File No: STD/1577
STD/1578
STD/1579

March 2016

NATIONAL INDUSTRIAL CHEMICAL NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1577: 1-Butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1)
STD/1578: 1-Butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1)
STD/1579: 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 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 the Environment.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1577, STD/1578 and STD/1579	Nuplex Industries (Aust) Pty Ltd	STD/1577: 1-Butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1) STD/1578: 1-Butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1) STD/1579: 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1)	Yes	≤ 7 tonnes per annum (each chemical)	Component of coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemicals are recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute toxicity, oral (Category 4)	H302 - Harmful if swallowed
Acute toxicity, dermal (Category 3)	H311 - Toxic in contact with skin
Specific target organ toxicity, single exposure (Category 2)	H370 – May cause damage to organs if inhaled
Serious eye damage/eye irritation (Category 2)	H319 – Causes serious eye irritation

Based on the available information, the notified chemicals are recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R22: Harmful if swallowed
R24: Toxic in contact with skin
R36: Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 2	H401 - Toxic to aquatic life
Chronic Category 2	H411 - Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemicals are not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified chemicals are not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemicals should be classified as follows:
  - Acute toxicity, oral (Category 4): H302- Harmful if swallowed
  - Acute toxicity, dermal (Category 3): H311- Toxic in contact with skin
  - Specific target organ toxicity, single exposure (Category 2): H370 – May cause damage to organs if inhaled
  - Serious eye damage/eye irritation (category 2) - H319 – Causes serious eye irritation

The above should be used for products/mixtures containing the notified chemicals, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

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 notified chemicals as introduced prior to its incorporation in coatings:
  - Enclosed and automated processes
  - Local exhaust ventilation where inhalation exposure may occur.

- 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 notified chemicals:
  - Avoid contact with skin and eyes
  - Avoid breathing vapours/spray
  - Apply product in a well-ventilated area

- 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 during handling of the notified chemicals:
  - Coveralls
  - Face masks
  - Gloves
  - Safety glasses

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

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

- If products and mixtures containing the notified chemicals 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.

Disposal

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

Storage

- The handling and storage of the notified chemicals should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - products containing the notified chemicals are intended for public use.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemicals has changed from component of coatings, or is likely to change significantly;
  - the amount of the chemicals being introduced has increased, or is likely to increase, significantly;
  - the chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemicals on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the product containing the notified chemicals provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemicals were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Ltd (ABN: 25 000 045 572)
49 – 61 Stephen Road
BOTANY NSW 2019

NOTIFICATION CATEGORY
Standard (Approved Foreign Scheme): Chemical other than polymer (more than 1 tonne per year).
Standard (Group Assessment): Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Canada 2015

2. IDENTITY OF CHEMICAL

MARKETING NAME
Acure 500

CAS NUMBER
STD/1577: 1338579-13-7
STD/1578: 478796-04-2
STD/1579: 17351-62-1

CHEMICAL NAME
STD/1577: 1-Butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1)
STD/1578: 1-Butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1)
STD/1579: 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1)

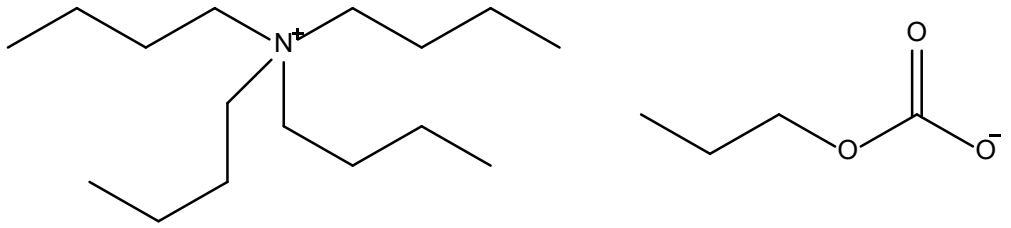
OTHER NAME
STD/1577:
Tetrabutylammonium propylcarbonate
TBA $PrCO_3$

STD/1578:
Tetrabutylammonium ethylcarbonate
TBA $EtCO_3$

STD/1579:
Tetrabutylammonium bicarbonate
TBA HCO_3

MOLECULAR FORMULA
STD/1577: $C_{16}H_{36}N.C_4H_7O_3$
STD/1578: $C_{16}H_{36}N.C_3H_5O_3$
STD/1579: $C_{16}H_{36}N.CHO_3$

STRUCTURAL FORMULA
STD/1577:



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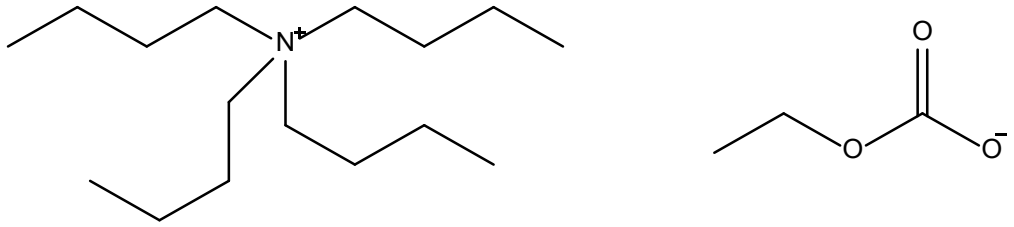
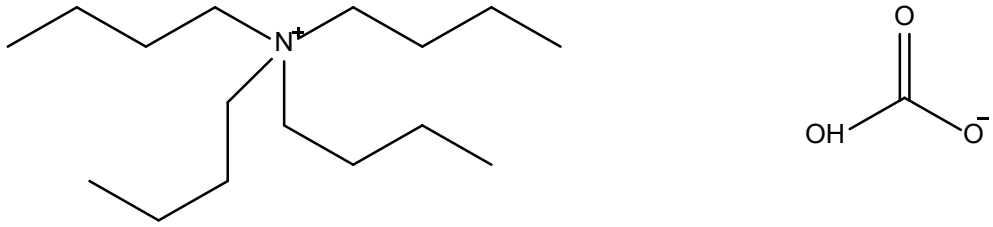


STD/1579:



MOLECULAR WEIGHT
STD/1577: 345.56 Da
STD/1578: 331.53 Da
STD/1579: 303.48 Da

ANALYTICAL DATA
Reference UV spectra were provided for the solution containing the notified chemicals.

3. COMPOSITION

DEGREE OF PURITY
Imported in solution at:
STD/1577: 8.6%
STD/1578: 4.0%
STD/1579: 16.9%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: Clear, colourless liquid (when present as the aqueous solution)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	244.31 °C	Calculated (US EPA EPISUITE software v4.11)*
Boiling Point	541.27 °C* 529.67 °C** 567.89 °C†	Calculated (US EPA EPISUITE software v4.11)
Density	1005.6 kg/m^3 at 19.5 °C	Measured‡
Vapour Pressure	2.56×10^{-12} kPa at 25 °C* 6.27×10^{-12} kPa at 25 °C** 2.8×10^{-13} kPa at 25 °C†	Calculated (Modified Grain Method)
Water Solubility	57 wt% solution in water†	The notified chemicals are prepared in water and are not available in isolated form. Therefore, the notified chemicals are considered to be fully miscible in water.
Hydrolysis as a Function of pH	Hydrolytically stable (no hydrolysis at 50 ºC at pH 4, 7, 9†	Measured
Partition Coefficient (n-octanol/water)	log Pow = -1.43 ± 0.02 at 22 °C†	Measured
Adsorption/Desorption	log Koc = 1.44 to 2.44†	Measured
Dissociation Constant	Not determined.	The notified chemicals are salts and are expected to be ionised under environmental conditions.
Flash Point	Not determined	Expected to be high based on predicted low vapour pressure and high melting point.
Flammability	Not determined	Not expected to be flammable.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Not expected to be explosive based on structure.
Oxidising Properties	Not oxidising	Estimated

* 1-Butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1) (STD/1577)
** 1-Butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1) (STD/1578)
† 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) (STD/1579)
‡ For the aqueous solution containing the notified chemical 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) at 27% concentration.

DISCUSSION OF PROPERTIES

Reactivity
The notified chemicals are 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 notified chemicals are 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 THE NOTIFIED CHEMICALS (100%) OVER NEXT 5 YEARS
The notified chemicals will be imported as components of an aqueous formulation at a combined concentration of < 30% [1-Butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1) at 8.6% concentration (STD/1577), 1-Butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1) at 4% concentration (STD/1578), and 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) at 16.9% concentration (STD/1579)] contained in 200 kg steel drums. The notified chemicals may also be manufactured in Australia as components of an aqueous formulation at the concentrations described previously.

MAXIMUM INTRODUCTION VOLUME OF EACH OF THE NOTIFIED CHEMICALS (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3	4	5	6	7

PORT OF ENTRY
Sydney and Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Nuplex Industries (Aust) Pty Ltd.

TRANSPORTATION AND PACKAGING
When manufactured within Australia, the aqueous solution containing the notified chemicals (at a combined concentration of < 30%) will be packaged into steel drums, pails or cans and then transferred by road and stored in the Notifier's storage facility in accordance with the Australian Code for the Transport of Dangerous Goods (NTC, 2015).

When imported, the aqueous solution containing the notified chemicals (at a combined concentration of < 30%) will be packed into either 1 L cans, 5 L cans, 20 L pails or 200 kg steel drums.

The aqueous solution containing the notified chemicals has a dangerous goods classification of Class 3, UN1992, Flammable liquid. Therefore, the aqueous solution containing the notified chemicals will be transported and stored in accordance with the Australian Code for the Transport of Dangerous Goods (NTC, 2015).

USE
The notified chemicals (at a concentration of < 0.5% each) will be used as components of coatings for use in products such as agricultural, mining, and construction equipment, flooring, timber and automotive, marine or aerospace products.

OPERATION DESCRIPTION
Manufacture of the notified chemicals
When the notified chemicals are manufactured within Australia, the reaction will take place within a registered pressure vessel with jacketed and internal cooling systems. The liquid reactants will be pumped in the reaction vessel using dedicated lines. Any solid reactants will be transferred either manually or with a hoist. The resulting aqueous solution containing the notified chemicals (at a combined concentration of < 30%) will be transferred through dedicated lines and pumped through sealed filters and packaged directly into bulk containers, steel drums or pails. Quality control personnel will be required to sample the aqueous solution containing the notified chemicals.

Reformulation into industrial coatings
After manufacture or importation, the aqueous solution containing the notified chemicals (at < 30% combined concentration) will be transferred to various manufacturers of industrial coatings, where the aqueous solution will be pumped to blend tanks (or other processing vessels with agitation) and blended with other raw materials to produce finished coatings containing each of the notified chemicals at < 0.5% concentration. The reformulation process is envisaged to be fully automated and performed under controlled conditions.

End use
The coatings containing the notified chemicals will typically be applied by air-less and air-assisted spray, with application by brush roller and squeegee also occurring.

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	1	10
Warehouse/store	8	30
Manufacture/blending	2	50
QC/testing	1	50
Dispatch	1	150
Industrial end users	8	200

EXPOSURE DETAILS
It is anticipated that transport and warehouse/store personnel would only be exposed to the notified chemicals (at a combined concentration of < 30%) in the event of an accident.

Manufacture of the notified chemicals
Dermal and ocular exposure to the notified chemicals (at a combined concentration of < 30%) may occur during connection and disconnection of transfer lines, quality control testing and equipment cleaning/maintenance. Exposure to the notified chemicals at other times is expected to be negligible given the manufacturing process, including the packing off process, will be largely enclosed and automated. Exposure to the notified chemicals is expected to be minimised by the use of personal protection equipment (PPE) including coveralls, face masks, gloves and safety glasses as stated by the notifier.

Reformulation into finished coatings
Dermal and ocular exposure to the notified chemicals (at a combined concentration of < 30%) may occur during connection and disconnection of transfer lines and equipment cleaning/maintenance. Exposure to the notified chemicals at other times is expected to be negligible given the reformulation process will be largely enclosed and automated. Exposure to the notified chemicals is expected to be minimised by the use of PPE (including coveralls, boots, face masks, gloves and safety glasses) as stated by the notifier.

Application of coatings
The finished coatings containing the notified chemicals will be used in industrial applications for use on products such as agricultural, mining, and construction equipment, flooring, timber and automotive, marine or aerospace products. Dermal, ocular and inhalation exposure to the notified chemicals (at a concentration of < 0.5% each) may occur when applying the coating to substrates by spray (air-less and air-assisted), roller, brush or squeegee. Exposure is expected to be minimised by the stated use of PPE (including coveralls, boots, face masks, gloves and safety glasses).

Once the coating has cured, the notified chemicals are incorporated into a solid, inert, polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The notified chemicals are intended for industrial use only, and will not be available to the public. Direct exposure would therefore not be expected. Indirect exposure from accidental spills or environmental sources may be possible, but are unlikely for the proposed use.

Members of the public may experience dermal contact with industrial items treated with coatings containing the notified chemicals. However, in such coatings the notified chemicals will be bound within a polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations were previously assessed by Canada. No additional studies were submitted. The results from the toxicological investigations conducted on 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) and tetra-n-butylammonium alkylcarbonate (TBAAC) are summarised in the following table. TBAAC is a combination of 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) (CAS No. 17351-62-1, STD/1579); 1-butanaminium, *N,N,N*-tributyl-, methyl carbonate (1:1) (CAS No. 156294-05-2); 1-butanaminium, *N,N,N*-tributyl-, propyl carbonate (1:1) (CAS No. 1338579-13-7, STD/1577); 1-butanaminium, *N,N,N*-tributyl-, ethyl carbonate (1:1) (CAS No. 478796-04-2, STD/1578); and 1-butanaminium, *N,N,N*-tributyl-, 1-methylethyl carbonate (1:1) (CAS No. 1803407-49-9). All studies were conducted on 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) with the exception of one acute inhalation toxicity study which was conducted on TBAAC and is noted as such in the table below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity*	LD50 = 550 mg/kg bw; harmful
Rabbit, acute dermal toxicity*	LD50 250 – 500 mg/kg bw; toxic
Rat, acute inhalation toxicity	LC50 > 2.57 mg/L/4 hour
Rat, acute inhalation toxicity**	LC50 > 2.58 mg/L/4 hour
Rabbit, skin irritation	slightly irritating at 27%
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation at 27%
Rat, repeat dose oral toxicity – 5 days	LOAEL = 1,000
Rat, repeat dose oral toxicity – 18 days*	NOAEL = 600 mg/kg bw/day
Rat, repeat dose oral toxicity – 28 days*	NOAEL = 100 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome Damage test	non genotoxic
Genotoxicity – in vivo Mouse Micronucleus test*	non clastogenic

* The purity of the test item (27%) was taken into consideration for dose-volume calculations.
** Test substance was TBAAC.

Toxicokinetics, metabolism and distribution.
No information on the toxicokinetics of the notified chemicals were provided. For dermal absorption, molecular weights below 100 Da. are favourable for absorption and molecular weights above 500 Da. do not favour absorption (ECHA, 2014). Water solubility above 10,000 mg/L and log P values < –1 suggest that a substance is not likely to be sufficiently lipophilic to cross the stratum corneum, therefore dermal absorption is likely to be low (ECHA, 2014). Therefore, absorption of the notified chemicals across biological membranes cannot be excluded based on the low molecular weight of the notified chemicals (< 500 Da) and their water solubility (miscible in water). However, the low partition coefficient (Log Pow -1.43) of the notified chemical 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) may limit dermal absorption. The systemic effects seen in the toxicity studies on 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) confirm that absorption through the skin and gastrointestinal tract is occurring.

Acute toxicity.
The notified chemical 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) was found to be acutely toxic in rabbits *via* the dermal route and to be harmful following acute oral exposure in rats. An LD50 was not established in inhalation studies with 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) and TBAAC, although deaths were seen at the maximum dose.

When exposed to the notified chemical 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) by oral gavage 4/4 rats dosed at 2,000 mg/kg bw died, 1/4 rats died at a dose of 550 mg/kg bw and neither of the 2 rats given a dose of 175 mg/kg bw died. The LD50 in this study was estimated to be 550 mg/kg bw with 95% confidence interval of 380.9 to 1,710 mg/kg bw. Clinical signs observed immediately after dosing included burrowing behaviour, salivation, repetitive jaw movements, wobbly gait and/or tremors. Recovery was indicated in all animals. No other clinical signs or signs of toxicity were observed.

Two preliminary range finding dermal toxicity tests were performed with 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) at doses of 2,000/1,000 and 500/250 mg/kg bw with the main study performed at 250 mg/kg bw. All animals dosed at 2,000 and 1,000 mg/kg bw died and one out of two animals dosed at 500 mg/kg bw also died. In the main study at 250 mg/kg bw one female exhibited laboured breathing, passivity and sternal recumbency following exposure with recovery observed at 3 hours post-exposure. Slight to well defined erythema was observed in all animals (10/10) which reduced over time, with recovery in all animals at the day 8

observation. Very slight oedema was observed in up to 4 animals between days 2 and 5 post exposure and skin desquamation was observed between days 5 and 11. No other clinical signs or signs of toxicity were observed.

Irregular respiration was observed in all animals (5 animals/sex/concentration) following acute inhalation exposure to a test substance containing 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) at a concentration of 27%. Anogenital staining was observed in animals exposed to 1.01 mg/L of the test substance and hypoactivity was observed in animals exposed to 2.57 mg/L of the test substance. Recovery was indicated on days 3 and 4 post-exposure. Overall weight gain was as expected, despite an initial loss over days 1 to 3 by one female. No other clinical signs or signs of toxicity were observed. Inhalation exposure to a test substance containing TBAAC at concentration of 33.1% resulted in the death of 3/10 animals at the maximum test substance concentration of 2.58 mg/L. At the lower concentration of 0.55 mg/L there were no deaths.

Prior to death, animals showed hypoactivity and abnormal respiration, tremors and anogenital staining. Other animals at 0.55 or 2.58 mg/L exhibited irregular respiration following exposure. All animals recovered by day 3 and appeared normal for the remainder of the 14-day observation period. All animals gained weight over the 14-day observation period. No gross abnormalities were noted at necropsy. Although the effects seen in the acute inhalation study with TBACC are not sufficient for classification under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute toxicity (chapter 3.1) as no LD50 was established; the significant toxicity seen at the highest dose tested would still warrant a hazard classification for specific target organ toxicity, single exposure (chapter 3.8).

Irritation.
In a dermal irritation study on rabbits with 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1), one animal exhibited no irritation effects. The remaining 2 animals exhibited very slight erythema and slight oedema 1 hour post exposure with erythema developing to slight to well-defined and persisting to day 7.

An eye irritation study was not conducted. However, based on the notified chemical's acute dermal toxicity and potential for skin irritation, there is sufficient evidence of toxicity to expect that the notified chemical has potential eye irritant effects (United Nations, 2009).

Sensitisation.
The notified chemical 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) showed no evidence of sensitisation in a Guinea Pig maximisation test (at a concentration of 27%).

Repeated dose toxicity.
Three repeated-dose oral toxicity studies were conducted on 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) for periods of 5, 18 and 28 days.

In the 5 day study mortality (1/3 males and 2/3 females) was recorded in animals exposed to an undiluted test sample at 1,000 mg/kg bw/day. In the same study all animals exposed to diluted sample at the same dose of 1,000 mg/kg bw/day survived to the end of the study period.

In the 18 day study animals were administered doses of up to 1,000 mg/kg bw/day that had been diluted in water. There were no unscheduled deaths and clinical observations were limited to passivity at a dose of 800 mg/kg bw/day and were, and a wobbly gait and passivity at a dose of 1,000 mg/kg bw/day.

Within the 28 day study, animals were dosed with the test sample diluted in water (0, 100, 500 and 1,000 mg/kg bw/day). Mortality was observed in 2/5 male and 2/5 female rats (exposed to the initial high-dose of 1,000 mg/kg bw/day) and 1/5 male rats (mid-dose of 500 mg/kg bw/day). Cause of death was determined by the study authors to be due to aspiration and/or regurgitation of the test substance given the presence of pulmonary lesions and/or fibronecrotizing tracheitis in 5/6 of the animals which died (no conclusions could be made regarding one female of the high-dose group). The highest dose in the 28 day study was subsequently lowered to 800 mg/kg bw/day on day 11 and a corresponding decrease in frequency and severity of clinical signs was observed. One female died (800 mg/kg bw/day group) following severe convulsions post dose. Overall mean body weights of male rats exposed to the highest doses were lower than those for animals in the control group and some changes were recorded in the glandular stomach of animals in the high-dose group.

The main clinical signs observed in animals exposed to doses of 800 mg/kg bw/day or higher in all studies were burrowing and salivation, wobbly gait and passivity (post-dosing). Adaptation to exposure to the test substance was indicated in animals across the three studies through decreasing recovery time (5 day study) or decreasing

frequency and severity of effects (18 and 28 day studies). Other clinical effects in high-dose animals (> 800 mg/kg bw/day) included piloerection, red-coloured eye discharge (5 day study), ptosis, reddening of eyes and snout, tremors and twitching (5 day and 28 day studies).

A NOAEL of 600 mg/kg bw/day was determined for the 18 day repeated-dose study based on the adverse effects observed at doses greater than or equal to 800 mg/kg bw/day. A NOAEL of 100 mg/kg bw/day was determined for the 28 day repeated-dose study based on the mortality and clinical signs observed at mid- and high- doses.

Mutagenicity/Genotoxicity.
The notified chemical 1-butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) was found to be non-mutagenic in a bacterial reverse mutation assay and non-clastogenic in an *in vitro* chromosome aberration test and an *in vivo* mouse micronucleus test.

Health hazard classification
Based on the available information, the notified chemicals are recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Acute toxicity, oral (Category 4)	H302 - Harmful if swallowed
Acute toxicity, dermal (Category 3)	H311 - Toxic in contact with skin
Specific target organ toxicity, single exposure (Category 2)	H370 – May cause damage to organs if inhaled
Serious eye damage/eye irritation (Category 2)	H319 – Causes serious eye irritation

Based on the available information, the notified chemicals are recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R22: Harmful if swallowed
R24: Toxic in contact with skin
R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Dermal, ocular and inhalation exposure to the notified chemicals at a combined concentration of < 30% may occur during manufacture, reformulation, and application of end-use coatings onto industrial items. Once the coatings containing the notified chemicals have cured, the notified chemicals will be incorporated into a polymer matrix and will not be bioavailable. Toxicological studies on the notified chemical 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (1:1) [STD/1579] indicate that the notified chemicals are toxic via the dermal route, harmful if swallowed or inhaled and cause mild skin irritation and potentially serious eye irritation. Therefore, their use is only considered to be reasonable when sufficient engineering controls, safe work practices and personal protective equipment (PPE) are used to reduce the potential for exposure. Dermal, ocular and inhalation exposure is expected to be limited with the use of PPE (gloves, face masks, coveralls and safety glasses/goggles).

Therefore, given the use of sufficient workplace controls, the risk to workers from use of the notified chemicals is not considered unreasonable.

6.3.2. Public Health
The notified chemicals will only be available to the public when present on industrial items, where it will be bound within a polymer matrix and as such will not be bioavailable. Therefore, the risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The chemical solutions are manufactured and formulated in closed reactors and drummed off for further processing into coating products. Environmental release of the notified chemicals is unlikely during manufacture and storage on site. Should a spill occur it will be contained to the plant by existing bunding. The notifier expects that at most 0.5% per notified chemical will be lost due to spills that occur during formulation via mixing vessels, holding vessels, filling pots and lines and empty drums. Wastes will be removed from the site by a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemicals will be incorporated into the surface matrix of the treated substrates used in coating formulations. The notified chemicals will only be available to the public when present on industrial items, where it will be bound within a chemical matrix. Any spills during application are expected to be collected and disposed of via a registered trade waste facility.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemicals are expected to adhere to the surface of the substrate to which it has been applied. Packaging and cleaning materials containing residual notified chemicals are expected to be released to landfill. It is expected that up to 0.5% per notified chemical may be released annually into landfill, from the disposal of product packaging and the cleaning and capture of materials containing notified chemicals.

7.1.2. Environmental Fate

The notified chemicals are expected to have low vapour pressures due to their ionic nature and are not expected to partition to air. If released to water, the notified chemicals are expected to remain in the water column based on the high water solubility. It is expected that the notified chemicals will not adsorb strongly to sediment based on their low Log Koc values. The rate of biodegradation in water is expected to be low, based on the measured ready biodegradability results [12.5% for 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (STD/1579)]. The notified chemicals are expected to remain in the water column where they will slowly biodegrade over time.

The majority of the notified chemicals are expected to adhere to the applied substrates following application of the product containing the notified chemicals. Treated articles and other dried residues containing the notified chemicals are expected to ultimately be disposed of to landfill. When associated with the articles to which the products containing the notified chemicals have been applied, the notified chemicals are not likely to be mobile or bioavailable. In landfill or agricultural soils, the notified chemicals are likely to be very highly mobile in soil based on the measured adsorption coefficient (log Koc = 1.44 - 2.44). While the notified chemicals are not readily biodegradable, they are not expected to bioaccumulate based on their low partition coefficient. The notified chemicals in solids will eventually degrade in landfill and agricultural soils, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the high water solubility of the notified chemicals, up to 2% of the import volumes of the notified chemicals are estimated to be released in wastewater and disposed to sewer following manufacture, reformulation and industrial use. Under a worst case scenario, with no further removal of the notified chemical in the STP, the resultant Predicted Environmental Concentration (PEC) per chemical in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	7,000	kg/year
Proportion expected to be released to sewer	2%	
Annual quantity of chemical released to sewer	140	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.54	kg/day

Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.12	µg/L
PEC - Ocean:	0.012	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m3). Using these assumptions, irrigation with a concentration of 0.12 µg/L may potentially result in a soil concentration of approximately 0.79 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 4.0 µg/kg and 7.9 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical 1-Butanaminium, *N,N,N*-tributyl-, carbonic acid (STD/1579) are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 ≥ 2023 mg/L	Not harmful to fish
Daphnia Toxicity	48h EC50 = 4.7 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	72 h EC50 = 4.55 mg/L	Toxic to algae
Inhibition of Bacterial Respiration	3 h EC50 = 363 mg/L	Not expected to inhibit microbial respiration

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is not harmful to fish but toxic to aquatic invertebrates and algae. It is formally classified as 'Acute Category 2: Toxic to aquatic life. On the basis of the acute toxicity and the lack of ready biodegradability, the notified chemical is classified 'Chronic Category 2: Toxic to aquatic life with long lasting effects.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) per chemical has been calculated from the acute algal toxicity of the notified chemical and an assessment factor of 100 as measured acute endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	4.55	mg/L
Assessment Factor	100	
PNEC:	45.50	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) per chemical has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.12	45.5	0.003
Q - Ocean:	0.012	45.5	0.0003

On the basis of the PEC/PNEC ratio the notified chemicals are not considered to directly pose an unreasonable to the aquatic environment. The reported use pattern of the notified chemicals indicates that there is no significant anticipated aquatic release. Moreover, after curing, the majority of the notified chemicals will be incorporated into an inert matrix and is not expected to be mobile, bioavailable nor biodegradable. Hence, the environmental exposure is expected to be minimal. On the basis of the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

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