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November 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Carbon nanotubes

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019 (the IC Act) and Industrial Chemicals (General) Rules 2019 (the IC Rules) by following the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act) and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules)*. The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on the AICIS website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1724	Parchem Constructions Supplies Pty Ltd	Carbon nanotubes	Yes	< 85 tonnes per annum	Component of concrete for industrial use

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information for other multi-walled carbon nanotubes, the assessed chemical is considered a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the assessed chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Specific Target Organ Toxicity – Repeated Exposure (Category 2)	H373 – May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure
Suspected Carcinogen (Category 2)	H351 – Suspected of causing cancer

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the assessed chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the reported use pattern, the assessed chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The assessed chemical should be classified as follows:
  - Specific Target Organ Toxicity – Repeated Exposure (Category 2): H373 – May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure
  - Suspected Carcinogen (Category 2): H351 – Suspected of causing cancer

  The above should be used for products/mixtures containing the assessed chemical, if applicable, based on the concentration of the assessed chemical present.

Exposure Standard

- Safe Work Australia should consider establishing a workplace exposure standard for the assessed chemical if introduced in solid/powder form.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical during repackaging and end-use:
  - Enclosed, automated processes where possible
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the assessed chemical during repackaging and end-use:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols, mists or dusts

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the assessed chemical during repackaging and end-use:
  - Impervious gloves
  - Safety glasses
  - Protective clothing
  - Appropriate respiratory protection if inhalation exposure may occur

  Guidance in selection of personal protective equipment can be obtained from Safe Work Australia's guidance on Safe Handling and Use of Carbon Nanotubes.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the assessed chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Storage

- The handling and 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, 2012a) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC Act the applicant of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the assessed chemical is introduced with parameters significantly outside those stated in this application, specifically particle size and size distribution, wall number, surface area, or impurities;
- the assessed chemical is intended to be introduced in a functionalised form;
- the final concentration of the assessed chemical in concrete mixtures exceeds 4%;
- the assessed chemical is intended to be imported in solid/powder form;
- the assessed chemical is imported for reformulation in Australia;
- the assessed chemical is proposed to be used in products involving spray application;
- information becomes available that indicates that the assessed chemical is significantly released from concrete matrices throughout its lifecycle;
- the function or use of the chemical has changed from a component of concrete for industrial use, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet

The SDS of the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT
Parchem Constructions Supplies Pty Ltd (ABN: 80 069 961 968)
7 Lucca Road
WYONG NSW 2259

APPLICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
No details are taken to be protected information.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for all physico-chemical, toxicological and ecotoxicological endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
Previous permit (NICNAS)

APPLICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

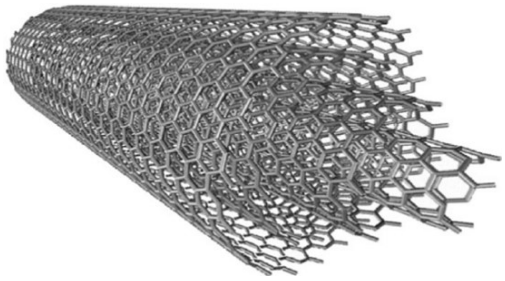
MARKETING NAME(S)
Edencrete HC (product containing < 4% assessed chemical)
Edencrete Pz (product containing < 4% assessed chemical)

CAS NUMBER
308068-56-6

CHEMICAL NAME
Carbon nanotubes

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA
The structure of the assessed chemical is multi-walled carbon nanotubes (MWCNTs). The applicant provided the following structure and description:



A very high percentage of the carbon atoms constituting the CNTs are in a sp^2 hybridized hexagonal aromatic lattice. Each carbon is bonded to 3 similar neighbouring carbon atoms in an almost flat conformation like in a graphene sheet. The diameter of the individual nanotubes dictates how much of a curvature that is needed for these "sheet" to create the tube structure. For diameters of the CNTs - this does typically not distort the individual carbon atoms much from the sp^2 hybridization.

MOLECULAR WEIGHT
Unspecified

ANALYTICAL DATA

METHOD	TEM, SEM, SHIM
Remarks	Microscopy images show the three dimensional structure of the assessed chemical.
TEST FACILITY	Provided by the applicant

METHOD	Raman Spectroscopy
Remarks	Spectra results are consistent with the expected structure of the assessed chemical.
TEST FACILITY	Provided by the applicant

3. COMPOSITION

DEGREE OF PURITY
99.95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None identified

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None identified

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Grey to black powder or granules

Property	*Value*	*Data Source/Justification*
Melting Point	3550-3697 °C (estimated)	SDS
Boiling Point	Not determined	Expected to be > 300 °C
Bulk Density	0.1 - 0.6 g/m^3	SDS
Powder Density	0.14 g/m^3	Provided by the applicant (study report not submitted)
Vapour Pressure	Not determined	Expected to be very low
Water Solubility	Insoluble	SDS
Hydrolysis as a Function of pH	Not determined	Chemically inert under ambient conditions
Partition Coefficient (n-octanol/water)	Not determined	Composed of insoluble inorganic nanoparticles
Adsorption/Desorption	Not determined	Composed of insoluble inorganic nanoparticles
Dissociation Constant	Not determined	Composed of insoluble inorganic nanoparticles with no dissociable functionality
Particle Size (diameter)	GM (GSD)* = 32 (2.0) nm Mean diameter = 35 ± 1.0 nm Range = 15-110 nm	Provided by the applicant (study report not submitted)
Particle Size (length)	GM (GSD)* = 0.7 (2) µm Mean length = 0.9 ± 0.1 µm Range = 0.2-9.5 µm	Provided by the applicant (study report not submitted)
Surface Area	91.51 ± 0.47 m²/g	Provided by the applicant (study report not submitted)
Wall Number	Mean = 41.5 ± 9.0	Provided by the applicant (study report not submitted)
Aspect Ratio	22 (2):1 Mean = 26: 1	Provided by the applicant (study report not submitted)

Property	*Value*	*Data Source/Justification*
Flash Point	Not determined	Study not required as inorganic solid
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	450 °C	SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

DISCUSSION OF PROPERTIES
The assessed chemical has particles with diameters in the nanoscale (15-110 nm), lengths between 0.2-9.5 µm, mean wall number of 41.5 ± 9.0 and a mean aspect ratio of 26 to 1 based on mean 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 (SWA, 2009).

Reactivity
The assessed chemical is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the assessed chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will not be manufactured in Australia. The assessed chemical will be introduced as a component of liquid concrete additive formulations at < 4% (w/v) concentration for incorporation into end-use products.

MAXIMUM INTRODUCTION VOLUME OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3	20	30	50	85

PORT OF ENTRY
Brisbane, Sydney, Melbourne and Perth

IDENTITY OF RECIPIENT
Parchem Construction Supplies Pty Ltd

TRANSPORTATION AND PACKAGING
Products containing the assessed chemical at < 4% concentration will be imported in 1000 L totes and transported primarily by road to the applicant's manufacturing plants for delivery to customers or repackaging into 4 L, 17 L and 19 L plastic containers. The imported or repackaged products will be transported by road to customers.

USE
The product containing the assessed chemical at < 4% concentration will be used as an additive in ready-mix concrete products, resulting in a final concentration of the assessed chemical at < 0.5 kg/m^3.

OPERATION DESCRIPTION
The assessed chemical will not be manufactured in Australia. It will be imported into Australia as a component of liquid concrete additive formulations at < 4% concentration for repackaging or addition into ready-made concrete products.

Repackaging
Repackaging from the 1000 L totes into 4 L, 17 L and 19 L plastic containers will be carried out using a metered sealed pump that has been manually connected to the tote.

End-use
At fixed sites or mobile concrete batch plants, the liquid concrete additive formulation containing the assessed chemical will be added to ready-mix concrete products using a mix of automated, manual, open and closed processes. The concrete mix containing the assessed chemical will then be poured into the prepared area at the residential, commercial or industrial site. Once the concrete has hardened, saw cutting, drilling, abrasive blasting and grinding may take place.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport & Delivery	1	104
Distribution Centre/Warehouse	1	104
Repackaging	8	10
Laboratory	4	8
Dispenser technicians	2	2
End users (Concrete Batchers)	1	3

EXPOSURE DETAILS

Transport and Storage
Transport and storage workers may come into contact with the assessed chemical (at < 4% concentration) in the unlikely event of accidental rupture of containers.

Repackaging
Dermal and ocular exposure to the assessed chemical (at < 4% concentration) may occur when connecting and disconnecting transfer hoses, and during cleaning and maintenance operations. Inhalation exposure is not expected given the estimated low vapour pressure of the assessed chemical and the proposed form of introduction (liquid concrete additive formulation). The applicant states that exposure is expected to be minimised through the use of personal protective equipment (PPE) such as protective clothing, impervious gloves and safety glasses.

End-use
Dermal, ocular and inhalation (if aerosols or mists may occur) exposure of workers to the assessed chemical (at < 4% concentration) may occur when workers manually pour the additive formulation into the ready-made concrete products, during cleaning and maintenance of equipment and during quality control of the product. Use of liquid formulations will not cause inhalation exposure to the assessed chemical. The applicant states that exposure is expected to be minimised through the use of PPE such as protective clothing, impervious gloves, safety glasses and respiratory protection if aerosols or mists may occur. Furthermore, the applicant advised that, once the assessed chemical is within the hardened concrete mix, it will not be released from the matrix as CNTs during further construction operations. This is supported by a test report (Galson, 2016), indicating that grinding of concrete containing the assessed chemical did not liberate detectable CNTs.

6.1.2. Public Exposure
The assessed chemical will be for industrial use only and will not be made available to the public. The public may come into contact with concrete containing the assessed chemical (at < 0.5 kg/m^3). However, once the concrete has hardened, the assessed chemical will become part of a cementitious matrix and will not be available for exposure.

The public may be in the vicinity of concrete remedial and maintenance operations. Given the low frequency of such events and the assessed chemical is not expected to be released as CNTs during further construction operations, public exposure to the assessed chemical is not expected.

6.2. Human Health Effects Assessment

Limited toxicological data for the assessed chemical were provided. The results from toxicological investigations conducted on other MWCNTs and reported in the SWA report (2012b) and two other publications (NTP, 2019 and Ema, *et al.,* 2016) were used to determine the hazards of the assessed chemical.

Toxicokinetics

There was one acute inhalation toxicity study and two repeated dose inhalation toxicity studies conducted using 3 types of MWCNTs in male rats or mice showing clearance of inhaled MWCNTs.

- In an acute inhalation study conducted in male C57BL/6 mice (OECD TG not specified), MWCNT-A (diameter: 30-50 nm; length: 0.3-50 µm; impurities: 0.34% nickel and 0.03% lanthanum) reached the sub-pleural tissue of the lung after a 6-hour nose-only aerosol exposure to the chemical at the 30 mg/m^3 dose. The aerosolised chemical comprised of agglomerated and individual nanotubes with lengths varying between < 100 nm to > 10 µm with a median mass aerodynamic diameter (MMAD) of 183 nm. By the end of the observation period (14 weeks), it was found that majority of the nanotubes were cleared; however, some of the inhaled nanotubes remained in the sub pleural wall (SWA, 2012b).
- In a nose-only inhalation exposure study (OECD TG not specified), male Wistar rats (six per group) were exposed to 0, 0.1, 0.4, 1.5 and 6 mg/m^3 of MWCNT-B (diameter: 10 nm; length: 200-300 nm; impurity: 0.115% cobalt; consists of tangled and intertwined agglomerates of 2-3 µm in diameter) for 6 hours a day, 5 days a week for 13 weeks to investigate the kinetics of MWCNT-AB in the lung and lung associated lymph nodes. Minimal to moderate lung overload was noted in the 0.1 and 0.4 mg/m^3 dose groups and impaired clearance to complete stasis was noted in the 1.5 and 6 mg/m^3 dose groups. There was also a time- and concentration-dependent increase in the amount of cobalt in the lung-associated lymph nodes at the two highest concentrations during post-exposure observation at weeks 17, 26 and 39 (NTP, 2019).
- In an inhalation study male C57BL/6 mice were exposed to 5 mg/m^3 MWCNT-C (diameter: 40-170 nm; length: 1-19 µm; consists of a mixture of single nanotubes to agglomerates with a MMAD of 1.5 µm) for 5 hours a day, 4 days per week for 3 weeks and observed for 336 days to determine distribution and lung burden of the test substance. Initially, 84% of the test substance was distributed to the alveolar region (with 1.2% in the subpleural region) and 16% in the airways; however by the end of the post-exposure period, 95.8% of the initial lung burden lingered in the alveolar region (4.7% in the subpleural region) and 4.2% in the airways. The decrease in the lung burden in the airways occurred rapidly post-exposure and reached a steady state after 14 days, whereas clearance in alveolar region occurred through the alveolar macrophage fraction followed by the alveolar tissue. Although agglomerates were mainly cleared from the lung, single MWCNT particles remained unchanged in the lung (NTP, 2019).

The applicant submitted a cytotoxicity study summary showing the assessed chemical is less damaging to cell walls than other MWCNTs tested (Hubczack *et al*., 2019). The applicant postulated that either the polarity of the assessed chemical, the ratio between sp^2 and sp^3 hybridization, or the size and aspect ratio make it a less good fit with the macrophage cell walls. This suggests that the assessed chemical will not be taken up by macrophages and therefore, will not be cleared from the body if exposed via inhalation as no phagocytosis is expected.

Acute Toxicity

Based on oral (OECD TG 423) and dermal (OECD TG 402) studies conducted in rats, MWCNT-D (mean diameter: 10-15 nm; mean length: ~0.2-1 µm; surface area: 257 m^2/g; impurity: 0.53% cobalt) was reported to be of low acute oral (LD50 > 5000 mg/kg bw) and acute dermal (LD50 > 2000 mg/kg bw) toxicity (SWA, 2012b).

Three acute inhalation toxicity studies reported no rat deaths at 0.241 mg/m^3 and no mice deaths up to 30 or 100 mg/m^3 with nose-only exposure to MWCNTs.

In an acute nose-only inhalation study using MWCNT-E (OECD TG not specified), Wister rats were exposed to aerosolised MWCNT-E (diameter: 10-16 nm; MMAD: 2.2 µm; impurity: 0.53% cobalt) or crystalline quartz (MMAD = 2.3 µm) at the nominal concentration of 241 mg/m^3 or 248 mg/m^3 (0.241 or 0.248 mg/L, respectively) for 6 hours followed by a 90-day observation period (SWA, 2012b). No deaths were observed during the study (indicating LC50 > 0.241 mg/L in rats); however, pulmonary inflammation was initially observed after exposure to MWCNT-E, which subsided over time. A comparative time course study conducted using MWCNT-E containing 0.12% (MMAD = 2.5 µm) and 0.53% (MMAD = 2.9 µm) of cobalt at 11 mg/m^3 demonstrated that pulmonary inflammation occurs independently from the concentration of residual cobalt (SWA, 2012b).

Two 6-hour nose-only inhalation exposure studies were conducted on MWCNT-A (diameter: 30-50 nm; length: 0.3-50 µm; impurities: 0.34% nickel and 0.03% lanthanum) in C57BL/6 mice (OECD TG not specified) using aerosolised saline as a control (SWA, 2012b). The first study was conducted on normal and ovalbumin (OVA)

sensitised mice using aerosolised MWCNT-A at the nominal concentration of 100 mg/m^3 (MMAD = 714 ± 328 nm). At Day 14 observation, significant airway fibrosis was observed in the OVA sensitised mice with no mortalities observed in either group of mice during the study, indicating that inhaled MWCNT-A require pre-existing inflammation to cause airway fibrosis. A no observed adverse effect concentration (NOAEC) of 100 mg/m^3 was established in OVA sensitised mice. In the second inhalation study, male C57BL/6 mice (10 mice/group) were exposed to aerosolised MWCNT-A at a nominal concentration of 1 or 30 mg/m^3 (MMAD = 164 and 183 nm for each dose, respectively) or saline aerosol for 6-hours and observed over 14 weeks. No mortalities was observed at concentrations up to 30 mg/m^3 (indicating LC50 > 30 mg/m^3 in mice); however, sub-pleural fibrosis was observed after 2 and 6 weeks in the 30 mg/m^3 group, which appeared to diminish after 14 weeks (SWA, 2012b).

Irritation and Skin Sensitisation
In skin irritation (OECD TG 404) and eye irritation (OECD TG 405) studies conducted in rabbits and a modified skin maximisation test (OECD TG 406) conducted in guinea pigs, MWCNT-D (mean diameter: 10-15 nm; mean length: ~0.2-1 µm; surface area: 257 m^2/g; impurity: 0.53% cobalt) was reported to not cause skin irritation or skin sensitisation; however, it was reported to have a very mild eye irritation potential (SWA, 2012b).

Respiratory Sensitisation
Two relevant studies were identified for this health effect. Intranasal administration of three doses (low, medium, high) of MWCNT-F (diameter: 15.04 ± 0.47 nm; length: 0.5-200 µm; surface area: 542.9 m^2/g; impurities: Ni-(Fe) complexes of 5-40 nm in size and Fe-(Ni) complexes of several hundreds of nanometres in size) with an allergen booster ovalbumin (OVA) to BALB/cAnNCrl mice resulted in allergic responses (SWA, 2012b). Effects included increases in the levels of IgE, neutrophil numbers, and the secretion of Th2-associated cytokines in the mediastinal lymph node as well as increases in eosinophil numbers, IgG2a levels, TNF-α levels and monocyte chemoattractant protein-1 levels in their bronchoalveolar lavage fluid (BALF). Additionally, an acute influx of neutrophils was observed in the mice not treated with OVA at the 24-hour observation period.

Mice were intratracheally instilled with 25 or 50 µg/animal MWCNT-G (chemical details not specified), with or without an allergen (OVA, 1 µg/animal), weekly for 6 weeks (SWA, 2012b). Exposure to the test substance with OVA aggravated allergen-induced airway inflammation (which was characterised by the infiltration of eosinophils, neutrophils and monocytes in the lung and increased goblet cells in the bronchial epithelium), increased lung protein levels of Th cytokines and chemokines and significantly increased allergen-specific IgG1 and IgE. The study concluded that MWCNT-G can aggravate murine allergic airway pathway, suggesting that inhalable MWCNTs may be an environmental risk factor for individuals with allergic asthma (SWA, 2012b).

Repeated Dose Toxicity
There are no repeated dose toxicity studies conducted on the assessed chemical, however, four 90-day or 13 week inhalation toxicity studies conducted in rats/mice with different MWCNTs were considered as relevant for the assessed chemical.

In a 90-day inhalation toxicity study (OECD TG 413) Wistar rats were exposed to aerosolised MWCNT-K (diameter: 5-15 nm; length: 0.1-10 µm; impurities: 10% metal oxide (9.6% aluminium oxide with traces of iron and cobalt); contains agglomerates with a hairy surface with an MMAD of 0.7-2 µm) at concentrations of 0, 0.1, 0.5 and 2.5 mg/m^3 (corresponding to 0.0001, 0.0005 and 0.0025 mg/L, respectively) through head and nose exposure for 6-hours/day, 5 days/week for 13 weeks (SWA, 2012b). No clinical signs of toxicity or systemic toxicity was observed; however, grey lung discolouration, concentration-dependent lesions in the lung and lymph nodes (which corresponded to inflammation and multifocal granuloma formation) and multifocal eosinophilic, granular material representative of alveoli lipoproteinosis in the alveoli was observed at the 0.5 and 2.5 mg/m^3 doses. As single granulomas was also observed at the lowest dose, the lowest observed adverse effect concentration (LOAEC) was determined to be 0.1 mg/m^3. The study authors claimed that the effects were not caused by the impurities of the chemical (aluminium oxide) but were caused by exposure to MWCNT-K (SWA, 2012b).

In another 90-day inhalation toxicity study (OECD TG not specified), Wistar rats were exposed (nose-only) to aerosolised MWCNT-L (diameter: 5-15 nm; length: 0.1-10 µm; impurity: ~0.5% cobalt; contains agglomerates of coiled, tangled assemblages with an MMAD of 2.7-3.4 µm) at doses of 0, 0.1, 0.4, 1.5 or 6 mg/m^3 (corresponding to 0.0001, 0.0004, 0.0015 and 0.006 mg/L, respectively) for 6 hours/day, 5 days/week (SWA, 2012b). No clinical signs of toxicity or systemic toxicity was observed. Histopathological analysis revealed exposure related lesions in the upper and lower respiratory tract (in the bronchoalveolar region) at 0.4 mg/m^3 dose as well as granulomatous changes and time dependent increases of bronchoalveolar hyperplasia at 6 mg/m^3 dose and the no observed adverse effect concentration (NOAEC) of 0.1 mg/m^3 was established.

In a nose-only inhalation study (OECD TG not specified), male and female Wistar rats were exposed to 0, 0.05, 0.25 or 5 mg/m^3 MWCNT-M (mean diameter: 11-12 nm; mean length: ~1 µm; MMAD: 1.6-2.3 µm; contains large agglomerates of entangled MWCNTs) for 90 days with a 90-day recovery period (NTP, 2019). Analysis revealed a decrease in macrophages as well as an increase in neutrophils, phospholipids, lactate dehydrogenase (LDH), alkaline phosphatase, gamma-glutamyl transferase and protein in the 0.25 and 5 mg/m^3 dose groups at 24 hours after 90-day exposure and in the 5 mg/m^3 dose group at 90 days after 90-day exposure. No pleural effects were observed at Day 90 post-exposure; however, several histopathological changes were noted such as eosinophilic inclusions in the respiratory and olfactory epithelium of the nose, minimal squamous metaplasia in the larynx and increased lymphocytes in the tracheobronchial lymph nodes. Although clearance of MWCNT-M was observed in the 0.25 and 0.5 mg/m^3 dose groups after the recovery period, there was no change in the 5 mg/m^3 dose group, suggesting 'lung overloading' and that the rats were unable to clear the MWCNT.

In a 13 week inhalation study (OECD TG not specified), male and female Fisher 344 (F344) rats were exposed to 0.2, 1.0 or 5 mg/m^3 MWCNT-C (diameter: 40-170 nm; length: 1-19 µm; consists of a mixture of single nanotubes to agglomerates with an MMAD of 1.5 µm) for 6 hours a day, 5 days per week (NTP, 2019). Effects observed included increased lung weights (1.2-fold and 1.3-fold increases at the 1 mg/m^3 and 5 mg/m^3 dose groups, respectively), dose-dependent increases in inflammatory cytokines (from concentrations > 2 mg/m^3), granulomatous changes in males rats of all dose groups and in females of the 1 and 5 mg/m^3 dose groups, focal fibrosis of the alveolar wall in both males and females at doses of ≥ 1 mg/m^3 and inflammatory infiltration of the visceral pleura and subpleural areas in the 5 mg/m^3 dose group (NTP, 2019).

Several short-term repeat-dose inhalation toxicity studies were reported for MWCNTs in mice (SWA, 2012b).

- C57BL/6 mice exposed (whole body) to respirable aggregates of MWCNT-H (diameter: 10-20 nm; length: 5-15 µm; impurities: 0.5% nickel and 0.5% iron; consists of flexible, coiled agglomerates with an MMAD up to 1.8 µm) at doses of 0.3, 1 or 5 mg/m^3 for 14 days (for 6 hours/day) showed a suppressed T-cell dependent antigen response at all concentrations. Suppression of the innate immune response was also observed in mice treated at 1 mg/m^3 for 7 or 14 days.
- Whole-body exposure to aerosolised MWCNT-I (diameter: 50 nm; length: 10 µm, surface area: 280 m^2/g; impurities: < 0.2% lanthanum and nickel ash, and < 3% amorphous carbon) in Kunming mice (n = 18) for 6 hours per day over a period of 5, 10 or 15 days at 32.61 mg/m^3 showed large aggregates of MWCNT-I in the lining of the bronchi but with no inflammation; smaller aggregates were found to distribute to the alveolar walls, where they induced proliferation and thickening of the alveolar walls.
- In another study with female Kunming mice (n = 9), exposure to aerosolised MWCNT-I (diameter: 50 nm; length: 10 µm, surface area: 280 m^2/g; impurities: < 0.2% lanthanum and nickel ash, and < 3% amorphous carbon) at a mean concentration of 32.61 mg/m^3 for 6 hours per day every 2 days for 60 days induced severe pulmonary toxicity based on changes in biochemical indices and increases in pathological lesions; exposure for 30 days showed slight increase in biochemical indices (compared to control), slight alveolar wall thickening as well as the formation of small aggregates on bronchial and alveoli walls.
- Suppression of immune function was observed at up to 30 days post exposure in C57BL/6 mice exposed to MWCNT-J (mean particle diameter: 590 nm) at 1 mg/m^3 for 6 hours/day for 14 days. This was suggested to be caused by the release of cytokine TGFβ from the lung after low level MWCNT inhalation, which activates the cyclooxygenase pathway in the spleen causing T-cell dysfunction and altered systemic immunity.
- Male C57BL/6 mice exposed to MWCNT-C (diameter: 40-170 nm; length: 1-19 µm; consists of a mixture of single nanotubes to agglomerates with a MMAD of 1.5 µm) at a concentration of 10 mg/m^3 for 5 hours a day for 2, 4, 8 or 12 days showed lung burden that correlates linearly to the number of exposure days. MWCNT-C appeared to be most commonly deposited in the bronchioles and proximal alveolar regions of exposed mice as well as the pleural wall. Effects of MWCNT-C exposure included an increase in lung inflammation and cytotoxicity as the number of exposure days increased (which was characterised by increased in neutrophils and LDH in BALF), bronchiolocentric inflammation, bronchiolar epithelial cell hyperplasia and hypertrophy, minimal to mild fibrosis, vascular changes and pleural penetration (NTP, 2019).

Among the data summarised in this section, there were two 90-d inhalation studies indicating systemic lung effects in rats at very low exposure doses - Wistar rats exposed via inhalation to aerosolised MWCNTs for 90 days had dose dependent increase in the incidences of granulomas in the lung and associated lymph nodes starting from the lowest dose of 0.1 mg/m^3 (0.0001 mg/L) and exposure related lesions in the upper and lower respiratory tract caused by inflammatory responses at the site of initial deposition and retention of MWCNTs at concentrations > 0.4 mg/m^3 (> 0.0004 mg/L) (SWA, 2012b). Although these effects may have been potentially caused by 'lung

overloading' of an inert dust, the effects observed in these studies occurred at concentrations significantly below the concentration cut off assigned by GHS for this type of hazard and is therefore considered to be an intrinsic property of these MWCNTs (SWA, 2012b). It is suggested that repeated inhalation exposure even at low doses to MWCNTs may be potentially harmful to humans (SWA, 2012b).

In the absence of repeated dose inhalation toxicity studies for the assessed chemical and based on the information available for the other MWCNTs, the assessed chemical 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.

Mutagenicity/Genotoxicity
Two studies reported negative results in a bacterial reverse mutation assay (Ames test; OECD TG 471) with MWCNT-N (diameter: 110-170 nm; length: 5-9 µm; impurities: < 0.1% unspecified metal(s)) and MWCNT-O (contains agglomerates with a diameter of 0.1-0.3 mm; impurity: < 1% cobalt). Negative results were also reported for MWCNT-O in a chromosomal aberration assay using Chinese hamster lung fibroblast V79 cells (OECD TG 473) (SWA, 2012b).

In an *in vivo* genotoxicity study conducted using MWCNT-P (known as bucky paper; similar to woven asbestos; diameter and length not specified; impurities: 1.65% iron and < 1% unspecified trace elements), a patch containing MWCNT-P was inserted into a pocket made between the muscular fascia and lumbar niusele of male Sprague Dawley rats (n = 25/group). Moderate inflammation with fibroblast deposition was observed in the area surrounding the patch containing the MWCNT. No mutagenic effects were observed five-weeks after implantation (SWA, 2012b).

After inhalation (whole-body exposure) of aerosolised MWCNT-Q (diameter: 10-15 nm; mean length 2.6 µm; impurities: 5% unspecified metal(s); consists of well-dispersed, straight fibres with lengths ranging from 0.2-20 µm) at 0.16, 0.34 or 0.94 mg/m^3 for 6 hours a day for 5 days, the lungs of male SD rats were analysed for DNA damage using a comet assay. A significant increase in DNA damage in the lung was observed immediately after exposure and at one month post-exposure at 0.94 mg/m^3 (NTP, 2019).

Following nose-only inhalation of aerosolised MWCNT-R (diameter not reported; mean length: 0.33 µm; consists of well-dispersed, straight fibres with lengths ranging from 0.068-1.5 µm) in male and female F344/N Slc rats at 0.17, 0.49 or 0.96 mg/m^3 for 6 hours a day for 28 days, a comet assay was conducted after the last exposure or at 3 months post-exposure (NTP, 2019). Significant increases in DNA damage was observed at all concentrations after the last exposure; however by 3 months post-exposure, there was only a small but significant increase in DNA damage in the higher exposure concentrations in both male and female rats.

In the 90-day inhalation (nose-only) study reported in the repeated dose toxicity section conducted on Wistar rats using MWCNT-M (mean diameter: 11-12 nm; mean length: ~1 µm; MMAD: < 3 µm; contains large agglomerates of entangled MWCNTs), there was no increase in micronucleated polychromatic erythrocytes or increases in DNA damage in the lung, kidney and liver cells when evaluated using a standard comet assay and a modified comet assay using human 8-oxoguanidine DNA *N*-glycosilase 1. Histological preparations did reveal deposits of aggregated MWCNT in the lung tissue after termination of exposure. The report suggested that MWCNTs are able to induce DNA damage in rats; however, genotoxicity is dependent on the physicochemical properties of the MWCNT (NTP, 2019).

Overall, MWCNTs have shown some potential to cause DNA damage under certain *in vivo* conditions. The genotoxicity of CNTs, in general, has been attributed to formation of reactive oxygen species and interference with chromosome segregation (NTP, 2019). However, based on the limited data available and that the toxicity proprieties of MWCNTs are dependent on their physical and chemical properties (such as dimensions, functionalisation, impurities, dispersibility and aggregation etc.), no conclusion can be derived on the genotoxicity potential of the assessed chemical.

Carcinogenicity
Several studies were conducted to determine the fibrogenic and carcinogenic potential of different types of MWCNTs, which are summarised in a review (SWA, 2012b). Most of these studies had used exposure routes not relevant for human exposure (e.g. injection into the intraperitoneal cavity, instilled into the intrapleural cavity, injected in the intrascrotal cavity), except for one chronic inhalation study in rats (NTP, 2019).

In a chronic inhalation study (OECD TG not specified), F344/DuCrlCrlj rats (n = 50/sex/dose) were exposed to aerosolised MWCNT-C (samples collected from the inhalation chambers were single straight fibres with an average width of 92.9-98.2 nm and an average length of 5.4-5.9 µm) at doses of 0, 0.02, 0.2 or 2 for 6 hours a day, 5 days a week for 104 weeks (NTP, 2019). Although there was no significant effects of MWCNT-C on survival, body weight, clinical chemistry, haematology or urinalysis, there was an increase in the incidences of bronchoalveolar carcinomas, total carcinomas (bronchoalveolar carcinoma, adenosquamous carcinomas, adenocarcinoma and squamous carcinoma) and/or adenomas in males of the 0.2 or 2 mg/m^3 dose groups and females of the 2 mg/m^3 dose group in comparison to the control group. A dose-dependent increase in preneoplastic lesions (bronchoalveolar epithelial hyperplasia and atypical epithelial hyperplasia) was also observed in the lungs of both male and female rats.

Other studies indicated carcinogenic or inflammatory/fibrogenic potential of MWCNTs include:

- To investigate the carcinogenic potential of MWCNT-S (diameter: 70-100 nm (82%); length: 1-4 µm (72.3%); impurity: 3,500 ppm iron), F344 rats (n = 7) were injected in the intrascrotal cavity with a single dose of the substance (1 mg/kg bw). Six rats developed mesothelioma before the end of the study and died.
- Five MWCNT types (MWCNT-T [diameter: ~15 nm; length: 1-5 µm; consists of tangled agglomerate within the respirable range (< 5 µm)], MWCNT-U [diameter: ~10 nm; length: 5-20 µm; consists of tangled agglomerate within the respirable range (< 5 µm)], MWCNT-V [diameter: 84 nm; length: 13 µm; consists of dispersed bundles and singlets], MWCNT-W [diameter: 165 nm; length: 56 µm; consists of suspended rod-shaped and fibrous aggregates] and MWCNT-X [diameter: 20-30 nm; length: 0.5-2 µm; consists of short and straight CNTs) were directly instilled into the intrapleural cavity of C57BL mice to observe the effects of length of MWCNTs on inflammatory responses after 24 weeks. There was no inflammatory response in the mice exposed to short (MWCNT-X) or tangled (MWCNT-T, MWCNT-U) MWCNTs, but acute inflammatory response, which was followed by progressive fibrotic lesions along the parietal pleura and proliferation in the mesothelial layers, was observed in the test animals exposed to the long MWCNTs (MWCNT-V or MWCNT-W).
- A single dose of MWCNT-Y (diameter: 100 nm; length: > 5 µm (27.5%) - < 20 µm (100%); consists of rod-shaped and fibrous aggregates suspended in 0.5% methyl cellulose solution) intraperitoneally injected into p53 heterozygous mice (known to be sensitive to asbestos and tend to develop mesotheliomas rapidly) (n = 19 mice/group) showed formation of large invasive mesothelial tumours in several tissues with incidences greater in the animals treated with MWCNT-Y, compared to the positive control crocidolite.
- To investigate whether lengths are contributed to fibrogenic and carcinogenic potential of MWCNTs, C57BL mice were injected with 50 µg of short-tangled MWCNTs (MWCNT-T [diameter: ~15 nm; length: 1-5 µm; consists of tangled agglomerate within the respirable range (< 5 µm)] or MWCNT-U [diameter: ~10 nm; length: 5-20 µm; consists of tangled agglomerate within the respirable range (< 5 µm)]) and long straight MWCNTs (MWCNT-V [diameter: 84 nm; length: 13 µm; consists of dispersed bundles and singlets] or MWCNT-W [diameter: 165 nm; length: 56 µm; consists of suspended rod-shaped and fibrous aggregates]) into the intraperitoneal cavity. Histopathological evaluation of the mice after 7 days revealed that long straight MWCNTs caused an early inflammatory response as well as the formation of foreign body giant cells (FBGCs) and granulomas similar to the positive control (long-fibre amosite [LFA]). On the other hand, the tangled MWCNTs and the negative control (short-fibre amosite [SFA]) did not cause significant inflammation or FBGCs formation. Based on these results, it was concluded that the asbestos-like pathogenic behaviour observed in these MWCNTs have a structure-activity relationship based on length.
- Four MWCNT types of different lengths, diameters and curvatures (MWCNT-Z [width: 85 µm; length: 8.57 µm; consists of medium length CNTs with large diameters], MWCNT-AA [width: 62 µm; length: 9.3 µm; consists of medium length CNTs with large diameters], MWCNT-AB [width: 40 nm; length: 10.24 µm; consists of long thin fibres] or MWCNT-AC [width: 37 nm; length: 7.91 µm; consists of thin fibres of medium length]) were injected once by intraperitoneally into male Wistar rats (50 rats/group) at a concentration of either 1×10^9 or 5×10^9 fibres per animal and observed over a 24 month period prior to necropsy (NTP, 2019). All four MWCNTs caused the formation of malignant mesotheliomas with the highest incidences (90-98% of animals) and earliest appearances (5-6 months) of mesotheliomas occurring after exposure to MWCNT-Z and MWCNT-AA. The appearance of mesothelioma occurred later after exposure for MWCNT-AB (84-94% of animals after 6-10 months) and MWCNT-AC (40-70% of animals after 11-20 months). In the control groups, mesothelioma was only observed in one vehicle control animal (frequency of 2%) and in 66% of the positive control (1×10^8 long amosite asbestos fibres).
- In a study conducted to determine the durability of 3 MWCNT types (MWCNT-AD [diameter: 9 ± 3 nm; length: 200-300 µm; impurities: iron and strontium at concentrations > 5 µg/g; consists of agglomerated

sheets of very long fibres with hair-like appearance], MWCNT-AE [diameter: 10.3 ± 5 nm; length: 5-20 µm; impurities: iron, molybdenum, aluminium and zinc at concentrations > 5 µg/g; contains stellate in form with longer fibres protruding from the central tangled agglomerates; large proportion of chemical < 5 µm (respirable range)] and MWCNT-AF [diameter: 64 ± 16 nm; length: 12 ± 6 µm; impurity: iron at > 5 µg/g concentration; consists of dispersed bundles and singlets of long and intermediate length (many > 10 µm) covered in short fibres]) in biological fluid for up to 24 weeks, MWCNT-AD and MWCNT-AE showed no change in mass or morphology. However, MWCNT-AF showed statistically significant decreases in mass (~30%) throughout the study with slightly decreased fibre length and decreased proportions of long fibres, suggesting that MWCNT-AF underwent fibre dissolution/breakage in biological solution. Based on this result, MWCNT-AF was selected to investigate whether incubation of the chemical in a biological solution had an impact on the pathogenicity of MWCNTs in comparison to asbestos fibres and glass wool fibres. In this study, female mice (4 mice/group) were injected into the peritoneal cavity with 50 µg MWCNT-AF in sterile saline with 0.5% BSA (OECD TG not specified) to determine whether this would induce an inflammatory response. Incubated MWCNT-AF showed decreased pathogenicity, whereas non-incubated MWCNT-AF had a strong inflammatory and granuloma response upon injection. The study concluded that if a CNT is of a sufficient length and aspect ratio, the CNT can induce asbestos-like response in mice, which may be mitigated if the CNT is of a less durable nature (i.e. contains surface defects that make the CNT vulnerable to chemical attack and biodegradable in biological systems).

The results of these studies (SWA, 2012b) suggest that length, rigidity (based on diameter) and durability of the MWCNT play a key role in the development of mesothelioma; however due to the limited amount of studies available, there are difficulties in determining the minimum physical parameters that would lead to the carcinogenic response. The SWA report (2012b) suggested that rigid, straight fibres (individual fibres or through aggregation) with pathogenic dimensions (i.e. length > 5 µm) and are biopersistent has the potential for mesothelioma formation.

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

Reproductive and developmental toxicity

There are several reproductive and developmental toxicity studies for MWCNTs reported in a review article (Ema *et al.*, 2016), however there is only one study that used a relevant route of exposure to humans (e.g. oral). The other studies used administration methods such as intraperitoneal injection and intratracheal instillation.

MWCNT-AG (diameter: 10-15 nm; length: ~20 µm; impurity: 5% iron) in 1% carboxymethyl cellulose (CMC) solution was administered to SD rats (n = 12 rats/dose) through oral gavage at doses of 8, 40, 200 or 1000 mg/kg bw/day on gestation day 6 to 9 (OECD TG not specified). A decrease in maternal thymus weight was observed at the 1,000 mg/kg bw/day. No effects were observed on foetal growth, viability, or morphological development.

Administration of unfunctionalised MWCNTs to pregnant mice induced foetal malformations after intraperitoneal injection and intratracheal instillation; however, no adverse effects on foetal development was observed after exposing rats to the MWCNTs through oral gavage (Ema, *et al*. 2016).

Health Hazard Classification

In the absence of toxicity data for the assessed chemical and based on the available information on other MWCNTs (as described above), the assessed chemical is considered a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the assessed chemical is presented in the following table.

Hazard Classification	***Hazard Statement***
Specific Target Organ Toxicity – Repeated Exposure (Category 2)	H373 – May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure
Suspected Carcinogen (Category 2)	H351 – Suspected of causing cancer

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available toxicological information on MWCNTs of various lengths, diameters and wall numbers (SWA, 2012, NTP, 2019 and Ema *et al.*, 2016), the assessed chemical is expected to be of low acute oral and dermal toxicity and not a skin irritant or sensitiser. Systemic effects after repeated exposure may cause damage to lungs/respiratory system and mesothelioma formation. The information available is insufficient to rule out potential for acute inhalation toxicity and eye irritation.

Dermal exposure of workers to the assessed chemical at < 4% concentration in liquid formulation may occur during repackaging (including connecting and disconnecting transfer hoses, and during cleaning and maintenance operations). Accidental ocular exposure is possible during handling of liquid formulations. Inhalation exposure is not expected given the estimated low vapour pressure of the assessed chemical and the proposed form of introduction (liquid concrete additive formulation). Exposure should be minimised through the use of control measures (such as enclosed, automated processes where possible) and PPE (impervious gloves, protective clothing and safety glasses).

Dermal, ocular and inhalation (if aerosols, mists or dusts are generated) exposure of workers to the assessed chemical (at < 4% concentration) may occur during end-use (when workers manually pour the additive formulation into the ready-made concrete products, during cleaning and maintenance of equipment and during quality control of the product). The use of suitable PPE, including impervious gloves, safety glasses, protective clothing and respiratory protection (if inhalation exposure may occur) is expected to minimise the exposure and hence reduce the risk to workers.

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The assessed chemical will be for industrial use only. The public may come into contact with concrete containing the assessed chemical; however, once the concrete has hardened, the assessed chemical will become part of a cementitious matrix and will not be available for exposure. The public may also be in the vicinity of concrete remedial and maintenance operations. Given the low frequency of such events and use of liquid formulations, the assessed chemical is not expected to be released during further construction operations, causing public exposure.

When used in the proposed manner, the assessed chemical is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed chemical will be imported as a component of liquid formulations for repackaging or addition into ready-made concrete products. Repackaging into smaller containers will be carried out using a metered sealed pump and release of the assessed chemical during this process is expected to be minimal. Any waste generated from the repacking process and accidental spills containing the assessed chemical will be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

At fixed sites or mobile concrete batch plants, the concrete additive formulations containing the assessed chemical will be added to ready-mix concrete products using a mix of automated, manual, open and closed processes. The concrete mix containing the assessed chemical will be poured into the prepared area at the residential, commercial or industrial site. The assessed chemical will then be embedded in the concrete matrix, remaining in a harden state. Once the concrete hardens, saw cutting, drilling, abrasive blasting and grinding may take place. Waste generated during use and accidental spills containing the assessed chemical will be collected and disposed of in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL
The assessed chemical is expected to share the fate of the concrete and is expected to be disposed of to landfill at the end of its life cycle. Residues of the assessed chemical in empty containers are expected to be disposed of to landfill in accordance with local government regulations.

7.1.2. Environmental Fate
No environmental fate studies were submitted. The majority of the assessed chemical is expected to share the fate of the concrete and be disposed of to landfill at the end of its life cycle. A minor amount of the assessed chemical is also expected to enter landfill as collected wastes and residues. In landfill, the majority of the assessed chemical will be cured within an inert concrete matrix and will be neither bioavailable nor mobile. Scanning Electron Microscopes (SEM) and Transmission Electron Microscopes (TEM) images from the applicant's investigation on possible release of the assessed chemical from concrete samples showed no release of the assessed chemical above detection limit in the concrete break surface. This supports the applicant's claim that no release of the assessed chemical from concrete is expected during any standard concrete usage and operation. The assessed chemical is likely to be very long-lived in the environment, similar to other materials based on elemental carbon (such as graphite and carbon black).

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) has not been calculated as release of the assessed chemical to the aquatic environment is not expected based on its reported use pattern as concrete additive.

7.2. Environmental Effects Assessment
No ecotoxicity studies were submitted. The applicant submitted a cytotoxicity study showing the assessed Multiwalled Carbon Nanotube (MWCNT) is less damaging to cell walls than other MWCNTs tested (Hubczack *et al*., 2019). They postulated that either the polarity of the assessed MWCNT, the ratio between sp^2 and sp^3 hybridization, or the size and aspect ratio make it a less good fit with the macrophage cell walls. The applicant claims that this cytotoxicity study can be extrapolated to ecotoxicity as the mechanisms of toxicity are relevant to all cells including aquatic species. The relative low toxicity is also a consequence of the extremely hydrophobic nature of the assessed MWCNT. The applicant supposed that the assessed MWCNT undergoes rapid agglomeration in most natural environments, either MWCNT to MWCNT or MWCNT to other organic, non-polar material, thereby entering a state of significantly reduced toxicity. The applicant's suppositions are in agreement with information on a wide range of MWCNTs which, have some toxic effects on aquatic organisms, but could generally be regarded as having low aquatic and terrestrial ecotoxicity (OECD 2016).

7.2.1. Predicted No-Effect Concentration (PNEC)
The PNEC has not been calculated as no ecotoxicity studies were submitted.

7.3. Environmental Risk Assessment
The Risk Quotient (PEC/PNEC) has not been calculated as no ecotoxicity studies were submitted and release of the assessed chemical to the aquatic environment is not expected based on its reported use pattern.

Based on the reported use pattern as concrete additive and the current available knowledge on toxicity of MWCNTs, the assessed chemical is not considered to pose an unreasonable risk to the environment.

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