Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Siloxanes and Silicones, di-Me, [[[3-[(2-aminoethyl)amino]propyl]silylidyne]tris(oxy)]tris-, methoxy-terminated, reaction products with hydroxy-terminated di-Me siloxanes and silica

1-Propanamine, 3-(trimethoxysilyl)-, reaction products with dichlorodimethylsilane and silica

Assessment statement (CA09729/CA09861)

21 February 2024

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AICIS assessment statement (CA09729/CA09861)

Chemicals in this assessment

Name	CAS registry number	Application ID
Siloxanes and Silicones, di-Me, [[[3-[(2-aminoethyl)amino]propyl]silylidyne]tris(oxy)]tris-, methoxy-terminated, reaction products with hydroxy-terminated di-Me siloxanes and silica	2376990-05-3	CA09729
1-Propanamine, 3-(trimethoxysilyl)-, reaction products with dichlorodimethylsilane and silica	2376990-04-2	CA09861

Reason for the assessment

Applications for assessment certificates under section 31 of the *Industrial Chemicals Act 2019* (the Act)

Certificate application type

AICIS received assessment certificate applications for the two chemicals in a Health and Environment Focus type. The chemicals in this assessment meet the similar chemical and same end use criteria.

Defined scope of assessment

The chemicals have been assessed:

- with less than 20% (by number size distribution) of the particles (unbound or aggregates) of the chemicals below 100 nm;
- as imported into Australia in sealed end use laser printer cartridges as components of the toner at up to 3% concentration;
- as imported into Australia at up to 3 tonnes/year.

Summary of assessment

Summary of introduction, use and end use

The proposed introduction of the assessed chemicals will be in a specified class of introduction with primary particles of the chemicals in the nanoscale (subsection 7(3)(c) of the *Industrial Chemicals (General) Rules 2019*).

The chemicals are surface modified hydrophilic synthetic amorphous silica (SAS). The primary particles of both chemicals are in the nanoscale when manufactured overseas, but bound together following manufacture to form aggregates. When introduced into Australia in the finished toner product, the particles will be mainly in aggregated forms binding to other

ingredients, with typically 10% to 20% of aggregates having size ≤ 100 nm (by number size distribution).

The assessed chemicals will not be manufactured in Australia. The assessed chemicals at up to 3% concentration will be imported into Australia as components of laser printer toner in sealed cartridges. No reformulation, filling or refilling of the cartridges containing the chemicals will occur in Australia.

The printer cartridges containing the assessed chemicals will be used in office and domestic applications for printing on paper. For each printer cartridge, about 94% volume of the toner is expected to be fused onto paper. As a process happening in the printing machines, excess toner will be removed from the printing drum unit and collected either in a separate waste bottle or in a separate container within the cartridge. Approximately 6% of the toner will be collected and discarded, including the toner residue in the cartridge at the end of the service life. If it is required, workers or consumers will remove empty cartridges and waste bottles from printers or photocopiers and insert new ones. Changes of empty cartridges by consumers are expected to be infrequent. The used empty cartridges with residual toner will be recycled or disposed of as normal household waste.

Modern printers and photocopiers are designed to minimise emissions of any toner particles from the machines. During printing, the toner containing the chemicals will be printed onto paper following its release from the cartridges and immediately fused into paper matrix under heat. The assessed chemicals will be irreversibly bound into the paper matrix and will not be available for further exposure.

Human health

Summary of health hazards

No toxicological data were provided for the assessed chemicals. The assessed chemicals are surface modified hydrophobic SAS with primary particle size in the nanoscale. For information read across purposes, the applicant submitted toxicological data on various particle sizes of surface coated (modified) or uncoated (unmodified) SAS analogues (see **Supporting information**) indicating that the assessed chemicals are:

- likely to be of low acute oral toxicity
- likely to be non-irritating to skin
- likely to be slightly irritating to eyes
- not likely to be skin sensitisers
- not likely to cause systemic toxicity following repeated oral exposure (NOAEL of 1,000 mg/kg bw/day in rats for coated and uncoated analogues)
- likely to cause lung damage following repeated inhalation exposure (LOAEC of 2.5 mg/m^3/6 hours/day in rats for an uncoated analogue)
- not expected to be genotoxic

The assessed chemicals contain particles in the nanoscale. Given that the toxicity of the silica particles depends on a number of factors including particle size distribution, surface area, surface chemistry, density and agglomeration (Gatoo *et al* 2014; Zhu *et al* 2013), the currently submitted data are insufficient to derive clear hazard conclusions for the assessed chemicals on specific human health end points such as acute oral toxicity, skin and eye irritation, and skin sensitisation. However, the repeated dose inhalation toxicity data could be considered as a worst-case scenario due to the uncoated SAS in nanoscale used in the study. Compared to large particles, nanoscale particles generally have different toxicokinetic properties.

Only limited read-across genotoxicity data were provided including a negative bacteria reverse mutation (Ames) assay (OECD TG 471) and equivocal results for *in vitro* alkaline comet assays using human bronchial tissue models (Haase et al. 2017). The Ames test is not considered to be a reliable test to confirm negative results for mutagenicity of nanoscale particles. However, the *in vitro* alkaline comet assay using human bronchial tissue model indicated that a close analogue, SiO_2 amino, is not genotoxic. The *in vitro* negative genotoxicity results of SiO_2 amino were confirmed by an *in vivo* lung cell alkaline comet assay in rats (non-OECD guideline) and an *in vivo* bone marrow micronucleus test in rats (OECD TG 474) (see **Supporting information** section).

Hazard classifications relevant for worker health and safety

Based on the limited analogue toxicology data provided on varying particle sizes tested (in or out of the nanoscale), the assessed chemicals cannot be classified using the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) criteria (UNECE 2017), as adopted for industrial chemicals in Australia.

The assessed chemicals were not classified for repeated dose inhalation toxicity as adverse effects reported in the submitted analogue data were for uncoated SAS particles while the assessed chemicals are coated SAS particles. The coating could change the toxicity profile of nanoscale particles (Gatoo *et al* 2014; Zhu *et al* 2013). No specific inhalation toxicity data on the assessed chemicals were provided.

Summary of health risk

The assessed chemicals are introduced as hydrophobic surface modified SAS aggregates in printer cartridges containing less than 20% (by number size distribution) of the particles (in an unbound state or as an aggregate) of the chemicals in the nanoscale (1 - 100 nm). For insoluble particles in the nanoscale, inhalation is generally considered as the main route of exposure for potential systemic effects.

Public

The possible exposure of the public to the assessed chemicals through the use of printer cartridges is expected to be limited and infrequent as domestic laser printing applications are often used at small scale. There is minimal potential for dermal exposure of the public to the assessed chemicals during changes of the used empty cartridges. As the assessed chemicals will be encapsulated in the cartridges, particles are not expected to be available for inhalation exposure, unless the cartridge is damaged. The applicant stated that the disposable gloves can be worn while replacing the empty cartridges to minimise the potential dermal exposure.

No risks are identified for public health during this assessment that require specific risk management measures.

Workers

Dermal and inhalation exposure of printer operators, office workers and service technicians to the assessed chemicals at up to 3% concentration may occur during replacement of cartridges or maintenance of printers. While changing cartridges, exposure of workers to the unprocessed toner containing the assessed chemicals is expected to be minimal due to the sealed nature of the cartridges. Under normal use conditions, inhalation and dermal exposure to the chemicals will be very limited due to the design of the printing machines minimising the emission of unprocessed toner particles. Professional workers may wear some personal protective equipment (PPE) such as gloves to further reduce the potential for dermal exposure.

Under normal conditions of use, no specific risk management measures for the safe use of toner cartridges containing the assessed chemicals are required.

Environment

Summary of environmental hazard characteristics

The assessed chemicals are inorganic silica based aggregates with organic surface modifications. As the assessed chemicals are primarily inorganic, the determination of whether they meet the PBT criteria are not applicable.

Environmental hazard classification

Based on the ecotoxicological information available for the assessed chemicals, they are not expected to be harmful to aquatic life. Therefore, the assessed chemicals are not formally classified under the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) for acute and chronic aquatic toxicities (UNECE 2017).

Summary of environmental risk

The assessed chemicals will be introduced as surface charge carriers for printing toners. This use may result in the release of the assessed chemicals to waste water treatment plants as a result of the paper recycling process. If released into environmental compartments, the assessed chemicals are expected to partition to soils and sediments.

The assessed chemicals are stable under environmental conditions and are not expected to cause harmful effects in aquatic organisms. Based on the assessed use patterns and low hazards, it is expected that the environmental risk from the introduction of the assessed chemicals can be managed within the existing frameworks.

Means for managing risk

Workers

The information in this statement should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Information relating to safe introduction and use

- Service technicians should wear disposable gloves and ensure adequate ventilation is present during maintenance and repairs of printing machines.

Conclusions

The Executive Director is satisfied that the risks to human health and the environment associated with the introduction and use of the industrial chemicals can be managed.

Note:

1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant State or Territory.

Supporting information

Chemical identity

Chemical identity of CA09729

Chemical name	Siloxanes and Silicones, di-Me, [[[3-[(2-aminoethyl)amino]propyl]silylidyne]tris(oxy)]tris-, methoxy-terminated, reaction products with hydroxy-terminated di-Me siloxanes and silica
CAS No.	2376990-05-3
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
Chemical description	Surface modified hydrophobic SAS with primary particle size in the nanoscale

Chemical identity of CA09861

Chemical name	1-Propanamine, 3-(trimethoxysilyl)-, reaction products with dichlorodimethylsilane and silica
CAS No.	2376990-04-2
Molecular formula	Unspecified
Molecular weight (g/mol)	Unspecified
Chemical description	Surface modified hydrophobic SAS with primary particle size in the nanoscale

Relevant physical and chemical properties

Application ID	**CA09729**	**CA09861**
Physical form	White powder	White powder
Melting point [1]	> 800 K (> 527 °C)	> 800 K (> 527 °C)
Boiling point [1]	> 800 K (> 527 °C)	> 800 K (> 527 °C)
Apparent density	Typical: 77 kg/m^3 Range: 20 – 120 kg/m^3	Typical: 60 kg/m^3 Range: 20 – 220 kg/m^3
Water solubility	73 mg/L (SiO_2 content)	81 mg/L (SiO_2 content)
Ionisable in the environment	Yes	Yes

Primary particle size [2]	Mean: 20.6 ± 9.8 nm Range: 4.5 – 58.4 nm d10: 8.9 nm d50: 18.8 nm d90: 34.8 nm	Mean: 16.8 ± 9.7nm Range: 6 – 58 nm d10: 9 nm d50: 14 nm d90: 27 nm
Aggregate size [2]	Mean: 342.7 ± 180 nm Range: 9 – 1474 nm d10: 110 nm d50: 353 nm d90: 628 nm Particles < 100 nm: 10%	Mean: 243.4 ± 165.7 nm Range: 12 – 1582 nm d10: 25 nm d50: 245 nm d90: 564 nm Particles < 100 nm: 19%
Specific surface area	Typical: 119 m^2/g Range: 110 – 140 m^2/g	Typical: 125 m^2/g Range: 110 – 140 m^2/g
Crystallinity [3]	No crystalline fraction detected	No crystalline fraction detected
Porosity (calculated)	Typical: 97.3% Bulk material: 96.5% Range: 94.5 – 99%	Typical: 97.3% Bulk material: 98.6% Range: 90 – 99%

[1] Based on an analogue of surface modified SAS
[2] Number based particle size distribution (d10 = the 10th percentile distribution, d50 = the median distribution and d90 = the 90th percentile distribution)
[3] Determined using X-ray diffraction measurement with representative SAS (with a detection limit of 0.1%, expert statements provided)

Health hazard information

Limited toxicology data were provided for this assessment from multiple forms of surface coated or uncoated SAS analogues with various particle sizes, including particles in the nanoscale.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 425), 5 female rats were administered surface coated silica (white flaky solid, particle size details not provided) via oral gavage at a single dose of 2,000 mg/kg bw.

One animal (1/5) was found dead on day 2 of the study. Clinical findings of the animal prior to the death included partial closure of both eyes, impaired equilibrium, hypoactivity, decreased respiration rate, soft faeces, pale body and extremities, and low body temperature. Gross necropsy of the dead animal revealed brown matting on the abdominal and urogenital areas.

All the other surviving animals showed wet yellow material on the urogenital, anogenital areas and/or ventral trunk. In one of the surviving animals, dried red material around the nose, hair loss and scabbing on the forelimbs were noted. All surviving animals showed the expected gains in bodyweight and recovered from the clinal symptoms during the 14 days observation period. No abnormalities were noted at necropsy.

The median lethal dose (LD50) of the analogue was determined to be greater than 2,000 mg/kg bw for rats. Based on the results of this study, the analogue chemical is likely to be of low acute oral toxicity.

Inhalation

No acute inhalation toxicity data were submitted for the assessed chemicals or analogues.

Corrosion/Irritation

Skin irritation

An amorphous silica (particle size not reported) was determined to be non-irritating to the skin in an *in vivo* skin irritation test (OECD TG 404) after a single 4-hour application to the intact skin of 1 male and 2 female albino rabbits under semi occlusive conditions. No clinical signs of skin irritation or systemic toxicity were observed.

Eye irritation

The amorphous silica (particle size not reported) was determined to be slightly irritating to the eyes in an *in vivo* eye irritation test (OECD TG 405) of 1 male and 2 female rabbits. One hour after the test item instillation, slight redness (grade 1) was observed in 2 females with slight chemosis (grade 1) also noted in 1 of the females. The effects were totally reversible after 24 hours. No clinical signs of systemic toxicity were observed.

Sensitisation

Skin sensitisation

Data on surface coated silica were provided for information read across purposes. The analogue chemicals were determined not to be skin sensitisers in *in vivo* guinea pig maximisation tests (OECD TG 406).

In a study on polydimethylsiloxanes with aminoalkyl groups, in the induction phase very slight (2/10) to well defined (7/10) and moderate to severe (1/10) erythema was observed in animals at 24 and 48 hours after treated with the test item at 75% concentration in olive oil. Very slight oedema was also observed in 1 animal at 24 hours. No skin reactions were noted in the challenge phase with the test item at 15% concentration in olive oil. All test animals gained body weight as expected.

In another study on siloxanes with terminal amine groups, in the induction phase very slight to moderate erythema were observed in all animals (10M/10F) at 24 and 48 hours after treated with the test item at 5% concentration in mineral oil. When challenged at 10% concentration, slight erythema (grade 1) was noted in 15 animals due to irritation. All irritation effects were reversible by day 2 of the study. The sensitisation incidence index was reported as 0% (0/20) for the test item following challenge phase. All test animals gained weight as expected during the study.

Repeat dose toxicity

Oral

Repeated dose toxicology information was not submitted for the assessed chemicals. For information read across purposes, the applicant provided a journal article describing a 28-day repeated dose oral toxicity study on 7 nanomaterials, including surface coated and uncoated SAS analogues (SiO_2 naked, SiO_2 PEG, SiO_2 phosphate and SiO_2 amino) (Buesen et. al. 2014).

Based on the journal article, the studies were performed as limit tests in accordance with OECD Test Guideline 407, applying the nanomaterials to rats at 1,000 mg/kg bw/day for 28 days. The acute phase proteins, haptoglobin and α2-macroglobulin as well as cardiac troponin I, were determined and metabolome analysis was performed in plasma samples. There were no test substance-related adverse effects reported for any of the 7 nanomaterials tested. Metabolomics changes were below the threshold of effects. However, since test substance organ burden was not analysed, it was not possible to establish whether the lack of findings related to the absence of systemic exposure or if the test substances were devoid of any potential for toxicity in the studies.

The journal article authors concluded that the results of the studies provided a first indication that the tested nanomaterials neither cause local nor systemic effects upon subacute oral administration under the study conditions. Further investigations should elucidate the gastrointestinal absorption of the nanomaterials. No no-observed-adverse-effect-level (NOAEL) or no-observed-effect-level (NOEL) for oral toxicity of the nanomaterials was reported in the article. Based on the journal article, no adverse systemic effects were reported in rats received the analogue chemicals at 1,000 mg/kg bw/day for 28 days.

Inhalation

The applicant provided a journal article (Landsiedel et al. 2014) describing short-term inhalation studies of various surface coated and uncoated synthetic amorphous silicon dioxide (SiO_2) analogues at nanoscale, including SiO_2 naked, SiO_2 acrylate, SiO_2 PEG, SiO_2 phosphate and SiO_2 amino.

Wistar (Crl:WI) rats were exposed (nose-head) to aerosols of various SiO_2 analogues at dose levels ranging from 0.5 to 50 mg/m^3 for 5 consecutive days at 6 hours per day and observed for 21 days. Recovery groups were included and observed for additional 21 days.

At the dose level of 10 mg/m^3/6 hours/day and above, SiO_2 naked induced a dose-related inflammatory response based on increases in lymphocytes and polymorphonuclear neutrophils in broncho-alveolar lavage fluid. Multifocal macrophage aggregates were observed in the lungs by the end of the recovery period also indicating pulmonary inflammation. No significant changes to cytokines or chemokines were observed. Based on the results, the no-observed-adverse-effect concentration (NOAEC) for SiO_2 naked was established as 2.5 mg/m^3/6 hours/day.

A NOAEC of 10 mg/m^3/6 hours/day was established for SiO_2 acrylate based on the deposition of electron-dense aggregates (size = 20 nm) in the respiratory tract of the test animals. Accumulation of thrombocyte and silicon particles were noted in the spleen and was considered to be treatment related.

No mortalities were observed during the study. No adverse effects were noted with other SiO_2 derivatives tested. Observed extra-pulmonary effects, immediately after the final exposure, were the splenetic alterations recorded for SiO_2 acrylate which were fully reversible within 3 weeks. However, the alterations in nasal cavity were only partially reversible. Lung clearance of SiO_2 acrylate seemed to be hampered by the surface modification. Apart from that, post recovery observations indicated lung clearance of 40 - 60% within 3 weeks for all other tested SiO_2 derivatives. Comparing the effects elicited by the surface modified silicas with those caused by SiO_2 naked, surface modifications of SiO_2 seemed to mask the toxicity of the core material (Landsiedel et. al. 2014).

The assessed chemicals have amino siloxane surface characterisation. Based on the provided information, the NOAEC of the assessed chemicals for short term inhalation toxicity is likely in the range of 2.5 to 50 mg/m^3/6 hours/day.

In a 90-day repeated dose inhalation toxicity study with up to 12 months recovery period (OECD TG 413 with modifications to specialise on respiratory tract), rats (10M/10F per group with a total of 450) were exposed (nose-only) to aerosols of 2 non-surface modified SAS analogues (SAS1: surface area 400 m^2/g, purity > 99.8%, mean particle size 10.9 nm; and SAS2: surface area 40 - 50 m^2/g, purity > 99.8%, mean particle size 33.5 nm), at concentrations of 0, 0.5, 1.0, 2.5 and 5 mg/m^3 at 6 hours/day and 5 days/week for 90 days.

During the study period, one rat each in the 0.5 mg/m^3 and the 5 mg/m^3 dose groups were found dead and one rat each in the 1.0 mg/m^3 and 2.5 mg/m^3 dose groups were killed in moribund condition. All other animals survived the study period and were euthanised at scheduled dates.

Gross pathology of the surviving animals showed enlarged lung associated lymph nodes 1 day after the exposure in most of the treated rats, considered to be related to lung overloading. A statistically significant increase in lung weight (absolute and relative wet weights) was noted with lung discolouration. These changes were associated with significant increases in immuno-responses, including inflammatory cells, biomarkers and cytokines in broncho-alveolar lavage fluid. In relation to lung clearance, SAS particles also accumulated in the regional lymph nodes enlarging lymph node size. The changes were mostly reversible in lower dose groups during recovery period. However, the effects remained irreversible in both males and females in the high dose SAS2 group within the 12-month recovery period.

Histopathology of the nasal cavities showed an increase in the severity of hyaline inclusions and the formation of small crystalloids (consisting of chitinase) in all treatment groups. Electron microscopy showed no indications of SAS in the mucosal basal lamina and the particles of the test substances were mostly found to be located at the surface of the olfactory mucosa.

Dose dependent increases in severity of fibrogenesis in lungs were noted from the lowest treated dose in both sexes in the study for SAS2 groups, with one animal in the high dose group developing interstitial fibrosis. Increase of alveolar macrophage agglomeration and inflammatory lesions were also noted.

After 12 months of recovery period, at necroscopy an increase in the number and severity of lymphoid hyperplasia and granulomas was noted in animals treated with SAS2 from the lowest treated dose but all lymph node gross lesions in animals treated with SAS1 appeared normal.

During the study, a statistically significant increase in uterus weight was noted in all the females treated with either SAS1 or SAS2 (except for SAS1 high dose group) but were recovered at 3 months post exposure.

Based on lung effects after 12 months recovery, a lowest-observed-adverse-effect-concentration (LOAEC) was established as 2.5 mg/m^3/6 hours/day for SAS2 and a NOAEC was established as 5.0 mg/m^3/6 hours/day for SAS1. No NOAEC could be established for SAS2.

Based on this study, SAS2 may warrant a hazard classification for STOT RE Cat 2 (H373: May cause damage to the lungs through prolonged or repeated exposure via inhalation) according to GHS criteria, as it caused irreversible adverse effects in the lungs of rats with 1 animal developing interstitial fibrosis, which were not recovered after 12 months. However, as the assessed chemicals are surface coated SAS, in the absence of specific toxicology data on the chemicals, this classification is not assigned for the assessed chemicals.

Genotoxicity

In a bacterial reverse mutation assay (similar to OECD TG 471) submitted, a surface coated silica with particle size in the nanoscale (white fine powder solid, particle size details not provided) was found to be non-mutagenic. However, in one experiment a statistically significant treatment related increase (two-fold increase) in revertant numbers was noted in *Escherichia coli* WP2 uvrA$^-$ strain in the presence and absence of metabolic activation. This observation could not be repeated in a second experiment or using *Escherichia coli* WP2 uvrA$^-$ pKM101 strain.

In a journal article provided by the applicant (Haase et al. 2017), different amorphous SiO_2 nanomaterials, with or without surface treatment, including SiO_2 unmodified, SiO_2 PEG, SiO_2 phosphate, SiO_2 amino (with average particle size at 15 nm and specific surface area at 200 m^2/g), were tested for genotoxicity using EpiAirway™ 3D human bronchial models. The tests were not based on OECD test guidelines. However, the results of the tests were confirmed using an *in vivo* bone marrow micronucleus test (OECD TG 474). In the *in vitro* alkaline comet assay using the human bronchial models, SiO_2 unmodified and SiO_2 phosphate produced a statistically significant increase in DNA comet tail at a concentration of 50 µg/cm^2 with 60-hour incubation. Under the condition of this study, SiO_2 unmodified and SiO_2 phosphate were considered to be genotoxic. However, SiO_2 amino was not reported as genotoxic. The article authors noted that, in cases of nanomaterials, *in vitro* genotoxicity assays often lead to false positive results and overprediction, and the results should be confirmed by *in vivo* tests. In a non-OECD guideline *in vivo* alkaline comet assay of the lung cells from the rats exposed via inhalation (head-nose only) to a dose of 50 mg/m^3/6 hours/day for 5 days, SiO_2 amino did not induce any statistically significant increases in the DNA comet tail. The negative genotoxicity results were further confirmed by an *in vivo* bone marrow micronucleus test (OECD TG 474) in rats exposed to SiO_2 amino via inhalation at 50 mg/m^3/6 hours/day for 5 days.

Based on the information provided on analogues, the assessed chemicals are unlikely to cause genotoxicity effects.

Environmental exposure

The assessed chemicals will be imported into Australia in sealed cartridges for use as surface charge carriers for printing toners. No manufacture or reformulation will occur within Australia. Therefore, releases are not expected to occur during import, transport or storage.

During use, the assessed chemicals are applied to the paper substrate where they will be heat treated and fused into the toner matrix on the paper substrate. The assessed chemicals will share the fate of the paper on which they are applied, either being recycled or disposed of to

landfill. The applicant has estimated that approximately 6% of the introduction volume will be collected as excess toner and disposed of to landfill.

According to the recent Australian National Waste Report (Blue Environment Ltd. 2022), 55% of wastepaper and cardboard is expected to be recycled domestically. During recycling processes, wastepaper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. These wastes will be treated at onsite wastewater treatment plants (WWTP) before release into environmental waters.

Environmental fate

The limited data provided for this assessment were on various forms of SAS derivatives with various particle sizes, including some in the nanoscale.

Partitioning

The assessed chemicals have water solubility of 73 - 81 mg/L (SiO_2 content). If released to the environmental waters, they are expected to agglomerate or aggregate to larger particles on the surface of the water, ultimately partitioning to soils and sediments where they will become immobile.

Degradation

No information on the biodegradation of the assessed chemicals were provided. The assessed chemicals are primarily inorganic, and therefore exempted from persistent classification.

The assessed chemicals are hydrolytically stable based on a tier 1 study conducted on one of the assessed chemicals according to OECD TG 111 which showed < 5% hydrolysis at 50°C.

Bioaccumulation

No information on the bioaccumulation potential of the assessed chemicals were provided. As the assessed chemicals are primarily inorganic, they are exempted from bioaccumulation classification.

The assessed chemicals contain a proportion of silica nanoparticles, available literature on the uptake of silica nanoparticles of various sizes has investigated the uptake in various biota. One study using fluorescent silica nanoparticles found no uptake or translocation in early life stage of the zebrafish (*Danio rerio*) (Fent et. al. 2010). However, a dietary study observed uptake and incorporation into the muscles of Nile Tilapia (*Oreochromis Niloticus*) (Bashar et. al. 2021).

Additionally, silicon nanoparticles have been investigated for their capacity to assist in the transportation of nutrients into terrestrial plants (Naidu et. al. 2023 and Mukarram et. al. 2022). However, it is unclear if this will result in the accumulation or magnification through trophic levels.

The uptake of nanoparticles by organisms is currently uncertain and an ongoing area of research. Silica-based nanoparticles may be taken up by fish through their diet, or by plants through their roots. However, there are no current indications that the nanoparticles will accumulate to high levels or magnify through trophic levels. Additionally, the hydrophobic properties of the assessed chemicals are expected to reduce the bioavailability of the chemicals.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) in Australian waters for each of the assessed chemicals was calculated assuming 60% of the introduction volume is released into sewage treatment plants (STP) over 260 days per annum.

A significant proportion of the notified chemicals may be removed in STP due to attachment to biosolids, sedimentation or flocculation (Rottman et. al. 2012). Total removal during STP treatment is estimated to be 99%. Therefore, < 1% of the total introduction volume is estimated to be released to the aquatic environment.

The calculation of the PEC for each of the assessed chemicals is detailed in the table below:

Total Annual Import Volume	3,000	kg/year
Proportion expected to be released to sewer	60%	
Annual quantity of chemical released to sewer	1,800	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	6.92	kg/day
Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	99%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.01	µg/L
PEC - Ocean	0.001	µg/L

Partitioning to biosolids in STPs Australia-wide may result in the assessed chemicals being repeatedly applied to agricultural soils. As the assessed chemicals are resistant to degradation, it is expected that the portion applied to agricultural soils will persist long term, ultimately being incorporated into the applied soil over time.

Environmental effects

The assessed chemicals contain a proportion of silica nanoparticles and information about the aquatic toxicity of nanoparticles is currently uncertain. However, the hydrophobic nature of the nanoparticles is expected to limit the bioavailability of these components of the assessed chemicals.

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50), and effective concentration (EC50) values for model organisms were supplied for the surface treatment chemical used on the component of the chemical of CA09729:

Taxon	Endpoint	Method
Fish	96 hr LC50 > 126 mg/L	*Brachydanio rario* (zebra fish) OECD TG 203 Semi-static conditions Nominal concentration
Invertebrate	48 hr EC50 > 100 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Semi-static conditions Nominal concentration
Algae	72 hr ErC50 > 118 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate EU Method C.3 Semi-static conditions Nominal concentration

The following median lethal concentration (LC50), and effective concentration (EC50) values for model organisms were supplied for the surface treatment chemical used on the component of the chemical in CA09861:

Taxon	Endpoint	Method
Fish	96 hr LC50 > 934 mg/L	*Brachydanio rario* (zebra fish) OECD TG 203 Semi-static/ conditions Nominal concentration
Invertebrate	48 hr EC50 = 331 mg/L	*Daphnia magna* (water flea) Immobility OECD TG 202 Semi-static conditions Nominal concentration
Algae	72 hr ErC50 > 1,000 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate EU Method C.3 Semi-static conditions Nominal concentration

Additionally, the applicant has provided literature references which indicate that SAS with nanoscale properties is not acutely harmful to fish (96 hr LC50 > 10,000 mg/L) and nano amorphous silica (NAS) is not harmful to aquatic algae (72 hr NOErC = 10,000 mg/L)

Chronic toxicity

The following measured no effect concentration (NOEC) values for model invertebrate organisms were supplied for the SAS material with nanoscale properties:

Taxon	Endpoint	Method
Invertebrate	21d NOEC = 250 mg/L	*Daphnia magna* (water flea) Reproduction OECD TG 211 Semi-static conditions Nominal concentration

The following measured no effect concentration (NOEC) values for model algae organisms were supplied for the surface coating chemical used on the chemical of CA09729:

Taxon	Endpoint	Method
Algae	72hr NOErC > 934 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate EU Method C.3 Semi-static conditions Nominal concentration

The following measured no effect concentration (NOEC) values for model algae organisms were supplied for the surface coating chemical used on the chemical of CA09861:

Taxon	Endpoint	Method
Algae	72hr NOErC > 126 mg/L	*Desmodesmus subspicatus* (green algae) Growth rate EU Method C.3 Semi-static conditions Nominal concentration

Effects on terrestrial Life

Studies have shown that silica nanoparticles have the potential for uptake into plant organisms through their roots. However, there are no current indications that the nanoparticles have adverse effects on plant life.

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration was not calculated for the assessed chemicals as no adverse effects were observed at any trophic level in the studies supplied.

Categorisation of environmental hazard

The assessed chemicals are primarily inorganic substances, and therefore classification according to PBT criteria is not appropriate.

Environmental risk characterisation

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the currently available information indicates the assessed chemicals are not harmful to aquatic organisms or terrestrial plants and will have limited bioavailability. Additionally, the untreated release to the environment is expected to be minimal. Therefore, the risk from the assessed chemicals can be managed.

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