Urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)-: Environment tier II assessment

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CAS Registry Number: 101-20-2.

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using

Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: www.nicnas.gov.au.

Disclaimer

Acronyms & Abbreviations

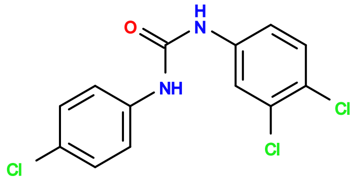
Rationale

This Tier II assessment considers the environmental risks associated with industrial uses of urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)-, which is more commonly known by its synonym, triclocarban. This chemical has antifungal and bacteriostatic properties. It is used as an antimicrobial ingredient in personal care products such as antibacterial bar soap and liquid hand wash. Triclocarban is used in significant volumes worldwide, and is released to sewers as a normal part of its use pattern.

The Tier I assessment of triclocarban found that this chemical is potentially of concern to the environment based on its very high toxicity to aquatic organisms, and an unacceptably high risk quotient for emissions of the chemical to surface waters in the treated effluent discharged from sewage treatment plants (STP). A more in-depth assessment at Tier II level was recommended under the IMAP framework.

Chemical Identity

Synonyms	triclocarban TCC
Structural Formula	



Molecular Formula	$C_{13}H_9Cl_3N_2O$
Molecular Weight (g/mol)	315.58
SMILES	c1(Cl)c(Cl)cc(NC(=O)Nc2ccc(Cl)cc2)cc1

Physical and Chemical Properties

The physical and chemical property data for triclocarban were retrieved from the scientific literature, regulatory reports and calculated using standard quantitative structure-property relationships (QSPR) (Haynes, 2016; US EPA, 2002a; 2008):

Physical Form	solid
Melting Point	254.4°C (exp.)
Vapour Pressure	4.98×10^{-7} Pa (calc.)
Water Solubility	0.11 mg/L (exp.)
Ionisable in the Environment?	no
log K_{ow}	4.2 (exp.)

Import, Manufacture and Use

Australia

Triclocarban is an antimicrobial ingredient in some personal care products available in Australia. No import or manufacturing information has been identified for this chemical.

International

Triclocarban has been produced on an industrial scale since 1957 for use as an antimicrobial agent (Halden and Paull, 2005). It is used in significant quantities worldwide: 100–1000 tonnes is used in the European Union (EU) per annum (REACH, 2017), and greater than 454 tonnes per annum is used in the United States of America (USA) (US EPA, 2002b). It is predominantly used in personal care products such as antibacterial soap, but is also used in plastics to stop bacterial growth (Brausch and Rand, 2011).

Environmental Regulatory Status

Australia

The use of triclocarban is not subject to any specific national environmental regulations.

There are no water quality guidelines available for this chemical under the National Water Quality Management Strategy (ANZECC, 2000). There are no national or state guidelines for levels of triclocarban in biosolids.

United Nations

Triclocarban is not currently identified as a Persistent Organic Pollutant (UNEP, 2001), ozone depleting substance (UNEP, 1987), or a hazardous substance for the purpose of international trade (UNEP & FAO, 1998).

OECD

Triclocarban is listed as an OECD High Production Volume chemical, indicating that more than 1000 tonnes of the chemical is produced per year in at least one member country of the OECD (OECD, 2004).

Canada

Triclocarban is listed on the Canadian Domestic Substances List (DSL). During the Categorization of the DSL, the chemical was categorised as Persistent (P), not Bioaccumulative (not B), and Inherently Toxic to the Environment (iT_E), and was prioritised for further assessment under the Chemicals Management Plan (CMP) (Environment Canada, 2013; Government of Canada, 2013).

European Union

Triclocarban was pre-registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation (ECHA, 2014). This chemical has undergone the full registration process (ECHA, 2016a).

United States of America

Triclocarban is listed on the inventory of chemicals manufactured or processed in the USA, as published under the *Toxic Substances Control Act 1976* (TSCA) (US EPA, 2015).

Triclocarban is listed as a US High Production Volume (HPV) chemical, indicating that at least 1 000 000 pounds (454 tonnes) is manufactured or imported into the USA annually (US EPA, 2010). A screening level assessment for the HPV Challenge Program was prepared by the TCC consortium in 2002 (US EPA, 2002b).

The U.S. Food and Drug Administration has ruled that consumer antiseptic wash products containing triclocarban will no longer be able to be marketed, since manufacturers did not demonstrate that these products are both generally recognised as safe and more effective than plain soap and water in preventing illness and the spread of certain infections.

The rule does not apply to antibacterial products used in health care settings. The rule comes into force on September 6, 2017 (United States Government, 2016; US FDA, 2016).

Environmental Exposure

Available international use data indicate that triclocarban is used primarily as an antimicrobial ingredient in bar and liquid soaps and washes. In the EU, it may also be found in paints and coatings, cosmetics, deodorants, fillers, putties, plasters, modelling clay, finger paints, inks and toners, pharmaceuticals, and washing and cleaning products (ECHA, 2016b; European Commission, 2005). Triclocarban is known to be used in soap formulations in Australia, and the majority of the chemical in use nationwide is expected to be released to sewers.

Triclocarban is a lipophilic chemical, and is largely removed in STPs by adsorption to sludge. A study in a typical activated sludge wastewater treatment plant in the USA found a removal efficiency of 96–98% from the influent. Approximately 76% of the triclocarban load entering the treatment plant did not undergo biological or chemical transformation and remained adsorbed to sludge, while 21% was biotransformed, or otherwise unaccounted for (Heidler, et al., 2006). A study of wastewater treatment plants in the greater Baltimore area found that greater than 98% of triclocarban was removed (Halden and Paull, 2005). Other studies have shown removal rates of 65–98% (US EPA, 2002b).

The emission scenarios considered in this assessment are emission of triclocarban to environmental surface waters in effluent from STPs and release to soil from biosolids applied as soil improver.

Environmental Fate

Partitioning

Triclocarban remains in soil if released to soil, or partitions between water and sediment when released to water. Triclocarban is predominantly sorbed to particulate matter in surface waters.

Triclocarban is a lipophilic neutral organic chemical that is slightly soluble in water and very slightly volatile from water and moist soil. It has a calculated Henry’s Law constant of 4.58×10^{-6} Pa-m^3/mol (US EPA, 2008). Release of triclocarban to air as a result of industrial use is therefore considered minimal.

Triclocarban partitions between water and sediment when released to surface waters. Venkatesan *et al*. measured concentrations of triclocarban in surface water and sediment samples taken from rivers, creeks and lakes near 12 wastewater treatment plants in Minnesota and found significant concentrations of the chemical in both compartments (Venkatesan, et al., 2012).

When released to soil, triclocarban remains strongly sorbed to soil. A 101 day soil column leaching experiment (Kwon and Xia, 2012) showed very limited leaching, with triclocarban detectable only in the top 10 cm of soil, and no detectable triclocarban in the leachate. In a monitoring study of agricultural soil amended with biosolids over a period of 33 years, concentrations of triclocarban in the microgram/kg (µg/kg) range were detected in the top 15 cm of soil, while only trace amounts were detected below 30 cm. The trace amounts detected below this level were attributed to ploughing and planting operations, and to the action of earthworms and plant roots (Xia, et al., 2010). A study of surface runoff from an agricultural field amended with dewatered municipal biosolids also found that levels of triclocarban were below the limit of detection of 2.5 nanograms/litre (ng/L) (Edwards, et al., 2009). Environmental release of triclocarban in runoff from biosolids-amended agricultural land is, therefore, not considered to be a significant exposure pathway.

Triclocarban sorbs strongly to particulate organic matter and non-filterable colloidal matter. Halden and Paull have estimated that in natural surface waters, 70% of the total mass of triclocarban present is adsorbed to the experimentally defined particulate fraction (Halden and Paull, 2004).

Degradation

Triclocarban degrades slowly in biosolids and soil, and is expected to biodegrade slowly in water.

Triclocarban is not predicted to partition significantly to the air compartment, and atmospheric degradation by hydroxyl radicals is, therefore, not expected to be a significant degradation pathway.

Triclocarban is stable to hydrolysis in water with an estimated hydrolysis half-life of 1.2 years in pure water at 25°C (Audu and Heyn, 1988). The chemical does undergo both direct and sensitised indirect photolysis in aqueous solution (Trouts and Chin, 2015). The half-life for direct photolysis of triclocarban in water at pH 7 under simulated sunlight is 24.2 hours (Guerard, et al., 2009). Based on these findings, photolysis of triclocarban may be a significant dissipation pathway for this chemical in clear surface waters.

Triclocarban is not readily biodegradable based on the results of a test conducted according to OECD Test Guideline 301C (US EPA, 2002a). This reported test result shows that there was no degradation of the chemical after 28 days. The first-order half-life for biodegradation of triclocarban in surface waters is assumed to be greater than 100 days based on this finding (EPHC, 2009).

Although triclocarban is not expected to be rapidly biodegraded in the environment, there is evidence to indicate that the chemical can undergo aerobic primary biodegradation under more favourable conditions. For example, a test conducted with adapted activated sludge microorganisms under continuous flow conditions did result in 70% biotransformation of triclocarban in 28 days. No biotransformation was observed after 3 months under anaerobic conditions with non-adapted sludge microorganisms from a domestic activated sludge plant (US EPA, 2002a)

Several studies have shown that only approximately 20% of the input load of triclocarban is biotransformed in activated sludge wastewater treatment plants (Heidler, et al., 2006). Heidler *et al*. showed that significant amounts of triclocarban were removed in the primary treatment sludge and were, therefore, not subjected to treatment in the aerated activated sludge tanks, where biotransformation rates would be expected to be greatest (Heidler, et al., 2006). They found that the majority (76%) of the mass of triclocarban in the influent partitioned to biosolids, with 3% emitted to surface waters in effluent.

In a soil study, triclocarban was reported as showing no change in concentration over 70 days in sterile soil, or in non-sterile soil under anaerobic conditions. Triclocarban did degrade slowly in soil under aerobic conditions, with an estimated half-life of 108 days (Ying, et al., 2007). This laboratory study suggests that triclocarban will degrade slowly in soil when released in biosolids. This finding is consistent with the field study of agricultural soil amended with biosolids over a period of 33 years described above. Only a small percentage of the cumulative input of triclocarban estimated to have been applied in biosolids over the 33 year period remained. This suggests that although slow, the rate of biodegradation of triclocarban in soil was faster than its rate of application in biosolids. Other studies have shown dissipation half-lives in agricultural soil in the range 51–191 days (Al-Rajab, et al., 2015).

Bioaccumulation

Triclocarban has low to moderate bioaccumulation potential in aquatic organisms, and is metabolised in higher tier organisms.

Triclocarban has a relatively high octanol-water partitioning coefficient (log K_{ow} = 4.2), suggesting that it has some potential to bioaccumulate, and this has been observed in a variety of aquatic and terrestrial organisms across multiple trophic levels. It is susceptible to metabolism in fish and mammals (Schebb, et al., 2011), which reduces its potential to bioaccumulate in higher tier organisms compared with the potential expected from its lipophilicity. A bioconcentration factor (BCF) of 724 L/kg has been determined in fish and triclocarban was found to be rapidly depurated in clean water (Schebb, et al., 2011).

Triclocarban has been shown to bioaccumulate in other aquatic organisms. A bioaccumulation factor (BAF) of 1600–2700 has been measured in algae (*Cladophora* spp. (Coogan, et al., 2007; Coogan and La Point, 2008)), and a BAF of 1600 has been measured in freshwater snails (*Helisoma trivolvis*, (Coogan and La Point, 2008)). A biota-sediment accumulation factor (BSAF) of 2.2 g organic carbon/g lipid has been measured in freshwater worms (Higgins, et al., 2009).

Uptake of triclocarban has also been demonstrated in wetland plants (*Typha latifolia*, *Pontederia cordata*, and *Sagittaria graminea*, (F.M. Zarate, et al., 2012)), bahia grass (*Paspulum notatum*, (Snyder, et al., 2011)), earthworms (*Eisenia foetida,* (Higgins, et al., 2011)) and soybeans (*Glycine max* (L.) Merr., (Wu, et al., 2010)).

Triclocarban has been measured in different trophic levels in a terrestrial food web at an agricultural site amended with biosolids for seven years, where it was detected in earthworms, deer mice and eggs of European starlings and American kestrels. However, biomagnification of the chemical was not apparent in this food web (Sherburne, et al., 2016).

Transport

Triclocarban is not expected to undergo long-range transport.

Triclocarban has very low volatility and adsorbs strongly to soil, sediment, and natural particulate matter in surface waters. These properties are expected to limit the potential for this chemical to undergo long-range transport in the environment. No environmental monitoring data were identified to indicate the presence of triclocarban in remote areas.

Predicted Environmental Concentration (PEC)

A reasonable worst case environmental concentration for triclocarban in Australian inland surface waters is predicted to be 416 ng/L, based on available international monitoring data.

As a first approximation, standard exposure modelling for the release of chemicals to surface water from STPs is used to estimate the concentration of triclocarban in river water receiving treated effluents (EPHC, 2009; Struijs, 1996). In accordance with the IMAP Framework, the annual maximum volume of this chemical introduced into Australia for industrial uses is assumed to be 100 tonnes (NICNAS, 2013). Based on measured removal rates in STPs, it is assumed that 98% of the triclocarban entering a typical STP will be removed from wastewater and that a cumulative total of two tonnes is released in treated effluent every year. The PEC for the riverine compartment is calculated to be 1.2 micrograms per litre (µg/L) (or 1200 ng/L), assuming the chemical is released into sewers on all 365 days of the year.

This is likely to be an overestimate of the maximum environmental concentration in Australian rivers. The mean, median and maximum triclocarban concentrations found in effluent from wastewater treatment plants in a United States Geological Survey (USGS) study were 115 ng/L, 96 ng/L and 416 ng/L, respectively (Lee, et al., 2016). Assuming that the use patterns for triclocarban are similar in Australia and in the USA, and considering that river flows can consists entirely of STP effluent in some drier parts of Australia, a reasonable worst case environmental concentration for triclocarban in domestic rivers is predicted to be 416 ng/L.

The one available study reporting triclocarban concentrations in Australian rivers found a maximum triclocarban concentration of 58 ng/L (Scott, et al., 2014). While this study shows that triclocarban is present in Australian rivers as an environmental contaminant, it is not possible to infer concentrations of the chemical in STP effluent, which are required for the standard reasonable worst case exposure scenario.

The concentration of triclocarban in biosolids amended soil is predicted using the standard approach used for industrial chemicals in Australia (EPHC, 2009). The 95th percentile value for the concentration of triclocarban in biosolids measured in the United States Environmental Protection Agency (US EPA) Targeted National Sewage Sludge Survey (131 mg/kg) is taken as the basis for calculating the concentration of triclocarban in biosolids-amended soil in Australia (US EPA, 2009). Using an application rate of 10 tonnes of biosolids per hectare, a mixing depth of 10 cm, and a soil bulk density of 1500 kg/m^3, the concentration of triclocarban in biosolids-amended soil is calculated to be 0.87 mg/kg immediately after application.

This estimated soil concentration for triclocarban is comparable with the results of a field study of agricultural soil amended with biosolids over a period of 33 years as described above (Xia, et al., 2010). The concentration of triclocarban in the top 15 cm of soil that received an annual application of 16.8 tonnes of biosolids per hectare was found to be 0.9 mg/kg.

In addition to being a ubiquitous contaminant in effluent and biosolids from wastewater treatment plants, triclocarban is also routinely detected in sediments in the USA (Venkatesan, et al., 2012). A USGS study of sediments near outflows from wastewater treatment plants found triclocarban concentrations in the range from 5 to 822 ng/g dry weight.

Environmental Effects

Effects on Aquatic Life

Triclocarban causes toxic effects at very low exposure concentrations in aquatic organisms across multiple trophic levels. Aquatic invertebrates are particularly sensitive to the toxic effects of this chemical.

The mode of toxic action for triclocarban at high concentrations is understood to involve non-specific membrane destabilisation (Orsi, et al., 2011; Yang, et al., 2008). However, the mode of toxic action at lower concentrations is not fully understood (Orsi, et al., 2011).

Acute toxicity

The following measured median lethal concentration (LC50) and median effective concentration (EC50) values for freshwater model organisms across three trophic levels were reported in the registration dossier for the chemical under the EU REACH legislation (REACH, 2017), and the databases included in the OECD QSAR Toolbox (LMC, 2013). Additional acute toxicity values can be found in the scientific literature (Chalew and Halden, 2009):

Taxon	Endpoint	Method
Fish	96 h LC50 = 0.04 mg/L	Experimental *Lepomis macrochirus* (Bluegill) Static
Invertebrates	48 h LC50 = 0.0077 mg/L	Experimental *Daphnia magna* (Water flea) Static
Algae	72 h EC50 = 0.029 mg/L	Experimental *Pseudokirchneriella subcapitata* (Green algae) OECD TG 201, Static Reduced growth rate observed

Chronic toxicity

The following no-observed-effect-concentration (NOEC) values for freshwater and estuarine model organisms across three aquatic trophic levels for triclocarban were reported in the registration dossier for the chemical under the EU REACH legislation (REACH, 2017), and databases included in the OECD QSAR Toolbox (LMC, 2013). Additional chronic toxicity values may be found in the scientific literature (Chalew and Halden, 2009):

Taxon	Endpoint	Method
Fish	21 d NOEC = 0.0016 mg/L (1.6 µg/L)	Experimental *Pimephales promelas* (Fathead minnow) Flow-through Reduced growth rate observed
Invertebrates	28 d NOEC = 0.00025 mg/L (0.25 µg/L)	Experimental *Daphnia magna* Flow-through Mortality observed
	28 d NOEC = 0.000056 mg/L (0.056 µg/L)	Experimental *Americamysis bahia* (Mysid shrimp) Estuarine species Flow-through Reproductive toxicity
Algae	72 h NOEC < 0.01 mg/L	Experimental *Pseudokirchneriella subcapitata* OECD TG 201, Static Reduced growth rate observed

Effects on Terrestrial Life

The only soil toxicity value identified for triclocarban is an LC50 of 40 mg/kg (dry weight) for the earthworm, *Eisenia foetida*, exposed to the chemical in fine sand amended with biosolids over four weeks (Snyder, et al., 2011). It is noted that this is a conservative test, and that when silty clay loam and artificial soil were tested, triclocarban had no apparent effect on earthworm mortality even when 10 000 mg triclocarban per kg biosolids was applied at an equivalent rate of 22 tonnes per hectare. This is presumably due to the reduced bioavailability of triclocarban in real or artificial soils.

The same study found that biosolids-borne triclocarban had no significant effect on soil microbial community respiration, ammonification or nitrification at the highest tested application rate of approximately 7 mg triclocarban per kg amended fine sand.

Effects on Sediment-Dwelling Life

The only sediment toxicity data identified were from a preliminary study on the California blackworm, *Lumbriculus variegatus*, which was used to determine appropriate exposure concentrations for triclocarban in a bioaccumulation study (Higgins, et al., 2009). No mortality was observed due to triclocarban exposure at sediment concentrations of up to 100 mg/kg dry weight.

Endocrine Activity

Triclocarban exhibits a novel form of endocrine activity.

The chemical is not a typical hormone mimic, but rather up-regulates androgen- and (o)estrogen-stimulated transcriptional activities (Chen, et al., 2008; Chung, et al., 2011).

This has been shown *in vitro* in human cell lines and *in vivo* in castrated rats, where male accessory sex organs increased significantly in size when the rats were fed with both testosterone and triclocarban, compared to testosterone or triclocarban treatments alone (Chen, et al., 2008; Duleba, et al., 2011). Similarly, overexpression of the gene which converts androgens to (o)estrogens (aromatase gene) was observed when early zebrafish embryos were treated with (o)estrogen and triclocarban, compared to (o)estrogen or triclocarban alone (Chung, et al., 2011).

A study of the freshwater mudsnail *Potamopyrgus antipodarum* (New Zealand mudsnail) showed that triclocarban stimulates embryo production at very low concentrations, with a lowest-observed-effect-concentration (LOEC) of 0.2 µg/L and a NOEC of 0.05 µg/L determined after a four week exposure period (Giudice and Young, 2010).

Predicted No-Effect Concentration (PNEC)

Aquatic invertebrates were found to be the most sensitive taxon to the toxic effects of triclocarban in both short- and long-term exposures. The freshwater PNEC derived for the chemical is 0.025 µg/L (25 ng/L), based on the 28 d NOEC of 0.25 µg/L for *D. magna* and an assessment factor of 10. In accordance with the standard approach, the minimum assessment factor of 10 was selected as there is a complete set of chronic toxicity data available across all three aquatic trophic levels (EPHC, 2009).

Soil and sediment PNECs have not been determined due to the limited ecotoxicological data available for triclocarban in these compartments.

Categorisation of Environmental Hazard

The categorisation of the environmental hazards of urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)- according to domestic environmental hazard thresholds is presented below (EPHC, 2009; NICNAS, 2013):

Persistence

Persistent (P). Based on the estimated slow rate of aerobic biodegradation in surface waters, the chemical is classified as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on a measured BCF in fish and evidence of metabolism of triclocarban in fish and other higher tier organisms, the chemical is classified as Not Bioaccumulative.

Toxicity

Toxic (T). Based on multiple measured acute aquatic toxicity endpoints less than 1 mg/L, and multiple measured chronic endpoints less than 0.1 mg/L, triclocarban is categorised as Toxic.

Summary

Triclocarban is categorised as:

- P
- Not B
- T

Risk Characterisation

Based on the PEC and PNEC values determined above, the following Risk Quotient (RQ = PEC ÷ PNEC) has been calculated for release of triclocarban into rivers:

PEC (µg/L)	PNEC (µg/L)	RQ
0.416	0.025	16.6

An RQ greater than 1 indicates that triclocarban may pose an unreasonable risk to the environment, as environmental concentrations may exceed levels that cause harmful effects. Therefore, industrial use of triclocarban may pose an unreasonable risk to the aquatic environment.

The PEC value used in this calculation potentially overestimates surface water concentrations as it is based on the assumption that triclocarban concentrations in STP effluents are comparable in the USA and Australia, and it takes into account that river flows may consist entirely of STP effluent in the drier parts of Australia. Although the risk may be overestimated in this scenario, there remains a significant concern for emissions even where mean concentrations of triclocarban are present in treated effluent. Based on the monitoring data from the USA, the mean measured concentration of triclocarban in effluent is 0.115 µg/L (Lee, et al., 2016). This emission concentration exceeds the freshwater PNEC by a factor of 4.6, which again suggests unacceptably high exposure concentrations in the aquatic compartment, especially in inland rivers under low water flow conditions.

A further cause for concern is the uncertain level of protection afforded by the freshwater PNEC derived in this assessment. Although this PNEC has been calculated according to standard methods, the value obtained is only a factor of two less than a NOEC obtained for reproductive effects in mudsnails exposed to triclocarban. The PNEC approach does not allow an estimate to be made of the level of protection that can be expected across multiple taxonomic groups with different sensitivities to an aquatic toxicant. This requires a more complex approach based on species sensitivity distributions (SSD), which is beyond scope of this assessment.

There is a well-developed approach under the National Water Quality Management Strategy for deriving guideline values based on SSDs for organic contaminants with specified levels of protection for aquatic ecosystems (Warne, et al., 2015). The use of the SSD approach is likely to provide a more reliable basis for managing the impacts of triclocarban on aquatic ecosystems than the PNEC methodology used in this assessment.

In a recent risk assessment, Snyder and O’Connor studied exposure of the environment to triclocarban resulting from application of biosolids to soil (Snyder and O'Connor, 2013). They identified two exposure pathways that were potentially of concern. The pathway involving exposure of predators to triclocarban through consumption of soil-dwelling organisms is not expected to be of concern based on the low concentrations of the chemical found in organisms in different trophic levels in a terrestrial food web at an agricultural site amended with biosolids for 7 years (Sherburne, et al., 2016). The exposure to soil-dwelling organisms through surface water runoff is also not expected to be of concern since measured concentrations of triclocarban in runoff from fields amended with biosolids was below the limit of quantitation of 2.5 ng/L (Edwards, et al., 2009). Based on these findings, direct application of biosolids containing triclocarban to soil is not expected to pose significant risks to the terrestrial environment in Australia.

There is insufficient ecotoxicological data available to adequately characterise the risk of triclocarban to sediment-dwelling organisms. However, given that triclocarban appears to be particularly toxic to aquatic invertebrates, and that concentrations of this chemical in sediments near outfalls from STP are expected to be high, there is a potential risk to sediment-dwelling invertebrates.

Key Findings

Triclocarban is an antimicrobial ingredient commonly used in personal care products such as antibacterial soaps. The majority of the triclocarban in use in Australia is expected to be released into sewers with wastewater. Triclocarban is efficiently removed from wastewater in STPs, primarily through partitioning to sewage sludge. The chemical does not degrade rapidly in sewage sludge and biosolids and it may eventually be released into agricultural soils when biosolids are applied as soil improvers. The chemical degrades slowly in soil, but is not expected to significantly accumulate over time or to leach through the soil horizon. The chemical is not released in runoff from agricultural land and is generally expected to pose a low risk to the soil compartment.

Although the majority of the triclocarban in wastewater is removed in STPs, some discharge of the chemical to surface water in treated effluents is expected. The maximum concentrations of the chemical in treated effluent in Australia are estimated to be significantly greater than the acceptable concentration in freshwater. The risks from the discharge of triclocarban in wastewater effluent derive from the very high aquatic toxicity of the chemical to species from all three aquatic trophic levels. Aquatic invertebrates are at particular risk from exposure to this chemical. This includes sediment-dwelling invertebrates for which no reliable toxicity data have been identified.

The risk characterisation for the aquatic compartment currently has a high level of uncertainty based on the absence of measured concentrations of triclocarban in sewage effluents produced in Australia and the lack of default guideline values for triclocarban in aquatic ecosystems. These represent key gaps in the available environmental information for triclocarban which would inform the application of effective risk reduction measures for this chemical. It is recommended that agencies and organisations responsible for water quality management in Australia prioritise addressing these information gaps for triclocarban.

The chemical is not a PBT substance according to domestic environmental hazard criteria.

Recommendations

Triclocarban has very high toxicity to aquatic organisms and may adversely impact aquatic ecosystems. It is recommended that default guideline values for triclocarban in surface waters be developed according to the methods specified under the National Water Quality Management Strategy.

It is recommended that triclocarban be added to the list of organic contaminants that are routinely monitored in sewage treatment effluents and surface waters in Australia.

Environmental Hazard Classification

In addition to the categorisation of environmental hazards according to domestic environmental thresholds presented above, the classification of the environmental hazards of urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)- according to the third edition of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is presented below (UNECE, 2009):

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Category 1 (H400)	Very toxic to aquatic life

Hazard	GHS Classification (Code)	Hazard Statement
Chronic Aquatic	Category 1 (H410)	Very toxic to aquatic life with long lasting effects

The classification of the acute and chronic aquatic hazards posed by this chemical was performed based on the measured ecotoxicity data presented in this assessment (UNECE, 2009).

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