals etc. Also plasticizers such as phthalates may leach out from microplastics. Altogether, there is sufficient evidence that wearing face masks causes additional inhalation of plastic micro- and nanoparticles above background levels, while an undisputable extrapolation to a distortion of human health is not possible at the moment.

Preliminary conclusion on plastic particles in face masks

Despite the uncertainty of the data and despite the need for cautious interpretation, the overall conclusion is that wearing commercially available face masks will result in additional bodily burden of micro/nano plastic particles on top of the existing background levels.

5 Modification of face masks to enhance antiviral and antibacterial properties with silver-based biocides

Face masks protect the wearer against micro-organisms in different ways (Liu & Kong, 2021). The main purpose of the masks is to prevent intake of hazardous agents such as viruses and fine dust particles. One of the layers in face masks is typically made from polypropylene by a process of melt spinning. The result of this process is a layer of a tightly fitting fabric that by itself will prevent the passage of microorganisms (Konda et al, 2020; Sankhyan et al, 2021). In experimental conditions, filtration efficiencies up to 99 % for particles > 300 nm have been obtained by Konda et al (2020) in N95 and surgical masks. Below 300 nm, the efficiency decreased to averages of 85 ± 15 % and 76 ± 22 % respectively. Similar results were obtained by Sankhyan et al (2021): the filtration efficiency at the most penetrating particle size (300 nm) on average ranged from 83 – 99 % for N95 and KN95 respirators, 42 – 88 % for surgical masks, 16 – 23 % for cloth masks, and 9 % for bandana. The average size of bacteria ranges between 1 - 10 µm, viruses are smaller (generally between 0.05 – 0.1 µm) but the transmission of respiratory viruses takes place via respiratory droplets with larger sizes. The minimum size of a respiratory particle to contain SARS-CoV-2 was calculated to be approximately 9.3 µm (Lee, 2020). Hence, the previously mentioned masks provide effective protection provided they are resistant to humidity.

Many **nanostructured materials** loaded with others substances (e.g. metals) could help reducing viruses (De Toledo et al, 2020; Lagana et al, 2021; Mallakpour et al, 2021). As an exemple, the inclusion of modified Chitosan/Silver nanoparticles in nylon fabric was found to have a strong antimicrobial effect, but the effect disappeared upon washing (Botelho et al, 2021).

Silver (Ag) in different forms is used in numerous commercial applications (ECHA, 2023). In spite of some deviant opinions (Drake & Hazelwood, 2005; Ferdous & Nemmar, 2020) and according to the CLP classification, silver is labelled as presumed toxic for human reproduction based on evidence from animal data (Repr. 1B) and as hazardous (acute and chronic) for the aquatic environment.

The Sciensano study of Montalvo et al (2023) could distinguish four types of silver-based biocides in the studied face masks:

1) Ag^{+} ions;
2) Metallic Ag^{0} nanoparticles distributed in the fiber matrix;
3) Ag^{0} nanoparticles and large silver particles at the surface (or close to it) of the cotton fibers in face masks with polycationic polymers binding Ag^{+} ions;
4) Coatings consisting of metallic silver releasing Ag^{+} ions, Ag^{0} nanoparticles and larger particles.

The permissible air exposure levels for **silver (metallic and ionic)**, are highly variable from 100 µg/m³ for metallic silver to 10 µg/m³ for ionic silver (American Conference of Governmental Industrial Hygienists) while OSHA set the occupational exposure limit to 10 µg/m³ for all types of silver (Drake & Hazelwood, 2005). An overview of Time Weighted Average values (TWA: average value of exposure over the course of an 8 h work shift):

- TWA: 0.1 mg/m³ (= 100 µg/m³) from ACGIH (2023) (Threshold Limit Value for metal dust and fume) [United States]
- TWA: 0.01 mg/m³ (= 10 µg/m³) from ACGIH (2023) (Threshold Limit Value for soluble compounds, as Ag) [United States]
- TWA: 0.01 mg/m³ (= 10 µg/m³) from OSHA (2021) (Permissible Exposure Limit) [United States]
- TWA: 0.01 mg/m³ (= 10 µg/m³) from NIOSH (2021) (Recommended Exposure Limit for total silver: metal dust, fume and soluble compounds, as Ag) [United States]

- TWA: 0.0009 mg/m³ (= 0.9 µg/m³) from NIOSH (2021) (Recommended Exposure Limit for silver nanomaterials: ≤ 100 nm primary particle size) [United States]

ECHA (2023) provides a **Derived No-Effect Level (DNEL)** for long-term, systemic and local effects after inhalation of silver (form not specified): 7.6 µg/m^3 for workers and 2.3 µg/m^3 for the general population. The DNEL is the level of exposure above which a human should not be exposed to a substance, to avoid adverse effects.

As far as the toxicity of silver-nanoparticles is concerned, the toxic effect of the nanoparticles has been described (Duran et al, 2019; Hadrup et al, 2020; Kittler et al, 2010). Sub-chronic toxicity tests in rats with silver nanoparticles derived a No Observed Adverse Effect Level (NOAEL) of 100 µg/m³ based on a 28-days inhalation toxicity study in rats (Ji et al, 2007). This dose was subsequently converted to a human equivalent workplace exposure concentration of 59 µg/m³ (Ji & Yu, 2012). In contrast to this relatively high level, an occupational exposure limit of 0.19 µg/m^3 for silver nanoparticles has recently been proposed based on a subchronic rat inhalation toxicity study and by taking the human equivalent concentration with kinetics into consideration (Weldon et al, 2016). NIOSH (2021) derived a recommended exposure limit (REL) for silver nanomaterials (≤ 100 nm primary particle size) of 0.9 µg/m^3 as an airborne respirable 8-hour time-weighted average (TWA) concentration. In addition, NIOSH (2021) continues to recommend a REL of 10 µg/m^3 as an 8-hour TWA for total silver.

Altogether, the lowest exposure limits for metallic and ionic silver are more or less accepted at 10 µg/m³, the exposure limits for silver nanoparticles are much more divers ranging from 0.19 µg/m³ over 0.9 µg/m³ up to 59 µg/m³ (one study).

The Sciensano report concludes that breathing and abrasion experiments in practice did not provide useful information; therefore, leaching experiments were included as representative of the worst-case scenario (Montalvo et al, 2023). From their data (Table 3, see Montalvo et al, 2023: p. 25), the quantity of silver leached from different masks ranged from less than 0.1 µg/mask to more than 70 µg/mask, representing between less than 0.1 and more than 40 % of the total Ag present in the mask. In most cases, < 10 % of the total Ag content leached.

This difference in leaching percentage is the consequence of the different forms of silver in the masks: Ag^+ ion are readily released, nanoparticles intertwined with the fabric are only little or not released at all. Again, any conclusion is speculative, but the following **conservative risk estimation** can be made:

- The worst-case situation as described by Sciensano is a total silver leaching of 76 µg/mask, measured after a contact time of 8 h. Because the release is not continuous over time, this maximum value is used here as a default.
- Assume this particular mask is used during an 8 h shift.
- For adults, the default short-term air inhalation rate used by ECHA in biocidal product assessments is 1.25 m³/h (ECHA, 2017). This is a volume of 10 m³ during 8 h.
- Assume the silver being released during 8 hours (worst case scenario), this would mean 76 µg / 10 m³ = 7.6 µg/m³ on average[4].
- **If we consider the released silver to be metallic or ionic silver, 7.6 µg/m³ is within the TWA of OSHA and NIOSH (10 µg/m³). It equals the DNEL of ECHA (7.6 µg/m³) for workers, but exceeds the DNEL for the general population (2.3 µg/m^3).**
- **If we consider the released silver to be nanosilver, the figure is higher than the lowest exposure level of 0.19 µg/m³ (Waldon et al, 2016) or 0.9 µg/m³ (NIOSH, 2021) µg/m³ but lower than the 59 µg/m³ limit calculated by Ji et al (2012).**

[4] The calculation approximates the silver release as a linear function, which is obviously an oversimplification of reality.

Although we are aware of the drawbacks of these conservative estimates, it is tempting to conclude that the amount of silver inhaled by the user is mostly below critical values. In some cases, however, an exceedance of these values cannot be excluded.

Table 3. *Amount of silver released into artificial acid sweat for face masks in the Sciensano study (Table 3 from Montalvo et al, 2023).*

Face mask	Layer	Contact time (h)	Amount of Ag leached (µg Ag/g sample[a])	Ag leached per mask (µg Ag/mask)	Ag leached (% of total Ag content)
AgMask08	External Central Internal	1	22 ± 1.1 1.3 ± 0.5 23 ± 4.1	61	0.03
	External Central Internal	4	27 ± 2.3 1.2 ± 0.3 23 ± 1.3	66	0.03
	External Central Internal	8	24 ± 0.8 1.6 ± 0.02 24 ± 2.5	65	0.03
	External Central Internal	24	21 ± 0.5 1.8 ± 0.5 22 ± 0.8	59	0.03
AgMask15	All	1	0.94 ± 0.02	9.3	6
	All	4	0.88 ± 0.02	8.8	5
	All	8	0.97 ± 0.16	9.6	6
	All	24	0.87 ± 0.10	8.6	5
AgMask18	External Internal	1	8.8 ± 0.31 8.2 ± 0.92	51	29
	External Internal	8	12.3 ± 5.8 13.0 ± 5.0	76	43
AgMask20	External Central Internal	1	<LOQ 4.9 ± 2.8 <LOQ	0.09	1
	External Central Internal	8	<LOQ 16 ± 3.2 <LOQ	0.3	5

[a] Average of duplicates ± standard deviation

<u>Conclusion on silver-based biocides in face masks</u>

A simple conclusion is not possible. Evidently, the presence of silver biocides in face masks will enhance the antibacterial capacity, guaranteeing the quality of the mask for a longer period of time and will consequently enhance the protection level of the user during pandemics. However, the contribution in the total antibacterial “capacity” of the masks because of the presence of silver could be low, since the physical filtering capacity of the masks (in particular the FFP2 and N95/KN95 masks) is already very high. Hence the additional benefit of the silver, either as ion, metal or in nanoparticles might be small for the general public.

6 Modifications of face masks to enhance their quality with TiO_2

Titanium dioxide (TiO_2) is frequently added to many commercial products (cosmetics, paint, textile etc.) because of its ultra-white color, anti-fogging properties in automobile windows, self-cleaning capacity and many other beneficial properties. Titanium dioxide nanoparticles are used in medicinal applications. It has shown to possess some antibacterial activity due to the photocatalytic effect and the generation of reactive oxygen species. It is also used in face masks (Verleysen et al, 2022; Montalvo et al, 2023).

Titanium dioxide has been used for a long time and, until recently, there were few alarming reports about its potential toxicity. Therefore, its long-term use without claims of toxicity was often used as an argument in favor of its harmlessness. However, over a decade ago, the International Agency for Research on Cancer (IARC) classified TiO_2 as a possible carcinogen to humans (Class 2B) (IARC, 2010). Similarly, ECHA (2021) classifies TiO_2 as a carcinogen if inhaled (Carc. 2, H351 inhalation) when supplied on its own or in mixtures, where the substance or mixture contains 1 % or more of TiO2 particles with an aerodynamic diameter ≤ 10 µm.

The scientific literature on the carcinogenicity of TiO_2 is disparate. A majority of independent authors claim that TiO_2 is carcinogenic (Rodriguez-Garraus et al, 2020; Rashid et al, 2021; Shabbir et al, 2021) and an initiative for formulating regulatory measures of its use is highly requested (Verleysen et al, 2022). There is also agreement on the impact of nanoparticles in general on human health (Kumah et al, 2023; Landsiedel et al, 2022; Liu & Kong, 2021; Riediker et al, 2019; Sharifi et al, 2012; Siivola et al, 2022). Kirkland et al (2022) rejects the claim of carcinogenicity in a study that was ordered by the Titanium Dioxide Manufacturing Association, which creates a hint of a conflict of interest (conscientiously mentioned by the authors). In a recent paper by Yamano et al (2022) no evidence for carcinogenicity of TiO_2 is found in a 26-week inhalation study in the rasH2 mouse model (Yamano et al, 2022), although the animal model is questioned (Suarez-Torres et al, 2020).

Besides, the situation is further more complex since TiO_2 generally exists in two main crystalline structures: rutile and anatase. The IARC-designation of TiO2 as class 2B carcinogen was based on animal experimental evidence with either rutile or a mixture of anatase and rutile (80/20). For this document, we accept that the carcinogenicity of TiO2 is present in both structures, albeit at different degree. The overall conclusion, however, is that the weight of evidence pro carcinogenicity is substantial.

The permission of the use of TiO_2 in Europe as food additive or as adjuvant in aerosols has been discussed between the European institutions. Since 2008, TiO_2 was allowed to use as food additive (E171) in particular for its coloring capacity. In 2021, EFSA concluded their concern for genotoxicity of TiO_2 and, consequently, since no safe dose can be predicted, the use of E171 in food must be prohibited (EFSA, 2021a-b). A request for stricter regulatory measures was already formulated about 5 years ago (EFSA, 2018). In the US, the addition of TiO_2 to food was considered by the FDA as harmless, which was also the case in Canada. In some other countries, TiO_2 was banned comparable to the EU.

TiO_2 is frequently used in cosmetic products for e.g. UV filter in sunscreens, tooth paste etc. The risk for toxicity is minimal since TiO_2 is not taken up through the skin. In a typical face make-up application (loose powder), TiO_2 is considered to be safe for the general consumer at concentrations below 25 % in the context of exposure through inhalation (SCSS, 2020). Except for accidental ingestion, no risk for adverse health effects are to be expected. Besides, the Scientific Committee on Consumer Safety (SCCS, 2020) considered TiO_2 in hair styling aerosol applications at a concentration of 25 % as unsafe and recommended a more appropriate maximum concentration of 1.4 % for general consumers and 1.1 % for hairdressers. Both the rutile and the anatase variant were mentioned in these studies, while anatase was considered more relevant.

Just as for silver, Sciensano performed leaching experiments for TiO_2. For one particular brand of masks, it was demonstrated that 47 µg Ti/mask or 78 µg TiO_2/mask was released after a contact time of 8 h (Table 4, see Montalvo et al, 2023: p. 26). Besides, Verleysen et al (2022; see supplementary information 7) calculated the mass of TiO_2 particles per mask that can be inhaled without adverse effects (AEL_{mask}). The threshold-based approach of ANSES was used to determine the professional exposure limit to TiO_2. Lung inflammation after subchronic inhalation exposure of rats was used as critical effect. The No Observed Adverse Effect Concentration (NOAEC) was corrected for human exposure, resulting in an AEL_{mask} of 3.6 µg, assuming an intensive exposure scenario of the general adult population with two face masks worn per day of 8 h. Hence, the AEL_{day} is 7.2 µg (2x AEL_{mask}). The AEL was calculated to be 0.72 µg/m³, slightly below the Occupational Exposure Limit (OEL) of 0.8 µg/m³ calculated by ANSES (2020).

Again, **a conservative risk estimation** can be made.

- The worst-case situation as described by Sciensano is a total TiO_2 leaching of 78 µg/mask (Table 4), measured after a contact time of 8 h. Because the release is not continuous over time, this maximum value is used here as a default.
- Assume this particular mask is used during an 8 h shift.
- For adults, the default short-term air inhalation rate used by ECHA in biocidal product assessments is 1.25 m³/h (ECHA, 2017). This is a volume of 10 m³ during 8 h.
- Assume the TiO_2 being released during 8 hours (worst case scenario), this would mean 78 µg / 10 m³ = 7.8 µg/m³ on average.
- **Hence, the estimated release of TiO_2 of 7.8 µg/m³ exceeds both the Sciensano AEL (0.72 µg/m³) and the ANSES OEL (0.8 µg/m³) more than 10-fold. As ANSES considers chronic exposure in the workplace, an additional safety margin should normally be provided for the general population.**

Alternatively, starting from the AEL_{mask} approach (4 h), we can assume (using an oversimplified linear function of release) that a total of 39 µg is released during 4 h. This concentration also exceeds the AEL_{mask} of 3.6 µg more than 10-fold. **While not every mask will have this much titanium dioxide exposure, risks can certainly not be excluded.**

Table 4. *Amount of titanium released into artificial acid sweat for face mask AgMask-18 tested by Sciensano (Table 4 from Montalvo et al, 2023).*

Face mask	Layer	Contact time (h)	Amount of Ti leached (µg Ti/g sample[a])	Ti leached per mask (µg Ti/mask)	Ti leached (% of total Ti content)
AgMask18	External	1	5.5 ± 1.6	34	0.3
	Internal		5.7 ± 1.8		
	External	8	8.4 ± 6.0	47	0.4
	Internal		7.1 ± 5.1		

[a] Average of duplicates ± standard deviation

<u>Conclusion on TiO_2 in face masks</u>

The conclusion of Sciensano and Verleysen et al (2022) is correct: there is a major exceeding of a conservative threshold level. Hence our conclusion on TiO_2 is simple: it should be banned in masks, as there is concern about the possible long term health effects. The main use of TiO_2 is for cosmetic purposes, but most masks are used only for a limited time (4 - 8 h). Given the limited antibacterial and antiviral capacity of TiO_2, the benefits do not outweigh the potential health risk.

7 Environmental effects of face masks

Wearing face masks was rightly and heavily promoted during the COVID-19 pandemic. However, billions of face masks ended in the environment and polluted all compartments of nature (soil, surface waters, oceans etc.). In particular, marine life was highly affected and illustrated abundantly in the media with pictures of fish captures in plastic recipients (Aydemir & Ulusu, 2022; Dharmaraj et al, 2021; Jiang et al, 2023; Ma et al, 2021; Mohamed et al, 2022; Spennemann, 2022). The most polluting fraction of these face masks consists of non-degradable plastics, particularly polypropylene-based materials. There is agreement on the impact of nanoparticles in general on human health and the environment (Kumah et al, 2023; Landsiedel et al, 2022; Liu & Kong, 2021; Riediker et al, 2019; Sharifi et al, 2012; Siivola et al, 2022). Furthermore, since nearly all masks (except the home-made cloth face masks) contain man-made polymers, masks contaminate the environment by chemicals used during manufacturing, including well known chemical-pollutants such as PFAS (forever chemicals), phthalates (endocrine disrupting substances) and some carcinogenic compounds such as formaldehyde. In addition, the degradation process of the masks is slow (Chen et al, 2021; Pizarro-Ortega et al, 2022). Prata et al, (2021) compared single-use face masks with reusable face masks on aspects such as user protection and environmental burden and concluded that reusable masks were less polluting than the single-use masks (Prata et al, 2021). Both UNCTAD (2020) and EEA (2023) gave detailed information on the environmental pollution due to face masks. The authors suggested methods to enhance safety (increase the filtering capacity of the masks) and decrease pollution (reusing masks after refurbishing) but a final straightforward conclusion was not given. Hence, while the masks saved many lives, the burden for the environment is/was high. It was calculated that 1 mask represents 0.050 kg CO_2 (ECOCHAIN) and with approximately 52 billion face masks produced in 2020, this represents 2.6 billion kg CO_2. EPA (2023) calculated at the CO_2 emission of a typical passenger vehicle emission to be 0.4 kg/mile. Hence, the equivalent of the face masks CO_2 is between 5 and 7.5 billion miles for passenger cars. Furthermore, of these 52 billion masks, it is estimated that about 1.6 billion ended in the oceans (Lu, 2021).

It should be clear that the situation in 2020 (i.e. during the pandemic) is not representative for the regular production and use of face masks. Indeed, the protective capacity of the face masks in view of the infectious properties of the virus was certainly beneficial. At the same time, wearing a face mask has become more and more common in highly air-polluted regions and big cities polluting the environment. The delicate balance between the beneficial effects versus the environmental burden has been discussed before (Matuschek et al, 2020).

The consequences for human health due to environmental pollution cannot be ignored: endocrine disrupting effects are possible in humans and wild life due to the presence of chemicals (Aydemir & Ulusu, 2022). Furthermore, the amount of litter and household waste has increased significantly. Some solutions have been formulated. The most appealing approach would be the design of biodegradable face masks (Babaahmadi, 2021; Shen et al, 2023) and the use of cellulose-type components in disposable masks (Garcia et al, 2021), but their performances are not necessary good enough for face mask applications.

Conclusion on the environmental effects of face masks

Face masks heavily polluted the environment during the COVID-pandemic and the consequences will remain for a long time (Roberts et al, 2022). The demand for biodegradability of masks may be an important parameter in future mask purchases. We could emphasize that revalorizing these masks could be also a viable option as end-life scenario.

8 Legal considerations

Including components such as silver or other biocidal material in face masks is subjected to legal regulations[5] including the Biocidal Product Regulation (BPR) (EU N° 528/2012) and the Belgian Royal Decree of 4 April 2019 on the marketing and use of biocides. The BPR distinguished 22 different products (PT1-PT22) divided in 4 family products. Of interest are PT1 (products used for human hygiene), PT2 (disinfectants) and PT9 (products for microbiological control in textiles). As far as silver is concerned, the following use is actually permitted or forbidden (Table 5):

Table 5. *Authorization regarding the use of silver in various forms as a biocide. RPS: Review Program Substance. UA: Under Assessment. This overview was provided on 22/9/20 by the Centexbel[6].*

	PT1: Human hygiene	PT2: Disinfectants	PT9: Preservatives for textiles
Silver (metallic)	Not allowed	Allowed (RPS)	Not allowed
Silver Chloride	Allowed (RPS)	Allowed (RPS)	Allowed (RPS)
Silver Nitrate	Allowed (RPS)	Not allowed (UA)	Allowed (UA)
Silver (nano)	Not allowed	Allowed (RPS)	Allowed (RPS)

It should be noted that a number of other substances containing silver in combination with other chemicals classified as PT9 are under investigation. These include: silver copper zeolite, silver on silicon dioxide and others.

Metallic silver is only allowed as a disinfectant, which means that the claim as disinfectants according to the PT9 type is not allowed, while the ionic form and the nano-form of the metal are allowed. Alternatively, the application of silver ions as a tissue preservative (face mask) is allowed.

Another observation is puzzling. As shown in the Sciensano report, the content of silver in face masks is highly variable, ranging from 6.5 µg/masks up to 235 044 µg/mask (Montalvo et al, 2023: table 2), which is a factor of 36,000. To the best of our knowledge, there is no indication on how much silver is needed in face masks for optimal antibacterial activity. Obviously, the higher the amount of silver in the mask, the higher will be the exposure of the user but, since information is lacking, no guidelines for optimal concentration (per gram, cm² textile or any comparable unit) can be given. It should be noted that the purchase of expensive high content silver face masks with high silver content may be superfluous. The need for standardization is high (Verleysen et al, 2022; Mast et al, 2023).

Although this seems simple, the possibility of mixing additive designations PT2 and PT9 on face masks inevitably leads to misclassification. This confusion is clearly welcomed by face mask companies.

Surgical face masks are not subject of the BPR regulation but are considered medical equipment. Legal obligations are beyond the scope of this discussion; guidelines have been published on the legal requirements for medical face masks in the context of the COVID-19 pandemic[7].

[5] https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr
[6] https://transfer.centexbel.be/duratex/Final_event_Biobased_Antimicrobials/Regulation%20biocides.pdf
[7] https://health.ec.europa.eu/system/files/2020-06/md_guidance-reg-req-med-face-masks_0.pdf

Conclusion on the legal considerations

Al this leads to the conclusion that responding to the legal obligations of silver or nanoparticles in face masks is less obvious than wanted. Any adaptation of the law need to be based on experimentally sound scientific data which are not obtained yet. The main conclusion related to the face masks is that the presence of metallic silver is not allowed in PT9 type masks. Ionic silver or nano-silver is allowed. If metallic silver is used in face masks, the designation should be PT2.

9 General conclusions and recommendations

Few new information was gathered since the publication of SHC 9654 in 2021. Any conclusion and advice should rely on recent evidence from the literature combined with reconsideration of previous views.

In the advice 9654, the SHC suggested:

> *"Although the pre-treatment of face masks with biocides (such as silver), has certain advantages, the question whether this is always needed should be put forward.*
> *The use of titaniumdioxide should be avoided. Any risk management decision should wait the result of the Sciensano study."*

There is no new solid information today that contradicts previous advisory reports of the SHC on this matter. Instead, interesting recent (published after 2020) literature evidence supports the previous views.

- The use of silver in different molecular forms (ion or metallic) or as nanoparticles may have advantages since the antibacterial properties of the metal are well described (e.g. Deshmukh et al, 2019). However, as mentioned in this document, the filtering capacity (> 300 nm) of some masks is up to 99 %, which is a nearly perfect protection against microbial contamination or viruses in respiratory droplets.

- One interpretation is that the filtering face masks, containing silver in any form, should only be worn by people having the highest chances of contact with e.g. COVID-19 patients, such as healthcare employees or contact professions (dentists, hair dressers, physiotherapist, etc.). If the addition of silver is required, silver in the form of embedded nanoparticles in the tissue of the masks is more appropriate compared to silver in ionic or metallic form, due to the lower release. The general public is probably protected sufficiently without the addition of these metals to the masks.

- The results of Sciensano indicate, albeit at worst, the possibility of the metals being released and inhaled by the user of the mask. Since this is not the case in all commercial face masks, a better selection of safe/low risk masks seems possible. As an alternative for the "*post-hoc*" selection of the most suitable mask, the suggestion of Sciensano to select intrinsic safe face masks based on the principle of safe-by-design is a valuable advice, provided that legally binding exposure limits and – consequently – optimal regulations for the manufacturing of the masks is available.

- From a worst-case exposure scenario, it was found that the amount of silver inhaled by users is generally below critical values for health, although exceptions remain possible.

- Our conservative risk assessment based on the Sciensano studies shows that health risks cannot be ruled out in certain cases of intensive use and strong mask-specific TiO_2 release. Since there is some evidence for the possible carcinogenicity of TiO_2 to humans (IARC Class 2B; IARC, 2010), **TiO_2 should be banned from face masks based on the precautionary principle, in particular in the disposable masks that are carried during 4 - 8 h. The predominantly cosmetic benefits and the limited antibacterial and antiviral capacity of TiO_2 in this short period do not outweigh avoidable health risks.**

The previous advisory report 9654 can be complemented with the following conclusions:

- Despite the uncertainty of the data and despite the need for cautious interpretation, the overall conclusion is that wearing commercially available face masks will result in additional bodily burden of plastic particles on top of the existing background levels.

- The environmental impact of the large quantity of discarded face masks during the COVID-19 pandemic is worrying, both acutely because of the significant contribution to medical and household waste (leading to environmental contamination) and in the long term because of the harmful impact on environmental and human health. The use of biodegradable face masks should be promoted and – if needed – research in this context should be supported. Besides, also revalorizing discarded face masks is an important option as end-life scenario.

- There is a plethora of legal restrictions on masks, additives and intended use. However, some combinations lack the strictness and clarity expected in legal rules, leaving room for personal interpretation. Moreover, the demand for standardization is high, as already mentioned in the Sciensano report.

- The suggestion in the Sciensano report to set up and invest in an independent research lab for further research is supported. Although the problem of inhalation of nanoparticles present in face masks is important, the subject should be broadened to the study of various aspects of nanomaterials in general. Established research labs in Belgium (e.g. Sciensano, VITO, Belgian universities) are highly suitable for this purpose.

- More than today, the government should require manufacturers to be transparent about the (chemical) composition of their masks and ensure their safety with independent testing.

V REFERENCES

Abbasi, S., Keshavarzi, B., Moore, F., Turner, A., Kelly, F. J., Dominguez, A. O., & Jaafarzadeh, N. (2019). Distribution and potential health impacts of microplastics and microrubbers in air and street dusts from Asaluyeh County, Iran. Environmental Pollution, 244, 153–164. https://doi.org/10.1016/j.envpol.2018.10.039

ACGIH (2023). Silver and Compounds. American Conference of Governmental Industrial Hygienists. https://www.acgih.org/silver-and-compounds/ (Accessed on 28/11/2023)

ANSES (2020). Valeurs limites d'exposition en milieu professionnel. Le dioxyde de titane sous forme nanométrique (TiO_2-NP, P25). Agence nationale de sécurité sanitaire, alimentation, environnement, travail. Saisine n° 2019-SA-0109 - VLEP TiO2-NP. https://www.anses.fr/fr/system/files/VSR2019SA0109Ra.pdf

Aydemir, D., & Ulusu, N. N. (2022). Fate of the face masks in the environment affect human and wildlife: tons of face masks are new source for the endocrine disrupting chemicals. Journal of Basic and Clinical Health Sciences, 6(2), 355-359. https://doi.org/10.30621/jbachs.869552

Babaahmadi, V., Amid, H., Naeimirad, M., & Ramakrishna, S. (2021). Biodegradable and multifunctional surgical face masks: A brief review on demands during COVID-19 pandemic, recent developments, and future perspectives. Science of the Total Environment, 798, 12. https://doi.org/10.1016/j.scitotenv.2021.149233

Bergmann, M., Mützel, S., Primpke, S., Tekman, M. B., Trachsel, J., & Gerdts, G. (2019). White and wonderful? Microplastics prevail in snow from the Alps to the Arctic. Science Advances, 5(8), eaax1157. https://doi.org/10.1126/sciadv.aax1157

Berman, J. D., & Ebisu, K. (2020). Changes in US air pollution during the COVID-19 pandemic. Science of the Total Environment, 739, 4. https://doi.org/10.1016/j.scitotenv.2020.139864

Bhangare, R. C., Tiwari, M., Ajmal, P. Y., Rathod, T. D., & Sahu, S. K. (2023). Exudation of microplastics from commonly used face masks in COVID-19 pandemic. Environmental Science and Pollution Research, 11. https://doi.org/10.1007/s11356-022-24702-1

Botelho, C. M., Fernandes, M. M., Souza, J. M., Dias, N., Sousa, A. M., Teixeira, J. A., . . . Zille, A. (2021). New Textile for Personal Protective Equipment-Plasma Chitosan/Silver Nanoparticles Nylon Fabric. Fibers, 9(1), 13. https://doi.org/10.3390/fib9010003

Bussan, D. D., Snaychuk, L., Bartzas, G., & Douvris, C. (2022). Quantification of trace elements in surgical and KN95 face masks widely used during the SARS-COVID-19 pandemic. Science of the Total Environment, 814, 7. https://doi.org/10.1016/j.scitotenv.2021.151924

Chang, Y. H., Huang, R. J., Cheng, K., Lin, C. S., Ling, Q. Y., Haque, M. M., . . . O'Dowd, C. (2022). Highly Time-Resolved and Nontargeted Characterization of Volatile Organic Compound Emissions from Face Masks br. Environmental Science & Technology Letters, 9(12), 1007-1013. https://doi.org/10.1021/acs.estlett.2c00524

Chen, X. C. A., Chen, X. F., Liu, Q., Zhao, Q. C., Xiong, X., & Wu, C. X. (2021). Used disposable face masks are significant sources of microplastics to environment. Environmental Pollution, 285, 6. https://doi:10.1016/j.envpol.2021.117485

Chua, M. H., Cheng, W. R., Goh, S. S., Kong, J. H., Li, B., Lim, J. Y. C., . . . Loh, X. J. (2020). Face Masks in the New COVID-19 Normal: Materials, Testing, and Perspectives. Research, 2020, 40. https://doi.org/10.34133/2020/7286735

Clawson, R. C., & Pariser, R. (2021). Formaldehyde-Induced Contact Dermatitis From an N95 Respirator Mask COMMENT. Cutis, 108(1), E11-E14. https://doi.org/10.12788/cutis.0305

Cox, K. D., Covernton, G. A., Davies, H. L., Dower, J. F., Juanes, F., & Dudas, S. E. (2019). Human Consumption of Microplastics. Environmental Science & Technology, 53(12), 7068-7074. https://doi.org/10.1021/acs.est.9b01517

Das, S., Sarkar, S., Das, A., Das, S., Chakraborty, P., & Sarkar, J. (2021). A comprehensive review of various categories of face masks resistant to Covid-19. Clinical Epidemiology and Global Health, 12, 15. https://doi.org/10.1016/j.cegh.2021.100835

De-la-Torre, G. E., Dioses-Salinas, D. C., Dobaradaran, S., Spitz, J., Nabipour, I., Keshtkar, M., . . . Javanfekr, F. (2022). Release of phthalate esters (PAEs) and microplastics (MPs) from face masks and gloves during the COVID-19 pandemic. Environmental Research, 215, 10. https://doi.org/10.1016/j.envres.2022.114337

De-la-Torre, G. E., Pizarro-Ortega, C. I., Dioses-Salinas, D. C., Ammendolia, J., & Okoffo, E. D. (2021). Investigating the current status of COVID-19 related plastics and their potential impact on human health. Current Opinion in Toxicology, 27, 47-53. https://doi.org/10.1016/j.cotox.2021.08.002

de Jesus, A. L., Rahman, M. M., Mazaheri, M., Thompson, H., Knibbs, L. D., Jeong, C., . . . Morawska, L. (2019). Ultrafine particles and PM2.5 in the air of cities around the world: Are they representative of each other? Environment International, 129, 118-135. https://doi.org/10.1016/j.envint.2019.05.021

Deshmukh, S.P., Patil, S.M., MUllani, S.B. & Delekar, S.D. (2023). Silver nanoparticles as an effective disinfectant: A review. Materials Science and Engineering: C, 97, 954-965. https://doi.org/10.1016.j.msec.2018.12.102

De Toledo, G. G., Toledo, V. H., Lanfredi, A. J. C., Escote, M., Champi, A., Da Silva, M. C. C., & Nantes-Cardoso, I. L. (2020). Promising Nanostructured Materials against Enveloped Virus. Anais Da Academia Brasileira De Ciencias, 92(4), 22. https://doi.org/10.1590/0001-3765202020200718

Dharmaraj, S., Ashokkumar, V., Hariharan, S., Manibharathi, A., Show, P. L., Chong, C. T., & Ngamcharussrivichai, C. (2021). The COVID-19 pandemic face mask waste: A blooming threat to the marine environment. Chemosphere, 272, 20. https://doi.org/10.1016/j.chemosphere.2021.129601

Drake, P. L., & Hazelwood, K. J. (2005). Exposure-related health effects of silver and silver compounds: A review. Annals of Occupational Hygiene, 49(7), 575-585. https://doi.org/10.1093/annhyg/mei019

Dris, R., Gasperi, J., Mirande, C., Mandin, C., Guerrouache, M., Langlois, V., & Tassin, B. (2017). A first overview of textile fibers, including microplastics, in indoor and outdoor environments. Environmental pollution, 221, 453-458. https://doi.org/10.1016/j.envpol.2016.12.013

Duran, N., Rolim, W. R., Duran, M., Favaro, W. J., & Seabra, A. B. (2019). Nanotoxicology of silver nanoparticles: toxicity in animals and humans. Quimica Nova, 42(2), 206-213. https://doi.org/10.21577/0100-4042.20170318

ECHA (2017). Default human factor values for use in exposure assessments for biocidal products. Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure. Revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017. European Chemicals Agency. https://echa.europa.eu/documents/10162/21664016/recom_14+_default+human_factor_values_biocidal+products_en.pdf/88354d31-8a3a-475a-9c7d-d8ef8088d004 (Accessed on 28/11/2023)

ECHA (2021). Guide on the classification and labelling of titanium dioxide. European Chemicals Agency. https://echa.europa.eu/documents/10162/17240/guide_cnl_titanium_dioxide_en.pdf/

ECHA (2023). Substance infocard. Silver. ECHA. https://echa.europa.eu/nl/substance-information/-/substanceinfo/100.028.301 (Accessed on 29/9/2023)

EEA (2023). COVID-19 in Europe: increased pollution form masks, gloves and other single-use plastics. European Environment Agency. https://www.eea.europa.eu/highlights/covid19-in-europe-increased-pollution (Accessed on 28/11/2023)

EFSA (2018). Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. EFSA Journal. https://doi.org/10.2903/j.efsa.2018.5327

EFSA (2021a). Safety Assessment of titanium dioxide (E171) as a food additive. EFSA Journal. https://doi.org/10.2903/j.efsa.2021.6585

EFSA (2021b). Titanium dioxide: E171 no longer considered safe when used as a food additive. European Food Safety Authority. https://www.efsa.europa.eu/en/news/titanium-dioxide-e171-no-longer-considered-safe-when-used-food-additive (Accessed on 28/11/2023)

EPA (2023). Greenhouse GAs Emissions from a Typical Passenger Vehicle. United Stades Environmental Protection Agency. https://www.epa.gov/greenvehicles/greenhouse-gas-emissions-typical-passenger-vehicle#:~:text=typical%20passenger%20vehicle%3F-,A%20typical%20passenger%20vehicle%20emits%20about%204.6%20metric%20tons%20of,8%2C887%20grams%20of%20CO2 (Accessed on 28/11/2023)

Ferdous, Z., & Nemmar, A. (2020). Health Impact of Silver Nanoparticles: A Review of the Biodistribution and Toxicity Following Various Routes of Exposure. International Journal of Molecular Sciences, 21(7), 31. https://doi.org/10.3390/ijms21072375

Fernández-Arribas, J., Moreno, T., Bartroli, R., & Eljarrat, E. (2021). COVID-19 face masks: A new source of human and environmental exposure to organophosphate esters. Environment International, 154, 8. https://doi.org/10.1016/j.envint.2021.106654

Forastiere, F., Badaloni, C., de Hoogh, K., von Kraus, M. K., Martuzzi, M., Mitis, F., . . . Briggs, D. (2011). Health impact assessment of waste management facilities in three European countries. Environmental Health, 10, 13. https://doi.org/10.1186/1476-069x-10-53

Fowler, J. F., Skinner, S. M., & Belsito, D. V. (1992). Allergic contact-dermatitis from formaldehyde resins in permanent clothing - an underdiagnosed cause of generalized dermatitis. Journal of the American Academy of Dermatology, 27(6), 962-968. https://doi.org/10.1016/0190-9622(92)70295-q

Garcia, R. A., Stevanovic, T., Berthier, J., Njamen, G., Tolnai, B., & Achim, A. (2021). Cellulose, Nanocellulose, and Antimicrobial Materials for the Manufacture of Disposable Face Masks: A Review. Bioresources, 16(2), 4321-4353. https://doi.org/10.15376/biores.16.2.Garcia

González-Pleiter, M., Edo, C., Casero-Chamorro, M. C., Aguilera, A., González-Toril, E., Wierzchos, J., ... & Rosal, R. (2020). Viable microorganisms on fibers collected within and beyond the planetary boundary layer. Environmental Science & Technology Letters, 7(11), 819-825. https://doi.org/10.1021/acs.estlett.0c00667

Hadrup, N., & Lam, H. R. (2014). Oral toxicity of silver ions, silver nanoparticles and colloidal silver - A review. Regulatory Toxicology and Pharmacology, 68(1), 1-7. https://doi.org/10.1016/j.yrtph.2013.11.002

Hadrup, N., Sharma, A. K., Loeschner, K., & Jacobsen, N. R. (2020). Pulmonary toxicity of silver vapours, nanoparticles and fine dusts: A review. Regulatory Toxicology and Pharmacology, 115, 9. https://doi.org/10.1016/j.yrtph.2020.104690

Hamra, G. B., Guha, N., Cohen, A., Laden, F., Raaschou-Nielsen, O., Samet, J. M., . . . Loomis, D. (2014). Outdoor Particulate Matter Exposure and Lung Cancer: A Systematic Review and Meta-Analysis. Environmental Health Perspectives, 122(9), 906-911. https://doi.org/10.1289/ehp/1408092

IARC (2010). Carbon Black, Titanium Dioxide and Talc. IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans Volume 93. International Agency for Research on Cancer, World Health Organization. https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Carbon-Black-Titanium-Dioxide-And-Talc-2010 (Accessed on 28/11/2023)

Ji, J. H., Jung, J. H., Kim, S. S., Yoon, J. U., Park, J. D., Choi, B. S., . . . Yu, I. J. (2007). Twenty-eight-day inhalation toxicity study of silver nanoparticles in Sprague-Dawley rats. Inhalation Toxicology, 19(10), 857-871. https://doi.org/10.1080/08958370701432108

Ji, J. H., & Yu, I. J. (2012). Estimation of human equivalent exposure from rat inhalation toxicity study of silver nanoparticles using multi-path particle dosimetry model. Toxicology Research, 1(3), 206-210. https://doi.org/10.1039/c2tx20029e

Jiang, H. R., Luo, D., Wang, L. Y., Zhang, Y. S., Wang, H., & Wang, C. Q. (2023). A review of disposable facemasks during the COVID-19 pandemic: A focus on microplastics release. Chemosphere, 312, 12. https://doi.org/10.1016/j.chemosphere.2022.137178

Kawakami, T., Obama, T., Sakai, S., Takagi, M., Takahashi, N., Oshima, N., . . . Ikarashi, Y. (2022). Free formaldehyde in non-medical face masks purchased from the Japanese market since the COVID-19 outbreak. Journal of Environmental Science and Health Part a-Toxic/Hazardous Substances & Environmental Engineering, 57(3), 193-197. https://doi.org/10.1080/10934529.2022.2047560

Kaya, A.T., Yurtsever, M. & Bayraktar, S.C (2018). Ubiquitous exposure to microfiber pollution in the air. European Physical Journal Plus, 133(11). https://doi.org/10.1140/epjp/i2018-12372-7

Kirkland, D., Aardema, M.J., Battersby, R.V., Beevers, C., Burnett, K., Burzlaff, A., Czich, A., Donner, E.M., Fowler, P., Johnston, H., Krug, H.F., Pfuhler, S., Stankowski Jr, L.F. (2022). A weight of evidence review of the genotoxicity of titanium dioxide (TiO2). REgul Toxicol Pharmacol 236,105263. https://doi.org/10.1016/j.yrtph.2022.105263

Kittler, S., Greulich, C., Diendorf, J., Koller, M., & Epple, M. (2010). Toxicity of Silver Nanoparticles Increases during Storage Because of Slow Dissolution under Release of Silver Ions. Chemistry of Materials, 22(16), 4548-4554. https://doi.org/10.1021/cm100023p

Konda, A., Prakash, A., Moss, G. A., Schmoldt, M., Grant, G. D., & Guha, S. (2020). Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks. Acs Nano, 14(5), 6339-6347. https://doi.org/10.1021/acsnano.0c03252

Krishnan, K. (2023). A Systematic Review on the Impact of Micro-Nanoplastics Exposure on Human Health and Diseases. Biointerface Research in Applied Chemistry, 13(4), 12. https://doi.org/10.33263/briac134.381

Kumah, E. A., Fopa, R. D., Harati, S., Boadu, P., Zohoori, F. V., & Pak, T. (2023). Human and environmental impacts of nanoparticles: a scoping review of the current literature. Bmc Public Health, 23(1), 28. https://doi.org/10.1186/s12889-023-15958-4

Kusumoputro, S., Tseng, S., Tse, J., Au, C., Lau, C., Wang, X., & Xia, T. (2020). Potential nanoparticle applications for prevention, diagnosis, and treatment of COVID-19. View, 1(4), 9. https://doi.org/10.1002/viw.20200105

Lagana, P., Visalli, G., Facciola, A., Ciarello, M. P., Lagana, A., Iannazzo, D., & Di Pietro, A. (2021). Is the Antibacterial Activity of Multi-Walled Carbon Nanotubes (MWCNTs) Related to Antibiotic Resistance? An Assessment in Clinical Isolates. International Journal of Environmental Research and Public Health, 18(17), 11. https://doi.org/10.3390/ijerph18179310

Landsiedel, R., Honarvar, N., Seiffert, S. B., Oesch, B., & Oesch, F. (2022). Genotoxicity testing of nanomaterials. Wiley Interdisciplinary Reviews-Nanomedicine and Nanobiotechnology, 14(6), 35. https://doi.org/10.1002/wnan.1833

Lee, B.U. (2020). Minimum Sizes of Respiratory Particles Carrying SARS-CoV-2 and the Possiblity of Aerosol Generation. International Journal of Environmental Research and Public Health, 17(19): 6960. https://doi.org/10.3390/ijerph17196960

Lee, S.A., Hwang, D.C., Li, H.Y., Tsai, C.F., Chen, C.W., Chen, J.K. (2016). Particle Size-Selective Assessment of Protection of Eurpean Standard FFP Respirators and Surgical Masks against Particles-Tested with Human Subjects. Journal of Healthcare Engineering, 2016, 8572493. https://doi.org/10.1155/2016/8572493

Leslie, H. A., van Velzen, M. J. M., Brandsma, S. H., Vethaak, A. D., Garcia-Vallejo, J. J., & Lamoree, M. H. (2022). Discovery and quantification of plastic particle pollution in human blood. Environment International, 163, 8. https://doi.org/10.1016/j.envint.2022.107199

Li, L., Zhao, X. L., Li, Z. Y., & Song, K. (2021). COVID-19: Performance study of microplastic inhalation risk posed by wearing masks. Journal of Hazardous Materials, 411, 9. https://doi.org/10.1016/j.jhazmat.2020.124955

Li, M. H., Hou, Z. K., Meng, R., Hao, S. L., & Wang, B. C. (2022). Unraveling the potential human health risks from used disposable face mask-derived micro/nanoplastics during the COVID-19 pandemic scenario: A critical review. Environment International, 170, 15. https://doi.org/10.1016/j.envint.2022.107644

Liccardi, G., Bilo, M.B., Milanese, M., Martini, M., Pane, G., De Maio, A., Rogliani, P. (2023). COVID-19 lockdown, personal protective equipment, hyper-hygiene and allergy. Eur. Ann. Allergy Clin. Immunol. 55 (2), 51-56. http://doi.org/10.23822/EurAnnACI.1764-1489.243

Liu, L., & Kong, L. (2021). Research progress on the carcinogenicity of metal nanomaterials. Journal of Applied Toxicology, 41(9), 1334-1344. https://doi.org/10.1002/jat.4145

Liu Y, Gayle AA, Wilder-Smith A, Rocklöv J. The reproductive number of COVID-19 is higher compared to SARS coronavirus. Journal of Travel Medecine 2020;1-4. https://doi.org/10.1093/jtm/taaa021

Liu, K., Wang, X., Fang, T., Xu, P., Zhu, L., & Li, D. (2019). Source and potential risk assessment of suspended atmospheric microplastics in Shanghai. Science of The Total Environment, 675, 462–471. https://doi.org/10.1016/j.scitotenv.2019.04.110

Liu, K., Wu, T., Wang, X., Song, Z., Zong, C., Wei, N., & Li, D. (2019). Consistent Transport of Terrestrial Microplastics to the Ocean through Atmosphere. Environmental Science & Technology, 53(18), 10612–10619. https://doi.org/10.1021/acs.est.9b03427

Lu, M. (2021). 1.6 Billion disposable masks entered our oceans in 2020. Visual Capitalist. https://www.visualcapitalist.com/1-6-billion-disposable-masks-entered-our-oceans-in-2020/ (Accessed on 28/11/2023)

Ma, J., Chen, F. Y., Xu, H., Jiang, H., Liu, J. L., Li, P., . . . Pan, K. (2021). Face masks as a source of nanoplastics and microplastics in the environment: Quantification, characterization, and potential for bioaccumulation. Environmental Pollution, 288, 6. https://doi.org/10.1016/j.envpol.2021.117748

Mallakpour, S., Azadi, E., & Hussain, C. M. (2021). The latest strategies in the fight against the COVID-19 pandemic: the role of metal and metal oxide nanoparticles. New Journal of Chemistry, 45(14), 6167-6179. https://doi.org/10.1039/d1nj00047k

Mast, J., Van Miert, E., Siciliani, L., Cheyns, K., Blaude, M. N., Wouters, C., . . . Verleysen, E. (2023). Application of silver-based biocides in face masks intended for general use requires regulatory control. Science of the Total Envirnoment, 870, 161889. https://doi.org/10.1016/j.scitotenv.2023.161889

Masselot, P., Sera, F., Schneider, R., Kan, H. D., Lavigne, E., Stafoggia, M., . . . Gasparrini, A. (2022). Differential Mortality Risks Associated With PM2.5 Components A Multi-Country, Multi-City Study. Epidemiology, 33(2), 167-175. https://doi.org/10.1097/ede.0000000000001455

Matuschek, C., Moll, F., Fangerau, H., Fischer, J. C., Zanker, K., van Griensven, M., . . . Haussmann, J. (2020). Face masks: benefits and risks during the COVID-19 crisis. European Journal of Medical Research, 25(1), 8. https://doi.org/10.1186/s40001-020-00430-5

Muensterman, D. J., Cahuas, L., Titaley, I. A., Schmokel, C., De la Cruz, F. B., Barlaz, M. A., . . . Field, J. A. (2022). Per- and Polyfluoroalkyl Substances (PFAS) in Facemasks: Potential Source of Human Exposure to PFAS with Implications for Disposal to Landfills. Environmental Science & Technology Letters, 9(4), 320-326. https://doi.org/10.1021/acs.estlett.2c00019

Mohamed, B. A., Fattah, I. M. R., Yousaf, B., & Periyasamy, S. (2022). Effects of the COVID-19 pandemic on the environment, waste management, and energy sectors: a deeper look into the long-term impacts. Environmental Science and Pollution Research, 29(31), 46438-46457. https://doi.org/10.1007/s11356-022-20259-1

Montalvo, D, Wouters, C., Siciliani, L., Vleminckx, C., Van Miert, E., Waegeneers, N., Van Loco, J., Verleysen, E., Cheyns, K. & Mast, J. (2023). Silver-based biocides and Titanium dioxide particles in face masks for general use. Final report of the TiO2Mask and AgMask COVID-19 projects. Sciensano, Brussels, Belgium, 48 p. https://www.sciensano.be/en/biblio/silver-based-biocides-and-titanium-dioxide-particles-face-masks-general-use-final-report-tio2mask-0 (Accessed on 28/11/2023)

NIOSH (2023). Silver (metal dust and soluble compounds, as Ag). National Institute for Occupational Safety and Health. https://www.cdc.gov/niosh/npg/npgd0557.html (Accessed on 28/11/2023)

O'Brien, S., Rauert, C., Ribeiro, F., Okoffo, E. D., Burrows, S. D., O'Brien, J. W., . . . Thomas, K. V. (2023). There's something in the air: A review of sources, prevalence and behaviour of microplastics in the atmosphere. Science of the Total Environment, 874, 33. https://doi.org/10.1016/j.scitotenv.2023.162193

OSHA (2021). Silver, metal and soluble compounds (as Ag). Occupational Safety and Health Administration. https://www.osha.gov/chemicaldata/519 (Accessed on 28/11/2023)

Park, J., Park, E. H., Schauer, J. J., Yi, S. M., & Heo, J. (2018). Reactive oxygen species (ROS) activity of ambient fine particles (PM2.5) measured in Seoul, Korea. Environment International, 117, 276-283. https://doi.org/10.1016/j.envint.2018.05.018

Peeples, L. (2020). What the data say about wearing face masks. Nature, 586(7828), 186-189. https://doi.org/10.1038/d41586-020-02801-8

Pizarro-Ortega, C. I., Dioses-Salinas, D. C., Severini, M. D. F., Lopez, A. D. F., Rimondino, G. N., Benson, N. U., . . . De-la-Torre, G. E. (2022). Degradation of plastics associated with the COVID-19 pandemic. Marine Pollution Bulletin, 176, 11. https://doi.org/10.1016/j.marpolbul.2022.113474

Prata, J. C., Silva, A. L. P., Duarte, A. C., & Rocha-Santos, T. (2021). Disposable over Reusable Face Masks: Public Safety or Environmental Disaster? Environments, 8(4), 10. https://doi.org/10.3390/environments8040031

Pullangott, G., Kannan, U., Gayathri, S., Kiran, D. V., & Maliyekkal, S. M. (2021). A comprehensive review on antimicrobial face masks: an emerging weapon in fighting pandemics. Rsc Advances, 11(12), 6544-6576. https://doi.org/10.1039/d0ra10009a

Rashid, M. M., Tavcer, P. F., & Tomsic, B. (2021). Influence of Titanium Dioxide Nanoparticles on Human Health and the Environment. Nanomaterials, 11(9), 20. https://doi.org/10.3390/nano11092354

Riediker, M., Zink, D., Kreyling, W., Oberdorster, G., Elder, A., Graham, U., . . . Cassee, F. (2019). Particle toxicology and health - where are we? Particle and Fibre Toxicology, 16, 33. https://doi.org/10.1186/s12989-019-0302-8

RIVM (2017). ConsExpo Web Consumer Exposure models, model documentation. Update for ConsExpo Web 1.0.2. National Institute for Public Health and the Environment. https://doi.org/10.21945/RIVM-2017-0197

Roberts, K.P., Phang, S.C., Wiliams, J.B., Hutchinson, D.J., Kolstoe, S.E., de Bie, J., Williams, I.D. & Stringfellow, A.M. (2021). Increased personal protective equipment litter as a result of COVID-19 measures. Nature Sustainability, 5, 272-279. https://doi.org/10.1038/s41893-021-00824-1

Rodriguez-Garraus, A., Azqueta, A., Vettorazzi, A., & de Cerain, A. L. (2020). Genotoxicity of Silver Nanoparticles. Nanomaterials, 10(2), 27. https://doi.org/10.3390/nano10020251

Sankhyan, S., Heinselman, K. N., Ciesielski, P. N., Barnes, T., Himmel, M. E., Teed, H., . . . Vance, M. E. (2021). Filtration Performance of Layering Masks and Face Coverings and the Reusability of Cotton Masks after Repeated Washing and Drying. Aerosol and Air Quality Research, 21(11), 13. https://doi.org/10.4209/aaqr.210117

Schoonjans, R., Castenmiller, J., Chaudhry, Q., Cubadda, F., Daskaleros, T., Franz, R., . . . Tarazona, J. (2023). Regulatory safety assessment of nanoparticles for the food chain in Europe. Trends in Food Science & Technology, 130, 98-111. https://doi.org/10.1016/j.tifs.2023.01.017

SCSS (2020). Opinion on Titanium dioxide (TiO_2) used in cosmetic products that lead to exposure by inhalation. Scientific Committee on Consumer Safety, SCCS/1617/20. https://health.ec.europa.eu/system/files/2021-11/sccs_o_238.pdf (Accessed on 28/11/2023)

Shabbir, S., Kulyar, M., Bhutta, Z. A., Boruah, P., & Asif, M. (2021). Toxicological Consequences of Titanium Dioxide Nanoparticles (TiO(2)NPs) and Their Jeopardy to Human Population. Bionanoscience, 11(2), 621-632. https://doi.org/10.1007/s12668-021-00836-3

Sharifi, S., Behzadi, S., Laurent, S., Forrest, M. L., Stroeve, P., & Mahmoudi, M. (2012). Toxicity of nanomaterials. Chemical Society Reviews, 41(6), 2323-2343. https://doi.org/10.1039/c1cs15188f

Shen, R. J., Guo, Y. L., Wang, S. J., Tuerxun, A., He, J. Q., & Bian, Y. (2023). Biodegradable Electrospun Nanofiber Membranes as Promising Candidates for the Development of Face Masks. International Journal of Environmental Research and Public Health, 20(2), 21. https://doi.org/10.3390/ijerph20021306

Siivola, K. K., Burgum, M. J., Suarez-Merino, B., Clift, M. J. D., Doak, S. H., & Catalan, J. (2022). A systematic quality evaluation and review of nanomaterial genotoxicity studies: a regulatory perspective. Particle and Fibre Toxicology, 19(1), 24. https://doi.org/10.1186/s12989-022-00499-2

Spennemann, D. H. R. (2022). Environmental Decay of Single-use Surgical Face Masks as an Agent of Plastic Micro-Fiber Pollution. Environments, 9(7), 31. https://doi.org/10.3390/environments9070094

Statista (2023). How we eat, drink and breath microplastics. Statista.com. https://www.statista.com/chart/18299/how-we-eat-drink-and-breathe-microplastics/ (Accessed on 29/9/2023)

Suarez-Torres, J. D., Jimenez-Orozco, F. A., & Ciangherotti, C. E. (2020). The 2-year rodent bioassay in drug and chemical carcinogenesis testing: Sensitivity, according to the framework of carcinogenic action. Toxicology Mechanisms and Methods, 30(6), 462-475. https://doi.org/10.1080/15376516.2020.1760986

Thangavel, P., Park, D., & Lee, Y. C. (2022). Recent Insights into Particulate Matter (PM2.5)-Mediated Toxicity in Humans: An Overview. International Journal of Environmental Research and Public Health, 19(12), 22. https://doi.org/10.3390/ijerph19127511

Thapliyal, J., Bhattacharyya, M., Prakash, S., Patni, B., Gautam, S., & Gautam, A. S. (2022). Addressing the relevance of COVID-19 pandemic in nature and human socio-economic fate. Stochastic Environmental Research and Risk Assessment, 36(10), 3239-3253. https://doi.org/10.1007/s00477-022-02191-5

Tunahan Kaya, A., Yurtsever, M., & Çiftçi Bayraktar, S. (2018). Ubiquitous exposure to microfiber pollution in the air. The European Physical Journal Plus, 133(11), 488. https://doi.org/10.1140/epjp/i2018-12372-7

UNCTAD. Growing plastic pollution in wake of COVID-19: How trade policy can help. UNCTAD. https://unctad.org/es/isar/news/growing-plastic-pollution-wake-covid-19-how-trade-policy-can-help (Accessed on 28/11/2023)

Vercauteren, M., Ting, Z., Janssen, C.R., Asselman, J. (2023). Policy informing brief: Analysis on the link between microplastics, the environment and public health. Ghent University, Belgium, 136 pp. http://hdl.handle.net/1854/LU-01HDMK3KNBHCQVGG1046QJ2XZ1 (Accessed on 28/11/2023)

Verleysen, E., Ledecq, M., Siciliani, L., Cheyns, K., Vleminckx, C., Blaude, M. N., . . . Mast, J. (2022). Titanium dioxide particles frequently present in face masks intended for general use require regulatory control. Scientific Reports, 12(1), 9. https://doi.org/10.1038/s41598-022-06605-w

Wang, X. Y., Okoffo, E. D., Banks, A. P. W., Li, Y., Thomas, K. V., Rauert, C., . . . Mueller, J. F. (2022). Phthalate esters in face masks and associated inhalation exposure risk. Journal of Hazardous Materials, 423, 9. https://doi.org/10.1016/j.jhazmat.2021.127001

Wang, Y., Tian, H. Y., Zhang, L., Zhang, M., Guo, D. D., Wu, W. T., . . . MacIntyre, C. R. (2020). Reduction of secondary transmission of SARS-CoV-2 in households by face mask use, disinfection and social distancing: a cohort study in Beijing, China. Bmj Global Health, 5(5). https://doi.org/10.1136/bmjgh-2020-002794

Weldon, B. A., M. Faustman, E., Oberdörster, G., Workman, T., Griffith, W. C., Kneuer, C., & Yu, I. J. (2016). Occupational exposure limit for silver nanoparticles: considerations on the derivation of a general health-based value. Nanotoxicology, 10(7), 945-956. https://doi.org/10.3109/17435390.2016.1148793

Xie, H. J., Du, J., Han, W. J., Tang, J. H., Li, X. Y., & Chen, J. W. (2021). Occurrence and health risks of semi-volatile organic compounds in face masks. Science Bulletin, 66(16), 1601-1603. https://doi.org/10.1016/j.scib.2021.04.009

Xie, H. J., Han, W. J., Xie, Q., Xu, T., Zhu, M. H., & Chen, J. W. (2022). Face mask-A potential source of phthalate exposure for human. Journal of Hazardous Materials, 422, 7. https://doi.org/10.1016/j.jhazmat.2021.126848

Yamano, S., Takeda, T., Goto, Y., Hirai, S., Furukawa, Y., Kikuchi, Y., . . . Umeda, Y. (2022). No evidence for carcinogenicity of titanium dioxide nanoparticles in 26-week inhalation study in rasH2 mouse model. Scientific Reports, 12(1), 14. https://doi.org/10.1038/s41598-022-19139-y

Zhu, X. Q., Wang, C. X., Duan, X. Y., Liang, B. X., Xu, E. G., & Huang, Z. L. (2023). Micro- and nanoplastics: A new cardiovascular risk factor? Environment International, 171, 14. https://doi.org/10.1016/j.envint.2022.107662

Ziani, K., Ionita-Mindrican, C. B., Mititelu, M., Neacsu, S. M., Negrei, C., Morosan, E., . . . Preda, O. T. (2023). Microplastics: A Real Global Threat for Environment and Food Safety: A State of the Art Review. Nutrients, 15(3), 34. https://doi.org/10.3390/nu15030617

VI COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Norbert FRAEYMAN**; the scientific secretary was Stijn EVERAERT.

CASTELAIN Philippe	Toxicology & human exposure	Sciensano
DELPORTE Cédric	Pharmacognosy, bioanalysis	ULB
DEVRIESE Herman	Prevention & environment	*UZ Leuven*
FRAEYMAN Norbert	Pharmacology	*UGent*
GODDERIS Lode	Occupational medicine & toxicology	*KU Leuven*
HENS Luc	Human ecology	VITO, VUB
MICHEL Olivier	Pneumology	ULB
MOENS Jonas	Pharmacy	Poison centre
RAQUEZ Jean-Marie	Polymer chemistry	*UMons*
SCHOETERS Greet	Environmental health & toxicology	*UAntwerpen*
SPANOGHE Pieter	Phytopharmacy & residue analysis	*UGent*
STEURBAUT Walter	Phytopharmacy & human exposure	*UGent*
VAN LANGENHOVE Lieva	Textile engineering	*UGent*

The following expert was heard but did not take part in writing and endorsing the advisory report:

MAST Jan	Trace elements & nano materials	Sciensano

VII APPENDICES

Appendix 1. Requirements for medical face masks (commercial example).

MEDICAL FACE MASK TESTS AND REQUIREMENTS

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<40 Pa/cm^2		<60 Pa/cm^2
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		• AQL 4% for BFE, PFE, Delta P • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) • 14 masks for Flammability			• Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)		

Nelson Labs
A Sotera Health company
801-290-7500 | nelsonlabs.com

About the Superior Health Council (SHC)

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.hgr-css.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.

www.shc-belgium.be

Health
Food Chain Safety
Environment