Office for Product Safety & Standards

SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Silver in Cosmetic Products.

1. Introduction

1.1 Silver (CAS No.7440-22-4; EC No. 231-131-3) is currently listed in Annex IV (entry 142), "List of colourants allowed in cosmetic products," of the Cosmetics Products (Safety) Regulations 2008[1], with no maximum use concentration.

1.2 Under the GB Classification, Labelling and Packaging (CLP) regulation No. 1272/2008 (as amended)[2], silver massive (particle diameter ≥ 1mm), silver powder (particle diameter > 100nm < 1mm) and silver nano (particle diameter > 1nm ≤ 100nm) have human health classifications for Reproductive Toxicity category 2 and Specific Target Organ Toxicity-Repeated Exposure category 2. Silver powder and silver nano also have classifications for Aquatic Acute Toxicity category 1 and Aquatic Chronic Toxicity category 1. All three silver forms are therefore included in the GB Mandatory Classification and Labelling (MCL) list[3].

1.3 The UK Cosmetic Regulation defines a nanomaterial as "an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure on the scale from 1

[1] Cosmetics product (safety) Regulations currently consists of the Regulation UK No 1223/2009 as amended by SI 696/2019 Product Safety and Metrology (EU Exit) Regulations. The full consolidated UK text will be available in due course.
[2] The GB CLP Regulation No 1272/2008 as amended by The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. The full consolidated UK text will be available in due course.
[3] Available at: https://www.hse.gov.uk/chemical-classification/classification/harmonised-classification-self-classification.htm

to 100 nm"[4]. Under UK REACH "a nanoform is a form of a natural or manufactured substance containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm"[5].

1.4 Following the classification of silver (massive, powder and nano) as a category 2 CMR substance for reproductive toxicity in the UK, under GB CLP regulation No. 1272/2008, the UK Cosmetics Industry have provided the OPSS with a dossier of information and original studies to support the safety of micron-sized particulate silver (particle diameter > 100 nm < 1mm) only, to be used as a conditioning agent in cosmetic products. An exemption is requested under Article 15 of the UK Cosmetics Products (Safety) Regulations, which prohibits the use of substances classified as category 1A, 1B or 2 CMR substances unless an exemption has been granted by the Secretary of State[6].

1.5 OPSS requested that the SAG-CS assesses the safety of micron-sized particulate silver intended to be used within cosmetic products at a maximum concentration of 0.3% in all rinse off products (excluding mouthwash and toothpaste), 0.3% in all leave on products (except lip products), 0.05% in mouthwash and toothpaste and 0.2% in lip products.

1.6 A summary of the key physicochemical, toxicological, and toxicokinetic information from the industry-submitted dossier was provided to the SAG-CS. To note, in some aspects of the safety assessment, the trade name 'MicroSilver BG™ as indicated by the applicant has been used when referring to micron-sized silver.

1.7 The applicant provided a detailed specification which describes MicroSilver BG™ as a porous, sintered, micron-sized silver material with no free nanoparticle content. MicroSilver BG™ has a particle size (laser diffraction after external dispersion in ethanol by ultrasound, ISO 13320-1) of approximately 6 µm (average of 466 batches), a porosity of 85–90 %, and a specific surface area of up to 5 m²/g. It is manufactured, placed on the market and used exclusively in this

[4] Article 2 of the UK's Regulation (EC) No 1223/2009 on Cosmetic Products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
[5] UK REACH Definition (Commission Regulation (EU) 2018/1881)
[6] Management of CMR substances under the UK Cosmetics Regulation - GOV.UK

micron-sized, sintered form; it is not present in colloidal or nano form. This specification will be considered in light of the definitions of a nanomaterial as per the UK Cosmetics Regulation and the UK REACH Regulation. Further information is noted in paragraphs 4.2 and 4.3.

2. Background

Intended function and uses of silver

2.1 Silver has several uses in cosmetic, industrial, household and pharmaceutical products, due to its antimicrobial properties which arise from the release of silver ions (Sim et al., 2018).

2.2 Silver is used primarily in cosmetic products, in its powder form, as a colourant, providing a metallic or shimmery effect in makeup products such as eyeshadows, highlighters, nail polishes and body powders (SCCS, 2024).

2.3 The dossier submitted to the OPSS reports the use of MicroSilver BG™ as a skin conditioning agent in a range of rinse-off and leave-on cosmetic products. The applicant states that “the microparticles offer a highly biocompatible depot of pure silver that provides a sustainable generation of silver ions. The special porous particle structure of MicroSilver BG™ allows sustainable generation of silver ions at low concentrations

2.4 Silver is also used for its antimicrobial and anti-inflammatory properties in cosmetic products, such as deodorants, shower gels and topical creams, with the anti-inflammatory properties largely attributed to silver nanoparticles (Sim et al., 2018; Carvalho-Silva and Reis, 2024; Murthy et al., 2025).

2.5 Under the GB Biocidal Products Regulation (GB BPR)[7], silver is currently under review (under the Review Programme for existing active substances[8]) for several product types including drinking water, disinfectants and algaecides not intended for direct application to humans or animals and food and feed area. Silver (nano) is included on the GB biocidal active substances list however it is not approved for any product types[9].

[7] The Biocidal Products Regulations 2001 The Biocidal Products Regulations 2001
[8] GB Review Programme for existing biocidal active substances - HSE
[9] BPR active substance lists for GB and NI BPR active substance lists for GB and NI - Biocides - HSE

3. Previous Scientific Opinions on Silver and Related Compounds

3.1 A number of previous scientific opinions on silver, along with related compounds, have been considered by the SAG-CS. Where there is a lack of specific data for silver, the SAG-CS has relied upon submitted data, and published opinions and literature, on silver salts and silver-containing active substances for relevant aspects of the safety assessment for micron-sized silver.

3.2 Silver salts such as silver nitrate and silver sulphate are chemical compounds formed when silver ions bind with non-metal ions to create an inorganic substance (Żyro et al., 2023).

3.3 Silver-containing active substances (SCAS) refer to a broader classification of these salts and other silver-based compounds specifically used as antimicrobial agents or preservatives in biocidal products and treated materials. These are larger complexes or solid matrices (like zeolites or glasses) that safely host silver, releasing the antimicrobial ions over time via a continuous ion-exchange mechanism. They are heavily used in polymers, food packaging, and consumer products. Examples of SCAS include Silver Zeolites and Silver Sodium Hydrogen Zirconium Phosphate (ECHA-EFSA, 2020).

Elemental silver (massive and powder)

3.4 The United States Environmental Protection Agency (US-EPA,1991) derived a chronic oral reference dose (RfD) for elemental silver of 0.005 mg silver/kg bw/day. This was established using a systemic lifetime exposure of 1 g silver from a study by Gaul and Staud (1935 and cited in SCCS, 2024) which the US-EPA considered to be a Lowest Observed Adverse Effect Level (LOAEL). The LOAEL was derived from the intravenous route used by Gaul and Staud (1935) and converted to an oral dose of 0.014 mg/kg bw/day by assuming an oral bioavailability of 4% (Furchner et al., 1968 cited in ECHA RAC, 2022) and dividing by a default adult body weight of 70 kg and 25,500 days (lifetime = to 70 years). Applying an uncertainty factor of 3 to account for differences in individuals results in a final (rounded up) chronic RfD value of 0.005 mg silver/kg bw/day (US-EPA., 1991; SCCS., 2024).

3.5 In 2016, the EFSA Panel on Food Additives and Nutrition Sources added to Food (ANS Panel) re-evaluated the safety of elemental silver (E174) when used as a food additive. The EFSA ANS Panel concluded that the available data were insufficient to assess the safety of silver

used as a food additive (E174). Major issues were identified on the characterisation of silver (E174), in particular, the quantity of nanoparticles and the release of ionic silver. Additionally, there was insufficient comparable information on the materials used in the available toxicity studies, which made it difficult to determine the applicability of these studies to the safety evaluation (EFSA ANS Panel, 2016).

3.6 With the aim of filling the data gaps identified by the EFSA ANS Panel in 2016, the European Commission (EC) issued a call for further data on the use of elemental silver as a food additive. In 2025, the EFSA Panel on Food Additives and Flavourings (FAF) published a follow-up of the re-evaluation of silver (E174) as a food additive. The Panel concluded that the technical data submitted in response to the call for data for the physicochemical characterisation of all types of silver used as a food additive were not adequate. Changes could therefore not be proposed to the EU specifications for silver (E174) on particle size and morphology. The EFSA FAF Panel stated that E174 requires risk assessment at the nanoscale alongside the standard risk assessment. The Panel also considered the submitted data for genotoxicity and sub-chronic toxicity to be inadequate and noted an absence of data on the release of silver ions from E174. Overall, the Panel were therefore unable to conclude on the safety of the food additive silver E174 (EFSA FAF PANEL, 2025).

3.7 In 2021, the World Health Organisation (WHO) published a guideline document, “Silver in drinking-water: background document for development of WHO Guidelines for drinking-water quality". This covers elemental silver generally, as well as considering silver salts most relevant to drinking water such as silver nitrate and silver chloride. A formal guideline value could not be derived for silver in drinking water because the toxicological database was inadequate. A provisional reference value of 0.1 mg/L (100 µg/L) was suggested as the maximum allowable concentration in drinking water. This is derived from the lowest chronic LOAEL in humans of 0.6 mg/kg bw/day from a human case report of argyria, when silver deposits build up in the body causing the skin and nails to turn a blue/grey colour, and applying an uncertainty factor of 100 and an allocation factor of 80% for drinking water exposure. A 60kg body weight and a 2L daily water intake have been used in the calculations, which are standardised constants used by the WHO to calculate a safe concentration limit based on total lifetime exposure, without overcomplicating calculations for varying global demographics. A formal guideline value was deemed

unnecessary because silver concentrations found in drinking water sources are usually not of a health concern and the WHO discourages using silver as a primary or secondary drinking water disinfectant due to limited evidence of efficacy (WHO, 2021). This follows on from the conclusions of a previous document for silver in drinking water published by the WHO in 2003. In this document, the WHO derived a total lifetime oral intake of about 10 g of silver to be considered a human No Observed Adverse Effect Level (NOAEL) but also noted the contribution of drinking water to this NOAEL will normally be negligible. Assuming a drinking water intake of 2 L/day, 0.1 mg/L as a concentration of silver in drinking water would give a total intake over 70 years to half of this NOAEL (WHO, 2003).

3.8 In 2022, the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) published an opinion proposing the harmonised classification and labelling at EU level of all forms of elemental or metallic silver. The Committee made the following human health classification decisions for all forms of silver: Reproductive Toxicity category 2 and Specific Target Organ Toxicity- Repeated Exposure (STOT RE) category 2. The classification for STOT RE was based on a weight of evidence approach of a selection of different studies, carried out mainly with silver nanoparticles, which consistently showed morphological and/or functional neurotoxic effects. The decision to classify silver as a category 2 reproductive toxicant was based on adverse effects on sexual function and fertility seen in animal studies (ECHA RAC, 2022).

3.9 In 2024, the Scientific Committee on Consumer Safety (SCCS) published an opinion on the safety of silver used in cosmetic products (SCCS, 2024). The opinion assesses only the safety of micron-sized particulate silver, which the SCCS confirmed does not meet the definition of a nanomaterial, as according to the EC definition 2011/696[10] as well as the new recommendation 2022/C 229/01[11]. The SCCS were critical of the submitted studies for dermal absorption and noted these did not meet the requirements as detailed in the SCCS Notes of Guidance (2023). The key study presented by the applicant, (Bornatowicz, 2006; also see paragraph 4.9 below), to determine the dermal absorption had several shortcomings identified by the SCCS, including that the ICP-MS (Inductively Coupled Plasma-Mass Spectrometry) method to determine silver content could not distinguish

[10] EC Recommendation 2011/696/EU
[11] EC Recommendation 2022/C 229/01

between particles and ions. There were also issues with not meeting the mass balance criterion and having no information on the composition of tested formulations. The SCCS therefore made the conservative assumption that from this study, the determined silver content is bioavailable as ions and considered a value of 2.14% (mean + 2SD) as appropriate to be used in the safety assessment. The SCCS considered oral bioavailability to be 0.01% based on an oral absorption study by Hassler, 2007 which was used to calculate the Margin of Safety (MoS) for oral products (SCCS, 2024).

The SCCS disagreed with the approach of the applicant to use the chronic Reference Dose (RfD) of 0.005 mg/kg bw/day established by the US-EPA as the Point of Departure (PoD) which was derived from an old clinical study (Gaul and Staud, 1935).

For their safety assessment, the SCCS used a NOAEL of 0.0045 mg/kg bw/day for silver-ion equivalents (corrected for oral bioavailability), from a chronic combined toxicity and carcinogenicity study (> 12 months) on silver zinc zeolite in rats as the PoD (Takizawa, 1992 cited in ECHA RAC, 2022).

Overall, based on the calculations of MoS, and considering the classification of silver as toxic for reproduction Category 2, the SCCS considered micron-sized particulate silver not safe at concentrations up to 0.2% in rinse-off and 0.3% in leave-on cosmetic products when used alone or in combination. However, the use of micron-sized particulate silver in eye shadow (0.2%) and oral care products (lip balm at 0.2% and toothpaste and mouthwash at 0.05%) is considered safe, when used alone or in combination, as acceptable MoS values were achieved for these product types (SCCS, 2024).

3.10 In 2025, after reviewing an updated dossier submission that included two new studies on dermal penetration, the SCCS published preliminary updated scientific advice regarding silver used in cosmetic products to that published in 2024. Whilst the SCCS agreed that the newly submitted data indicates that Microsilver BG™ particles do not (or negligibly) penetrate the skin further than the stratum corneum (outer most layer of the skin) and therefore do not contribute to the systemic exposure dose of silver, a dermal safety assessment was still carried out for silver ions already present in the formulations. For such silver ions, a dermal absorption of 0.1% and an oral absorption of 5% were considered (SCCS, 2016 and SCCS, 2023). Overall, the SCCS concluded that, in light of the new data provided which indicates that

micron-sized particulate silver does not (or negligibly) penetrate the skin further than the stratum corneum, micron-sized particulate silver is safe when used up to a maximum concentration of 0.2% in rinse-off and 0.3% in leave-on cosmetic products. This evaluation by the SCCS does not include the use in propellant-based spray products as this was not covered by the applicant (SCCS, 2025).

3.11 The final scientific advice was published by the SCCS in April 2026, following a commenting period from 18 December 2025 to 23 February 2026, in which main changes were made to the discussion section and conclusions. In their final conclusions, the SCCS have additionally stated that for cosmetic products intended for use by children, micron-sized particulate silver is also considered safe at the same concentrations as detailed in paragraph 3.10 above, except for mouthwash which is considered safe at a concentration of up to 0.05%. No other major changes were made to the conclusions. A corrigendum to this opinion was adopted on 20th May 2026 to amend the table in Appendix B with missing values for hand cream but this did not affect the final conclusions already presented by the SCCS (SCCS, 2026).

Silver nanoparticles

3.12 In 2021, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (EFSA CEP) published a safety assessment for silver nanoparticles as an additive intended to be used in food contact materials (plastics). The additive is intended for use as a surface biocide up to a concentration of 0.025% w/w in non-polar plastics for contact with a wide range of foods, times, temperatures and food contact surface/mass of food ratios. The EFSA CEP Panel concluded that under the intended and tested conditions of use, the particles of the additive silver nanoparticles stay embedded in the polymer, do not migrate, are not released by abrasion and therefore do not give rise to exposure via food. The EFSA CEP Panel concluded that under the intended and tested conditions of use the particles did not raise a toxicological or safety concern. Low levels of migration of silver in soluble ionic form (up to 6 µg/kg food) from the surface of additive particles is observed. This is, however, below the group restriction of 50 µg silver/kg food proposed by the Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) Panel (EFSA, 2004) and would lead to a maximum exposure from food contact materials below the ADI of 0.9 µg/kg bw/day established by ECHA (EFSA CEP, 2021).

Silver salts

3.13 In 2009, the SCCS published an opinion on the safety of citric acid and silver citrate used in cosmetic products. Based on the available data, the SCCS concluded that both citric acid and silver citrate pose no risk to the health of the consumer when used as a preservative in cosmetic products up to a concentration of 0.2% (equivalent to 0.0024% silver according to the SCCS, 2009). This excludes oral care products and products intended to be used near the eyes. The SCCS also considered citric acid and silver citrate to be safe when used as a preservative or an active ingredient in deodorants and anti-perspirants up to a concentration of 0.2% (SCCS, 2009).

Silver-containing active substances (SCAS)

3.14 The European Food Safety Authority (EFSA) have evaluated silver-based preservatives used in food-contact materials and derived a group restriction limit of 0.05 mg silver/kg food based on the NOAEL reported in WHO, 2003. This has been considered by the SCCS in their 2024 opinion on silver (EFSA, 2004; SCCS, 2024).

3.15 A 2016 opinion of the SCCS looked at the safety of 'EcoG+', a silver-containing phosphate glass, as a preservative in cosmetics packaging. The safety assessment was based on the release of silver ions from the packaging material. The SCCS concluded that the release of silver ions from 'EcoG+' when used as a component of packaging for cosmetic products is safe up to a maximum concentration of 0.2% in the packaging material (SCCS, 2016).

3.16 A joint EFSA-ECHA document published in 2020 states that the Acceptable Daily Intake (ADI) value set in the context of the EU Biocidal Product Regulation (BPR), is more recent than the human NOAEL reported by the WHO (WHO, 2003), and therefore should be considered in the assessment of the risk of specific migration for silver compounds under the Food Contact Material (FCM) regulation. This ADI is 0.9 µg Ag/kg bw/day (equivalent to 0.0009 mg Ag/kg bw/day) based on the NOAEL of 0.0045 mg/kg bw/day derived from a chronic combined toxicity and carcinogenicity study (> 12 months) on silver zinc zeolite in rats (Takizawa, 1992 cited in ECHA RAC, 2022). Considering a default adult body weight of 60 kg, this ADI corresponds to 54 µg Ag/kg food (ECHA-EFSA, 2020).

3.17 In 2023, the SCCS published an opinion which considered silver zinc zeolite, incorporating a maximum silver content on 2.5%, to be

safe when used as a preservative in spray deodorant and powder foundation at a maximum concentration of 1% (SCCS, 2023).

4. Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

4.1 At their meeting in November 2025, the SAG-CS discussed a paper which focused on the safety of micron-sized silver when used in cosmetic products.

4.2 The applicant stated that the material under assessment was micron-sized particulate silver (particle diameter > 100 nm < 1mm), which was not considered to be a nanomaterial because the external dimensions of the basic units of MicroSilver BG™ particles clearly exceeded 100 nm.

4.3 The particle size distribution (SEM/TEM) analysis submitted by the applicant for MicroSilver BG™ showed that no free nanoparticles were present in the sample tested. For the unbound basic units of MicroSilver BG™, of which 75 particles were counted, the mean measured particle size was 2.35 µm ± 3.38 µm, with the lowest measured particle size being 0.13 µm. The applicant describes MicroSilver BG™ as consisting of highly porous, sintered, micro-sized particles of pure silver with an average particle size (measured by laser diffraction after external dispersion in ethanol by ultrasound according to ISO 13320-1) of approximately 6 µm (average of 466 batches), a porosity of 85-90%, and a specific surface area up to 5 m^2/g. Across all the batches tested, the smallest detected size fraction was never below 0.114 µm (114 nm). The micro-sized particles are internally built from finer sintered substructures, but these substructures are not free or separable constituent particles; they are fused (sintered) into a single porous particle, and no release of nanoparticles is observed. The micron-sized silver is therefore not present in colloidal or nano form in cosmetics. The Members of the SAG-CS requested that the applicant provided a product specification to ensure that their product could not be made up of nanoparticles, the specification was provided which the Chair reviewed, and it confirmed that there were no nanoparticles within the product. Given this additional information the Chair, on behalf of the SAG-CS, was content to accept that the information provided demonstrates that MicroSilver BG™ does not contain free

nanoparticles and does not meet the definition of a nanomaterial as per the UK Cosmetics Regulation[12] and UK REACH[13] definitions.

4.4 Members discussed the analytical methods available for silver in cosmetic products. A single-step process for the quantification of bulk silver in cosmetics could not be identified; however, literature was identified which separated silver ions from silver metal (both silver nanoparticles and bulk silver) and literature which speciated silver nanoparticles from bulk silver. Members noted that HPLC-sp-ICP-MS (High-Performance Liquid Chromatography-single particle Inductively Coupled Plasma-Mass Spectrometry) and AF4-ICP-MS (Asymmetric Flow Field Flow Fractionation-Inductively Coupled Plasma-Mass Spectrometry) in combination with total silver content determination, for example by Microwave Plasma Atomic Emission Spectrometry (MP-AES), are the most promising methods for the determination of bulk and nano-silver in cosmetic products (Cascio et al., 2015; Sötebier et al., 2016; Varbanova and Stefanova, 2019 and Kantorová et al., 2021) Members considered that laboratories are likely to have LC-ICP-MS (Liquid Chromatography-Inductively Coupled Plasma Mass Spectrometry) capabilities and with some work should be able to apply LC-single particle ICP-MS. However, Members noted that AF4-ICP-MS is a specialised approach not available in the Public Analyst (PA) and routine laboratory sectors Members considered that an appropriate analytical method could be available for micron-sized silver in cosmetic products subject to method development and validation (Blaimer and Leopold, 2024; Revenco et al., 2024).

4.5 Members discussed the dermal absorption of micron-sized silver. Two new dermal absorption studies submitted by the applicant indicate that micron-sized silver is not dermally absorbed (Krutmann, 2025; Meinke, 2025). Members discussed these studies, noting good methodologies for both.

4.6 The study by Meinke, (2025) is a non-OECD Test Guideline (TG) *ex vivo* dermal absorption study using two excised skin models, namely porcine ear skin (full thickness) and human abdominal skin (1.5 cm thickness). A test formulation containing 0.3% MicroSilver BG™ was applied evenly to both skin models at a dose of 2 mg/m^2, corresponding to 0.006 mg silver/cm^2, and left for 24 hours. Time-of-Flight Secondary Ion Mass Spectrometry (TOF-SIMS) was used to

[12] Article 2 of the UK's Regulation (EC) No 1223/2009 on Cosmetic Products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
[13] UK REACH Definition (Commission Regulation (EU) 2018/1881)

visualize and semi-quantitatively assess the presence and localisation of silver in the stratum corneum and deeper skin layers following exposure. The TOF-SIMS analysis demonstrated that any silver penetrating from the applied dose was restricted to the skin surface and the upper layers of the stratum corneum. Across all samples, no silver was detected in the viable epidermis or dermis.

4.7 The study by Krutmann, (2025), which was an *in vivo* human volunteer study, was carried out under international Good Clinical Practice (ICH-GCP). The skin penetration of silver was evaluated following repeated topical application of a cosmetic cream containing 0.3% MicroSilver BG™ (corresponding to a dose of 2 mg/m^2) on the lower abdomen of 10 healthy human volunteers (7 females and 3 males; aged range between 42-59), once a day, for 28 days. The dose in the tape stripping area corresponded to 6 µg silver/cm^2. Tape stripping was performed at three time points (1, 4 and 28 days) to assess silver penetration in the stratum corneum over time. A clear, declining gradient from the outermost to the deeper layers of the stratum corneum was observed with quantitative analysis of the sequential tape strips. A mass balance experiment was undertaken on day 4 with a higher MicroSilver BG™ dose application of approximately 142.23 µg of silver per subject. The total recovery of silver was within an acceptable range of 88.2-104.5%. Following the last application on day 28, a 4 mm punch biopsy was collected from the designated site on each subject, with samples analysed by TOF-SIMS. Silver was detected exclusively in the stratum corneum, in various forms including metallic silver, silver ions and silver precipitates, with no signals in the viable epidermis or dermis.

4.8 Members discussed, and were satisfied with, the analytical approaches applied in both the Meinke, (2025) and Krutmann, (2025) studies.

4.9 Members also discussed the Bornatowicz, (2006) dermal absorption study used in a previous dossier submission and considered by the SCCS in their 2024 opinion on silver (SCCS, 2024). This was an *in vitro* OECD TG 428 and GLP compliant study to determine the absorption of MicroSilver BG™ through pig skin. Two formulations, an ointment (1.5% MicroSilver BG™) and a hydrophilic cream (0.5% MicroSilver BG™), were applied topically to pig skin at doses corresponding to 0.3 and 0.1 mg silver/cm^2, respectively, and left for 24 hours. Following this, the stratum corneum was removed by repeated tape stripping and the remaining skin sample was used to determine the absorbed test substance. The dermal absorption was determined to be 1.38 ± 0.38% and 2.00 ± 0.54% for 0.5% and 1.5% MicroSilver BG™, respectively.

No test substance was identified to be in the receptor fluid above the limit of quantification (Bornatowicz, 2006). The SCCS noted several methodological limitations for this study as discussed already in paragraph 3.9. This study has also since been discounted by the applicant, noting several shortcomings which may affect its validity of use for safety assessment purposes. The SAG-CS agreed with both the SCCS and the applicant regarding the shortcomings of this study.

4.10 Overall, Members of the SAG-CS agreed that the dermal absorption of micron-sized silver following a single topical administration for 24 hours and repeated topical application is low (or negligible) and is not expected to contribute to the systemic exposure dose. Both studies by Meinke, (2025) and Krutmann, (2025) show that MicroSilver BG™ particles are retained at or within the stratum corneum, with no silver ions detected below the upper dermis. Any silver particles in the stratum corneum will therefore be sloughed off naturally by desquamation of the skin and will not be systemically available.

4.11 It was noted that for silver zinc zeolite, the SCCS used a highly conservative approach for dermal penetration, using a value of 0.1% based on the penetration of silver ions from silver salts, as used also in their opinion on the preservative 'EcoG+' (SCCS, 2016; SCCS, 2023; SCCS, 2026).

4.12 Members agreed that a dermal absorption value of 0.1% was appropriate to be used in the safety assessment, which accounts for the potential dermal penetration of silver ions The applicant has submitted a report in which the release of silver ions from MicroSilver BG™ in different formulations by Anodic Stripping Voltammetry (ASV) was calculated. From this, a conservative ionisation rate of 0.5% can be obtained. This value has also been used by the SCCS to calculate the systemic exposure dose from the dermal absorption of silver ions (SCCS, 2026).

4.13 The use of micron-sized silver-containing leave-on cosmetic products on broken or damaged skin was discussed in the context of products specifically for use on acne such as an anti-pimple face cream and products which may be used in the nappy area. The applicant stated that no significant systemic exposure via the dermal route is expected even on acne-affected, but non-eroded, skin. This is because acne typically only shows modest barrier perturbation with an intact stratum corneum and a tight-junction barrier along the follicle

(Sukanjanapong et al., 2024; Zorn-Kruppa et al., 2018). Additionally, MicroSilver BG™ consists of micro-scaled particles that stay on the surface of the skin. Silver ions released from metallic silver require aqueous/oxidative conditions, which on intact/oily follicular skin, are locally generated at low flux and rapidly complexed/bound, which constrains deeper transport. Additionally, for the nappy area, the applicant refers to a number of reviews and clinical studies which indicate that full-term infant skin generally reaches adult-like barrier function early (Garcia Bartels et al., 2012; Telofski et al., 2012; Ludriksone et al., 2014; Gustin et al., 2021; Rahma and Lane, 2022; Choi, 2025). They have also stated that visible inflammation in this area does not automatically equal a severely leaky barrier. For non-lesional atopic skin, i.e., between flares, the epidermal barrier is still present and functional, although may be impaired in comparison with healthy controls (Polańska et al., 2012; Polańska et al., 2013; Zolotas et al., 2023; Schmuth et al., 2024). When the stratum corneum is still present, systemic exposure to micron-sized silver through the skin is negligible. The applicant has also referred to an *in vitro* buccal tissue permeability study with MicroSilver BG™ where even in the absence of a stratum corneum, there was no evidence of permeation (Graf and Amann, 2007).

4.14 As a general point, Members noted that relatively few of the studies included in the dossier were conducted using pure metallic micron-sized silver, with the majority of studies conducted using silver nanoparticles, silver salts or silver-containing active substances (SCAS) as the test substances. Comparing studies was therefore challenging and significant differences in reported NOAELs and LOAELs have been observed. Additionally, the presence of counter ions may influence toxicity and the subsequent measured endpoints. Members suggested that, where required, the test material with the most toxicologically inert counter-ion should be considered ahead of other substances containing counter-ions. Higher priority should be given to studies where it has been identified that silver is the primary driver of toxicity. When considering studies using silver salts and SCAS as the test substance, toxicity is assessed on the basis of released silver ions rather than the other component compounds.

4.15 Members discussed the reproductive and developmental toxicity of silver, acknowledging the Category 2 CMR classification for reproductive toxicity. The EU Harmonised Classification and Labelling (CLH) report states this is based on adverse effects on sexual function and fertility observed in animal studies (ECHA RAC, 2022). Members

considered the potential to release silver ions as an important factor which will drive toxicity. Variation in dissolution rates between different test materials could therefore be contributing to significant differences seen in reported NOAELs and LOAELs for reproductive endpoints. Adverse reproductive and developmental effects were seen in the foetus and maternal test subjects. Additionally, in two separate two-generation reproductive toxicity studies carried out according to OECD TG 416, with silver sodium zirconium hydrogen phosphate and silver zinc zeolite as the test substances, adverse effects were seen in the F2 generation (Wood, 2002 cited in ECHA RAC, 2022; Schroeder, 2002 cited in ECHA RAC, 2015). Members were in agreement that there is sufficient evidence to indicate that silver is a reproductive toxicant, however, noted it was difficult to pinpoint a single most sensitive endpoint. Consideration was given to the mode of action of toxicity, which appears to arise from the biocidal properties of silver and the subsequent generation of reactive oxygen species (ROS) which can lead to mitochondrial and DNA damage.

4.16 Members discussed whether adverse reproductive effects could result from dermal exposure to silver, as the majority of studies were carried out via the oral route. Considering the available evidence, such as the low to negligible dermal penetration of silver and the reported NOAEL and LOAEL values in the reproductive toxicity studies, Members agreed that reproductive toxicity is unlikely via the dermal route. Members also agreed that, considering overall exposure from the oral and dermal routes, at the proposed maximum concentrations of silver in cosmetic products, reproductive toxicity is unlikely to occur.

4.17 Members queried whether it was possible for silver ions to reside in organs and tissues without being cleared. A number of studies were identified in the literature, of varying relevance and reliability, which looked at the accumulation of silver following oral exposure only (van der Zande et al., 2012; Mertens et al., 2023). One 28-day repeated dose oral exposure study in rats (six-week-old male specific pathogen free Sprague Dawley rats), with silver nanoparticles and silver ions, measured the retention and clearance rates of silver for different tissues in the body. Both the brain and testes retained silver to a greater extent than other organs following the wash out periods of 1 or 8 weeks. After 8 weeks post-dosing, silver was cleared from most organs but not the brain and testes (van der Zande et al., 2012). Members discussed how this may relate to adverse reproductive effects observed in other studies, noting, however, that the doses tested in this study, and the other references, are much higher than

would result from cosmetic exposure and also the NOAEL values reported from reproductive toxicity studies. In relation to the detection of silver ions in the testes, which Members highlighted as a target organ for silver effects, after the clearance period, one study by Baki et al., (2014) demonstrated that silver nanoparticles can diminish the number of Leydig cells and sperm parameter indices in the testes of male prepubertal Wistar rats. This study and the study by Mertens et al (2023) were carried out after the 2013 animal testing ban[14] for cosmetics in the UK, however both studies may be referred to because they have been conducted for a purpose other than for cosmetics, and are highly relevant to the safety assessment by the SAG-CS.

4.18 The mutagenicity and genotoxicity data for silver were mixed, with many of the studies not claiming GLP compliance or carried out in accordance with OECD Test Guidelines. The majority of the data were based on silver nanoparticles and Members therefore noted the importance of considering factors like silver ion dissolution and how nanoforms might enter cells differently in comparison to micron-sized silver. *In vitro,* all the Ames tests were negative for mutagenicity however, Members deemed the Ames tests to be inappropriate for inclusion in the weight of evidence for genotoxicity. This was due to the bacteriostatic properties of silver, which may have influenced the test results by preventing the growth of the test organisms and thus potentially generating false negative results. There was evidence *in vitro* of clastogenicity and several positive results were reported in the micronucleus assay. Additionally, two *in vivo* studies reported positive results for chromosomal damage and there are several positive Comet assays indicating DNA damage, all conducted with silver nanoparticles. Members decided to take a weight of evidence approach given the mixed results, with GLP and OECD TG *in vivo* compliant studies given the greatest weighting. It was agreed based on the available evidence that silver nanoparticles have genotoxic potential *in vivo,* via routes likely to result in systemic exposure. There are insufficient genotoxicity data to conclude on the genotoxic potential of micron-sized silver *in vivo*.

4.19 Members queried the mode of action of genotoxicity of silver nanoparticles, and whether this is due to the nanoparticle itself or the dissolution to silver ions. This was inconclusive. Members considered that silver ion genotoxicity arises from ROS production, as also stated

[14] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) Article 18

in the SCCS opinion (SCCS, 2024). Members discussed how nanoparticle size may influence the toxicity but noted this is of less relevance when considering micron-sized silver. Overall, Members concluded that silver has genotoxic potential, which was almost exclusively observed with the nanoform. Silver nanoparticles are outside the scope of this opinion, the scope of which is outlined in paragraphs 1.4- 1.5. Considering that silver nanoparticles have a faster ion release and a higher ability to penetrate cells compared with bulk silver, Members concluded that micron-sized silver is unlikely to pose a genotoxic risk at the low concentrations used in cosmetic products (Li et al., 2017; Rezvani et al., 2019; Mertens et al., 2023).

4.20 Members disagreed with the approach in the dossier submission to use a reference dose as the Point of Departure (PoD) in the safety assessment. The data this reference dose is based on is from an old, clinical study by Gaul and Staud (1935) using silver arsphenamine as the test substance. Members noted this was not an appropriate study and instead attempted to identify the most sensitive endpoint across the available toxicity studies, taking into account the test substance and the presence of any counter ions.

4.21 Members discussed a limited one-generation study in Sprague Dawley rats by Sprando et al., (2017) in which rats were dosed with silver acetate via drinking water at doses equivalent to approximately 0, 0.25, 2.5 and 25 mg silver ions/kg bw/day. This study is summarised in the ECHA RAC, 2022 opinion on silver and was part of their evidence base for reproductive and developmental toxicity. This study was carried out after the 2013 animal testing ban[15] for cosmetics in the UK, however because it has been conducted for a purpose other than for cosmetics, the SAG-CS are able to consider this in their assessment. At the top dose of 25 mg silver ions, statistically significant reductions were observed in the mean number of implantations, the litter size and the number of live pups in comparison to the controls. Overall, the fertility index at this dose was reduced by 10% compared to the controls. No statistically significant differences were observed at the other doses tested. Members also discussed the chronic combined toxicity and carcinogenicity study by Takizawa et al., 1992 (> 12 months) on silver zinc zeolite in rats, which the SCCS used to derive a PoD of 0.0045 mg/kg bw/day to be used in the safety assessments of their 2024 and 2025 opinions. The full study paper was not accessible,

[15] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) Article 18

and only short summaries could be found in the opinions of ECHA RAC, 2022, SCCS, 2023, SCCS, 2024 and SCCS, 2025. Members therefore discounted this study as a full review of the data could not be undertaken.

4.22 Overall, Members were unable to conclude on a Point of Departure value to be used in the safety assessment because a single most sensitive endpoint could not be identified across the available toxicity data which was highly variable with regard to test substance

4.23 An estimate of exposure has been undertaken using the maximum requested use concentrations for silver. For the dermal route, exposure from available silver ions is considered only, as in paragraph 4.10 members agreed that the absorption of silver particles would be negligible and would not contribute to the systemic exposure dose. The detailed calculations can be found in the Appendix to this opinion. Given no PoD value could be identified, no Margin of Safety calculations have been undertaken. The exposure estimates, which represent a worst-case exposure scenario, show that exposure to silver via the dermal, oral and inhalation routes is very low with an aggregate systemic exposure dose (SED) calculated to be 0.000037 mg/kg bw/day. This is a conservative value which has been calculated using the maximum use levels for each product type rather than the intended use values proposed by the applicant.

4.24 For the inhalation route, the potential for local lung toxicity must be considered. Sub-chronic inhalation studies with silver nanoparticles suggests local adverse effects, which are largely reversible, but persistent lung inflammation has also been observed. Such effects are not expected with micron-sized silver (ECHA RAC, 2022). The available data shows that silver (non-nano) has low acute inhalation toxicity, with LC_{50} values consistently above 1400 mg/m^3. In one OECD TG 436 compliant study with micron-sized silver metal powder in rats, an acute inhalation LC_{50} was considered to be greater than 5160 mg/m^3 air (Unnamed study report cited in ECHA RAC, 2022). Given that for micron-sized silver local lung effects have not been observed, acute inhalation toxicity is low and there is no evidence for mucosal irritation, MicroSilver BG™ is not expected to cause local toxicity in the lower respiratory tract when used in spray products. This applies only to pump sprays as propellant-based spray products were not included in the applicant's dossier.

4.25 Data for children was only submitted for toothpaste exposure where a bodyweight of 21.7 kg was considered, which as according to the EFSA, (2012) guidance on default values, is the median bodyweight for children aged 3-10 years. An acceptable Margin of Safety is achieved in this scenario. A recommendation was made that a full risk assessment should be carried out for children and adolescents when adequate data becomes available, and an appropriate methodology is subsequently agreed by the committee.

5. Conclusions

The conclusions presented here relate only to micron-sized particulate silver of particle diameter > 100 nm < 1mm. Members were content that the material characterisation submitted by the applicant for MicroSilver BG™ shows that it does not meet the definition of a nanomaterial as per the UK Cosmetics Regulation definition and does not contain free nanoparticles.

Members noted that a single-step process for the quantification of bulk silver in cosmetics could not be identified but were of the opinion that an appropriate analytical method could be available for micron-sized silver in cosmetic products subject to method development and validation, in addition to an assessment of laboratory capabilities in the suggested methods.

The two dermal absorption studies by Meinke, (2025) and Krutmann, (2025) show that MicroSilver BG™ does not penetrate beyond the stratum corneum. To account for the potential dermal absorption of silver ions, a value of 0.1% has been selected for the safety assessment.

Members agreed that silver is a reproductive toxicant, however, when considering the overall low exposure from cosmetic product use, and the comparatively high NOAEL and LOAEL values reported in the available studies, reproductive toxicity is unlikely to pose a concern for micron-sized silver.

Members agreed that micron-sized silver is unlikely to pose a genotoxic risk when considering the low systemic exposure to silver from cosmetic products considered within this Opinion.

Members noted that the available data suggests that silver nanoparticles have genotoxic potential in vivo, however silver nanoparticles are outside the scope of this opinion and are not being considered for use in cosmetic products.

Given the variability of the data presented, Members were unable to identify a Point of Departure to be used in the safety assessment, however, given the

expected low systemic exposure and considering all the available toxicological data which shows adverse effects occur at much higher levels than relevant to cosmetic use, Members concluded that micron-sized particulate silver is acceptable for use in cosmetic products at the following maximum concentrations:

- *Leave-on cosmetics (excluding lip products): 0.3%*
- *Lip products: 0.2%*
- *Rinse-off cosmetics (excluding mouthwash and toothpaste): 0.3%*
- *Mouthwash and toothpaste: 0.05%*

The use of micron-sized particulate silver in propellant sprays is excluded from the conclusions as this product type was not included in the applicant dossier.

Members recommended that a full risk assessment should be carried out in children and adolescents, when adequate data becomes available, and an appropriate methodology has subsequently been agreed by the committee.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

June 2026

Office for Product Safety & Standards

Abbreviations

ADI	Acceptable Daily Intake
AF4-ICP-MS	Asymmetric Flow Field Flow Fractionation-Inductively Coupled Plasma Mass Spectrometry
ANS	EFSA Panel on Food Additives and Nutrition Sources added to Food
BPR	Biocidal Products Regulation
CLH	Harmonised classification and labelling (ECHA)
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, mutagenic or reprotoxic
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
FAF	EFSA Panel on Food Additives and Flavourings
HPLC-sp-ICP-MS	High-Performance Liquid Chromatography-single particle Inductively Coupled Plasma Mass Spectrometry
ICH-GCP	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use- Good Clinical Practice
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
ISO	International Organisation for Standardisation
LC-ICP-MS	Liquid Chromatography-Inductively Coupled Plasma Mass Spectrometry
LOAEL	Lowest Observed Adverse Effect Level
LOQ	Limit of Quantification
MCL	Mandatory Classification and Labelling
MoS	Margin of Safety
MP-AES	Microwave Plasma Atomic Emission Spectrometry
NOAEL	No Observed Adverse Effect Level
PoD	Point of Departure
RAC	The Committee for Risk Assessment of ECHA

REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
RfD	Reference Dose
SCCS	Scientific Committee on Consumer Safety
SD	Standard Deviation
SED	Systemic Exposure Dose
SEM	Scanning Electron Microscope
TEN	Transmission Electron Microscope
TOF-SIMS	Time-of-Flight Secondary Ion Mass Spectrometry
US-EPA	United States Environmental Protection Agency
WHO	World Health Organization

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Appendix- Safety Assessment

The full industry dossier, key unpublished studies and other references have been supplied to the committee.

An estimate of exposure has been undertaken using the maximum requested use levels for silver:

- Leave-on cosmetics (except lip products): 0.3%
- Lip products: 0.2%
- Rinse-off cosmetics (except mouthwash and toothpaste): 0.3%
- Mouthwash and toothpaste: 0.05%

Exposure has been estimated using the default values for product use amounts, and the methodology, as defined in the SCCS Notes of Guidance (2023) unless otherwise stated.

Based on two studies by Meinke, 2025 and Krutmann, 2025, conducted with a commercial skin cream containing 0.3% MicroSilver BG™, the dermal absorption of silver particles following acute and repeated topical application is not expected to be significant. MicroSilver BG™ particles are retained within the stratum corneum and therefore are not expected to contribute to the systemic exposure dose (SED). Members however considered the potential absorption of silver ions below the stratum corneum and into the dermis. As a highly conservative measure, a dermal absorption value of 0.1% will therefore be applied when considering dermal exposure to silver ions. An ionisation rate of 0.5% for silver is applied as a conservative estimate of the release of ionic silver in cosmetic products.

No Margin of Safety calculations have been undertaken as an appropriate Point of Departure value could not be identified.

Oral bioavailability has been set at 0.01% based on a study by Hassler, 2007. This will be applied when considering oral exposure.

Data was not presented for children's exposure, except in the instance of toothpaste, therefore no exposure assessment in children has been carried out at this time.

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Dermal Exposure

Table 1) Tier 1 deterministic aggregate exposure assessment for dermal exposure products to calculate the SED_{dermal}

Product category	Individual products	Relative daily exposure (mg/kg bw/day)[1]	Maximum Silver concentration (%)	Dermal absorption (%)	Ionised silver (%)	SED (mg/kg bw/day)[3]
Skin care	Face cream	24.14	0.3	0.1	0.5	0.0000004
	Face cream tonic	24.14	0.3	0.1	0.5	0.0000004
	Face cream anti-redness	24.14	0.3	0.1	0.5	0.0000004
	Face cream anti-pimple	24.14	0.3	0.1	0.5	0.0000004
	Face refresh spray	24.14	0.3	0.1	0.5	0.0000004
	Hand cream	32.7	0.3	0.1	0.5	0.0000005
	Body lotion	123.2	0.3	0.1	0.5	0.0000018
Hair care	Shampoo	1.51	0.3	0.1	0.5	0.00000002
Deodorant	Deodorant spray (dermal exposure)	93.7	0.3	0.1	0.5	0.0000014
	Deodorant non-spray	22.08	0.3	0.1	0.5	0.0000003
Foot care	Foot cream	20.00[2]	0.3	0.1	0.5	0.0000003
Make up	Eyeshadow	0.33	0.3	0.1	0.5	0.000000005
Men's cosmetics	After shave	20.00[2]	0.3	0.1	0.5	0.0000003
				Aggregate	excl. spray deodorant[4]	0.0000051

SED – Systemic exposure dose
1 – As in Table 3A and 3B of the SCCS Notes of Guidance (2023). The product categories have been taken from the applicant dossier.
2 – From the applicant dossier as no such value in the SCCS Notes of Guidance (2023)
3 – SED= relative daily exposure x maximum silver concentration x dermal absorption x ionised silver
4- deodorant spray has been excluded to avoid duplication of product types (with non-spray deodorant) and also because the relative daily exposure includes the inhaled fraction (as per the SCCS Notes of Guidance (2023)). The inhalation exposure has been considered separately in Table 3.

Oral Exposure

Table 2) Tier 1 deterministic aggregate exposure assessment for oral exposure products to calculate the SED_{oral}

Product category	Individual products	Retention factor[1]	Relative daily exposure (mg/kg bw/day)[2]	Silver concentration (%)	SED (mg/kg bw/day)[4]
Make-up products	Lip Balm	1	0.9	0.2	0.0000002
Oral Hygiene	Toothpaste (adult)	0.05	2.16	0.05	0.0000001
	Toothpaste (children)[3]	0.4	9.22	0.05	0.0000005
	Mouthwash	0.1	32.54	0.05	0.000002
				Aggregate (excl. children)	0.0000019

SED – Systemic exposure dose
1 – As in Table 3A SCCS Notes of Guidance (2023), with the exception of toothpaste for children, where the retention factor has been conservatively assumed to be 0.4 based on SCCP (2005)
2 – As in Table 3A of the SCCS Notes of Guidance (2023), with the exception of toothpaste for children.
3 – The relative daily exposure for toothpaste (children) has been calculated by assuming a pea-sized amount of toothpaste (0.25g) is used twice a day (SCCNFP, 2003), multiplying by the retention factor of 0.4 and dividing by a mean bodyweight of 21.7 kg for the 3–10-year age group (EFSA, 2012)
4 – Accounting for an oral bioavailability of 0.01%

Inhalation Exposure

Table 3) A two-box inhalation model, as in the SCCS Notes of Guidance, to calculate the $SED_{inhalation}$ for a pump spray

	Pump spray	Parameter reference
Amount per application (mg/application)[1]	6100	Hall et al., 2007 in SCCS, 2023
Concentration of silver (%)	0.30	Dossier submission
Proportion non-propellant	1	SCCS, 2023
Airborne fraction	0.2	SCCS, 2023; Bremmer et al., 2006
Potential amount inhaled (mg/application)[2]	**3.66**	
Box 1 volume (L)	1000	SCCS, 2023
Duration in box 1 (min)	2	SCCS, 2023
Inhalation rate (L/min)	13	US EPA, 2011
Potential amount inhaled in box 1 (mg/application)[3]	**0.095**	

Box 2 volume (L)	10000	SCCS, 2023
Duration in box 2 (min)	10	SCCS, 2023
Inhalation rate (L/min)	13	US EPA, 2011
Potential amount inhaled in box 2 (mg/application)[4]	**0.048**	
Retention fraction in lungs (25% exhaled)	0.75	SCCS, 2023
Respirable fraction	0.01	Rothe et al., 2011
Frequency of application (/day)	2	SCCS, 2023
Body weight (kg)	70	SAG-CS, 2023
$SED_{inhalation}$ (mg/kg bw/d)[5]	**0.00003**	

SED – Systemic exposure dose
1 – Amount of 6.1 g/day is sprayed, reported as the weight loss after use of spray (Hall et al., 2007 in SCCS, 2023)
2 – Calculated as amount per application x silver concentration x proportion non-propellant x airborne fraction
3 – Calculated as (potential amount inhaled/box 1 volume) x duration in box 1 x inhalation rate
4 – Calculated as (potential amount inhaled/box 2 volume) x duration in box 2 x inhalation rate
5 – $SED_{inhalation}$ = (Box 1 + Box 2) x retention in lungs x respirable fraction x frequency of application / body weight

Aggregate exposure

Table 4) Aggregate calculation of systemic exposure for all exposure routes

Total oral SED (mg/kg bw/day)	0.0000019
Total inhalation SED (mg/kg bw/day)	0.00003
Total dermal SED (mg/kg bw/day)	0.0000051
Aggregate SED (mg/kg bw/day)	**0.000037**

SED – Systemic exposure dose