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

Amides, from alkanoic acid, ethylenediamine, hydrogenated plant-based oil fatty acids and octanoic acid

Amides, from alkanediamine, decanoic acid, hydrogenated plant-based oil fatty acids and octanoic acid

Assessment statement (CA09678/CA09809)

25 October 2023

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AICIS assessment statement (CA09678/CA09809)

Chemicals in this assessment

AICIS Approved Chemical Name (AACN)	Application No.
Amides, from alkanoic acid, ethylenediamine, hydrogenated plant-based oil fatty acids and octanoic acid	CA09678
Amides, from alkanediamine, decanoic acid, hydrogenated plant-based oil fatty acids and octanoic acid	CA09809

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 Very Low to Low Risk type. The chemicals in this assessment meet the similar chemical and same end use criteria.

Defined scope of assessment

This assessment was performed on a reaction mixture which is comprised of two chemicals, assessed as:

- imported into Australia for use by consumers and professional workers up to a combined volume of 5 tonnes/year
- imported neat for local reformulation of end-use surface coatings at up to 2% concentration and end-use sealant products at up to 7% concentration
- imported as a component of finished end-use coatings at up to 2% concentration and finished end-use sealant products at up to 7% concentration
- imported in inks at up to 3% concentration contained within writing implements at up to 1 tonne/year (included in the total import volume of up to 5 tonnes/year)

Summary of assessment

Summary of introduction, use and end use

The assessed chemicals will not be manufactured in Australia. The assessed chemicals will be imported into Australia in neat form as a raw material in 15 kg multi-ply paper bags for local reformulation into solvent-based industrial coatings and sealant products. While no reformulation activity will occur at the applicant's facility in Australia, bags containing the assessed chemicals will be transported by road directly to industrial customers for reformulation, from the customs warehouse.

The assessed chemicals may be imported as components of finished end-use industrial coatings at up to 2% concentration in various size containers including 1 L, 4 L and 10 L cans, and 210 kg lined steel drums. They may also be imported as components of finished end-use sealant products at up to 7% concentration in 310 mL or 600 mL caulking gun cartridges. In addition, the assessed chemicals may also be imported as components of inks at up to 3% concentration, contained within writing implements such as pens and markers.

Products containing the assessed chemicals will be available for both professional use and for use by consumers in do-it-yourself (DIY) applications.

Human health

Summary of health hazards

The identified health hazards are based on available data for the assessed chemicals. Based on the physicochemical properties, the assessed chemicals are expected to be readily absorbed following inhalation exposure but are not expected to be readily absorbed following dermal exposure (see **Supporting information)**.

Based on the data submitted on the assessed chemicals, the assessed chemicals are:

- of low acute oral, dermal and inhalation toxicity
- not irritating to skin
- slight eye irritants
- not considered to be skin sensitisers up to 25% concentration
- not considered to be genotoxic
- not likely to cause systemic health effects following repeated oral exposure (up to 1,000 mg/kg bw/day in rats)
- not likely to cause adverse effects in reproductive organs, embryotoxicity or teratogenicity following repeated oral exposure (up to 1,000 mg/kg bw/day in rats).

For further details of the health hazard information, see **Supporting information**.

Hazard classifications relevant for worker health and safety

The chemicals do not satisfy the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017), as adopted for industrial chemicals in Australia.

Summary of health risk

Public

The public may be exposed to the assessed chemicals at concentrations of up to 7% in inks, coatings and sealants. While the exposure will be mainly dermal, ocular and inhalation exposure may also occur.

This assessment does not identify any risks to public health that would require specific risk management measures when the assessed chemicals are introduced in accordance with the terms of the assessment certificate.

Workers

Potential exposure of workers to the assessed chemicals at various concentrations, including in a neat form, may occur during various formulation operations and during professional end use applications. While the exposure to the assessed chemicals will be mainly dermal, ocular and inhalation exposure may also occur.

Workers may experience slight eye irritation if exposed to the assessed chemicals at high concentrations during end-use product formulation activities. Control measures to minimise eye contact and inhalation exposure may be needed if aerosols or mists are formed during these processes.

Environment

Summary of environmental hazard characteristics

According to domestic environmental hazard thresholds and based on the available data, the assessed chemicals are:

- Not Persistent (not P)
- Bioaccumulative (B)
- Toxic (T)

Environmental hazard classification

The chemicals satisfy the criteria for classification according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) as Acute Category 1 (H400) and Chronic Category 1 (H410) based on the toxicity data for algae. Considerations were also made for the rapid biodegradation and bioaccumulation potential of the assessed chemicals.

Environmental Hazard	Hazard Category	Hazard Statement
Hazardous to the aquatic environment (acute / short-term)	Aquatic Acute 1	H400: Very toxic to aquatic life
Hazardous to the aquatic environment (long-term)	Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects

Summary of environmental risk

The assessed chemicals will be introduced as a neat powder or as components in finished products to be used in a variety of end-uses including coatings, sealants and inks. These uses may result in the release of the assessed chemicals to wastewater treatment plants and sewers.

The assessed chemicals are readily degradable and not persistent. The assessed chemicals are potentially bioaccumulative and are toxic to aquatic organisms.

Although the assessed chemicals are potentially bioaccumulative and toxic, they do not meet all three PBT criteria. They are unlikely to have unpredictable long-term effects and their risk may be estimated by the risk quotient method (RQ = PEC ÷ PNEC). Based on calculated RQ

values < 1 for the river and ocean compartments, the environmental risk from the introduction of the assessed chemicals can be managed.

Means for managing risk

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.

Workers may experience slight eye irritation if exposed to the assessed chemicals at high concentrations during end-use product formulation activities. Control measures to minimise eye contact and inhalation exposure may be needed if aerosols or mists are formed during these processes.

Conclusions

The conclusions of this assessment are based on the information described in this statement.

Considering the means of managing risks, the Executive Director is satisfied that when the assessed chemicals are introduced and used in accordance with the terms of the assessment certificate the human health and environment risks can be managed. This is provided that:

- all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.
- the means of managing the risks identified during this assessment are implemented.

Note: Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

Supporting information

The information regarding physico-chemical properties, health hazards, and the environmental fate and effects presented in this section have been derived from studies conducted on a less pure formulation of the assessed chemicals that will not be introduced into Australia. Compared to the less pure formulation, certain impurities are absent or present at lower concentrations in the formulation to be introduced.

Chemical identity

Chemical identity of CA09678

AACN	Amides, from alkanoic acid, ethylenediamine, hydrogenated plant-based oil fatty acids and octanoic acid

Chemical identity of CA09809

AACN	Amides, from alkanediamine, decanoic acid, hydrogenated plant-based oil fatty acids and octanoic acid

Chemical Description

The chemicals are unknown or variable composition, complex reaction products or biological materials (UVCB) and assessed as a reaction mixture.

Relevant physical and chemical properties

Physical form	White crystalline solid
Melting point	81 - 117°C
Boiling point	N/A
Vapour pressure	< 8.4 x 10^{-7} Pa at 20°C
Water solubility	< 0.024 mg/L at 20°C, pH 7.8
Ionisable in the environment?	No
log K_{ow}	> 6.5 at 20°C, pH 7
log K_{oc}	> 5.63 at 20°C

Human exposure

Workers

Reformulation

Transport, storage and warehouse workers are not expected to be exposed to the assessed chemicals or products containing the assessed chemicals, except in an unlikely event of an accidental rupture of containers. During reformulation activities, dermal, ocular and perhaps inhalation exposure (if aerosols or mists are formed) of workers to the assessed chemicals in a neat form or at up to 7% concentration may occur during weighing and transfer stages, blending, quality control analysis, and cleaning and maintenance of equipment. However, according to the applicant, the transfer and blending operations will be conducted under local and general ventilation in bunded areas.

Coatings or sealants containing the assessed chemicals at up to 7% concentration will be transferred by gravity feed or low-pressure pump transfer into lined steel containers (coatings) or 310 mL or 600 mL caulking gun cartridges (sealants). Coatings in sealed, lined steel containers or sealed cartridges will be packed for distribution to stores and end-users.

According to the applicant, worker exposure is expected to be minimised through the use of personal protective equipment (PPE) such as a suitable dust mask or respirator, protective glasses, impervious gloves, hard hat, overalls, and safety boots.

Professional end use

End-user exposure to the coatings containing the assessed chemicals at up to 2% concentration may occur during application by brush, roller or spray in a variety of industrial locations by trained workers. Spray application will take place under ventilation in purpose-built spray facilities.

End-user exposure to the sealant products containing the assessed chemicals at up to 7% concentration may occur during application to surfaces or cavities using either a manual application gun or a compressed air-assisted gun. Any excess product will be removed using a scraper and cloth. Curing of the sealant occurs within 2–4 hours, after which no further reworking is required.

According to the applicant, the potential for dermal or ocular exposure during coating/sealant applications will be minimised through the use of PPE (goggles, impervious gloves, coveralls) by workers. As stated by the applicant, the potential for inhalation exposure during spray application of coatings will be mitigated by the conduct of spray application under ventilation in engineered facilities and through the expected use of air-fed respirators. Once the coating/sealants have dried/cured, the assessed chemicals are bonded to the absorbent surface and are not available for exposure.

The potential for occasional dermal exposure to the assessed chemicals at up to 3% concentration within writing implements (pens and markers) is limited as the ink is contained within the implements. Once the ink has dried, the assessed chemicals are bonded to the absorbent surface (such as paper or cardboard) and dermal exposure is not expected.

Public

Products containing the assessed chemicals at up to 7% concentration (coatings, sealants, writing implements) will be available for use by DIY users. The methods of application of these products will be similar to their professional end use with the exception of the use of purpose-built spray facilities for coating application.

According to the applicant, the potential for dermal or ocular exposure during coating and sealant application may be minimised, as per their professional uses, through the use of PPE (goggles, impervious gloves, coveralls). The potential for inhalation exposure during spray application of coatings will be limited as the spray applications will be conducted under open areas/exhaust ventilation.

The potential for occasional dermal exposure to the assessed chemicals at up to 3% concentration within writing implements (pens and markers), similar to their professional end use, is limited as the ink is contained within the implements. Once the ink has dried, the assessed chemicals are bonded to the absorbent surface (such as paper or cardboard) and are not available for exposure.

Health hazard information

Toxicokinetics

The assessed chemical, being a solid with a relatively high molecular weight, has limited potential for dermal absorption. Furthermore, based on the physicochemical properties of the assessed chemical (log K_{ow} > 6.5 and water solubility < 2.4 x 10^{-5} g/L), dermal absorption is expected to be low.

Particles of the assessed chemical with a diameter less than 100 µm have the potential to be inhaled. Particles will either settle in the nasopharyngeal region (particles with aerodynamic diameter > 1-5 µm) or in the tracheobronchial or pulmonary region (particles with aerodynamic diameter < 1-5 µm). The very low water solubility of the assessed chemical indicates the potential for accumulation, while their lipophilic character indicates the potential for absorption directly across the respiratory tract epithelium.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), 2 groups of fasted female Wistar rats (3/group) were administered the assessed chemical as a single dose of 2,000 mg/kg bw via oral gavage. The animals were observed for 14 days after administration. Clinical signs observed between days 1 and 2 included lethargy, hunched posture, uncoordinated movements, laboured and shallow respiration, piloerection, and salivation. No mortality occurred during the observation period. All animals showed the expected body weight gains over the study period. No treatment-related gross necropsy findings were observed. The oral median lethal dose (LD50) of the assessed chemical was determined to be > 2,000 mg/kg bw.

Dermal

In an acute dermal toxicity study (OECD TG 402), no mortality was observed when a single dose of 2,000 mg/kg bw was applied to the skin of Wistar rats (5/sex) for 24 hours. Clinical

signs of systemic toxicity on the day of dosing included flat posture, ptosis (drooping of upper eyelid) and chromodacryorrhoea (secretion of red tears). In addition, scales, scabs and/or erythema were seen in the treated skin area during the observation period. All animals showed the expected body weight gains over the study period and no treatment related gross necropsy findings were observed. The dermal LD50 of the assessed chemical was determined to be > 2,000 mg/kg bw.

Inhalation

In an acute inhalation toxicity study (OECD TG 403), Wistar rats (5/sex) were exposed to the assessed chemical administered as an aerosol for 4 hours to a concentration of 6.3 mg/L (mass median aerodynamic diameter of up to 1.5 µm). No treatment-related deaths following the exposure period were observed. One male was found dead during the exposure period; no further mortality occurred. After exposure to the assessed chemical, most of the animals displayed a hunched posture, laboured respiration and slow breathing. Ptosis was noted in one male and 2 females on Day 1. Lethargy, quick breathing and/or rales were noted among the males on Days 1 and/or 4. Piloerection or tremors were observed in 2 females on Day 1. Red staining of the head or snout was noticed in most of the animals between Day 1 and Day 6. All animals showed the expected body weight gains over the study period. The inhalation median lethal concentration (LC50) of the assessed chemical was determined to be > 5 mg/L.

Corrosion/Irritation

Skin irritation

The assessed chemical was determined not to be irritating to the skin of rabbits (OECD TG 404). Treatment of 3 male New Zealand White rabbits with 0.5 g of assessed chemical (applied to the skin under semi-occlusive conditions for 4 hours) induced no skin reactions up to 72 hours after exposure. Furthermore, no symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

Eye irritation

The assessed chemical was tested for eye irritation potential in rabbits (OECD TG 405). Approximately 31 mg of assessed chemical was instilled into the lower conjunctival sac of one eye of each of 3 male New Zealand White rabbits. Instillation of the assessed chemical into the eye had no effects on cornea or iris in any animal at any time point. The irritation of the conjunctivae consisted of redness, chemosis and discharge and these changes completely resolved within 7 days.

The mean eye irritation scores for conjunctival effects for the 3 test animals were 1.7, 0.7 and 0.7 for redness and 0.0, 0.3 and 0.0 for chemosis. Under the conditions of the study and according to the test guideline, the assessed chemical was considered to be slightly irritating to the eye.

Sensitisation

Skin sensitisation

The skin sensitisation potential of the assessed chemical was tested using a local lymph node assay (LLNA) (OECD TG 429). Three groups of female mice (CBA strain) (5/dose) were treated by daily application of 25 µL of the assessed chemical at concentrations of 5%, 10% or 25% (v/v), to the dorsal surface of each ear for three consecutive days. The highest

concentration of assessed chemical was selected from a preliminary irritation study for practical reasons, as a 50% formulation was too dry to stick to the ear after application. On day 6, all animals were injected via the tail vein with 0.25 mL of sterile phosphate buffered saline containing 25 µCi of ^{3}HTdR and, after five hours, the draining (auricular) lymph nodes were excised.

There were no deaths or signs of systemic toxicity in the treatment groups, and body weights were comparable to controls. The majority of lymph nodes were normal in size, except for one enlarged node from one animal treated with a concentration of 25% (v/v) of assessed chemical.

The stimulation indices (SI) calculated for the assessed chemical at 5%, 10% and 25% (v/v) concentrations were 2.5, 2.8 and 2.3, respectively. None of the applied concentrations induced a biologically relevant increase (SI ≥ 3). Therefore, under the conditions of the study and according to the test guideline, the assessed chemical was not considered to be sensitising to the skin, up to 25% concentration.

Repeat dose toxicity

Oral

In a repeated dose toxicity study (OECD TG 407), the assessed chemical in propylene glycol was administered to groups of Wistar rats (5 /sex/dose) by oral gavage for 28 days, at doses of 50, 150 and 1,000 mg/kg bw/day. The control group were dosed with vehicle alone (propylene glycol).

There were no treatment-related clinical signs, deaths or treatment-related changes observed in food consumption, body weight, functional tests, haematological parameters, clinical biochemistry, macroscopic examination, organ weight or microscopic examination in any animals at any tested dose.

The no observed adverse effect level (NOAEL) was established at 1,000 mg/kg bw/day in this study, based on an absence of adverse effects in rats up to the highest tested dose (1,000 mg/kg bw/day).

Genotoxicity

The assessed chemical was found to be non-mutagenic in a bacterial reverse mutation assay using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2uvrA, with or without metabolic activation (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any tested dose (1, 3, 10, 33, 100, 333 µg/plate), with or without metabolic activation.

The assessed chemical was tested for its clastogenic and aneugenic potential in an in vitro mammalian micronucleus test using human lymphocytes (OECD TG 487). The assessed chemical demonstrated no evidence of cytotoxicity in any of the exposure groups. No increase in the frequency of cells with aberrations or the incidence of polyploidy was recorded in the absence or presence of metabolic activation, at any dose tested (3, 10, 33, 100, 200, 333 µg/mL without metabolic activation; 3, 10, 33 µg/mL with metabolic activation). Precipitation of the assessed chemical was seen at concentrations of 33 µg/mL and above. The results indicate that the assessed chemical is unlikely to be clastogenic or aneugenic to human lymphocytes in vitro.

The assessed chemical was also tested in vitro for its potential to induce mutations at the thymidine kinase locus in mouse lymphoma L5178Y cells (OECD TG 490). The concentrations used in the main experiments (0.03, 0.1, 0.3, 1, 3, 10, 33, 100 µg/mL) were based on data from a preliminary toxicity test. No toxicity was seen up to and including a dose of 100 µg/mL, which was beyond the limit of solubility (33 µg/mL). No biological relevant increase in mutation frequency was found after treatment with the assessed chemical at any tested concentration, with or without metabolic activation. The numbers of small and large colonies in the cultures treated with the assessed chemical were comparable to the numbers of the respective colonies in the solvent controls. The assessed chemical was therefore considered to be non-mutagenic and non-clastogenic under the conditions of the study.

Reproductive and development toxicity

In a reproductive/developmental toxicity screening study (OECD TG 421), the assessed chemical was administered to Crl:WI(Han) rats (10/sex/group) via oral gavage at dose levels of 0, 50, 150 and 1,000 mg/kg bw/day, once daily for 14 days prior to cohabitation, during cohabitation, and continuing through the day before euthanasia for male rats or for at least 3 days of lactation for female rats that delivered a litter.

There were no mortalities or treatment-related changes in clinical signs, body weight, food consumption or organ weights. Furthermore, macroscopic and microscopic examination did not reveal any findings that were related to treatment with the assessed chemical at up to the highest tested dose (1,000 mg/kg bw/day).

The number of corpora lutea, implantation sites, implantation index, number of pups born, number of litters, live and dead pups at first litter check, postnatal loss, delivery index, viability index and duration of gestation were unaffected by treatment with up to 1,000 mg/kg bw/day of assessed chemical.

No treatment-related clinical signs were noted for F_1 pups up to the highest tested dose (1,000 mg/kg bw/day). Body weights remained similar between control and F_1 pups from all treatment groups on Days 1 and 4 of lactation. The numbers of pups that died prior to the scheduled necropsy in each treatment group were 12/97 (control), 3/82 (low dose), 5/70 (medium dose) and 3/78 (high dose). Macroscopic findings from the dead pups revealed no relationship with treatment.

The NOAEL for parental, reproductive, and developmental toxicity was considered to be 1,000 mg/kg bw/day, based on no treatment related effects observed in this study at the highest tested dose (1,000 mg/kg bw/day).

Environmental exposure

The assessed chemicals will be imported into Australia in a neat powder form to be reformulated into finished products or as components in finished products to be used in a variety of applications including industrial coatings, sealants and inks.

Reformulation of the assessed chemicals into coatings and sealants will occur domestically (see **Human Exposure – Workers**).

Coatings and sealants containing the assessed chemicals will be used by professional workers in industrial settings, and by DIY users. The coatings will be applied by spray, brush or roller. After application, the assessed chemicals will be cured into the coating matrix which will be disposed of with the substrate at the end of its useful life.

During professional use, release of the assessed chemicals may occur through overspray and accidental spills. Incidental releases are expected to be collected for appropriate disposal. Wastes and residues in empty containers are expected to be collected and disposed of to landfill according to local government regulations.

Conservatively, for DIY use, it is assumed that up to 5% of the annual import volume of the assessed chemicals may be incorrectly disposed of to sewers, down drains, or to the ground from spills, inappropriate waste disposal and washing of application equipment.

The assessed chemicals used in sealants are expected to be cured onto the surface they are incorporated onto, following application, and hence are expected to share the fate of the product and be disposed of to landfill at the end of their useful lives. Any spills and excess product containing the assessed chemicals, are expected to be collected and disposed of according to local, state and federal regulations.

The assessed chemicals in inks will be imported into Australia as a finished product and no reformulation to inks will occur domestically.

According to the recent Australian National Waste Report (Blue Environment Ltd. 2022), 60% of the wastepaper treated with the assessed chemicals 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 which will be treated at onsite wastewater treatment plants (WWTP).

Environmental fate

Partitioning

The assessed chemical is very slightly water soluble (water solubility < 0.024 mg/L), very slightly volatile (vapour pressure < 0.00000084 Pa), have a high log K_{ow} (log K_{ow} > 6.50) and high K_{oc} value (log K_{oc} > 5.63). If the assessed chemical is released to water, a proportion of the chemical is expected to readily partition to organic matter in soil and sediments and become immobile.

Based on its slight volatility, the assessed chemical is not expected to evaporate and partition to air.

Degradation

Based on its ready degradability in water, the assessed chemical is not persistent.

Degradation studies in water indicate that, in the presence of silicone oil and surfactant to increase the solubility and bioavailability, the assessed chemical is readily biodegradable. The result of a supplied biodegradation study for the assessed chemical was 67% degradation (OECD 301F) over 28 days. The 10-day-window criterion is waived as the assessed chemical is a mixture of compounds (OECD 2005). The addition of silicone oil and surfactant to improve the solubility of the assessed chemicals is considered an acceptable modification to the experiment based on Annex III of OECD TG 301 Ready Biodegradability (OECD 1992).

Bioaccumulation

Based on its log K_{ow} value, the assessed chemical is potentially bioaccumulative.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical is log K_{ow} > 6.5, which exceeds the domestic bioaccumulation threshold for a chemical's bioaccumulation potential (log K_{OW} = 4.2), indicating the potential for bioaccumulation.

Predicted environmental concentration (PEC)

Two predicted environmental concentrations (PEC) for Australian waters were calculated assuming 5% of the total introduction volume used in coatings and sealants is expected to be released to sewers due to improper disposal from DIY users and 60% of the total introduction volume used in inks will be detached from substrates during the paper recycling process and will result in release to WWTP.

The portion of the assessed chemicals that will be released to sewers from uses of coating and sealants is not expected to undergo any treatment, resulting in 0% removal in the PEC calculations.

The calculation of the PEC for total introduction volumes of the assessed chemicals used in coatings and sealants that are released to sewers due to improper disposal by DIY users is detailed in the table below:

Total Annual Import Volume (coatings and sealants)	4900	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	245	kg/year
Days per year where release occurs	365	days/year
Daily chemical release	0.67	kg/day
Water use	200.0	L/person/day
Population of Australia	25.423	Million
Removal within STP	0%	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.13	µg/L
PEC - Ocean	0.013	µg/L

Based on their very low water solubility (< 0.024 mg/L) and very high log K_{ow} of > 6.5, the majority of the assessed chemicals that will be released to WWTP from uses of inks is expected to adsorb to biosolids and be removed during wastewater treatment. Additionally, the assessed chemicals are readily biodegradable, therefore a significant proportion of the assessed chemicals are also biodegraded during wastewater treatment.

The extent to which the assessed chemicals are removed from the effluent in WWTP processes is based on their physicochemical properties, modelled by SimpleTreat 3.0 (Struijs 1996), and is estimated to be 89%. Therefore 11% of the introduction volume used in inks is estimated to be released to the aquatic environment.

The calculation of the PEC for total introduction volumes of the assessed chemicals used in inks that are released to WWTP during paper recycling processes is detailed in the table below:

Total Annual Import Volume (Inks)	100	kg/year
Proportion expected to be released to sewer	60%	
Annual quantity of chemical released to sewer	60	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	0.23	kg/day
Water use	200.0	L/person/day
Population of Australia	25.423	Million
Removal within STP	89%	Mitigation
Daily effluent production	5085	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.005	µg/L
PEC-Ocean	0.0005	µg/L

The cumulative PECs of the assessed chemicals that will be released to river and ocean waters from the assessed chemicals' end uses are calculated to be 0.135 µg/L and 0.0135 µg/L respectively.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50), effective concentration (EC50), and inhibition concentration (IC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 >100 mg/L Water accommodated fraction (WAF)	*Cyprinus carpio* (carp) Mortality OECD TG 203 Static Nominal loading rate
Invertebrate	48 h EC50 > 100 mg/L WAF	*Daphnia magna* (water flea) Immobility OECD TG 202 Static Nominal loading rate
Algae	72 h ErC50 = 0.025 mg/L	*Selenastrum capricornutum* (not provided) Growth rate OECD TG 201 Static Measured concentration
Microorganisms	3 h IC50 > 100 mg/L	Activated sludge from a STP Respiration inhibition OECD TG 209 Static Nominal concentration

Chronic toxicity

The following measured no effect concentration (NOEC) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Invertebrates	21 d NOEC > 100 mg/L WAF	*Daphnia magna* (water flea) Reproduction OECD TG 211 Semi-static Nominal loading rate
Algae	72 h NOEC = 0.0073 mg/L	*Selenastrum capricornutum* (not provided) Growth rate OECD TG 201 Static Measured concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 0.25 µg/L was calculated for the assessed chemicals in the aquatic environment. This value was derived using the most sensitive acute endpoint, the 72 h EC50 for algae (0.025 mg/L). An assessment factor of 100 was applied

based on data available for acute endpoints for three trophic levels and chronic endpoints for two trophic levels (EPHC 2009). The lowest acute endpoint was selected as the basis of the PNEC calculation in the absence of comparable chronic endpoints to support the algal growth inhibition NOEC (ECHA 2008).

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemicals according to domestic environmental hazard thresholds is presented below:

Persistence

Not Persistent (Not P). Based on supplied degradation studies, the assessed chemicals are categorised as Not Persistent.

Bioaccumulation

Bioaccumulative (B). Based on a measured log K_{ow} value above the domestic threshold, the assessed chemicals are categorised as Bioaccumulative.

Toxicity

Toxic (T). Based on an available ecotoxicity value below 1 mg/L, the assessed chemicals are categorised as toxic.

Environmental risk characterisation

Although the assessed chemicals are potentially bioaccumulative and toxic, they do not meet all three PBT criteria. They are hence unlikely to have unpredictable long-term effects (EPHC 2009). An estimate of risk may therefore be determined using the risk quotient method.

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed chemicals to water from uses in coatings, sealants and inks:

Compartment	PEC	PNEC	RQ
River	0.135 µg/L	0.25 µg/L	0.54
Ocean	0.0135 µg/L	0.25 µg/L	0.054

For the river and ocean compartments, an RQ less than 1 indicates that introduction of the assessed chemicals, in line with the terms outlined in this assessment certificate, is not expected to pose a significant risk to the environment. As such, the risk from the assessed chemicals can be managed, based on consideration of the environmental hazard characteristics and estimated releases.

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