Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

Bronopol and bronidox

Evaluation statement

14 January 2022

Table of contents

Contents

AICIS evaluation statement

Subject of the evaluation

Bronopol and bronidox

Chemicals in this evaluation

Name	CAS number
1,3-Propanediol, 2-bromo-2-nitro-	52-51-7
1,3-Dioxane, 5-bromo-5-nitro-	30007-47-7

Reason for the evaluation

The Evaluation Selection Analysis indicated a potential risk to environment.

Parameters of evaluation

This evaluation considers the environmental risks associated with the industrial uses of the two synthetic biocides listed on the Australian Inventory of Industrial Chemicals (the Inventory); bronopol (CAS No. 52-51-7) and bronidox (CAS No. 30007-47-7). These chemicals have been assessed for risks to the environment according to the following parameters:

- Industrial uses as outlined in the 'Summary of Use' section
- Default domestic introduction volumes of 100 tonnes per annum.
- Expected emission to sewage treatment plants (STPs) due to consumer and commercial use.

The chemicals been assessed together due to structural similarity, similar mode of action and similar industrial uses.

The chemicals may be released from their use in hydraulic fracturing products. The use of bronopol in domestic coal seam gas extraction has been evaluated under technical report 14 prepared by the Department of Environment and Energy (Commonwealth of Australia, 2014). Emissions under this scenario will not be considered further in this evaluation.

Summary of evaluation

Summary of introduction, use and end use

Bronopol has reported use in cosmetics and hydraulic fracturing in Australia (NICNAS, 2014). There is currently no specific information about the introduction, use and end use of the bronidox in Australia Bronopol and bronidox are used as biocides and preservatives in a variety of consumer and industrial products worldwide.

The chemicals are used in the following products according to reported domestic and international use data:

- Adhesive and sealant products
- Personal care products
- Paint and coating products
- Construction products
- Ink, toner and colourant products
- Automotive care products
- Cleaning and furniture care products
- Laundry and dishwashing products
- Water treatment products
- Extractive products not covered by other end uses

Bronopol has non-industrial use in therapeutic and agricultural products.

Bronopol has a global use volume in the thousands of tonnes per year. There are no specific domestic introduction volume data available for the chemicals in this group.

Environment

Summary of environmental hazard characteristics

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

- Not persistent (not P)
- Not bioaccumulative (not B)
- Toxic (T)

Environmental hazard classification

Bronopol and bronidox satisfy the criteria for classification according to the Globally Harmonised System (GHS) (UNECE, 2017) of Classification and Labelling of Chemicals for environmental hazards as follows. This does not consider classification of physical hazards and health hazards:

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 2	H411: Toxic to aquatic life with long-lasting effects

Summary of environmental risk

Bronopol and bronidox are synthetic biocides with industrial uses in Australia. These chemicals are expected to be released to the aquatic compartment in treated sewage treatment plant (STP) effluent following industrial use.

Both chemicals are not persistent in the environment and have a low potential for bioaccumulation. The chemicals are toxic, particularly towards algae and microbes at low chemical concentrations.

The disposal of these chemicals when used in industrial process water or circulated cooling water poses risk to the environment due to the high concentrations typically required for these applications, however, State-based use and disposal regulations are deemed sufficient to mitigate this risk.

Based on predicted surface water concentrations, bronopol and bronidox are expected to be present in Australian rivers at concentrations below the level of concern.

Conclusions

The conclusions of this evaluation are based on the information described in this statement. Obligations to report additional information about hazards under section 100 of the *Industrial Chemicals Act 2019* apply.

The Executive Director is satisfied that the identified environment risks can be managed within existing risk management frameworks. 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.

Supporting information

Grouping rationale

This evaluation considers the environmental risks associated with the industrial uses of bronopol and bronidox. The evaluation of these substances has been conducted as a group due to structural similarity and similar industrial uses.

The known industrial uses for the chemicals in this group will lead to their release into sewers which may result in their emission to the aquatic environment in the treated effluents produced by sewage treatment plants (STPs). This is of potential environmental concern because chemicals with preservative and biocidal properties are often very toxic to aquatic life. This evaluation will assess the potential for emissions of these chemicals to the aquatic environment in Australia and whether risk reduction measures are required for industrial uses of these chemicals.

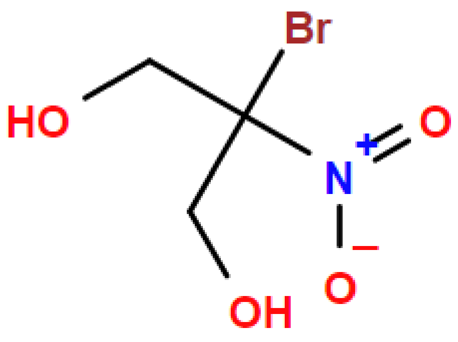
The Evaluation Selection Analysis (ESA) of the chemicals highlighted potential persistence and toxicity characteristics, which indicate a concern for the environment.

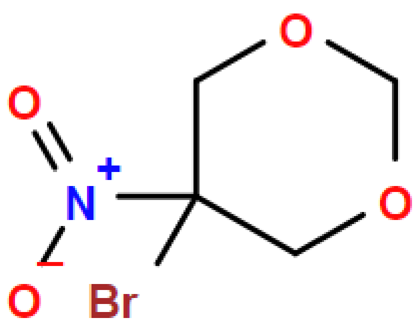
Chemical identity

The chemicals in this group have a common structural motif consisting of a quaternary carbon atom substituted with a bromo and nitro functional group. In bronopol, the quaternary carbon is substituted with two hydroxymethyl groups, while in bronidox a methylene group bridges the two hydroxymethyl oxygen atoms to form a cyclic ether.

Bronopol is synthesised from the hydroxyalkylation of nitromethane (CAS No. 75-52-5) with formaldehyde (CAS No. 50-00-0) which is then subsequently brominated under basic conditions (Markofsky, 2011). Bronidox is manufactured by acid-catalyzed condensation of bronopol and paraformaldehyde (Liebert, 1990).

Bronopol and bronidox are members of a class of biocides known as ‘activated halogen’ biocides (Uhr, et al., 2013). Members of this group possess a variety of different chemical structures but contain a common motif; a halogen in the alpha position to a strongly electron withdrawing group. This motif is the origin of their biocidal mode of action:

Chemical name	1,3-Propanediol, 2-bromo-2-nitro-
CAS No.	52-51-7
Synonyms	bronopol bactronol BNPD myacide
Structural formula	
Molecular formula	$C_3H_6BrNO_4$
Molecular weight (g/mol)	199.99
SMILES	O=N(=O)C(Br)(CO)CO
Chemical description	-

Chemical name	1,3-Dioxane, 5-bromo-5-nitro-
CAS No.	30007-47-7
Synonyms	bronidox
Structural formula	
Molecular formula	$C_4H_6BrNO_4$
Molecular weight (g/mol)	212.00
SMILES	C1C(COCO1)([N+](=O)[O-])Br
Chemical description	-

Relevant physical and chemical properties

Measured physical and chemical property data for bronopol and bronidox were retrieved from the databases included in the OECD QSAR Toolbox (LMC, 2020) and the dossiers submitted under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (REACH, 2021a; 2021b). Where measured data were not available, values were calculated using standard quantitative structure property relationships (QSPR), and the Henry's Law constant was calculated from measured values for water solubility and vapour pressure (US EPA, 2020a):

Chemical	Bronopol	Bronidox
Physical form	Solid	Solid
Melting point	129°C (exp.)	59°C (exp.)
Boiling point	Decomposition (exp.)	185.2°C at 200 hPa (exp.)
Vapour pressure	0.0051 Pa (exp.)	1.6 Pa (exp.)
Water solubility	286 g/L (exp.)	4.77 g/L (exp.)
Henry's Law constant	3.57×10^{-6} Pa·m^3/mol (calc.)	0.0711 Pa·m^3/mol (calc.)
Ionisable in the environment?	no	no
pKa	9.56 (exp.)	N/A
log K_{OW}	0.22 (exp)	1.6 (exp.)

The acid dissociation constant (pK_a) for bronopol indicates that the majority of the chemical will not be ionised in the environmental pH range of 4–9. Bronidox has no ionisable functional groups.

The chemicals are readily soluble in water based on measured values for these properties. The low measured logarithmic octanol-water partition coefficients (log K_{OW}) values for both bronopol and bronidox indicate that both chemicals have a low tendency to partition from water into octanol and that they are not lipophilic.

Introduction and use

Australia

Based on previous calls for information, bronopol is used in Australia as a preservative in cosmetics. It also has reported use in hydraulic fracturing (NICNAS, 2014).

No specific Australian use, import, or manufacturing information has been identified for bronidox.

Bronopol is listed as a preservative in therapeutic goods and as a registered active constituent in veterinary and/or agricultural products (APVMA, 2021; TGA, 2021). The use of bronopol in these products is beyond the scope of this assessment.

International

Bronopol and bronidox are used worldwide as biocides and preservatives in a range of products and industrial processes. Biocides and preservatives are added to consumer products or industrial liquids to prevent or inhibit microbial growth. Microbial and algal growth in products can lead to destruction of the product, reduced efficacy and/or consumer harm.

The chemicals in this group are used internationally in cosmetics and personal care products such as hair care products, cleansers and liquid soaps (Pubchem, 2021a; 2021b).

Bronopol is used to control microbes and algae in industrial systems that use water and fluids (US EPA, 1995). Products containing this chemical are registered for use in the United States of America (USA) for use in recirculating water systems (industrial cooling tower water, laboratory water baths, air conditioning/humifying systems), fluid systems (metal work cutting fluids) and other liquid products (printing inks). It is also used as a slimicide added to processing water in pulp and paper manufacturing processes. For use in cooling water, bronopol may be added in high concentrations up to 700 ppm (WTP, 2021).

Bronopol is also added as an in-can preservative to construction products such as paints and adhesives (Pubchem, 2021a). For these uses, bronopol may be present up to 500 ppm in products (BASF, 2021).

In the United States of America (USA) bronopol had an annual use volume of less than 454 tonnes from 2012 to 2015 (US EPA, 2016b). Bronidox does not have reported volume of use information in the USA, but it is listed as active on the Toxic Substances Control Act (TSCA) chemical substance inventory. An active listing indicates the chemical has been recently manufactured, imported or processed by industry in the USA (US EPA, 2016a; 2020b).

In the European Union (EU), bronopol and bronidox have registered use volumes of 100–1000 and 10–100 tonnes per year (t/year), respectively (ECHA, 2021c).

Bronopol and bronidox have reported use in the Nordic countries, with average annual use volumes over a five-year period from 2015-2019 of 416 and 0.4 tonnes, respectively (Danish EPA, 2021).

Existing Australian regulatory controls

Environment

The use of bronopol and bronidox is not subject to any specific national environmental regulations.

International regulatory status

Canada

Bronopol and bronidox are listed on the Cosmetic Ingredients Hotlist where use in cosmetics is not permitted when interactions with amines or amides may occur. In other cosmetics the maximum permitted concentration is 0.1% (Health Canada, 2019).

European Union

Bronopol and bronidox are restricted under the Cosmetics Products Regulation, Annex V, that restricts maximum cosmetic concentrations to 0.1% and limits use to formulations without amines or amides, where formation of nitrosamines may occur upon interaction (ECHA, 2021b).

Bronopol is under review for use under the EU Biocidal Products Regulation (BPR) (ECHA, 2021a). The regulation authorises the manufacture and use of biocidal and preservative chemicals on the European market, with the aim of high level consumer and environmental protection. It is currently being reviewed for use in the following product types: PT02: Disinfectants not intended for direct application to humans; PT6: in-can preservatives; PT9: Fibre, Leather and Rubber preservatives; PT11: preservatives in liquid cooling and processing systems; PT12: slimicides; and PT22: Embalming and taxidermist fluids.

Bronidox has not been nominated by industry as an active substance on the BPR and has not been authorised for use under the EU Biocidal Products Regulation.

Environmental exposure

Bronopol and bronidox may be found in household and industrial products available for use in Australia. The substances are used as preservatives internationally and products on the Australian market are assumed not to differ significantly from those available in other parts of the world.

Emissions of bronopol and bronidox to the environment may occur through point source emission sources such as STPs, or from diffuse sources such as paints and coatings applied to surfaces.

Chemicals used as preservatives in consumer products, such as personal care products and cosmetics, are typically released to wastewater as a normal part of their use. Treatment of wastewater is expected to remove a fraction of the quantity of chemicals through degradation and partitioning processes. Emission of bronopol and bronidox to surface waters from STPs is the most relevant release scenario in this evaluation.

Chemicals used in construction products, including paints, coatings and adhesives, have the potential to leach from painted surfaces and exposed construction materials when exposed to weathering and rainfall (Lebow, 2014; Schoknecht U and Töpfer, 2012; Schoknecht Ute, et al., 2016). The surface run-off containing these leached chemicals can be discharged directly onto soil or indirectly into surface waters through the discharge of stormwater from drainage systems. Emissions from these sources may also contribute to the total diffuse exposure load of the chemicals. Release of preservatives from coated surfaces and adhesives are often decreased by photodegradation of the chemical when it is bound in the polymer matrix of the paint or adhesive (Paijens, et al., 2020).

Biocides used in processing water in pulp and paper manufacturing or circulated cooling system water may enter the environment through maintenance activities and spent water disposal. Emissions from these sources may occur to surface waters or STP. Maintenance and disposal activities for these systems are controlled and regulated by state and territory hazardous waste disposal directives with emissions expected to be managed within these mechanisms (Pickin, 2017; State Government of Victoria, 2017).

Environmental fate

Partitioning

Bronopol and bronidox are expected to partition to the aquatic compartment following release to the environment.

The chemicals in this group are readily soluble in water and have low to moderate volatility. The calculated Henry's Law constants indicate very slight to slight volatility from water. The chemicals are not expected to appreciably partition to air from soil and water compartments of the environment.

Experimentally determined soil adsorption coefficients (log K_{OC}) indicate that bronopol and bronidox will have very high mobility in soil (REACH, 2021a; 2021b).

Degradation

Bronopol and bronidox are not expected to persist in the environment. The chemicals will degrade in the environment by a combination of abiotic and biodegradation processes.

The chemicals in this group are slowly degraded in the atmosphere by reactions with photogenerated hydroxyl radicals. Atmospheric oxidation modelling indicates that bronopol and bronidox have half-lives of 8 and 4 days, respectively (US EPA, 2020a). Direct photodegradation of the chemicals have been documented in multiple studies with reported half-lives of up to 24 hours; equivalent to 2 days of 12 hours of sunlight (Cui, et al., 2011; ECHA, 2021c; US EPA, 1995).

Bronopol and bronidox demonstrate pH and temperature-dependent stability to hydrolysis. Degradation rates for bronopol increase with increased pH and temperature. An aqueous stability study showed that bronopol has a half-life of more than 5 years at pH 4, 1.5 years at pH 6 and 2 months at pH 8 at 20°C (Bryce, et al., 1978). Bronidox is stable at temperatures of less than 50°C and pH of 5–9, but is unstable at pH values less than 5 (Cosmetic Ingredient Review, 1990).

Although apparently resistant to hydrolysis under standard laboratory conditions, bronopol rapidly degrades when exposed to natural waters. In a river die-away test, hydrolysis half-lives of 120 hours at pH 6.7, 14 hours at pH 7.6 and 1.9 hours at pH 9 were measured (Cui, et al., 2011). The presence of cupric and ferric ions found in low concentrations within natural waters have been found to facilitate degradation of aqueous solutions of bronopol (US EPA, 1995). This type of degradation pathway is also expected to be exhibited by bronidox after release to environmental waters.

Standard ready biodegradability studies on these chemicals are complicated by the inherent toxicity to the microbes in activated sludge innocula. Tests conducted with bronopol at 100 mg/L show 0% degradation after 28 days (NITE, 2021). The chemicals are expected to prevent microbial growth and respiration at concentrations at and above their minimum inhibition concentration (MIC). MICs of 12.5 to 25 mg/L for bronopol and 10 to 50 mg/L for bronidox have been measured for antimicrobial efficacy against key test microorganisms (BASF, 2021).

Biodegradation tests conducted at lower concentrations indicate that bronopol is readily biodegradable. In a test conducted according to OECD test guideline (TG) 301B using a concentration of 0.1 mg/L, 70–80% degradation based on CO_2 evolution was achieved within 28 days demonstrating ready biodegradability of the test substance (REACH, 2021a). An additional test conducted according to OECD TG 314B simulating the biodegradability of chemicals discharged in wastewater found 0.5 mg/L of bronopol was degraded by 99% within 1 hour in municipal activated sludge (REACH, 2021a).

No suitable biodegradation studies for bronidox are available. The structural similarity of bronopol to bronidox would suggest that the latter is unlikely to be persistent in the environment based on the ready biodegradability of bronopol. The degradability of bronopol is suitable to be read across to bronidox for the following reasons:

- *Structural similarity*: The chemicals have similar functional groups, bronidox differing only by the addition of a methylene group linking the hydroxyl groups to form a cyclic ether. Both chemicals contain a highly reactive activated quaternary carbon which is expected to be the primary reactive site of enzymatic degradation. The cyclic ether moiety of bronidox is not expected to affect this degradation pathway.
- *Physicochemical property similarity*: the chemicals have a high water-solubility and similar lipophilicity (log K_{OW} = 0.22 vs 1.6) implying similar biopartitioning and bioavailability of the chemicals.

The chemicals in this group can react with naturally occurring nucleophilic thiols. The bromine on the activated quaternary carbon exchanges with soft nucleophiles such as thiols (Challis and Yousaf, 1991; Fishwick, et al., 1983). A study on the efficacy of biocides when exposed to ubiquitous nucleophiles showed a 16–64 fold reduction in bacteriostatic activity when organisms are exposed to a combination of bronopol and cysteine hydrocholoride (CAS RN 7048-04-6) (Bryce, et al., 1978). This reduced efficacy was attributed to abiotic degradation of the chemical by reaction with cysteine. Thiols such as cysteine are expected to be ubiquitous in sewage influent and this abiotic degradation pathway is likely to be significant in natural waters and sewage treatment plants where thiols are abundant.

Bioaccumulation

Bronopol and bronidox have a low potential to bioaccumulate in aquatic life.

Bronopol and bronidox have log K_{OW} values of 0.22 and 1.6, respectively, which are below the domestic categorisation threshold for aquatic bioaccumulation hazards (log K_{OW} ≥ 4.2), indicating low potential for bioaccumulation. Calculated BCF values of 3.16 and 5.28 L/kg wwt for bronopol and bronidox respectively are also below the domestic categorisation threshold (BCF ≥ 2000 L/kg wwt).

Environmental transport

The chemicals in this group are not expected to undergo long range transport based on their short half-lives in the environment.

Predicted environmental concentration (PEC)

The predicted concentration of bronopol and bronidox in Australian river water is 7.3 µg/L.

Australian environmental monitoring data is not available for the chemicals in this group.

The chemicals are expected to enter the environment in treated STP effluent. Predictive models for the partitioning and removal of chemicals from wastewater at STPs indicate a removal rate of 87% through degradation with 13% remaining in effluent. Assuming a default introduction volume of 100 tonnes per year and considering the ready biodegradability of the chemicals, a concentration of 7.3 µg/L for a bronopol and bronidox in Australian rivers is estimated (Struijs, 1996).

The predicted concentration is likely an overestimate of actual concentrations in the environment. In a screening study of countries in the Nordic environment it was found that despite high use volumes of 700 tonnes per annum, bronopol was not detected in STP effluent nor the environment (Dye, 2007). Another study of building materials in Sweden as a source of biocide emissions was unable to detect bronopol in the environment based on annual use volumes of 100 tonnes (Schoknecht Ute, et al., 2016). As a conservative estimate, the value of 7.3 µg/L has been used as the predicted concentration of these chemicals in river water in Australia for the purposes of risk characterisation.

Environmental effects

Effects on Aquatic Life

Bronopol and bronidox cause toxic effects at low concentrations in aquatic organisms across multiple trophic levels.

Incomplete acute and chronic toxicity data are available to fully assess the toxic effects of bronidox to aquatic life. The missing acute and chronic endpoints for bronopol are suitable to be read across to bronidox for the following reasons:

- *Structural similarity*: the chemicals have similar functional groups, bronidox differing only by the addition of a methylene group linking the hydroxyl groups to form a cyclic ether. Both chemicals contain an activated quaternary carbon which is expected to be the primary driver for toxicity for both chemicals. The cyclic ether moiety of bronidox is not expected to drastically affect this mode of toxicity.
- *Hydrophobicity*: the chemicals have a low lipophilicity (log K_{OW} = 0.22 vs 1.6) implying similar magnitude of potential baseline narcotic effects.
- *Mode of action (MoA)*: the chemicals share a mode of toxic action. The chemicals have an unspecific reactivity related to their common nitro- substituted activated quaternary carbon. The chemicals bind to thiol functional groups and react with membrane bound enzymes leading to oxidative stress and reduction of cell vitality. Formaldehyde may be generated under acidic and basic conditions and during abiotic and biotic degradation, however the generation of formaldehyde is not the driver of observed toxic effects of these chemicals in aquatic organisms. Available ecotoxicity endpoints for formaldehyde are much greater than those observed for bronopol.
- *Similar magnitude of available endpoints*: the available acute and chronic endpoints for both chemicals are of a similar order of magnitude, and this trend is expected to continue for the remaining endpoints for bronidox based on MoA and structural similarity.

Acute toxicity

The following measured median lethal concentration (LC50) and median effective concentration (EC50) values for model organisms across three trophic levels exposed to bronopol (BNP) and bronidox (BNDX) were obtained from dossiers submitted under REACH (REACH, 2021a; 2021b) and the ECOTOX knowledgebase (US EPA, 2020c):

Taxon	Endpoint	Method
Fish	BNP: 96 h LC50 = 11.17 mg/L	*Lepomis macrochirus* (bluegill sunfish) Mortality Flow-through EPA OPP 72-1
	BNDX: 96 h LC50 = 11.17 mg/L	Read across from bronopol *Lepomis macrochirus* (bluegill sunfish) Mortality Flow-through, EPA OPP 72-1
Invertebrate	BNP: 48 h EC50 = 1.4 mg/L BNDX: 48 h EC50 = 1.32 mg/L	*Daphnia magna* (water flea) Mobility Static, measured OECD TG 202
Algae	BNP: 72 h EC50 = 0.37 mg/L	*Pseudokirchneriella subcapitata* (microalgae) Growth rate Static, nominal OECD TG 201
	BNDX: 72 h EC50 = 0.265 mg/L	*Pseudokirchneriella subcapitata* (microalgae) Growth rate Static, measured OECD TG 201

The chemicals in this group are more toxic to algae than other aquatic trophic levels. The toxic mode of action of these chemicals stems from reaction with cellular thiols or reaction with enzymatic active sites (Shepherd, et al., 1988). Reaction with biomolecules such as the cellular antioxidant glutathione can rapidly disrupt the cellular reduction potential leading to oxidative stress and reduced cellular viability. These chemicals may also inhibit membrane-bound enzymes, causing alterations in membrane structure and resulting in membrane lysis, cell leakage and death (Bryce, et al., 1978). Unicellular organisms, such as algae, are more susceptible to these stressors than higher order organisms.

Chronic toxicity

The following measured no-observed-effect concentrations (NOEC) for model organisms across three trophic levels for BNP and the following 10% effect concentration (EC10) for algae for BNDX were obtained from databases submitted under REACH (REACH, 2021a; 2021b):

Taxon	Endpoint	Method
Fish	BNP: 49 d NOEC = 1.94 mg/L	*Oncorhynchus mykiss* (rainbow trout) Mortality Flow through OECD TG 210
	BNDX: 49 d NOEC = 1.94 mg/L	Read across from bronopol *Oncorhynchus mykiss* (rainbow trout) Mortality Flow through OECD TG 210
Invertebrates	BNP: 21 d NOEC = 0.27 mg/L	*Daphnia magna* (water flea) Reproduction Flow-through, nominal OECD TG 211
	BNDX: 21 d NOEC = 0.27 mg/L	Read across from bronopol *Daphnia magna* (water flea) Reproduction Flow-through, nominal OECD TG 211
Algae	BNP: 72 h NOEC = 0.08 mg/L	*Skeletonema costatum* (diatom) Growth rate Static, nominal ISO guideline 10253
	BNDX:72 h EC10 = 0.088 mg/L	*Pseudokirchneriella subcapitata* (microalgae) Growth rate Static, measured OECD TG 201

Effects on sediment dwelling life

No studies have been identified for toxicity effects on sediment dwelling life.

Effects on terrestrial Life

The chemicals in this group exhibit low to moderate toxic effects to terrestrial organisms.

A laboratory study conducted according to OECD TG 207, testing the toxicity of bronopol towards the earthworm *Einsenia fetida,* measured a 14 day LC50 value of > 500 mg/kg soil dry weight (dw), and a NOEC of 12.8 mg/kg dw (REACH, 2021a).

Tests for avian toxicity of bronopol on the northern bobwhite (*Colinus virginianus)* measured a medial lethal dose (LD50) value of 7379 ppm after 5 days. Another oral toxicity study on the mallard duck (*Anas platyrhynchos)* measured an LD50 value of 464 mg/kg body weight after 14 days (REACH, 2021a).

Predicted no-effect concentration (PNEC)

The PNECs for bronopol and bronidox are 8 µg/L and 8.8 µg/L, respectively.

Available acute and chronic toxicity endpoints demonstrates that algae are the most sensitive species for both chemicals.

The PNECs for both chemicals were derived from their respective chronic algal toxicity values. The 72 hr NOEC of 0.08 mg/L was used for bronopol and the 72 hr EC10 of 0.088 mg/L was used for bronidox. An assessment factor of 10 was selected for both chemicals as a full set of data are available for three trophic levels which includes measured data for the most sensitive species.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemicals according to domestic environmental hazard thresholds is presented below (EPHC, 2009):

Persistence

Not Persistent (Not P). Based on biodegradation study results for bronopol demonstrating ready biodegradability, both chemicals are categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on low calculated bioconcentration factors (BCF) in fish, and low measured log K_{OW} values, both chemicals are categorised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on available acute ecotoxicity values below 1 mg/L the chemicals are categorised as Toxic.

GHS classification of environmental hazard

The chemicals are formally classified as Acute Category 1 (H400): Very toxic to aquatic life and Chronic Category 2 (H411): Toxic to aquatic life with long-lasting effects under the Globally Harmonised System of Classification and Labelling of Chemicals (UNECE, 2017). The classification of the acute and chronic (long-term) aquatic hazards posed by the chemicals was performed based on the measured ecotoxicity data presented in this assessment and noting that both substances are readily degradable and have BCF values < 500 L/kg.

Environmental risk characterisation

Bronopol and bronidox are very toxic to unicellular organisms including aquatic primary producers such as algae. This toxicity is necessary for their functional use as preservatives and industrial biocides which involves controlling the growth of unicellular organisms such as bacteria, fungi and algae. These industrial uses also have the potential to release these biocides directly or indirectly to the aquatic environment which is of potential concern.

Based on the PEC and PNEC values determined above, the following Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of bronopol and bronidox into the riverine aquatic compartment:

Chemical	PEC (µg/L)	PNEC (µg/L)	RQ
bronopol	7.3	8	0.913
bronidox	7.3	8.8	0.830

An RQ less than 1 indicates that bronopol and bronidox are not expected to pose a high risk to the environment based on estimated emissions, as environmental concentrations are below levels likely to cause harmful effects.

The major use of these chemicals is as preservatives in consumer products which are likely to be released to the environment in treated effluent. The environmental risks associated with these emissions are likely to be mitigated by the ready degradation through abiotic and biotic processes within STPs. International monitoring studies were unable to detect bronopol in STP effluent despite high consumer use. These results indicate that environmental concentrations estimated in this evaluation may be overestimated.

The chemicals are used in high concentrations in paints and other water-based construction products to protect from degradation when these products are in storage. Available information indicates a recommended use concentration of 50-500 ppm of bronopol in these products depending on the chemical composition of the product. Direct release of the chemical in these concentrations is unlikely to occur during normal use of these products. The biocide will remain in the polymer matrix of the paint or adhesive after drying. Some of the chemical may slowly leach out upon exposure to rainwater, however, significant proportions of the chemical in the matrix are expected to decompose by photodegradation and thermal degradation processes based on the measured photodegradation half-life. Leaching from surfaces and exposed adhesives may contribute to small and diffuse releases of the chemical which are unlikely to pose a risk to the environment.

Disposal of spent cooling tower water treated with biocides may be of concern to the aquatic environment. The typical concentrations of bronopol used in these applications are 250-700 mg/L (WTP, 2021) significantly greater than adverse effect concentrations presented in this evaluation. However, the risk to environment from disposal of the treated water is recognised and regulated by state and territory hazardous waste disposal guidelines. Current risk management measures are considered adequate for addressing the risk of these uses and emission scenarios.

Uncertainty

This evaluation was conducted based on a set of information that may be incomplete or limited in scope. Some relatively common data limitations can be addressed through use of conservative assumptions (OECD, 2019) or quantitative adjustments such as assessment factors (OECD, 1995). Others must be addressed qualitatively, or on a case-by-case basis (OECD, 2019).

The most consequential areas of uncertainty for this evaluation are:

- The risk quotient determined through this evaluation is close to a value of 1 indicating a potential risk to the environment if the parameters of the evaluation change. As the evaluation has used modelling and international use patterns to estimate the Australian risk to the environment certain assumptions have been made. If new hazard or volume of use data is made available the chemicals may need to be re-evaluated.

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