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U.S. Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814  
Fax: 301-504-0127  
Email: [CPSCFOIARequests@cpsc.gov](mailto:CPSCFOIARequests@cpsc.gov)  
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May 23, 2024

**Via Box**

**RE:** Freedom of Information Act Request #24-F-00393: I request a copy of the reports and/or presentations provided by University of Cincinnati to CPSC during the last few years regarding:  
1) Risk Assessment Report of Silver Released from Nano-Enabled Consumer Products.

Thank you for your Freedom of Information Act (FOIA) request seeking the above-referenced information from the U.S. Consumer Product Safety Commission (CPSC). On April 18, 2024, you confirmed via email correspondence that you would accept receipt of a draft version of the "Risk Assessment Report of Silver Released from Nano-Enabled Consumer Products," prepared by the University of Cincinnati for CPSC. In response to your amended request, enclosed please find a draft copy of the "Risk Assessment Report of Silver Released from Nano-Enabled Consumer Products."

CPSC considered the foreseeable harm standard when reviewing these records.

If you need any further assistance, or you would like to discuss any aspect of your request, please contact me, or CPSC's FOIA Public Liaison, Robert Dalton ([rdalton@cpsc.gov](mailto:rdalton@cpsc.gov)), via email or at 1-800-638-2772.

*Fees.* We are not charging you fees in this instance to cover the costs to the CPSC in processing this request, performing the file searches, and preparing the information.

Sincerely,

**DAVID  
KAPLOVITZ**

Digitally signed by  
DAVID KAPLOVITZ  
Date: 2024.05.23  
09:27:09 -04'00'

**David Kaplovitz**

**Attorney, Division of Information Access**

**U.S. Consumer Product Safety Commission | Office of the General Counsel**

**4330 East West Highway | Bethesda, MD 20814**

**(301) 504-7708**

**[dkaplovitz@cpsc.gov](mailto:dkaplovitz@cpsc.gov)**

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Enclosure: "Risk Assessment Report of Silver Released from Nano-Enabled Consumer Products."  
(University of Cincinnati) (Draft Version) (20 pgs.)

## Introduction and Scope

Consumers have the potential to be exposed to silver ions and nanoparticles through a wide range of nano-silver enabled products. Silver (Ag) has long been used as an anti-microbial agent; silver oxidizes and releases silver ions, which kill bacteria, a property extensively exploited for commercial products. Silver nanoparticles (Ag NPs), with their greater surface area per mass, have greater antimicrobial activity than larger silver particles (Foldbjerg et al., 2015, as cited in Hansen and Mackevica, 2017). Use of nanosilver allows for better control of the release of free silver ions than other forms of silver (Som et al., 2011), which is the intent of the product. In consumer products, Ag NPs may be incorporated into solid matrices (e.g., plastics, textiles), used as coatings (e.g., home appliances, cutlery, textiles), or be suspended in liquids (e.g., spray cleaners).

Many types of consumer products using nanosilver have been identified, including clothing, cleaning and disinfecting sprays, toys, personal care products, appliances, food storage and preparation products, bedding, and furniture. The extent of consumer use of nanosilver-enabled products is not known. Data on nanosilver product concentrations are limited, and reported concentrations vary widely among and within product categories. Use of nanosilver consumer products may result in human exposure via air, dust, or direct contact with products; therefore, inhalation, ingestion, and dermal routes of exposures are all possible.

This assessment addresses the risk to humans from use of nanosilver-enabled household cleaning sprays. Exposure potential will depend upon the characteristics of the sprays, including the presence of free particles, direct exposure from application, and potential exposure from multiple indirect exposure routes (Wijnhoven et al., 2009a, as cited in U.S. EPA, 2012). Inhalation is expected to be the most significant exposure route for sprays, followed by dermal, and then ingestion (Wardak et al., 2008, as cited in EPA, 2012). For this assessment we focused on inhalation and dermal exposures. Users will inhale droplets of the product produced from spraying. Spraying will generate an aerosol cloud of various sized droplets that will fall with gravity. Dermal contact is expected when the droplets fall on the skin and from contact with cleaning cloths/sponges wet with cleaner.

## Kitchen Cleaning Scenario

This assessment focused on inhalation and dermal exposure to consumers using a spray cleaner to clean kitchen surfaces. We found several spray cleaning products for sale on-line that contain nano-Ag and two were described as kitchen cleaning sprays. The products are sold with a trigger or pump type of spray mechanism.

- Silver Shield Sanitizer from Silver Botanicals. Colloidal<sup>1</sup> Silver MicroCleanser for Hands and Surfaces (<https://silver-botanicals.com/products/silver-shield-sanitizer.html>). “We source our colloidal silver from a premium manufacturer whose end product is a refined nanosilver concentration suspended in distilled water. Our silver particles contain, on average, around 30 atoms (~0.65 nanometers in diameter). Our products contain between 10-30 ppm<sup>2</sup> of

<sup>1</sup> Dispersion of insoluble particles in a medium with diameters between 1 nm to 1 µm.

<sup>2</sup> Assuming the product is mostly water, 1 ppm is essentially equivalent to 1 mg/L.

nanosilver. Both particle size and concentration (ppm) are ideal for our products' intended use.” (<https://silver-botanicals.com/about/about-our-ingredients.html>)

- Colloidal Silver Kitchen & Home Cleaner by Old Factory LLC. “Use as a multipurpose micro-cleaner on virtually any surface in the kitchen, and around the house, on your hands, in the bathroom and any other germ communicable surfaces!” Contains 10-30 ppm nanosilver. <https://oldfactorysoap.com/product/colloidal-silver-kitchen-homecleaner/>

We modeled exposures for users: adults and children six years of age and older. We assumed they would use the spray product to clean hard surfaces in the kitchen (e.g., counters and sink). The ready to use product would be sprayed onto the surfaces, left to sit for a short time, and then the surface would be wiped with a wet cloth or sponge. We assumed that the user does not wear gloves, that their hands and forearms are exposed, and that they remain in the kitchen for a total time of one hour.

We estimated exposure to users via inhalation and dermal routes. Major pathways included:

- Mediated exposure: Emission from spray to aerosolized particles in indoor air
- Contact exposure: Dermal contact with spray

We selected parameter values to represent a reasonable worst-case exposure. We used a combination of high end and central tendency values, assumptions, and defaults to generate deterministic estimates of exposure for users per event, which can be used to estimate longer-term or life-time exposure.

## Model Selection

An extensive review of existing exposure assessment models with the purpose of assessing nanomaterials in consumer products was conducted by the Danish Ministry of the Environment (Danish EPA, 2015). This report also provides information on the exposure algorithms and identifies the most important parameters determining consumer exposure to nanomaterials. Several modeling tools were evaluated, though only some were applicable for consumer exposure. Thus, only the modeling tools developed for consumer exposure are presented below.

### Summary of the exposure assessment tools

A summary comparison of the consumer exposure relevant exposure assessment models for nanomaterials is provided in Table 1. These models are described in detail in the Danish EPA report and appendix documents (Danish EPA 2015a, 2015b).

- NanoRiskCat – A risk categorization tool to be used for screening and communication.
- Swiss Precautionary Matrix – A scoring tool incorporating exposure and hazard potential for banding nanomaterials to determine whether precautionary actions are needed.
- ECETOC Targeted Risk Assessment (TRA) – A screening tool for estimating exposure and risk that provides a rough quantitative output for preselected products and articles. This tool is the preferred approach for REACH when conducting screening-level exposure assessments because of its ease of use.
- ConsExpo – A tool developed by RIVM to evaluate consumer exposure to chemical substances, and it has been used extensively to prepare consumer exposure assessments under REACH.
- Margin of Exposure (MoE) – An approach or framework (not a tool *per se*) developed by the American Cleaning Institute to present exposure information for screening-level risk

assessments of high production volume (HPV) chemicals through manufacturing and use of consumer products.

Table 1. Comparison of nanomaterial exposure models for consumer exposure.

	NanoRiskCat	Swiss Precautionary Matrix	ECETOC TRA	ConsExpo	Margin of Exposure
<b>Tier (0, 1, 2)*</b>	Pre-0	Pre-0	0/1	0/1/2	NA
<b>Inhalation module</b>	Exposure addressed, but not by route	Exposure addressed, but not by route	Yes	Yes	Yes
<b>Dermal module</b>			Yes	Yes	Yes
<b>Oral module</b>			Yes	Yes	Yes
<b>Level of quantification</b>	Qualitative	Semi- quantitative	Quantitative	Quantitative	Quantitative
<b>Metric applied Results</b>	NA Exposure categorization	Mass Score as either cautionary or non-cautionary	Mass Quantitative	Mass Quantitative	Mass Margin of exposure

\*Tier 0 – Lower level assessment tool that does not require training beyond the written manual to run.

\*Tier 1 – Higher level assessment tool (beyond Tier 0) that operates with default values but has the possibility of entering specific values. Some experience on exposure estimation is needed for using these tools to get meaningful output.

\*Tier 2 – Highest level assessment tool (beyond Tiers 0 and 1), which involves more detailed calculations and input parameters. Expert knowledge is required in specifying proper input parameters to get meaningful output.

All the nano-specific exposure assessment models, except for ConsExpo, are lower tier tools with less complexity that reportedly provide conservative assessments. The qualitative and semi-quantitative tools (Pre-0) do not provide exposure estimates, whereas the quantitative tools provide a mass-concentration exposure estimate. It should be noted that these quantitative tools do not provide particle size and surface area exposure estimates, which could be important in assessing risk of nanomaterials.

Three of the general assessment tools (ECETOC TRA, ConsExpo, and MoE) have built-in quantitative scenarios for nanomaterials in spray consumer products. However, these consumer product spray specific models only contain models for inhalation and dermal exposures, not oral. Of these three assessment tools, only ConsExpo provides for aerosol particle-size distribution inputs.

### Selection of Exposure Model

Based on this evaluation of potential modeling tools, we decided to use ConsExpo for assessing nano-Ag exposure in consumer cleaning products. This decision is based on the fact that only ConsExpo provides for aerosol particle-size distribution inputs and that ConsExpo has default values available for consumer cleaning spray products. For example, the ConsExpo Cleaning Product Fact Sheet (RIVM, 2018, section 4.2.2) describes default values for our kitchen surface cleaning scenario.

ConsExpo has two modeling tools available for assessing nanomaterials in consumer cleaning spray products, i.e., ConsExpo Web and ConsExpo Nano. Since the exposure modules are the same in both modeling tools, we decided to use ConsExpo Web (<https://www.rivm.nl/en/consexpo/consexpoweb>) for our exposure assessments (Tables 3-5).

## Concentrations in Cleaning Sprays

We identified a number of studies in the experimental literature that measured silver concentrations in cleaning products. These studies primarily measured total silver content (not the nanosilver fraction). Table 2 lists measured total silver (Ag) concentrations for spray cleaning products. Some of these studies also measured concentrations of Ag sprayed into the air. Reported concentrations for two commercial products that are available for purchase online are also listed in Table 2. Below we briefly describe each of these studies.

Calcaterra et al. (2020)

Calcaterra et al. evaluated aerosol exposure of silver nanoparticles from two consumer spray products (disinfectant spray and dietary supplement). Aerosol and bulk product samples were analyzed by single-particle inductively coupled plasma mass spectrometry (SP-ICP-MS). The disinfectant spray product Silver Shield Sanitizer (Silver Botanicals, Austin, Texas) was evaluated in this study. The mean bulk product Ag concentration before spraying from three samples was 1.793 mg/L, whereas the mean aerosolized Ag concentration over a 20 min sampling time in the glovebox experiment was 0.0273 µg/L (~15 cm from product spray emission source).

Calderon et al. (2017)

Calderon et al. investigated near field airborne exposures from silver sprays using a 124 L glove box with measurements taken ~30 cm from the source in order to simulate an untreated aerosol that would be present near a consumer's breathing zone. They measured the concentration of metals in each product and reported a concentration of 1.21 mg-Ag/L for product S130S (a nanosilver surface cleaner). Particle loss due to settling was expected to be low. The authors estimated the total airborne mass concentration of Ag in the cleaning spray to be 11 ng/m<sup>3</sup> [presented in Figure 2].

Quadros et al. (2013)

Quadros et al. assessed release from a variety of children's articles and consumer products (e.g., a plush teddy bear, infant/toddler training cups, a disinfecting spray, blanket, sleepsuit, breast milk storage bags) under multiple conditions to mimic intended use. They measured a silver concentration of 27.1 mg-Ag/L for the disinfecting spray. Measured ambient aerosol concentrations from product use in a 36 m<sup>3</sup> room were not significantly different than background.

Quadros and Marr (2011)

Quadros and Marr measured the concentration of Ag in a surface disinfectant spray to be 27.5 mg/L (ppm) in the liquid phase (product was advertised to have 30 ppm), with nearly all the silver in ionic form. The disinfecting spray produced a bimodal size distribution of all particles, with peaks around 20 nm and 500 nm. The pump spray produced aerosols with "very low" silver concentrations, which the authors attributed to the pump spray producing large droplets that settled too quickly to be sampled and detected, and they therefore concluded the Ag NPs do not present much of an inhalation risk. Moreover, it was found that these products released 0.24 to 56 ng of Ag/spray and the presence of Ag NPs was confirmed, although the majority of the silver ranged from 1 to 2.5 µm in diameter.

Rogers et al. (2018)

In the Rogers et al. study of commercially available spray disinfectants (surface sanitizers) and dietary supplements, the authors measured total silver concentrations in the products that ranged from 0.54 to

960 mg-Ag/L. Ag NPs were found in all product suspensions, with primary particles falling into two populations - smaller particles (<5 nm) and larger particles (20 to 40 nm). Two sanitizing sprays (products 8 and 20) had total Ag concentrations of 6.12 mg/L and 8.72 mg/L, respectively.

Tulve et al. (2015)

Tulve et al. identified 165 consumer products that claimed nanosilver content, and analyzed 19 of them for silver content, including a spray cleaner and a disinfecting spray. Total Ag concentration measured with ICP was 24.4 mg-Ag/L for the spray cleaner and 25.8 mg-Ag/L for the disinfecting spray. Both measured concentrations were similar to the manufacturer's reported content of 30 and 20 mg-Ag/L, respectively. Ag NPs were present in both agglomerated and dispersed states. For the spray cleaner, the ionic Ag concentration (measured with an ion selective electrode) was 29.8 mg/L, indicating that the silver in this product was in a dissolved and not particulate form. The disinfecting spray had a lower ionic Ag concentration, 7.7 mg/L, indicating that this product was mostly in a particulate form.

Wasukan et al. (2015)

Wasuken et al. measured total dissolved Ag concentration (using wet acid digestion and graphite furnace atomic absorption spectrophotometry) analysis for 20 commercial nanosilver products purchased in Thailand. Two all-purpose anti-bacterial sprays were tested; product A2 had an initial Ag concentration of 94 mg/L and product A4 had an initial Ag concentration of 0.094 mg/L. The study also evaluated *in vitro* dermal penetration of Ag using a polyethersulfone (PES) membrane through a Franz cell and reconstructed human epidermis (RhE) tissue and OECD Test Guideline 439 was used to measure *in vitro* skin irritation.

Hagendorfer et al. (2010)

Hagendorfer et al. measured a concentration of 1040 mg-Ag/L in a commercially available water-based nano-Ag spray product, which corresponded closely with the manufacturer's claim of 1000 mg-Ag/L. However, the type of product was not mentioned. The authors also measured particle size distributions in controlled spray experiments using gas propellant and pump type spray dispensers. The pump spray produced no measurable nanoparticle release.

## Selection of Product Ag Concentration for Modeling

The Ag concentration of surface cleaning spray products made with nano Ag will be product dependent. Measured concentrations in various nano-Ag cleaning or disinfecting spray products investigated were discussed above. The authors generally reported the total Ag concentration (mass). These studies reported total Ag concentrations ranging from <0.1 to 1040 mg-Ag/L (Table 2).

We found two multi-purpose nano-Ag cleaning sprays for sale online (see Table 2). One is described as a kitchen and home cleaner and the other as a "MicroCleanser" for hands and surfaces. Both reported nano-Ag concentrations ranging from 10 to 30 mg-Ag/L and are described similarly as colloidal silver cleaners that disperse "around 1 quadrillion nanosilver particles with every spray" (Old Factory LLC 2022). The spray products have different names, and one of them (Silver Shield Sanitizer) has the same name as the spray tested by Calcaterra and colleagues. Calcaterra et al. (2020) measured the silver concentration of Silver Shield Sanitizer at 1.8 mg-Ag/L, which is about an order of magnitude lower than the 10-30 mg-Ag/L concentration claimed on the seller's website.



Table 2. Measured total Ag concentrations in spray cleaning and disinfection/antibacterial products.

Product Type/Description	Product Concentration (mg-Ag/L)	Source
<b>Experimental Studies</b>		
Disinfectant Spray	1.8 (measured)	Calcaterra et al. (2020) Silver Shield Sanitizer Seller reported concentration 15 mg/L
Surface Cleaner	1.2 (measured)	Calderon et al. (2017) Product Code S13OS
Disinfecting Spray	27.1 (measured)	Quadros et al. (2013)
Surface Disinfectant Spray	27.5 (measured)	Quadros and Marr (2011) Advertised concentration 30 mg/L
Spray Cleaner	24.4 (measured)	Tulve et al. (2015) Manufacturer reported 30 mg/L
Disinfectant Spray	25.8 (measured)	Tulve et al. (2015) Manufacturer reported 20 mg/L
Antibacterial Spray	19.3 (measured)	Tulve et al. (2015)
Colloidal Ag sanitizing spray	6.1 (measured)	Rogers et al. (2018) Product 8
Colloidal Ag sanitizing spray H2O2	8.7 (measured)	Rogers et al. (2018) Product 20
All-purpose Antibacterial Spray	94.0 (measured)	Wasukan et al. (2015) Product A2
All-purpose Antibacterial Spray	0.094 (measured)	Wasukan et al. (2015) Product A4
Unknown Spray	1040.0 (measured)	Hagendorfer et al. (2010) Commercially available water based nano Ag spray product. Manufacturer's specification was 1000 mg/L
<b>Products Found for Sale</b>		
Colloidal Silver Cleaning Spray. Trigger spray bottle	10-30 (reported)	Product for sale online. Old Factory, LLC. <a href="https://oldfactorysoap.com/new-product-colloidal-silver-cleaning-spray/">https://oldfactorysoap.com/new-product-colloidal-silver-cleaning-spray/</a> <a href="https://oldfactorysoap.com/product/colloidal-silver-kitchen-home-cleaner/">https://oldfactorysoap.com/product/colloidal-silver-kitchen-home-cleaner/</a>
Silver Shield Sanitizer. Trigger spray bottle	10-30 (reported)	Product for sale online. Silver Botanicals <a href="https://silver-botanicals.com/products/silver-shield-sanitizer.html">https://silver-botanicals.com/products/silver-shield-sanitizer.html</a>

Wasuken et al. (2015) reported the highest Ag concentration in the literature for cleaning and disinfecting spray products. They measured Ag concentrations in 20 personal care nanoproducts purchased online or at department stores in Thailand. None were specifically labeled as cleaning products, but two were described as "all-purpose anti-bacterial sprays" and therefore, might be used for cleaning. The Ag concentration of one of the products was 94 mg/L.

We considered the concentration of 1040 mg-Ag/L reported by Hagendorfer et al. (2010) for a nano-Ag spray product to be an outlier. The type of product was not specified, and the concentration is far greater than the advertised and measured concentrations of cleaning sprays found in the literature and online. Note that the Danish EPA disinfectant pump spray nano-Ag assessment (Scenario 14) cited the

Hagendorfer paper for their assumed worst-case concentration of 1% by weight (Danish EPA, 2015b). However, the concentration of 1040 mg-Ag/L that was reported by Hagendorfer is actually 0.1%, not 1% by weight.

## Model Input Parameters

### Parameters for ConsExpo Inhalation Model

A major pathway of exposure for surface cleaning spray products is inhalation of respirable aerosol particles. Inhalation exposure estimates for nonvolatile aerosol particles like Ag are driven by a variety of exposure parameters that are associated with the release of nano-Ag from the spray bottle, including population and environmental characteristics, and characteristics of the nano-Ag particles in the spray products. The **exposure to spray-spraying model** in ConsExpo is used to estimate inhalation exposure to nonvolatile substances in cleaning spray products. The web version of the model has built-in default values, and we have listed these in the first row of Tables 3-5 below. RIVM also provides a series of Fact Sheets to be used with the ConsExpo models that contain default parameter values and explanations, many of which are drawn from a 2009 RIVM validation study (Delmaar and Bremmer, 2009). The most recent and relevant Fact Sheet to this scenario is the updated 2018 cleaning products Fact Sheet with an update regarding airborne fraction (Meesters et al., 2018). We also consulted the 2006 disinfectant products Fact Sheet (Prud'Homme de Lodder et al., 2006), and the 2014 general default parameters document (Te Biesebeek et al., 2014). In addition, we considered relevant exposure factors developed by the U.S. EPA in their Exposure Factors Handbook (U.S. EPA, 2011), as well as parameter values used by others as reported in nanosilver assessments from the literature; in particular, the 2018 Danish EPA biocides assessment (Danish EPA, 2018).

### Parameters to Estimate Release for ConsExpo exposure to spray-spraying model

Table 3 contains input parameters (ConsExpo defaults and parameters from relevant publications) that are needed to estimate the release from spray cleaners in the ConsExpo Web **exposure to spray-spraying model**. These parameters and selected values are described below.

- **Frequency of use (times/yr)** – Frequency of product use is defined as the number of times per year the cleaning spray product is used. The RIVM 2006 Disinfectants Products Fact Sheet (Prud'homme de Lodder et al., 2006) provides a default value of daily use (365 times/yr). This default value is supported by a survey performed by Garcia-Hidalgo et al. (2017), which applies to cleaning kitchen surfaces. This value is also the default value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018) and was used in the Danish EPA 2018 Biocides in Spray Products Assessment of Ecolab Micro-Quat Extra<sup>3</sup> (Danish EPA, 2018). A default of daily use is also consistent with the U.S. EPA Exposure Factors Handbook value of 7 times/week for kitchen sink cleaning (U.S. EPA, 2011 – chapter 17). Therefore, a frequency of use of **365 times/yr** was selected for the ConsExpo simulations.
- **Spray duration (min)** – Spray duration is defined as the total or net time spent actively spraying the product (Delmaar and Schuur, 2016). This definition and the corresponding default value were revised from the RIVM 2006 Disinfectants Products Fact Sheet (Prud'homme de Lodder et al., 2006) wherein spray duration had been defined as the total time of the spray activity (including pauses during intermittent spraying actions). The updated spray duration value is

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<sup>3</sup> Active ingredients were benzalkonium chloride and didecyl dimethyl ammonium chloride.

based upon the amount of product that needs to be applied to the surface (22 g; Weerdesteinjm et al., 1999) and the mass generation rate of the spray (1.6 g/s; Delmaar and Bremmer, 2009). This calculation yields a net spraying time of 14 s (0.23 min). A value of **0.23 min** was used in our assessment, which is also the value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018).

- **Exposure duration (min)** – Exposure duration is defined as the total amount of time the person will stay in the room during and for some time after completing the cleaning task. For this assessment we used a value of **60 min**, which was recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018). This value is based on expert judgement. Sixty minutes was also used by the Danish biocide assessment (Danish EPA, 2018). The U.S. EPA Exposure Factors Handbook lists event durations for a variety of cleaning tasks including cleaning kitchen sinks (10 min) and wiping kitchen counters (10 min) (U.S. EPA, 2011 – Chapter 17), and provides support for a total time in the kitchen of 60 min to include active cleaning and some additional time after completing the cleaning tasks.
- **Weight fraction** – Based on studies reported in the literature, the total Ag concentration of surface cleaning spray products ranged from <0.1 to 94 mg/L (Table 1). For this screening assessment, we chose to use a silver concentration of **94 mg-Ag/L** (or **weight fraction of 0.000094**) in our ConsExpo model simulations. This value is at the upper range of reported and measured Ag concentrations for cleaning spray products, and we believe represents an upper concentration for cleaning products available to U.S. consumers.
- **Mass generation** – Mass generation rate is defined as the active substance mass that is generated during the net spraying time. Mass generation rates were experimentally determined by Delmaar and Bremmer (2009) and Tuinman (2004, 2007). Delmaar and Bremmer (2009) determined a mass generation rate of 1.6 g/s for all-purpose cleaners, and Tuinman (2004, 2007) determined the 75<sup>th</sup> percentile to be 1.6 g/s for trigger spray products. Since the experimental values were similar, the selected mass generation value was **1.6 g/s** for the ConsExpo simulations. This value is also the default value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018).

Table 3. Inhalation input parameters related to release of nano-Ag from cleaning products.

Frequency of Use (times/yr)	Spray Duration (min)	Exposure Duration (min)	Weight Fraction	Mass Generation Rate (g/s)	Source
365	0.51	60	NA	0.8	Default ConsExpo Web
365	0.23	60	NA	1.6	Meesters et al. (2018) Cleaning Products Fact Sheet - Table 8.5: All purpose cleaning spray
NA	0.1	NA	NA	1.6	RIVM (2009) ConsExpo Spray Model
365	0.41 (Danish EPA) 0.1 (Ecolab Micro-Quat Extra)	60	NA (active ingredient benzalkonium chloride)	0.78	Danish EPA (2018) Ecolab Micro-Quat Extra (Scenarios 4 and 5, Table 6-19)
NA	NA	NA	0.000094	NA	Wasukan et al. (2015) Product A2 (See Table 1)
<b>365</b>	<b>0.23</b>	<b>60</b>	<b>0.000094</b>	<b>1.6</b>	<b>Recommended Values</b>

NA = Not Available

Parameters for Population and Environmental Characterization for ConsExpo exposure to spray-spraying model

Table 4 contains input parameter information for population and environmental characteristics needed in the ConsExpo model. These parameters and selected values are described below.

- Body weight** – Body weight is defined as the average weight of a person for a given age group. Values recommended for adults in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018) and the Danish biocides assessment (Danish EPA, 2018) are 68.8 kg and 65 kg, for males and females respectively. We used the U.S. EPA recommended mean body weight values obtained from the U.S. EPA Exposure Factors Handbook for our ConsExpo simulations (Table 9-1 in U.S. EPA, 2011). These values are **31.8 kg for ages 6 to < 11 years, 56.8 kg for ages 11 to < 16 years, 71.6 kg for ages 16 to < 21 years, and 80.0 kg for ages 21+ years.**
- Inhalation rate** – The inhalation rate is defined as the rate at which a person inhales air over time. Default values recommended for adults in the ConsExpo Web model (Delmaar and Schuur, 2016) and used in the Danish biocides assessment (Danish EPA, 2018) were 24.1 L/min and 20.8 L/min, for males and females, respectively. We used the U.S. EPA recommended mean values for short-term light intensity activity with males and females combined because we felt it was more representative of the U.S. scenario (U.S. EPA, 2011). These values are **11 L/min for ages 6**

**to < 11 years, 13 L/min for ages 11 to < 16 years, 12 L/min for ages 16 to < 21 years, and 12.5 L/min for ages 21+ years.**

- **Room Volume** – The room volume for a kitchen scenario was used for the exposure assessment. The 2018 RIVM Cleaning Products Fact Sheet (Meesters et al., 2018) recommends a kitchen room volume of 15 m<sup>3</sup> (Table 8.5: All-purpose cleaning spray). Kitchen sizes vary widely, and the U.S. EPA Exposure Factors Handbook does not provide a recommendation for kitchen room volume. Using a relatively smaller value for the kitchen room size provides for a more conservative (health protective) exposure estimate. Therefore, we used **15 m<sup>3</sup>** for use in the ConsExpo simulations.
- **Room Height** – The room height used is for a standard kitchen scenario. A standard room height of 2.5 m was provided in the ConsExpo General Fact Sheet (Te Biesebeek et al., 2014) and the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018). The Danish biocides assessment (Danish EPA, 2018) used this value as the default for a kitchen scenario. This is approximately 8 ft, which is a common room height in the U.S. and therefore, **2.5 m** was selected.
- **Ventilation rate** – The ventilation rate is defined as the number of total air changes in the room per unit time. The ConsExpo Web default is 2.5 air changes/h (ACH), which is consistent with the 2018 RIVM Cleaning Products Fact Sheet (Meesters et al., 2018) and what was used in the Danish biocide assessment (Danish EPA, 2018). The U.S. EPA Exposure Factors Handbook (Table 19-1 Building Characteristics) lists a median air exchange value, based on all U.S. regions and various housing types, of 0.45, which is significantly lower than the ConsExpo default value. ASHRAE recommends a minimum of 0.25 ACH (U.S. EPA 2022 [<https://www.epa.gov/indoor-air-quality-iaq/how-much-ventilation-do-i-need-my-home-improve-indoor-air-quality>]). Murray & Burmaster (1995) recommend 0.76 ACH for U.S. housing stock, whereas Jayjock and Havics (2018) recommend 0.4 ACH (25<sup>th</sup> percentile) from a more recent exhaustive study of interzonal room ventilation rates. We selected the Jayjock and Havics recommended air exchange rate of **0.4 ACH** to provide for a more reasonable (health protective) exposure estimate. This value is similar to the air exchange rate of 0.35 ACH used by the CPSC staff in a recent study modeling reactive sulfur emissions from problem drywall.

Table 4. Inhalation input parameters related to population and environmental characteristics.

Body Weight (kg)	Inhalation Rate (L/min)	Room Volume (m <sup>3</sup> )	Room Height (m)	Ventilation Rate (air changes per hr)	Source
68.8	24.1	15 (kitchen)	2.5	2.5	Default ConsExpo Web
NA	NA	15 (kitchen)	2.5 (kitchen)	2.5 (kitchen)	Meesters et al. (2018) Cleaning Products Fact Sheet - Table 8.5 All purpose cleaning spray.
65	20.8	15 (default)	2.5 (default)	2.5 (default)	Danish EPA (2018)
		20.3 (exper.)	2.5 (exper.)	0.5 (exper.)	Ecolab Micro-Quat Extra Scenario 4 and Scenario 5 (default and experimental setup parameter values)
NA	NA	NA	NA	0.76	Murray & Burmaster (1995) U.S. housing stock, all regions and seasons
31.8 (for ages 6 to <11)	11 (for ages 6 to <11)	NA	NA	0.45 (median based on all US regions and various housing types)	U.S. EPA (2011). Exposure Factors Handbook. Table 19-1, Building Characteristics; Table 8-1 Body Weight, Table 6.2, Inhalation Rates (short term, light intensity, mean values);
56.8 (for ages 11 to <16)	13 (for ages 11 to <16)			0.18 (10 <sup>th</sup> percentile).	Ventilation rates based on Koontz and Rector (1995);
71.6 (for ages 16 to <21)	12 (for ages 16 to <21)				Persily et al. (2010)
80 (for adults 21+)	12-13 (for adults 21+)				ASHRAE Standard 62.2-2016 as cited by U.S. EPA (2022)
NA	NA	NA	NA	0.25	Jayjock & Havics (2018)
NA	NA	NA	NA	0.4 (25% percentile) 0.7 median and 0.6 mean	
<b>31.8 (for ages 6 to &lt;11)</b>	<b>11 (for ages 6 to &lt;11)</b>	<b>15</b>	<b>2.5</b>	<b>0.4</b>	<b>Recommended Values</b>
<b>56.8 (for ages 11 to &lt;16)</b>	<b>13 (for ages 11 to &lt;16)</b>				
<b>71.6 (for ages 16 to &lt;21)</b>	<b>12 (for ages 16 to 21+)</b>				
<b>80 (for adults 21+)</b>	<b>12-13 (for adults 21+)</b>				

NA = Not Available

Parameters Related to Product Characteristics for ConsExpo exposure to spray-spraying model  
Table 5 contains model input parameters for the characterization of nano-Ag particles. Some of these parameters are used to estimate inhalation and oral exposure via secondary ingestion and calculate lung deposition of particles. Selected values are described below.

- **Airborne fraction** – The airborne fraction is defined as the fraction of the sprayed aerosol that is respirable particles available for inhalation. Delmaar and Bremmer (2009) experimentally determined the airborne fraction for cleaning spray products to range from 0.006 to 0.18 (0.6% to 18%). Bremmer et al. (2006) recommended a default value of 0.2 (18%). In 2018, RIVM in an

Erratum of the Cleaning Products Fact Sheet recommended that the default value for all purpose cleaners be scaled with a factor of 0.03 to complement the initial particle size distributions from the work of Delmaar and Bremmer (2009) and RIVM (2010), resulting in a recommended default value of 0.006 for all purpose cleaner trigger sprays (Meesters et al., 2018). We used the recommended value of **0.006** from the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018).

- **Density nonvolatile** – Density of nonvolatile substances is defined as the density of the aerosol droplets that become airborne. Together with the droplet diameter, the aerosol density determines the time that the aerosol is airborne and available for inhalation. The density of salts generally ranges between 1.5 to 3.0 g/cm<sup>3</sup> and for dilute substances a density of 1.0 g/cm<sup>3</sup> is generally assumed (Meesters et al., 2018). The 2018 RIVM Cleaning Products Fact Sheet specifically recommended using a default of 1 g/cm<sup>3</sup> for all-purpose spray cleaners (Meesters et al., 2018). This default is based on the work of Delmaar and Bremmer (2009) who based their estimate on the elemental composition of the non-volatile compounds in all-purpose cleaners. The default is further supported by the work of Calderon et al. (2017), which measured the density of a nanosilver surface cleaner at 1.05 g/cm<sup>3</sup>. We selected the cleaning product default value of **1 g/cm<sup>3</sup>** for use in the ConsExpo simulations.
- **Inhalation cutoff diameter** – The inhalation cutoff diameter is defined as the diameter below which the sprayed particles can be inhaled and reach the lower areas of the lungs (alveolar region). Aerosol particles with a diameter larger than this cut-off are assumed to be deposited in the higher parts of the respiratory tract and cleared via the gastrointestinal tract, leading to oral exposure. The inhalation cut-off diameter is only an approximation of the complex process of deposition of particles in the lung. In practice, its value is suggested to range between 10 to 15 µm. The most used value in model simulations is 15 µm. Thus, the selected inhalation cutoff diameter value for cleaning spray products used in the ConsExpo simulations was **15 µm**.
- **Aerosol diameter distribution** – The aerosol diameter distribution is defined as the (mass-based) diameter distribution of the aerosol particles or droplets immediately after they are sprayed. The ConsExpo user has a choice of two parametric distribution functions: normal or log normal. For both distributions an average aerosol particle diameter (mean or median) and a distribution width (standard deviation or coefficient of variation) must be specified. In addition, the maximum aerosol particle diameter that is produced by the spray needs to be given. Delmaar and Bremmer (2009) determined that a log normal distribution best fit experimental data for cleaning spray products. Thus, a **log normal distribution** with a median and coefficient of variation was selected for the ConsExpo simulations.
- **Median diameter** – The mass median aerosol particle diameter value measured in the RIVM spray model validation study (Delmaar and Bremmer, 2009) is 2.4 µm and is the default value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018). This value was also used in the Danish biocides assessment (Danish EPA, 2018). With no specific data available, a median aerosol particle diameter value of **2.4 µm** was selected for the ConsExpo simulations.
- **Arithmetic coefficient of variance** – The arithmetic coefficient of variance is defined as the distribution variance around the median aerosol particle diameter. The value determined in the Delmaar and Bremmer (2009) spray model validation study for nano-Ag cleaning spray products was 0.37. This value is also the default value recommended in the RIVM 2018 Cleaning Products

Fact Sheet (Meesters et al., 2018) and the Danish biocides assessment (Danish EPA, 2018). Thus, an arithmetic coefficient of variance value of **0.37** (with a median diameter of 2.4  $\mu\text{m}$ ) was selected for the ConsExpo simulations.

- **Maximum diameter** – The maximum diameter is defined as the upper limit for inhalation of aerosol particles. It is recommended that the maximum particle diameter should not be set too high (preferably <50  $\mu\text{m}$ ), since only inhalable particles are relevant in the ConsExpo simulations. We used a maximum diameter default value of **50  $\mu\text{m}$** .

*Table 5. Inhalation input parameters related to characteristics of the nano-Ag particles in cleaning products.*

Airborne Fraction	Density Nonvolatile (g/cm <sup>3</sup> )	Inhalation Cutoff Diameter ( $\mu\text{m}$ )	Aerosol Diameter Distribution	Median Diameter ( $\mu\text{m}$ )	Arithmetic Coefficient of Variance	Maximum Diameter ( $\mu\text{m}$ )	Source
0.008	1.8	15	log normal	7.7	1.9	50	Default ConsExpo Web
0.2 [Table 12 (2006) and Table A1 (2018)]	1.8 [Table 64 (2006)]	15 [Table A1 (2018), Section 2.3.1 (2006)]	log normal	100 [Table A1 (2018)]	0.6 [Table A1 (2018)]	NA	Bremmer et al. (2006)
0.006 [Erratum Table 2]	1 [Table 8.5]	15 [Table 8.5]	log normal	2.4 [Table A1]	0.37 [Table A1]	NA	Meesters et al. (2018) Cleaning Products Fact Sheet with September 2018 Erratum RIVM (2009)
0.006	1.0	NA	log normal	2.4	0.37	NA	Danish EPA (2018)
0.2	1.8	15 (ConsExpo default) 10 (experimental)	log normal	2 [Section 8 Discussion, page 56]	0.6	50	Danish EPA (2018)
<b>0.006</b>	<b>1.0</b>	<b>15</b>	<b>log normal</b>	<b>2.4</b>	<b>0.37</b>	<b>50</b>	<b>Recommended Values</b>

### Parameters for ConsExpo Dermal Model

The **direct product constant - constant rate** loading model in ConsExpo is used to calculate dermal exposure from spray cleaning products that are directed towards a surface. Dermal exposure is based on the exposed skin area, fractional weight of the active substance in the spray product, contact rate of the spray product, and retention of the active substance.

Parameters for ConsExpo direct product constant - constant rate loading model

Table 6 contains the model input parameters for the dermal model. The input parameters and selected values are described below.

- **Exposed skin area (cm<sup>2</sup>)** – The exposed skin area is defined as the exposure area of unprotected skin when using a spray product (hands and forearms). The ConsExpo General Fact Sheet (Te Biesebeek et al., 2014) states an exposed skin area of 2200 cm<sup>2</sup> (900 cm<sup>2</sup> for hands and 1300 cm<sup>2</sup> for forearms). This value is also the default value recommended in the RIVM 2018 Cleaning



Products Fact Sheet (Meesters et al., 2018). The Danish biocides assessment (Danish EPA, 2018) used exposed skin area for hands and head. We calculated the skin surface area of the hands and forearms, based on values from the U.S. EPA Exposure Factors Handbook (U.S. EPA, 2011). Arm values were divided by 2 to approximate the skin area of forearms as was done by Te Biesebeek et al., 2014, Table 33. The resulting values are **1265 cm<sup>2</sup> (hands and forearms ages 6 to <11)**, **1855 cm<sup>2</sup> (hands and forearms ages 11 to <16)**, **2175 cm<sup>2</sup> (hands and forearms ages 16 to <21)**, **2358 cm<sup>2</sup> (the average of males and females 21+ [2640 cm<sup>2</sup> (hands and forearms males 21+), 2075 cm<sup>2</sup> (hands and forearms females 21+)]**.

- **Weight fraction** – The weight fraction of the active substance (nano-Ag) is product dependent. Based on studies reported in the literature, the total Ag concentration of surface cleaning spray products ranged from <0.1 to 94 mg/L (Table 1). For this screening assessment, we chose to use a silver concentration of **94 mg-Ag/L (or weight fraction of 0.000094)** in our ConsExpo model simulations. This value is at the upper range of reported and measured Ag concentrations for cleaning spray products, and we believe represents an upper concentration for cleaning products available to U.S. consumers.
- **Contact rate (mg/min)** – The contact rate is defined as the rate at which the active substance is deposited on the skin surface (mg/min). ECHA (2015) described a contact rate for non-professional hand-held trigger sprays of 36.1 mg/min for hands and forearms, and 9.7 mg/min for legs and feet (ECHA, 2015 as cited in Meesters et al., 2018). This yields a total contact rate of 46 mg/min. This is the default value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018) and was used in the Danish biocides assessment (Danish EPA, 2018). We used this recommended default of **46 mg/min** in our ConsExpo Web simulations.
- **Release duration (min)** – The release duration is defined as the time that the active substance is available to deposit on the skin. This time includes the net spraying time and the time between spraying events. Thus, the dermal exposure release rate is not equal to the net spray duration for the inhalation of spray products. In our assessment we assume the release rate is twice the net spray duration or **0.46 min**. This is the default value recommended in the RIVM 2018 Cleaning Products Fact Sheet (Meesters et al., 2018).
- **Retention factor** – The retention factor is defined as the amount of active substance that penetrates the skin following deposition. To be conservative, we assumed that dermal uptake is 100% (retention factor of **1**), or that 100% of the deposited active substance will penetrate the skin.

Table 6. Dermal input parameters.

Exposed Area (cm <sup>2</sup> )	Weight Fraction	Contact Rate (mg/min)	Release Duration (min)	Retention Factor	Source
2200 (hands and forearms)	NA	46	0.51	1	Default ConsExpo Web
2200 (hands and forearms)	NA	46	0.46 (assumed twice spray duration of 0.23)	1	Meesters et al. (2018) [Cleaning Products Fact Sheet Tables 8.5 and 8.6]
NA	0.000094	NA	NA	NA	Wasukan et al. (2015) Product A2 (See Table 1)
1582 (hands and head ages 16 to 21) 2537 (hands and head males 40 to < 50) 2076 (hands and head females 40 to < 50) 1265 (hands and forearms ages 6 to <11) 1855 (hands and forearms ages 11 to <16) 2175 (hands and forearms ages 16 to <21) 2358 cm <sup>2</sup> (hands and forearms 21+)	NA	46	0.41 (ConsExpo default) 0.1 (from experimental setup)	1	Danish EPA (2018) [Danish EPA (2015) Exposure Appendix Scenario 14 for exposed skin ]  U.S. EPA (2011). Exposure Factors Handbook. Table 7-2 (Arms and Hands)*
<b>1265 (hands and forearms ages 6 to &lt;11) 1855 (hands and forearms ages 11 to &lt;16) 2175 (hands and forearms ages 16 to &lt;21) 2358 cm<sup>2</sup> (hands and forearms 21+)</b>	<b>0.000094</b>	<b>46</b>	<b>0.46</b>	<b>1</b>	<b>Recommended Values</b>

NA = Not Available

\* Arm values were divided by 2 to convert to forearms (Te Biesebeek et al., 2014, Table 33)

## ConsExpo Simulation Results

### Summary of ConsExpo Input and Population Parameters

A summary of the input parameters used in the ConsExpo simulations is provided in Table 7. The derivation of these parameter values was previously presented.

*Table 7. Summary of ConsExpo input parameters.*

Input Parameters	Value	Units	Source
<b>Product</b>			
Weight fraction	9.4e-5	fraction	Wasukan et al., 2015
Frequency of use	365	times per year	Meesters et al., 2018
<b>Inhalation</b>			
Spray duration	0.23	min	Meesters et al., 2018
Exposure duration	60	min	Meesters et al., 2018
Room volume	15	m <sup>3</sup>	Meesters et al., 2018
Room height	2.5	m	Meesters et al., 2018
Ventilation rate	0.4	ACH	Jayjock and Havics, 2018
Mass generation rate	1.6	g/s	Meesters et al., 2018
Airborne fraction	0.006	fraction	Meesters et al., 2018
Density nonvolatile	1	g/cm <sup>3</sup>	Meesters et al., 2018
Inhalation cutoff diameter	15	μm	Meesters et al., 2018
Aerosol diameter distribution	log normal		Meesters et al., 2018
Median diameter	2.4	μm	Meesters et al., 2018
Arithmetic coefficient of variation	0.37		Meesters et al., 2018
Maximum diameter	50	μm	Danish EPA (2018)
<b>Dermal</b>			
Contact rate	46	mg/min	Meesters et al., 2018
Release duration	0.46	min	Meesters et al., 2018

A summary of the population parameters used in the ConsExpo simulations is provided in Table 8. These values were obtained for the U.S. EPA Exposure Factors Handbook (U.S. EPA, 2011).

*Table 8. Summary of ConsExpo population parameters (U.S. EPA 2011).*

Population Parameters	Age 6 - 11	Age 11 - 16	Age 16 - 21	Age 21+	Units
Body weight	31.8	56.8	71.6	80.0	kg
Inhalation rate	11	13	12	15.5	L/min
Exposed area	1265	1855	2180	2358	cm <sup>2</sup>

### Summary of Results from the ConsExpo Simulations

Results from the ConsExpo simulations are provided in Table 9. The definitions of the output parameters are provided below.

#### **Inhalation**

- **Mean event concentration** – is the average air concentration during exposure event. [Note: depends strongly on chosen exposure duration.]
- **Peak concentration (TWA 15 min)** – is the 15-minute time weighted average peak air concentration. [Note: if exposure duration is less than 15 minutes, then the mean event concentration is given.]

- **Mean concentration on day of exposure** – is the average air concentration over the day. [Note: accounts for the number of events on one day.]
- **Year average concentration** – is the mean daily air concentration averaged over a year.
- **External event dose** – is the amount that can potentially be absorbed per kg body weight during one event.
- **External dose on day of exposure** – is the amount that can potentially be absorbed per kg body weight during one day.

**Dermal**

- **Dermal load** – is the amount per cm<sup>2</sup> on the skin.
- **External event dose** – is the amount that can potentially be absorbed per kg body weight during one event.
- **External dose on day of exposure** – is the amount that can potentially be absorbed per kg body weight during one day.

*Table 9. Results from the ConsExpo simulations.*

Results	Age 6 - 11	Age 11 - 16	Age 16 - 21	Age 21+	Units
<b>Inhalation</b>					
Mean event concentration	6.0e4	6.0e4	6.0e4	6.0e-4	mg/m <sup>3</sup>
Peak concentration (TWA 15 min)	7.6e-4	7.6e-4	7.6e-4	7.6e-4	mg/m <sup>3</sup>
Mean concentration on day of exposure	2.5e-5	2.5e-5	2.5e-5	2.5e-5	mg/m <sup>3</sup>
Year average concentration	2.5e-5	2.5e-5	2.5e-5	2.5e-5	mg/m <sup>3</sup>
External event dose	1.3e-5	8.3e-6	6.1e-6	5.7e-6	mg/kg-bw
External dose on day of exposure	1.3e-5	8.3e-6	6.1e-6	5.7e-6	mg/kg-bw
<b>Dermal</b>					
Dermal load	1.6e-6	1.1e-6	9.1e-7	8.4e-7	mg/cm <sup>2</sup>
External event dose	6.3e-5	3.5e-5	2.8e-5	2.5e-5	mg/kg-bw
External dose on day of exposure	6.3e-5	3.5e-5	2.8e-5	2.5e-5	mg/kg-bw

These results illustrate that the worst-case external event dose and external dose on day of exposure occurs for the 6 - 11 year old age group. For inhalation exposure, since there is only one event per day the external event dose and daily dose of exposure are the same (1.3e-5 mg/kg-bw). Likewise, the dermal external event dose and dose on day of exposure are the same (6.3e-5 mg/kg-bw).

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