



Australian Government

Department of Health, Disability and Ageing

Australian Industrial Chemicals Introduction Scheme

Boronitrene

Assessment statement (CA09938)

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AICIS assessment (CA09938)

Chemical in this assessment

Name	CAS registry number
Boronitrene	1643932-81-3

Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act 2019* (the Act).

Certificate application type

AICIS received the application in a Health and Environment Focus type.

Defined scope of assessment

The chemical has been assessed as manufactured in Australia as three different nanoparticle forms (neat powder) with no surface functionalisation:

- as nanosheets at up to 5 tonnes/year with particle dimensions:
 - thickness between 1 to 100 nm
 - length and width between 0.3 to 10 µm
 - layer number between 1 to 300
- as nanoribbons at up to 0.5 tonnes/year with particle dimensions:
 - width between 20 to 500 nm
 - length between 10 to 300 µm
 - layer number less than 10
- as nanotubes at up to 30 kg/year with particle dimensions:
 - diameter between 20 to 150 nm
 - length up to 40 µm
 - wall number between 20 to 30
- for reformulation at up to 2% concentration into:
 - plastic and polymer products
 - lubricants and greases
- for reformulation of nanosheets at up to 15% concentration into:
 - paints and coatings
 - ink, toner and colourant products with a maximum volume of 2.5 tonnes applied on paper per annum
- for use only by workers in a professional setting

Summary of assessment

Summary of introduction, use and end use

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

The assessed chemical will be manufactured in Australia as a neat powder, with three nanoparticle forms manufactured separately – nanosheets (BNNS), nanoribbons (BNNX) and nanotubes (BNNT). Two grades of BNNT (BNNT-S and BNNT-P) will be manufactured (see **supporting information**).

The assessed chemical in powdered nanoparticle forms will be reformulated into end use industrial products. The assessed chemical in all three forms (BNNS, BNNX and BNNT) will be incorporated into plastic and polymer products as well as lubricants and greases at up to 2% concentration. The assessed chemical as nanosheets (BNNS) will be incorporated into paints and coatings as well as ink, toner and colourant products at up to 15% concentration.

Reformulation procedure will likely vary depending on the nature of the formulated products. End use products containing the assessed chemical at various concentrations will be packaged appropriately for the end use products. End use products containing the assessed chemical will only be used by workers in a professional setting.

The assessed chemical is not intended to be included in consumer products in an unbound form, do-it-yourself (DIY) products or food packaging materials.

Human health

Summary of health hazards

The submitted toxicological data on the assessed chemical in nanosheet and nanotube forms (see **Supporting information**) indicate that the chemical:

in nanosheet form is:

- of low acute oral, dermal and inhalation toxicity
- not irritating to skin
- slightly irritating to the eyes
- not sensitising to the skin
- not mutagenic based on an *in vitro* mammalian cell gene mutation test

in nanotube form is:

- of low acute oral, dermal and inhalation toxicity
- not irritating to skin and eyes
- not sensitising to the skin
- not mutagenic based on an *in vitro* mammalian cell gene mutation test

Using the submitted toxicological data on the assessed chemical in nanosheet or nanotube forms as read across, the assessed chemical in nanoribbon form is likely to be:

- of low acute oral, dermal and inhalation toxicity
- not irritating to skin
- slightly irritating to the eyes
- not sensitising to the skin
- not considered mutagenic

The assessed chemical in sheet form (BNNS) has particles with a thickness in the nanoscale (1-100 nm), widths/lengths between 0.3-10 µm, layer number between 1 to 300 and an aspect ratio of 1:1 to 1:30 based on length and width.

The assessed chemical in ribbon form (BNNX) has particles with a width in the nanoscale (20-500 nm), lengths between 10-300 µm, layer number less than 10 and an aspect ratio of 20 - 15,000:1 based on length and width.

The assessed chemical in tube form (BNNT) has particles with diameters in the nanoscale (20-150 nm), lengths up to 40 µm, wall number ranging between 20 to 30 and an aspect ratio of 33 - 1500:1 based on length and width.

The World Health Organisation (WHO) has defined fibres > 5 µm with a diameter < 3 µm and an aspect ratio of > 3:1 as pathogenic fibres (WHO 1985; SWA 2009). Based on this definition, both BNNX and BNNT meets the criteria for pathogenic fibres.

For insoluble nanomaterials, the inhalation route is generally considered as the main route of exposure for potential systemic toxicity. Toxicity of the boronitrene particles depends on a number of factors including particle size distribution, aspect ratio, surface area, surface chemistry, density and agglomeration (Gatoo *et al* 2014; Zhu *et al* 2013). The submitted data are insufficient to derive hazard conclusions for the assessed chemical (all three particle forms) on repeated dose toxicity, clastogenicity and carcinogenicity. Based on the submitted repeated dose toxicity data on graphene (structural analogue for BNNS) and multi-walled carbon nanotubes (MWCNTs) (structural analogue for BNNT), the assessed chemical in all three forms may have the potential for causing lung toxicity, if inhaled. However as only short-term inhalation toxicity studies are available, and toxicity can be dependent on a number of factors in the test material, the assessed chemical in sheet form was not classified (see **Supporting information**).

Hazard classifications relevant for worker health and safety

Based on the available information on carbon nanotubes (structural analogue), the assessed chemical in ribbon (BNNX) and tube (BNNT) forms is considered a hazardous chemical according to the *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) (UNECE 2017) for hazard classes relevant for worker health and safety as adopted for industrial chemicals in Australia.

Health hazards	Hazard category	Hazard statement
Carcinogenicity	Carc. 2	H351: Suspected of causing cancer
Specific target organ toxicity (repeated exposure)	STOT Rep. Exp. 2	H373: May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure

Summary of health risk

Public

When introduced and used in the proposed manner, it is unlikely that the public will be exposed to the assessed chemical. The public may come into contact with solid products containing the assessed chemical (such as coated substrates). However, as the assessed chemical will be encapsulated in an article or within a solid matrix on the substrate, it is not expected to be available for exposure.

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

Workers

Given the lack of toxicity data and uncertainty regarding systemic health effects from inhalation of insoluble nanoscale particles, workers may experience adverse health effects if exposed to the assessed chemical during its manufacture, reformulation and some end uses (e.g. use by spray application). Control measures to minimise inhalation exposure are required to manage the risks to workers (see **Means for managing risk** section).

Environment

Summary of environmental hazard characteristics

As the assessed chemical is inorganic, it is excluded from categorisation under the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022).

Environmental hazard classification

There is currently no global consensus as to whether the aquatic hazard of nanomaterials can be classified according to the GHS (UNECE 2017). Hence, the aquatic hazards of the assessed chemical have not been classified for this assessment. Nevertheless, it is noted that ecotoxicity data evaluated for this assessment does show that the assessed chemical can adversely affect aquatic life.

Summary of environmental risk

The assessed chemical will be manufactured in Australia in three nanoparticle forms, BNNS, BNNT and BNNX. At industrial sites, BNNS, BNNT or BNNX will be added to enhance the existing physical properties of plastic and polymer products, and lubricants and greases. BNNS will also be used as an additive to enhance the existing physical properties of paints and coatings and ink, toner and colourant products. Up to 62% of the BNNS used in paints and coatings, and ink, toner and colourant products could be released to the aquatic environment from paper recycling processes. For the BNNS, BNNT and BNNX incorporated in other products, significant release to the environment in nanoscale sizes is not expected. Based on the calculated RQ value < 1 for the river and ocean compartments, the environmental risk from the introduction of the assessed chemical can be managed when introduced in line with the defined scope of assessment.

Means for managing risk

Workers

Recommendation to Safe Work Australia

- It is recommended that Safe Work Australia (SWA) update the *Hazardous Chemical Information System* (HCIS) to include classifications relevant to work health and safety (see **Hazard classifications relevant for worker health and safety**).
- The CAS identity can apply to a number of different forms of the chemical. The listing in the HCIS should make it clear that the classification only applies to the ribbon and tube forms of the chemical.

Information relating to safe introduction and use

The information in this statement, including recommended hazard classifications, 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.

The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during manufacturing, reformulation and end use (if used by spray application):

- Use of engineering controls such as
 - Enclosed and automated systems where possible
 - Local exhaust ventilation fitted with high-efficiency particulate air (HEPA) filter
- Use of safe work practices to
 - Avoid generation of dusts, aerosols or mists
 - Avoid contact with eyes
 - Avoid inhalation of dusts, aerosols or mists
- Use of personal protective equipment (PPE)
 - Appropriate respiratory protection (such as a P2 respirator) if inhalation exposure may occur
- Service technicians should wear disposable gloves and ensure adequate ventilation is present when replacing printer cartridges containing the assessed chemical and during routine maintenance and repairs.
- Spray applications should be carried out in accordance with the Safe Work Australia *Code of Practice for Spray Painting and Powder Coating* (SWA 2020) or relevant State or Territory Code of Practice.
- The storage of the assessed chemical should be in accordance with the Safe Work Australia *Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA 2023) or relevant State or Territory Code of Practice.
- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

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

Note:

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

Supporting information

Chemical identity

CAS number	1643932-81-3
CAS name	Boronitrene
Molecular formula	BN
Associated names	White graphene Monolayer hexagonal boron nitride

Additional chemical identity information

The assessed chemical is a nanomaterial representing three separate forms: sheets, ribbons, and cup-stacked tubes. The typical purity levels of the three forms are 98% for sheets and 90% for ribbons and tubes.

The CAS notes describe the identity as “a hexagonal single atom thick layer of boron nitride, similar to graphene”.

Relevant physical and chemical properties

Chemical	BNNS	BNNX	BNNT
Physical form	White powder	White aerogel or powder	Dark grey or grey powder
Melting point*	Up to 1,000 °C	Up to 1,000 °C	Up to 1,000 °C
Density*	55 kg/m ³ (bulk)	20 to 30 kg/m ³	2,200 kg/m ³
Water solubility	0.0253 g/L at 20°C	0.0253 g/L at 20°C	0.0253 g/L at 20°C
Particle Size (thickness)	1–100 nm	-	-
Particle Size (width or diameter)	GM (GSD) [‡] : 883.1 (1.7) nm Mean: 1.08 ± 0.75 µm Range: 0.3 - 10 µm	20–500 nm (est. via SEM)	20–150 nm (est. via SEM)
Particle Size (length)	GM (GSD) [‡] : 883.1 (1.7) nm Mean: 1.08 ± 0.75 µm Range: 0.3 - 10 µm	10–300 µm (est. via SEM)	5–40 µm (BNNT-S), 3–30 µm (BNNT-P) (est. via SEM)
Number of walls or number of layers	1–300 layers	< 10 layers	20–30 walls

Chemical	BNNS	BNNX	BNNT
Crystalline phase	Crystalline (hexagonal) regions detected	Crystalline (hexagonal) regions detected	Crystalline (hexagonal) regions detected
Aspect ratio	1:1–1:30 (range)	20–15,000: 1 (calc.)	33–2,000: 1 (BNNT-S), 20–1,500: 1 (BNNT-P) (calc.)
Shape	Sheet	Ribbon	Tube
Specific surface area	13.3 m ² /g	107 m ² /g (average)	36.5 m ² /g (average)
Zeta potential	+ 4.3 – +27.6 mV at pH = 7 in distilled water	-15 – -40 mV (pH 4 - 13)~	-18.98 ± 0.55 mV (average)
Dustiness	Respirable fraction: 55 mg/kg	Not provided	Not provided
Oxygen content	0.3–4% (range)	5–15% (range)	5–12% (BNNT-S), 5–15% (BNNT-P)

* Based of literature values on hexagonal boron nitride

* GM (GSD): Geometric Mean (Geometric Standard Deviation)

~Based of literature values on boronitrene

Introduction and use

Manufacture

The manufacturing processes described by the applicant are provided below for each nanoparticle form.

BNNS

BNNS will be manufactured from a process that uses mechanical exfoliation of boron nitride (BN). Boron nitride powder will be received at the manufacturing site in sealed containers. The powder will be manually emptied into a high efficiency particulate air (HEPA) filtered hooded feeder in the presence of ducting to remove any potential dust. Captured dust will be directed through a high efficiency polytetrafluoroethylene membrane filter followed by release of purified air to the atmosphere through a stack on the roof. The removal of dust is in accordance with Environment Protection Regulations 2021 (Environment Protection Authority (EPA) Victoria).

From the feeder, the BN powder will be transferred into an agitator tank containing a precursor solution and then the mixture will be transferred into a mechanical exfoliation chamber. Following manufacture from BN, BNNS will be separated from the precursor solution and transferred to the drying station to evaporate excess liquid. BNNS will then be heat-treated in a furnace to remove any residual chemicals and passed through a filtration set for collection.

The produced powder will be packaged into sealable plastic bags of 0.3 to 1 kg in size or dispersed in water or other solvent solutions that are packaged in tightly sealed plastic containers. Blending and packaging will be performed under an enclosed fume hood with any generated dust captured by a HEPA filter. Bags and plastic containers will be stored at the applicant's warehouse and then distributed to reformulation sites by road, rail, sea and air.

BNNX

BNNX will be manufactured in a three-step process that involves formation of precursor hydrogel, formation of precursor aerogel and formation of BNNX aerogel. Precursor reagents comprising boron- and nitrogen-containing compounds are reacted under controlled conditions. The precursor aerogel will be placed in a high temperature furnace for annealing. After annealing, the BNNX aerogel will be formed and then packaged in a sealed container.

The produced powder will either be packaged into sealable plastic containers or dispersed in water and other solvent solutions that are packaged in tightly sealed plastic containers. Blending and packaging will be performed under fume hoods with local exhaust ventilation fitted with HEPA filters. Plastic containers are stored at the applicant's warehouse and then distributed to reformulation sites by road, rail, sea and air.

BNNT

Two grades of BNNT (BNNT-S and BNNT-P) will be manufactured, both with 90% purity. BNNT will be manufactured using boron- and nitrogen-containing compound and metal catalyst in a two-step process that involves production of highly reactive nanoscale precursors and production of BNNT. Two different purification processes will be used to produce BNNT-S and BNNT-P.

During the precursor production, highly reactive precursors in powder form are generated via a high energy physical and chemical method. BNNT is produced via a thermal and mechanical processing under inert or reducing atmospheres at elevated temperature. The purification process to obtain BNNT-S and BNNT-P is followed with a physical and chemical approach, respectively. The as-synthesized BNNT and purified products (BNNT-S and BNNT-P) will be collected under appropriate ventilation and stored in a sealed plastic container.

The produced powder will either be packaged into sealable plastic containers or dispersed in water and other solvent solutions that are packaged in tightly sealed plastic containers. Blending and packaging will be performed under fume hoods with local exhaust ventilation fitted with HEPA filters. Plastic containers are stored at the applicant's warehouse and then distributed to reformulation sites by road, rail, sea and air.

Reformulation

At the end-use manufacturing site, the assessed chemical in all three nanoparticle forms will be reformulated as a component of lubricants and greases and in plastic and polymer products (such as teflon, rubbers, elastomers, polyurethane, resins and epoxies) at up to 2% concentration. The assessed chemical in nanosheet form will be reformulated as a component of paints and coatings and ink, toner and colourant products at up to 15% concentration. The reformulation procedure will likely vary depending on the nature of the formulated products. However, these procedures are likely to be highly automated and use closed systems with adequate waste management and ventilation systems in place in accordance with individual state and territory regulations. End-use products containing the assessed chemical for professional uses will be in packaging appropriate for the end uses.

Human exposure

Workers

Transport and Storage

Transport and storage workers may come into contact with the manufactured assessed chemical in the neat powder form or in a dispersion only in the unlikely event of accidental rupture of containers during transportation to formulation sites. The applicant states that exposure is expected to be minimised through the use of PPE including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) for workers when handling any spills of the assessed chemical.

Manufacture

During manufacture, dermal, ocular and inhalation exposure of workers to the assessed chemical at up to 100% concentration may occur during transfer, blending, quality control analysis, packaging, and cleaning and maintenance of equipment. Inhalation exposure to vapour of the assessed chemical is not expected given the estimated very low vapour pressure of the assessed chemical. The applicant states that exposure is expected to be minimised through the use of enclosed and automated systems, high efficiency membrane filters, adequate ventilation and appropriate PPE for workers including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) if exposed to dust.

Reformulation

According to the applicant, reformulation processes are expected to incorporate blending operations that are highly automated and occur in a fully enclosed/contained environment, followed by automated filling using sealed delivery systems into containers of various sizes. Dermal, ocular and inhalation exposure (if aerosols, mists or dusts are formed) of workers to the assessed chemical at up to 100% concentration may occur during transfer, blending, quality control analysis, packaging, and cleaning and maintenance of equipment. Exposure to workers is expected to be minimised using the same controls employed for the manufacturing process. The applicant states that external reformulation sites are expected to have similar enclosed and automated systems, adequate ventilation and PPE for workers including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) if required.

Professional End Use - Plastic and polymer products

Dermal and ocular exposure to the assessed chemical (at up to 2% concentration) may occur during the use of polymer composites containing the assessed chemical in professional settings. The applicant states that exposure is expected to be minimised through the use of local exhaust ventilation and PPE (including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) if required). Once in the finished products/articles are formed, the assessed chemical will be bound into a solid matrix and will not be available for exposure.

Professional End Use - Lubricants and Greases

Dermal and ocular exposure to the assessed chemical (at up to 2% concentration) may occur during the use of lubricants and greases containing the assessed chemical in professional settings. Inhalation exposure to nanoparticles is not expected given the end use products are used in liquid forms. The applicant states that exposure is expected to be minimised through the use of PPE (including protective clothing, impervious gloves and safety glasses).

Professional End Use – Paints and Coatings

Dermal, ocular and inhalation (if aerosols or mists are formed) exposure to the assessed chemical at up to 15% concentration may occur during mixing, transfer and application (by brush, roller or spray) and also during equipment cleaning and maintenance. The applicant states that exposure is expected to be minimised by the use of engineering controls (such as spray booths) and PPE (including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) if required). Once the paint/coating is dried, the assessed chemical will be bound into a solid matrix and will not be available for exposure.

Professional End Use – Ink, toner, and colourant products

Dermal and inhalation exposure of printer operators and service technicians to the assessed chemicals at up to 15% concentration may occur during loading or unloading inks or toners from bulk packaging and also during equipment cleaning and maintenance. The applicant states that exposure is expected to be minimised by the use of engineering controls and PPE (including protective clothing, impervious gloves, safety glasses and appropriate respiratory protection such as a particle filter device (with filter type P2) if required). Once the ink/toner is dried, the assessed chemical will be bound into a solid matrix and will not be available for exposure.

Health hazard information

The applicant has provided test data on the assessed chemical in nanosheets (BNNS) and nanotubes (BNNT) for most health endpoints. Data on the assessed chemical, BNNS and BNNT-S particle forms have been used as read across to the assessed chemical in nanoribbons (BNNX) and the other grade of BNNT (BNNT-P). The applicant has submitted repeat dose toxicity and clastogenicity data on analogues for BNNS (graphene as structural analogue) and BNNT (various BNNT analogues, with or without modification and carbon nanotubes as structural analogue), which were considered as appropriate to read across.

Acute toxicity

Oral

In each of the two *in vivo* acute oral toxicity studies (OECD TG 423) (one for BNNS and one for BNNT-S), two groups of female Wistar rats (six per group) were administered a single dose of the test substance (in analytical grade water with 0.2% Tween 80) at 300 mg/kg bw or 2,000 mg/kg bw. No mortalities, test substance-related clinical signs or macroscopic findings were observed in any treated animals. Body weight gain appeared normal. The oral LD50 was determined to be greater than 2,000 mg/kg bw in both studies, indicating BNNS and BNNT-S are of low acute oral toxicity.

Using BNNS and BNNT-S as analogues, BNNX and BNNT-P are likely to be of low acute oral toxicity.

Dermal

In each of the two *in vivo* acute dermal toxicity studies (OECD TG 402) (one for BNNS and one for BNNT-S), a single dose of the test substance at 2,000 mg/kg bw was applied (semi-occlusive) for 24 hours on the intact skin of two female Wistar rats. There were no mortalities, signs of systemic toxicity or treatment-related macroscopic findings. No skin reactions were observed at 24, 48 and 72 hours after patch removal. Body weight gain was normal. The dermal LD50 was determined to be greater than 2,000 mg/kg bw in both studies, indicating BNNS and BNNT-S are of low acute dermal toxicity.

Using BNNS and BNNT-S as analogues, BNNX and BNNT-P are likely to be of low acute dermal toxicity.

Inhalation

In two *in vivo* acute inhalation toxicity studies (OECD TG 403), Wistar rats (three per sex) were exposed (nose-only) to an aerosol of BNNS or BNNT-S (at an adjusted measured concentration of 8.78 mg/L and 16.69 mg/L, respectively) for 4 hours and observed for 14 days. The aerosolised chemical comprised of particles with a median mass aerodynamic diameter (MMAD) of 1.87 µm for BNNS and 1.25 µm for BNNT-S. No mortalities were observed. Clinical signs of toxicity observed after administration included:

- nasal discharge (4/6) and/or hypoactivity (4/6) for BNNS
- nasal discharge (6/6) and/or abdominal breathing (5/6) for BNNT-S

All effects were transient in nature with all animals appearing normal one day after exposure. The inhalation LC50 was determined to be greater than 5 mg/L indicating BNNS and BNNT-S are of low acute inhalation toxicity.

Using BNNS and BNNT-S as analogues, BNNX and BNNT-P are likely to be of low acute inhalation toxicity.

Corrosion/Irritation

Skin irritation

In each of the two *in vivo* skin irritation tests (OECD TG 404) (one for BNNS and one for BNNT-S), a single dose of the test substance at 0.5 g was applied to the intact skin of three male New Zealand White rabbits (semi-occlusive) for 3 minutes, 1 hour and 4 hours. No mortalities or signs of systemic toxicity were observed. No skin reactions were observed at 24, 48 and 72 hours after patch removal. Based on the results, BNNS and BNNT-S are not irritating to skin.

Using BNNS and BNNT-S as analogues, BNNX and BNNT-P are likely to be not irritating to skin.

Eye irritation

In an *in vivo* eye irritation test (OECD TG 405), a single dose of the BNNS at 42 mg was applied to one eye of three female New Zealand White rabbits for 1 hour and rinsed with analytical grade water. No mortalities or signs of systemic toxicity were observed. No corneal or iridial

effects was observed at 24, 48 and 72 hours after removal. Very slight conjunctival irritation (maximum score of 1) was observed in the treated eye of all animals at the 1-hour observation. The mean individual conjunctival redness scores at 24, 48 and 72 hours were 0.3, 0, 0, respectively. The mean individual conjunctival oedema scores at 24, 48 and 72 hours were 0.3, 0, 0, respectively. Under the conditions of the study, BNNS was slightly irritating to the eyes but does not meet the GHS criteria for classification. Using BNNS as an analogue, BNNX is likely to be slightly irritating to eyes.

In another *in vivo* eye irritation test (OECD TG 405), a single dose of the BNNT-S at 50 mg was applied to one eye of three male New Zealand White rabbits for 1 hour and rinsed with analytical grade water. No mortalities or signs of systemic toxicity were observed. No corneal, iridial or conjunctival effects were observed at 1, 24, 48 and 72 hours after removal. The mean individual conjunctival redness and conjunctival oedema scores at 24, 48 and 72 hours were 0, 0, 0, respectively. Under the conditions of the study, BNNT-S was not irritating to the eyes.

Using BNNT-S as an analogue, BNNT-P is likely to be to be not irritating to eyes.

Sensitisation

Skin sensitisation

In each of the *in vivo* skin sensitisation study (OECD TG 406) using the Buehler method (one for BNNS and one for BNNT-S), 20 male Hartley guinea pigs were induced by topical administration with 10% (w/v) of the test substance in corn oil and then challenged by topical administration with 10% (w/v) of the test substance in corn oil. There were no mortalities or test substance-related clinical observations. None of the test substance-treated animals showed skin reactions during both the induction and challenge phases. Based on the results, BNNS and BNNT-S are not skin sensitisers.

Using BNNS and BNNT-S as analogues, BNNX and BNNT-P are not likely to be skin sensitisers.

Repeat dose toxicity

Inhalation

Repeated dose toxicology information was not submitted for the assessed chemical. Based on the similarity of the physical properties of BNNS and graphene, the results from toxicological investigations conducted on graphene as reported in two publications (Kim *et al.* 2016 and Ma-Hock *et al.* 2013) were used as read-across to determine the inhalation hazards for BNNS.

In a 28-day repeated dose inhalation toxicity study with a 90-day recovery period (OECD TG 412), rats were exposed (nose-only) to an aerosol of graphene (average lateral dimension: < 2 µm; surface area: 750 m²/g; density: 0.2 g/mL; average thickness of aggregates: 20 – 30 layers [size in nm not provided]) at measured concentrations of 0.12, 0.47 and 1.88 mg/m³ for 5 days/week 6 hours/day. No significant toxicological effects were observed. Graphene was mostly deposited in lung macrophages with some deposition in lung epithelial cells. Translocation of graphene to lung lymph nodes was observed. No adverse lung pathology (no lung epithelial cell proliferation, no inflammatory cell migration to the alveolar space, and no fibroblast proliferation after 90-day recovery period) was reported in exposed animals within all treated groups following recovery. This finding was supported by an absence of any significant increases in inflammatory cells, inflammatory biomarkers or cytokines in the broncho-alveolar fluid or lung tissue lysate in all treatment groups when compared to control

animals. Furthermore, no oxidative stress markers (hydrogen peroxide, glutathione and malondialdehyde) were elevated indicating that graphene had no effect on oxidative stress at the concentrations tested. The No Observed Adverse Effect Concentration (NOAEC) was established as greater than 1.88 mg/m³ in this study, based on no toxicological effects in rats up to the highest dose tested (Kim *et al.* 2016).

In a 5-day repeated dose inhalation toxicity study with a 24-day recovery period (OECD TG not specified), rats were exposed (head-nose) to an aerosol of graphene (particle size distribution (SEM) primary structure: ≤ 10,000 nm diameter, flakes; nano pore size: 9 nm, 100 nm, 40,000 nm; purity: approximately 85%) at measured concentrations of 0.54, 3.05 and 10.1 mg/m³ for 6 hours/day. At 3.05 and 10.1 mg/m³, graphene induced a concentration-related inflammatory response based on increases in lymphocytes, polymorphonuclear neutrophils and cytokines in broncho-alveolar lavage fluid. Microgranulomas were also observed in the lungs. No clinical signs of toxicity were observed, and body weight changes were comparable to control animals. No toxicologically relevant changes were observed regarding haematology and protein levels (α2-macroglobulin and haptoglobin). There were no other effects reported in other organs. A NOAEC for graphene was not reported in this study (Ma-Hock *et al.*, 2013).

Based on the findings of the two repeated dose inhalation toxicity studies for graphene, BNNS may have the potential for lung toxicity (e.g. inflammation and microgranulomas) at exposure concentrations of 3.05 mg/m³ or above with even short-term exposures. However, given only short-term inhalation toxicity studies are available, and toxicity can be dependent on a number of factors including lateral size, number of layers and surface chemistry, and impurities in the test material, there remains uncertainty as to the potential lung toxicity of the assessed chemical in sheet form.

In the absence of repeated dose inhalation toxicity studies on the assessed chemical in ribbon and tube form, and based on the similar structural properties and information available on various types of carbon nanotubes (SWA 2012), the assessed chemical in ribbon and tube form (BNNT-S and BNNT-P) is recommended for classification as causing Specific Target Organ Toxicity – Repeated Exposure (Category 2) (H373 – May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure).

Genotoxicity

In each of the *in vitro* mammalian cell gene mutation test (OECD TG 476) with Chinese hamster ovary (CHO) cells at the Hypoxanthine-Guanine Phosphoribosyl Transferase (HPRT) locus (one for BNNS and one for BNNT-S), BNNS and BNNT-S were negative in the presence or absence of metabolic activation. Using BNNS and BNNT-S as analogues, BNNT-P are likely to be non-mutagenic.

Toxicology information on chromosomal damage was not submitted for the assessed chemical.

Based on the information available on graphene (Kim *et al.* 2016) and similarity to the structural properties of BNNS, the results from toxicological investigations as reported in the publication (Kim *et al.* 2016) was provided by the applicant to use as read across to determine the clastogenicity potential for BNNS. In a comet assay (OECD TG not specified) using cells from the lungs of rats repeatedly exposed to an aerosol of graphene (average lateral dimension: < 2 µm; surface area: 750 m²/g; density: 0.2 g/mL; average thickness of aggregates: 20 – 30 layers [particle size in nm not provided]) for 28 days at up to 1.88 mg/m³, no DNA damage was detected at 1-day post-exposure and at 28-day post exposure. Furthermore, the 28-day repeated dose inhalation toxicity study also showed that there were

no increases in inflammatory cytokines or hydrogen peroxide release, both known to mediate oxidative stress and be associated with DNA damage (Kim et al. 2016).

For the assessed chemical in tube form, the applicant provided a journal article on an *in vitro* genotoxicity study conducted on BNNT analogue, with or without modification, including unmodified BNNT, hydroxylated BNNT and carbohydrate-modified BNNT for read across purposes (Emanet et al. 2015). In an *in vitro* alkaline comet assay (single cell gel electrophoresis) using adenocarcinoma human alveolar basal epithelial cells (A549) (OECD TG not specified), the BNNT analogue (particle size details not provided) produced an increase in DNA comet tail at a concentration of 100 µg/mL with 24-hour incubation. Under the condition of this study, the test substance was considered to be genotoxic. However, it was suggested by the study authors that DNA damage was likely caused by reactive oxygen species (ROS) due to an observed dose-dependent increase in ROS levels at the tested concentrations (5–200 µg/mL) (Emanet et al. 2015).

Overall, the clastogenicity of boron nitride materials, in general, has been attributed to formation of ROS (Emanet et al. 2015, Taskin et al. 2019). However, based on the limited data available and that the toxicity properties of boronitrene and structurally analogous nanomaterials are dependent on their physical and chemical properties (such as dimensions, functionalisation, impurities, dispersibility and aggregation etc.), no conclusion can be derived on the clastogenicity potential of the assessed chemical.

Carcinogenicity

In the absence of carcinogenicity data on the assessed chemical in ribbon and tube form and based on the available carcinogenicity data on various types of carbon nanotubes and similarity of those to the structural properties of BNNT-S and BNNT-P, potential for the assessed chemical in tube form to cause carcinogenicity cannot be ruled out. Therefore, the hazard classification recommended for MWCNTs in the SWA report (SWA 2012) is considered to be applicable for the assessed chemical in ribbon and tube forms - Suspected Carcinogen (Category 2): H351 – Suspected of causing cancer.

Environmental exposure

The assessed chemical will be manufactured in Australia in three nanoparticle forms, which are boronitrene nanosheets (BNNS), boronitrene nanotubes (BNNT) and boronitrene nanoribbons (BNNX). Each nanoparticle form will be manufactured by different processes as described in the **Manufacture section** above. Significant release of the assessed chemical to the environment is not expected during manufacture as the processes are mostly enclosed, with controls in place to prevent releases. Any waste generated is collected for recycling or disposed of in accordance with relevant Local, State, Territory and Federal regulations.

At industrial sites, through enclosed reformulation processes, BNNS, BNNT and BNNX will be added to enhance the existing physical properties of plastic and polymer products, and lubricants and greases. BNNS will also be used as an additive to enhance the existing physical properties of paints and coatings, and ink, toner and colourant products. The assessed chemical will be bound into the matrix of host material if it is solid or homogeneously dispersed if the host material is liquid. Significant release of the assessed chemical to the environment is not expected during reformulation, transport or storage. Accidental release of the assessed chemical to the environment is expected to be collected on suitable materials, and disposed of in accordance with relevant local, State, Territory and Federal regulations.

For the BNNS incorporated into paints and coatings, ink, toner and colourant products and applied on paper substrate, it is expected to share the fate of the paper substrate to which it has been applied, either subjected to paper recycling processes, or being disposed of to landfill at the end of their useful lives. According to the applicant, up to 50% of the import volume of BNNS may be applied to paper substrates. A recent Australian waste study reported a paper recycling rate of 62% (Blue Environment Pty Ltd., 2022). Therefore, up to 62% of BNNS used on paper, could be released to the aquatic environment from paper recycling processes.

For the BNNS, BNNT and BNNX incorporated in other products, as these products are only for professional uses, significant release to the environment is not expected during use and disposal as the products will be disposed of in accordance with relevant local, State, Territory and Federal regulations.

Environmental fate

Once engineered nanomaterials such as boronitrene nanoparticles are released into aquatic ecosystems, they may undergo various transformations which alter their original state. These transformations are due to the engineered nanoparticles inherent properties and can also be influenced by the chemistry of the aquatic environment (Dube et al., 2023). Information related to the environmental fate of boronitrene nanoparticles in the environment is limited. Available information on environmental fate of boronitrene nanoparticles in aquatic environments is discussed below.

Dispersion and dissipation in aquatic environments

Due to their nano structure and partially ionic covalent bonding, boronitrene nanomaterials have high surface energy, as well as high van der Waals and electrostatic forces. Therefore, in an unfunctionalized state they are expected to agglomerate in aquatic environment (Wang et al., 2018; Rasul et al., 2021).

In an algal toxicity study, BNNS with the average thickness of 1.95 nm was found to rapidly aggregate in deionised water and algal culture medium BG-11. The average particle sizes of BNNS in water and algal culture medium were 2.49 and 3.06 μm . Its zeta potential in water was -21.8 mV and the contact angle was 97.9°, confirming that BNNS is hydrophobic (Zou et al., 2024).

In another study on the dispersibility of double walled BNNT with a diameter of approximately 5 nm and a length in the micrometre range, the BNNT was found to be poorly dispersed in water (Castillo et al., 2020).

Recently, colloidal stability studies of BNNS (100 mg/L) were conducted according to the OECD guidance for dispersion stability of nanomaterial in simulated environmental media. A notable tendency of BNNS to aggregate and precipitate over time was reported. This behaviour was evidenced by a decrease in particle number and an increase in the hydrodynamic diameter. However, when BNNS was combined with 10 mg/L natural organic matter (NOM), significant changes were observed. There was an increase in particle number, suggesting a stabilization effect conferred by NOM. This was further supported by a decrease in both the hydrodynamic diameter and the polydispersity index and a reduction in the surface charge in the BNNS-NOM complexes (da Silva, 2025). This could be because the NOM adsorbed on the BNNS surface serving as a source of surface coating (Dube et al., 2023). These findings demonstrate that NOM plays a crucial role in influencing BNNS behaviour and enhancing the stability of the non-agglomerated form in aqueous environments.

Overall, the assessed chemical is expected to agglomerate in aquatic environment and partition to sediment overtime. However, the presence of high concentration of NOM (≥ 10 mg/L) is expected to stabilize the assessed chemical.

Degradation

No information on the degradation of the assessed chemical was provided. The assessed chemical is inorganic and therefore excluded from persistence classification. The assessed chemical consists of B and N atoms bonded by strong covalent bonds in a hexagonal configuration and is considered to be chemically inert and not susceptible to biodegradation (Li et al., 2022). Therefore, the assessed chemical is expected to be long lived in the environment.

Bioaccumulation

No information on the bioaccumulation of the assessed chemical was provided. The assessed chemical is inorganic and therefore excluded from bioaccumulation classification.

Available information on the bioaccumulation of boronitrene nanomaterials is currently limited. Some investigations have been conducted which indicate the potential for accumulation of boronitrene nanoparticles in the liver, spleen and gut in test organisms which may be excreted (Soares et al. 2012; Mortimer et al. 2021). Additionally, investigations have been conducted on chemically inert hexagonal graphene nanomaterials (Dong et al. 2018; Guo et al. 2013; Lu et al. 2017) which indicated accumulation within the gut of test organisms, generally followed by rapid excretion. However, this is an ongoing area of research and the accumulation potential of boronitrene nanoparticles may be lower or higher than indicated in these reports.

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) for Australian waters was calculated based on 50% of the import volume of BNNS, equivalent to 2.5 tonnes per annum, being applied to paper substrates of which, 62% is expected to be released to sewers from paper recycling processes (Blue Environment Pty Ltd., 2022). It is assumed that the paper recycling process will release the assessed chemical as nanoparticles. As paper recycling occurs at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum. The removal of BNNS during wastewater treatment processes is expected to be similar to few-layered graphene which is calculated to be removed with 73% efficiency (Suárez-Iglesias et al, 2017). Therefore, it is expected that 73% of BNNS released to sewers will be removed during wastewater treatment processes.

The calculation of the PEC (EPHC, 2009) is detailed in the table below:

Annual Import Volume used on paper substrate	2,500	kg/year
Proportion expected to be released to sewer	62 %	
Annual quantity of chemical released to sewer	1,550	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	5.96	kg/day

Water use	200	L/person/day
Population of Australia	25.423	Million
Removal within STP	73 %	Mitigation
Daily effluent production	5,085	ML/day
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River	0.32	µg/L
PEC - Ocean	0.03	µg/L

Environmental effects

As available information on environmental effects of boronitrene nanoparticles is currently limited, where relevant, information has been read across from graphene nanoparticles. Both graphene and boronitrene nanomaterials are chemically inert, and any adverse effects will be attributed to physical interactions on organisms. The selected studies were conducted using graphene nanoparticles with similar hexagonal structure and particle sizes to the assessed boronitrene nanoparticles.

Effects on aquatic Life

Acute toxicity

The following acute toxicity endpoints on boronitrene nanoparticles and graphene nanoparticles are available in the public domain or were supplied by the applicant:

Taxon	Endpoint	Method
Fish	Multi-walled carbon nano tubes (MWCNTs): 96 h LC50 > 100 mg/L	<i>Danio rerio</i> embryos (Zebrafish) Mortality Non-standard test Semi-static conditions Nominal concentration
	BNNS: Study 1: 48 h EC50 > 100 mg/L	<i>Daphnia magna</i> (water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Invertebrate	MWCNTs: Study 2: 48 h EC50 = 8.723 mg/L	<i>Daphnia magna</i> (Water flea) Immobility OECD TG 202 Static conditions Nominal concentration
	BNNS: Study 1: 96 h ErC50 = 1.27 mg/L	<i>Chlorella vulgaris</i> (green algae) Growth inhibition Non-standard test Static conditions Nominal concentration
Algae	MWCNTs: Study 2: 72 h ErC50 = 1.8 mg/L	<i>Chlorella vulgaris</i> (green algae) Growth inhibition OECD TG 201 Static conditions Nominal concentration

In the supplied acute fish toxicity study detailed above, the tested MWCNTs had lengths of 10-30 µm and diameters of 10-20 nm which are similar to the low end of the assessed BNNT and BNNX. No obvious morphological malformation or mortality was observed in the zebrafish embryos after 96 h exposure to the tested material up to the highest test concentration of 100 mg/L (Liu et al., 2014).

In the acute invertebrate toxicity study 1 detailed above, the tested BNNS had a thickness of 5 - 6 nm which is within the thickness range of the assessed BNNS (1 - 100 nm). The lateral size of the tested BNNS is 0.5 - 1 µm which is within the lateral size range of the assessed BNNS (0.3 - 10 µm). The tested BNNS was found not to cause acute toxic effects up to 100 mg/L. The study also found that in hyperspectral microscopy images, the gut was brighter in tested *Daphnia magna* exposed to BNNS compared to control samples. This indicates that agglomerated particles may have been ingested by the organism (da Silva, 2025).

In the acute invertebrate toxicity study 2 detailed above, the tested material was MWCNTs with lengths of 5-15 µm and diameters of 10-20 nm which are similar to the low end of the assessed BNNT and BNNX. The study found increasing concentration of the carbon-based nanomaterials such as MWCNTs, to which the daphnids were exposed, caused increases in toxicity and 100% mortality occurred at 100 mg/L test concentration. The 48 h EC50 and 48 h LC50 for MWCNTs were 8.723 and 22.751 mg/L, respectively (Zhu et al., 2009).

In the algae toxicity study 1 detailed above, a 96 h ErC50 = 1.27 mg/L to algae was determined. The study found the toxicity mechanism involves phospholipid membrane damage and carbon assimilation inhibition (Zou et al., 2024). The tested BNNS has an average thickness of 1.95 nm which is within the thickness range of the assessed BNNS (1 - 100 nm).

In the algae toxicity study 2 detailed above, a 72 h ErC50 to algae was determined as 1.8 mg/L (Schwab et al., 2011). The tested pristine MWCNTs have lengths of 2-5 µm and diameters of 5-15 nm which are smaller than those of the assessed BNNT and BNNX. As the MWCNT test material used in this study is smaller than the assessed chemical (in terms of thickness), this could represent a conservative estimate of algae toxicity.

Chronic and reproductive toxicity

The following chronic and reproductive endpoints on graphene nanomaterials are available in the public domain or were supplied by the applicant:

Taxon	Endpoint	Method
Fish (embryo acute toxicity)	Pristine graphene (PG):	<i>Danio rerio</i> (zebrafish) Mortality
	96h LOEC = 0.005 mg/L	Non-standard test Semi-static conditions Nominal concentration
Invertebrates	Few layered graphene:	<i>Daphnia magna</i> (water flea) OECD TG 211
	21d NOEC = 0.1 mg/L	Reproduction Semi-static conditions Nominal concentration
Algae	MWCNTs:	<i>Chlorella vulgaris</i> (green algae) Growth inhibition
	72 h NOEC = 0.04 mg/L	OECD TG 201 Static conditions Nominal concentration

The effects of graphene on the survivability and development of zebrafish embryos were investigated using pristine graphene (PG; single layer thickness, 170–390 nm lateral) (Manjunatha et al. 2018). All embryos exposed to PG at concentrations of 30 µg/L or higher died within 2 hours of exposure. Various developmental effects were observed for embryos exposed to PG at concentrations as low as 5 µg/L. The PG used in this study is smaller than the assessed chemical (in terms of thickness and lateral size) and therefore may more readily accumulate within the chorions of the embryos and cause development damage. As such, this could represent a conservative estimate of fish embryo acute toxicity.

In the chronic invertebrate toxicity study detailed above, the tested graphene has lateral sizes of 0.5 - 2 µm which are within the lateral size range of the assessed BNNS (0.3 - 10 µm). The study show that the tested graphene can inhibit reproduction at concentrations above 0.1 mg/L. Exposure to graphene caused reduced size in daphnia offspring and reduced numbers of offspring. As the graphene accumulated within the digestive tract of the daphnia, it was believed that the changes in reproduction may have been caused by malnutrition resulting from reduced digestive efficiency (Fan et al. 2016).

In the algae toxicity study detailed above, a 72 h NOEC = 0.04 mg/L was determined. The tested pristine MWCNTs have lengths of 2-5 µm and diameters of 5-15 nm which are smaller than those of the assessed BNNT and BNNX. As the MWCNT test material used in this study is smaller than the assessed chemical (in terms of thickness), this could represent a conservative estimate of algae toxicity (Schwab et al., 2011).

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) of 0.5 µg/L was calculated for the assessed chemical in the aquatic environment. This value was derived using the most sensitive chronic endpoint value, which is for zebrafish larval malformation (5 µg/L). An assessment factor of 10 was applied to this endpoint as chronic or reproductive toxicity data were available for at least three trophic levels and was expected to have considered the most sensitive cases (EPHC 2009).

Categorisation of environmental hazard

As the assessed chemical is inorganic, it is excluded from categorisation under the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW, 2022).

Environmental risk characterisation

Based on the PEC and PNEC values determined above, Risk Quotients (RQ = PEC ÷ PNEC) have been calculated for release of the assessed chemical to river and ocean:

Compartment	PEC	PNEC	RQ
River	0.32 µg/L	0.5 µg/L	0.633
Ocean	0.03 µg/L	0.5 µg/L	0.063

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

This current assessment may require revisions if information becomes available that indicates the bioaccumulation potential, toxic effects or environmental exposure of hexagonal boronitrene nanoparticles, are greater than outlined in this assessment.

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