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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Triethanolamine Acetate

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Additive in HEA2-6 and related products

1. APPLICANT

Grace Australia Pty Ltd of 1126-1134 Sydney Road, Fawkner, VICTORIA 3060 has submitted a standard notification statement in support of their application for an assessment certificate for Additive in HEA2-6 and related products.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Names:	HEA2-6; HEA2-6R; BCSC-4; BCSC-2-6; CBA 1115; CBA 1215; DARACCEL WR; DARAGRIND 150; DARASET AF
Analogue:	Ethanol, 2,2',2"-nitrilotris-; Triethanolamine (TEA) The notified chemical is an ionic salt of TEA, a salt of an aliphatic hydroxy amine, differing only by the salt ion. Thus, it is expected to possess properties shared with the named analogue. TEA is accepted as a suitable chemical that is sufficiently similar to the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES

All of the physicochemical properties were measured for the analogue.

Appearance at 20°C & 101.3 kPa:	White crystalline powder
Boiling Point:	> 300-400°C, decomposition occurs prior to reaching BP (estimated from analogue)
Specific Gravity:	1.124 kg/m^3 at 20°C (measured for analogue)
Vapour Pressure:	< 0.0013 kPa at 20°C (measured for analogue)

Water Solubility:	Completely soluble (estimated from analogue)
Partition Co-efficient (n-octanol/water):	log P_{ow} < - 1.59 (measured for analogue)
Hydrolysis as a Function of pH:	Not susceptible to hydrolysis
Adsorption/Desorption:	log K_{oc} > 0.19 (estimated from analogue)
Dissociation Constant:	pK_a = 7.76 (measured for analogue)
Particle Size:	Not applicable (TEA salt is produced in situ and is not isolated as a separate chemical/substance)
Flash Point:	179°C (measured for analogue)
Flammability Limits:	Ability to form a flammable mixture with air is predicted to be insignificant
Autoignition Temperature:	> 300-400°C (estimated for analogue)
Explosive Properties:	Not explosive (determined for analogue)
Reactivity/Stability:	May react with nitrite or oxides of nitrogen (determined for analogue)

Comments on Physico-Chemical Properties

The notified chemical is never isolated, but is produced *in situ* in a liquid product. Therefore, the physico-chemical parameters are estimated from the data for TEA.

The Handbook of Chemistry and Physics (Weast, 1976) states that TEA is soluble in water in all proportions. Since the notified chemical is an ionic form of TEA, it is likely to be highly soluble in water.

The notified chemical consists of three hydroxyl functional groups (OH), a tertiary ammonium cation and a carboxylate anion. Since the chemical contains functional groups that will not hydrolyse and does not have covalent bonds, the notifier has indicated that it is unlikely hydrolyse.

The partition coefficient for the notified chemical will be similar to that for TEA. However, since the chemical is the protonated form of TEA it is likely that the partition coefficient will be less than that for TEA (i.e. less than log K_{ow}=-1.59 (OECD, 1997)).

Regression equations (Gusten & Sabljic, 1995) were used to estimate the log K_{oc} for TEA (log K_{oc}=0.19). This indicates that TEA has a high mobility in soil. However, since the notified chemical is an ionic form of TEA, it is more likely than TEA to adsorb to soil components (eg clay). Thus, the log K_{oc} estimate for TEA is likely to be an underestimate of the adsorption coefficient for the notified chemical. In the protonated form TEA may adsorb to some soil/sediment components to a greater degree than TEA (OECD, 1997).

The notifier has provided two references quoting a value for the dissociation constant, but neither provides any indication as to how the value was determined. The pK_a is given as 7.76 (Knaak et al., 1997) or 7.92 (OECD, 1997).

4. PURITY OF THE CHEMICAL

TEA used in manufacture of the notified chemical contains up to 20% diethanolamine (DEA) and 1% monoethanolamine (MEA). The manufacturing process produces products with a range of concentrations of the notified chemical depending on requirements. DEA and MEA are assumed to react with the added organic acid to produce the DEA salt and MEA salt, with the amounts depending on the amount of acid added to the mix. The ranges of concentrations of the various components in the final cement additive product are given below.

Degree of Purity: 10 - 25% (TEA salt)

Hazardous Impurities:

Chemical name:	TEA
CAS No.:	102-71-6
Weight percentage:	5 – 20%
Toxic properties:	See section 9

Chemical name:	DEA or DEA salt
CAS No.:	111-42-2
Weight percentage:	1 – 5%
Toxic properties:	Irritating to skin, eyes and respiratory tract, low acute oral toxicity, degeneration of liver and kidneys of rats in oral repeated dose studies, developmental effects in rats, not genotoxic (Knaak et al., 1997). Causes allergic contact dermatitis (Blum & Lischka, 1997) and occupational asthma (Savonius et al., 1994).

Chemical name:	MEA or MEA salt
CAS No.:	111-42-2
Weight percentage:	0 – 0.5%
Toxic properties:	Irritating to skin, eyes and respiratory tract, low acute oral toxicity, altered liver and kidney weights at high doses in oral repeated dose studies, low level developmental effects in rats, not genotoxic (Knaak et al., 1997). Causes allergic contact dermatitis (Blum & Lischka, 1997) and occupational asthma (Savonius et al., 1994).

Non-hazardous Impurities (> 1% by weight): None

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will be manufactured in Australia as an *in situ* component of cement additives for use in the building industry. It is a dispersant used as a grinding aid/pack set inhibitor for cement, by reducing the surface energy forces that cause agglomeration of the newly fractured cement particles. Less than 400 tonnes/year will be manufactured over five years.

Approximately 99% of the manufactured cement additive, containing the notified chemical, will be used to make concrete for industrial purposes, with the remaining 1% bagged and palletised for repackaging and sale in 25-40 kg bags as a consumer ready mix product for home use and for small industrial use.

6. OCCUPATIONAL EXPOSURE

The manufactured cement additive products containing the notified chemical will be used at a variety of sites including those of the manufacturer and customer.

Manufacture of cement additives
Cement additive products are manufactured at the notifier's sites by reaction of an organic acid and TEA in saline to produce a 20% solution of the notified chemical. There is approximately 10 tonnes of reaction mixture in the reactor vessel and the ingredients are pumped into the vessel from 20 000 L tanker trucks, 1 000 L totes, storage tanks, 200 L drums or bags. The bagged materials are added directly to the mixing vessel by the use of vacuum hoists.

After mixing, the cement additive product is pumped from the mix tank to a bulk storage tank. Transfer is conducted by 10 plant operators who are potentially exposed to the notified chemical at a concentration of 20% for 2 hours/day. The system is enclosed. Therefore, potential exposure is greatest from residues in transfer lines or on couplings and would be mainly dermal. The notifier states that lines are flushed with compressed air using specific equipment designed to minimise spills and reduce worker exposure to material left in the lines. A potential source of mainly dermal exposure also originates from flushing of mix and storage tanks with 50 to 200 L of water. The wash water is either recycled into the next batch of additive or is collected and removed by licensed waste haulers.

Five quality control workers sample and test the cement additive mix and are potentially exposed for 1 hour/day. Mainly dermal exposure to small quantities of the cement additive should occur from drips and spills.

Ten truck drivers transport the cement additive containing 20% notified chemical to customers and to other notifier's distribution warehouses. The products may be shipped in 1 000 L totes, iso-tanks or in 20 000 L tanker trucks. If transported in bulk, the workers are

required to hook up a sealed delivery system that pumps the cement additive into tanker trucks and dispenses the product into storage tanks at customer sites. The maximum duration of exposure is expected to be 2 hours/day and dermal exposure to drips and spills may occur.

Five workers in a supervisory role are potentially exposed for 1 hour/day.

The notifier states that site personnel are required to wear safety glasses at all times and impervious gloves are used when handling cement additives.

Cement Production
Cement additive is added to the cement mill in each batch to a final concentration of 0.03%. The cement additive is stored in bulk storage tanks and is added using a sealed delivery system which automatically adds the correct amount to the cement mill. Baghouses and electrostatic precipitators are used to collect cement dust when cement is transferred for transport to concrete producers. The 140 mill workers are stated by the notifier to be exposed to the notified chemical in the finished cement product for 8 hours/day.

Twenty laboratory technicians are responsible for checking product quality for raw materials and the cement product. Exposure is for 1 hour/day and should involve testing of small samples.

Twenty process engineers are responsible for keeping the plant running optimally in a technical and supervisory role. Potential exposure is 2 hours/day but contact with the notified chemical should be rare.

Ten maintenance fitters are responsible for general installation of the cement additives dispensing units. Maximum exposure is expected to be 1 hour/day and would be mainly dermal.

Ten storemen receive deliveries but are unlikely to be exposed to the notified chemical.

Approximately 99% of the powdered cement is shipped to concrete producers and 1% is bagged for sale to consumers.

Concrete Production
Powdered cement is delivered to the industrial concrete producers via bulk road tanker, bulk rail car or ship. The powdered cement is transferred to concrete mixing vessels and concrete (containing approximately 0.003% of the notified chemical) transferred to trucks using sealed delivery systems and automated transfer. Twenty-five quality control workers test the concrete mix, 100 labourers perform general labour at the concrete plant and 400 truck drivers transport concrete to concrete contractors. All workers are expected to be exposed to cement or concrete for 4 hours per day. During handling of concrete all workers wear rubber boots and impervious gloves to protect against the high pH.

Concrete contractor
Approximately 1 000 workers will place and finish the concrete wearing personal protective equipment to minimise dermal exposure. Exposure to the concrete containing 0.003% notified chemical is for 8 hours/day.

Laboratory testing of concrete
One hundred laboratory technicians spend 6 hours/day testing small samples of fresh concrete which are hardened in moulds. Concrete is handled using rubber boots and impervious gloves.

7. PUBLIC EXPOSURE

Exposure of the general public as a result of manufacture, transport and disposal of the product containing the notified chemical is assessed as being improbable. Although the majority of the product containing the chemical is likely to be used in the construction industry, it will also be used by the general public in domestic situations. Dermal, inhalation and ocular contact with the product containing the notified chemical is likely during use. However, the concentration of notified chemical in the products used by the general public is low (0.003 – 0.03%).

8. ENVIRONMENTAL EXPOSURE

Release

At the additive manufacturing sites the process equipment will either be air or water purged. The resultant wash water is recycled back into the process. The notifier has estimated that up to 10 L of residual additive is recycled in this way.

Any spills of the product either during manufacture or transport to customer sites would be cleaned up with an absorbent (eg sand) and disposed of to landfill. The notifier has estimated that less than 2 L would be spilt at any one time. Spills during the manufacture are likely to be collected and recycled back into the process if possible. If it is assumed that approximately 100 L of the additive is spilt this equates to 20 L of notified chemical being released.

At the cement manufacture sites some of the delivery lines are air purged. The majority would use the delivery of a new batch of additive to purge the line, thus using any residue from the previous delivery in the current batch. There is also the possibility for fugitive atmospheric emissions. Based on its vapour pressure being less than 1.3 Pa, the notified chemical could be considered to be volatile (Mensink et al., 1995). However, this is for the free base and the salt form may be expected to be much lower. Typically the cement manufacturer will have baghouses and electrostatic precipitators in place with any collected dust being recycled back into the process. These emissions are expected to be minimal.

There is also potential for release of notified chemical via waste water from external and internal washing of ready mix concrete mixing trucks. This waste water is stored temporarily in concrete setting bays and reused in subsequent admixtures. The notifier has stated that setting bays are designed to minimise risk of overflow during significant rainfall events. Where occasional overflow does occur, contaminated waste water will be discharged to the sewer in a diluted form. The notifier estimates that up to 0.2% residue is left in the trucks.

The balance of the notified chemical will be bound within the concrete matrix where minimal migration of the notified chemical is expected.

Fate

The majority of the notified chemical will be bound within the matrix of the concrete and once hardened, minimal migration of the notified chemical is expected.

It is anticipated that the notified chemical will enter both the aquatic compartment (from truck wash water) and landfill (incorporated in rubble concrete, as residual in drums not processed through recycling facilities, and in absorbents used to recover spills).

The notifier provided two articles dealing with the biodegradation of triethanolamine (Dow Chemical Co, 1992; West, 1996). Biodegradation in an aerobic soil, freshwater river system and in activated sludge waste treatment has been investigated using [^{14}C]TEA as a marker. The soil and river system studies used batch microcosms. In the soil microcosms, 20 g of soil and 20 mL of deionized water were combined in 100 mL glass bottles with TEA added to a concentration of 1.4, 201 and 2000 mg/kg. In river water/sediment tests, 10 g of sediment and 50 mL of river water were combined in 100 mL glass bottles, while for river water only 50 mL was placed in the bottle. TEA was added in the river system tests to give a concentration of either 100 or 489 µg/L. In the activated sludge study 600 µg/L or 5700 µg/L of TEA was combined with either 164 or 818 mg/L MLSS (mixed liqour suspended solids) in a salts basal medium in 500 mL Erlenmeyer flasks. The bottles were incubated at 25ºC and continuously shaken at 100rpm. A strong cation-exchange HPLC coupled with a flow-cell radiochemical detection was used to determine the distribution of ^{14}C between TEA and its degradation products. The $^{14}CO_2$ was collected in caustic traps and measured by liquid scintillation counting. The biodegradation half-life results from the activated sludge tests ranged from 0.02 to 0.51 day. The results for the river water only ranged from 0.8 to 1.7 day, while for the sediment/water tests the range was 0.2 to 0.6 day. The half-life in soil ranged from 0.5 to 1.8 day. These were consistent with earlier literature results.

The Dow Chemical Company conducted a similar ^{14}C-radiolabelled study using microcosms set up with either sediment and river water or river water only in 100 mL glass bottles (Dow Chemical Co, 1992). The sediment/water microcosms were set up with 10 g of sediment and 49 mL of river water with the nominal concentration of TEA of 100 or 500 µg/L. The river water only microcosms were set-up with 49 mL of river water and nominal TEA concentrations of 100 and 500 µg/L. The biodegradation in the sediment/water microcosms was calculated to be 94-96% in 24 hours for 100 µg/L and 56-80% for 500 µg/L. In the water only microcosms the biodegradation at 100 µg/L was 80-96% over a 24-31 days period and at 500 µg/L it was 95% over 24 days.

An OECD report (OECD, 1997) of a number of biodegradation studies using OECD guidelines showed ready biodegradability (91-97% except for two outliers, a 14 day result of 2% and a 28 day result of 0-9%), inherent biodegradability (82%) and simulation (91%). From these results it was determined that TEA was readily biodegradable. It was suggested that in sewage treatment plants, an acclimatisation period would be needed before a significant degree of biodegradation occurred.

Due to the chemical's likely high solubility, low log K_{ow} and ready biodegradability it is not likely to bioaccumulate.

9 EVALUATION OF TOXICOLOGICAL DATA

9.1 General

The alkanolamines, of which the notified chemical is a member, have been extensively studied and their toxicity profile reviewed extensively. This report provides an up-to-date summary of toxicological information available for TEA, which is chemically similar to the notified chemical additive in HEA2-6 and related products. Full study reports and published reviews supplied by the notifier were utilised in assessing the toxicological profile of TEA, and hence that of the notified chemical. A number of reviews were consulted on the toxicology of TEA (CIR, 1983; Benya & Harbison, 1994; Knaak et al., 1997; OECD, 1997), NTP (in press) and other published reports that were not supplied by the notifier.

9.2 Pharmacokinetics

Studies on percutaneous absorption in mice and rats indicated that TEA is rapidly absorbed via the skin, almost completely in 24 hours in mice (Knaak et al., 1997). When ingested or absorbed through the skin, TEA is neither metabolised to other compounds as TEA nor incorporated into phospholipids. It is readily eliminated from body tissues and excreted as TEA primarily in the urine, with feces being the secondary route (OECD, 1997; Knaak et al., 1997).

9.3 Summary of the acute toxicity of Triethanolamine (TEA)

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat: Male Female Mouse	 LD_{50} 8.4-11.3 g/kg bw LD_{50} 5.5-8.9 g/kg bw LD_{50} 5.4-7.8 g/kg bw	Union Carbide Corporation, 1988 and BIBRA, 1990 in (Knaak et al., 1997); CIR (1983)
Acute dermal toxicity	Rabbit	LD_{50} > 2 g/kg bw	Union Carbide Corporation, 1988 and BIBRA, 1990 in (Knaak et al., 1997); CIR (1983)
Acute inhalation	Rat	No mortality after 8 hours exposure to saturated atmosphere; LC_{50} > 0.0047 ppm (estimated)	Knaak et al., 1997

9.4 Irritation

9.4.1 Skin irritation

Animal studies- Rabbit

Concentration	*Method*	*Result*	*Reference*

100%	Semi-occluded, intact skin	Slightly-moderately irritating*	(CTFA, 1959)
100%	Semi-occluded, abraded skin	Slightly-moderately irritating*	(CTFA, 1959)
100%	Occluded	Slightly irritating$	Weil & Scala (1971)#

* Prolonged or repeated exposure may be irritating
$ Study of intra- and inter-laboratory variability
# cited in OECD (1997)

Human- case reports

Concentration	***Method***	***Result***	***Reference***
Not supplied	Semi-occlusive	Not irritating	OECD (1997)
50%	Occlusive	Not irritating	OECD (1997)
100, 10 & 5% in ethanol	Chamber; scarified/non-scarified skin	100%: irritant, non-scarified 10%: irritant, scarified 5%: slight irritant, scarified	Frosch & Kligman, (1976)#
5 & 1% in eucerin+water	Patch tests	Irritating	Suurmond (1966)#

cited in OECD (1997)

9.4.2 Eye irritation

Animal studies- Rabbit

Concentration	***Method***	***Result***	***Reference***
100%	Irrigated/un-irrigated	Slightly-moderately irritating*	CTFA (1959)
10%	Irrigated/un-irrigated	Not irritating	CTFA (1959)
100%	Un-irrigated	Corrosive$	Carpenter & Smyth, 1946#
100%	Un-irrigated	Not irritating	Griffith et al., 1980#
100%	Not supplied	Irritation scores indicate slight irritation	Weil & Scala, 1971#

* No corneal damage likely
$ Severe injury and necrosis (~ 75%) of the cornea
# cited in OECD (1997)

9.5 Sensitisation

Animal studies assessing the skin sensitisation potential of TEA revealed that it did not induce sensitisation. A number of recent reports and clinical testing in humans provided evidence supporting the role of TEA as an allergen responsible for some cases of allergic contact dermatitis and occupational asthma (Tosti et al., 1990; Batten et al., 1994; Savonius et al., 1994; Hamilton & Zug, 1996; Blum & Lischka, 1997). TEA has also been shown to cause intractable sneezing due to IgE-mediated sensitivity (Herman, 1983).

Animal studies- Guinea pig

Concentration	***Method***	***Result***	***Reference***
Not supplied	Patch test	Not sensitising	IBR, 1975a[#]
Not supplied	Patch test	Not sensitising	IBR, 1945[#]
Not supplied	Patch test	Not sensitising	IBR, 1975b[#]
Not supplied	Patch test	Not sensitising	IBR, 1975c[#]
25% solution	Patch test	Not sensitising	HTR,1973[#]
100%	Not supplied	Not sensitising	LSR, 1975[#]

[#] cited in OECD (1997)

Human- case reports

Concentration	***Method***	***Result***	***Reference***
1% solution	Semi-occlusive induction	Not sensitising	CTFA, 1974[#]
5%	Patch test, 1979-1980	Sensitising	NACDG, 1980[#]
2% in water	Patch tests, 1974-1976	Sensitising	Calas et al., 1978[#]
5% in petrolatum	Patch tests	Sensitising	Fisher et al., 1971[#]

[#] cited in OECD (1997)

9.6 Short and Long Term Repeated dose studies

Subacute, subchronic and chronic toxicity studies have been conducted for TEA in rats and mice utilising inhalation, oral and dermal routes. In general, these studies revealed the test animals' tolerance to relatively high dosages of TEA for prolonged periods of time.

9.6.1 Subchronic

Route	***Duration***	***Test Animal***	***Potential Effects***	***Reference***
Inhalation	16 days	Rat- Fischer 344	2 000 mg/kg- decreased body weight;	Mosberg et al., 1985a[@]

			≥ 500 mg/kg- increased kidney weight*; LOAEL = 125 mg/m^3; minimal to slight acute inflammation of the submucosa of the larynx	
Inhalation	16 days	Mouse- B6C3F1	2 000 mg/kg- increased body weight (males), decreased body weight (females); All doses- haematological findings* (males), decreased thymus & heart weight*	Mosberg et al., 1985b@
Inhalation	28 days	Rat- Wistar	Slight irritation of upper respiratory tract at highest dose; Dose related inflammatory changes in the submucosa of the larynx; NOEL (systemic) > 0.5 mg/L; NOEL (irritation) = 0.02 mg/L	BASF, 1993 in OECD (1997)
Oral (drinking water)	14 days	Rat- Fischer 344	≥ 4% dose- decreased body weight (severe dehydration); 2% dose (females)- increased kidney weight	Hejtmancik et al., 1985a@
Oral (drinking water)	14 days	Mouse- B6C3F1	8% dose- decreased body weight, dehydration, histologic changes in liver; ≥ 4% dose- decreased thymus weight; NOEL = 9 000-10 000 mg/kg/day	Hejtmancik et al., 1985b@
Oral (diet)	28 days	Rat	> 80 mg/kg/day- mortality, decreased growth rate, multi-organ histopathology	Smyth et al., 1951@
Oral (feed)	≤ 168 days	Rat	Kidney and liver histopathology	Kindsvatter, 1940@
Oral (gavage)	≤ 168 days	Guinea pig	Kidney and liver histopathology	Kindsvatter, 1940@
Dermal	14 days	Rat- Fischer 344	2 250 mg/kg/d- decreased body weight; ≥ 563 mg/kg/d- skin irritation	Hejtmancik et al., 1985c@; Melnick et

				al., 1988[@]
Dermal	14 days	Mouse- B6C3F1	All doses- skin irritation (males); ≥ 427 mg/kg/d- skin irritation (females); NOAEL = 281 mg/kg/day(rat), 1 686 mg/kg/day (mouse)	Hejtmancik et al., 1985d[@]; Melnick et al., 1988[@]
Dermal	91 days	Rat- Fischer 344	2 000 mg/kg/d- decreased body weight, blood and urinary effects, pituitary gland hypertrophy; ≥ 250 mg/kg/d- skin irritation (males); ≥ 500 mg/kg/d- increased kidney weight (males); ≥ 1 000 mg/kg/d- increased kidney weight and pathology (females); ≥ 500 mg/kg/d- skin irritation (females)	Hejtmancik et al., 1987e[@]; NTP (1994)[@]
Dermal	91 days	Mouse- B6C3F1	4 000 mg/kg/d- skin irritation, increased liver and kidney weight*; increased spleen weight (females); All doses- decreased body weight* (males)	Hejtmancik et al., 1987f[@]; NTP (1994)[@]
Dermal	91 days	Mouse- C3H/HeJ	Skin irritation	DePass et al., 1995[@]

* Changes observed were not dose related and their correlation with treatment is inconclusive
[@] cited in Knaak et al. (1997)

The most reliable repeat-dose oral exposure studies in rats and mice indicate that the NOAEL for TEA is in the order of 1 000 mg/kg/day and ≥ 2 400 mg/kg/day, administered in diet and water, respectively (OECD, 1997). In the absence of full study reports, it is not possible to determine specifically the NOEL/NOAEL for TEA in rats and mice independently.

9.6.2 Chronic

Oral: Depressed body weights and histopathological changes in kidney were the most significant treatment-related effects observed in rats treated with high doses of TEA (Maekawa et al., 1986 cited in Knaak et al., 1997). TEA ingestion by mice showed no treatment-related changes in organ weights or in gross or histopathological parameters (Konishi et al., 1992 cited in Knaak et al., 1997). Both previous studies indicated the lack of carcinogenic activity by TEA.

Dermal: As with subchronic studies, long term investigations into the effects of dermally administered TEA may be influenced by a number of confounding factors. For example, ingestion of TEA during grooming presents an additional route of exposure, and the frequent use of neat TEA at all dosages may increase the potential to modify the skin as a barrier and subsequently lead to systemic effects at lower doses (Knaak et al., 1997). Overall, TEA induced changes at treatment sites indicative of chronic irritation including acanthosis, inflammation, ulceration and erosions (Hejtmancik et al., 1995; NTP, 1994 cited in Knaak et al., 1997). In addition, systemic effects primarily limited to kidney tissues were also observed in rats and mice, exposed dermally to TEA. These studies failed to generate unequivocal evidence of a carcinogenic response to dermally applied TEA.

In general, the skin is the target tissue in dermal toxicity studies, while kidney and liver are the most sensitive systemic target organs of TEA. A positive trend in the occurrence of tumors in different tissues was observed in long-term studies of orally and dermally administered TEA in rats and mice. However, the correlation between chronically administered TEA at high doses and increased tumors in animals is difficult to ascertain due to confounding factors in the bioassays (Knaak et al., 1997).

9.7 Reproductive and Developmental Toxicity

The No Observed Effect Level (NOEL) for reproductive toxicity of dermally administered TEA in rats is > 500 mg/kg bw/day (Battelle, 1988 cited in Knaak et al., 1997). Developmental toxicity studies, including maternal, embryofetal and teratogenicity revealed that the NOEL for dermally applied TEA in rats is > 30 mg/kg bw/day (Burnett et al., 1976 cited in Knaak et al., 1997). Oral administration of 1 125 mg/kg/day TEA to pregnant mice had no effects on maternal mortality, number of viable litters, litter size and survivability, birth weight or weight gained by pups (EHRT Inc., 1989 cited in Knaak et al., 1997).

9.8 Genotoxicity

TEA was non-mutagenic to bacteria when evaluated in the Ames *Salmonella* tester strains and in *Escherichia coli* with or without metabolic activation (NRC, 1981; Inoue et al., 1982; Pathak et al., 1982; Dean et al., 1985; Mortelmans et al., 1986; Wang et al., 1988; NTP, 1994 all cited in cited in Knaak et al., 1997). Similarly, sex-linked recessive lethal mutations or reciprocal translocations were not induced by TEA in *Drosophila* assays (Yoon et al., 1985; NTP, 1994 cited in Knaak et al., 1997). TEA also failed to induce DNA-damage leading to repair synthesis in primary rat hepatocyte Unscheduled DNA Synthesis (UDS) assay (Litton Bionetics, 1982; Beyer et al., 1983 cited in Knaak et al., 1997).

Clastogenic *in vitro* assays revealed that TEA did not induce chromosomal aberrations in the examined cell lines (Inoue et al., 1982; Dean et al., 1985; NTP, 1994 all cited in Knaak et al., 1997). A sister chromatid exchange *in vitro* assay in Chinese hamster ovary cells was also negative (Galloway et al., 1987 cited in Knaak et al., 1997).

9.9 Overall Assessment of Toxicological Data

TEA was of very low acute oral toxicity in rats with LD_{50} > 2 000 mg/kg bw and of low dermal toxicity in rabbits (LD_{50} > 2 000 mg/kg bw). It was slightly irritating to rabbit skin at 100%. At neat concentration, it was irritating to non-scarified human skin, whereas at 10% and 5% it was irritating and slightly irritating to scarified human skin, respectively. Neat

TEA was slightly to moderately irritating to the rabbit eyes, with one study report indicating corrosive effects.

TEA was not sensitising to the skin of animals. However, several clinical studies and case reports in humans indicated that TEA is a skin and respiratory sensitiser responsible for allergic contact dermatitis and occupational asthma.

Repeated dose inhalation toxicity study in rats resulted in minimal to slight acute inflammation of the submucosa of the larynx, but a NOEL could not be determined. However, the LOAEL is determined to be 125 mg/m^3. Similar observation were reported in another inhalation study in rats with a NOEL for systemic and irritation effects of > 0.5 mg/L and 0.02 mg/L, respectively. For orally administered TEA in rats and mice, the NOAEL was determined to be in the order of 1 000 mg/kg/day and ≥ 2 400 mg/kg/day administered in diet and water, respectively.

The notified chemical was considered non-mutagenic to bacteria and non-genotoxic in *in vitro* assays.

The toxicity profile and health effects of the notified chemical (TEA salt) would be expected to be similar to that of TEA. The salt component in the notified chemical may be irritating to the skin, eyes and respiratory tract, though not sufficient to classify it as hazardous.

The notified chemical is classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* based on the findings of skin irritation and the potential for skin and respiratory sensitisation reported for TEA in humans. The overall classification is Irritant (Xi) and the risk phrases R38 – Irritating to Skin, R42 – May Cause Sensitisation by Inhalation and R43 - May Cause Sensitisation by Skin Contact, are assigned. The safety phrase S25 – Avoid Contact with Eyes, is suitable as warning of possible eye irritation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied the following ecotoxicity studies for the precursor TEA. From the information provided it could not be confirmed if the tests were carried out according to OECD Test Methods.

Species	***Test***	***Concentrations (mg/L)***	***Result (mg/L)***	***Reference***
Fish	96 h acute static		LC_{50} > 1000	(EN-CAS Analytical Laboratories, 1977)
Water Flea (*Daphnia magna*)	24 h acute		EC_{50} = 1390 NOEC = 875	(Bringmann & Kuhn, 1977)
Algae (*Selenastrum subspicatus*)	48 h growth	16 - 2000	$E_\mu C_{50}$ = 750 $E_B C_{50}$ = 470	(Kuhn & Pattard, 1990)

* NOEC - no observable effect concentration

The EN-CAS Analytical Laboratories (1977) reference supplied by the notifier only consists of a listing of the worst case results for 3 substances, including TEA, and the raw laboratory records for one of the TEA studies quoted in the listing.

It should be noted that the Bringmann and Kuhn (1977) reference was in German with an English summary.

Kuhn and Pattard (1990) used the German test method using water organisms, DIN 38 412, Part 1, 1982, to test the impact of 68 chemicals, including TEA, on the alga *Selenastrum subspicatus*. Stock solutions (800 mL) of each test chemical were prepared 24 hours before the test. At the time of the test a series of dilutions (16 - 2000 mg/L TEA) was made up with an algal cell count of 10^4 per mL and pH 8.0, in 250 mL glass bottles. Controls were also run and treated in the same way. Cell counts were taken at 0, 24 and 48 hours. The environmental assessment accepts this method but notes that it is shorter than the usual 72 hours.

The ecotoxicity results for TEA from OECD (1997) are presented in the following table.

Species	***Test***	***Result (mg/L)***
Fish	96 h acute static	LC_{50} = >8000-11 800
Water Flea (*Daphnia magna*)	24 h acute static	EC_{50} = 1386–1850
	21 day	NOEC = 16; EC_{50} = 2038
Brine Shrimp(*Artemia salina*)	24 h	5600
Algae (*Selenastrum subspicatus*)	72 h growth	EC_{50} = 216-512

The results were taken from published articles and agree with other literature data (Newsome et al., 1993; GDCh - Advisory Committee on Existing Chemicals of Environmental Relevance, 1994).

The ecotoxicity data for TEA indicate that it is practically non-toxic to fish, daphnia and algae, with the algae being the most sensitive organism. However, the notified chemical is the salt form of TEA and consequently is consists of the acetate anion and ammonium cation. The presence of the ammonium cation it is likely to render the salt form more toxic than TEA. The notifier provided an OECD (1997) Screening Information Data Set (SIDS) report on TEA. The report indicates that in the environment pH range 4 to 9 TEA is likely to exist as a mixture of protonated $(HOCH_2CH_2)_3N^+H$ and neutral $(HOCH_2CH_2)_3N$. Thus the above data may be taken as representative of the notified salt.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified chemical will be incorporated into the matrix of the concrete. Once solidified, the notified chemical is expected to pose minimum risk to the environment.

The main environmental hazard would arise from release of the notified chemical during storage or transport. The use of bunded containment minimises the risk of release at storage sites. If it is assumed that 100 L of additive product are spilt annually, then approximately 20

L of notified chemical will be released to the environment annually via spills. This spillage is expected to be distributed across several sites and not restricted to a single site. This would minimise the degree of risk to the environment at any given time. The Material Safety Data Sheet (MSDS) appears to adequately address spills and disposal.

The capacity of the bulk tankers used to transport the liquid additive is 20 000 L. If one of these tankers was involved in an accident and the tank was ruptured with a resultant loss of 10% of the volume (i.e. 2000 L), then 300 L of the notified chemical would be released. It is likely that the spilt material would enter stormwater drains or an open water body. The water courses in urban areas tend to be seasonal, with low flow. In a worst case scenario, where the 300 L of notified chemical entered a standing body of water containing 1.5 ML, the resultant predicted environmental concentration (PEC) would be 0.2 mg/L. This PEC is at least two orders of magnitude below the EC_{50} for algae.

A further environmental hazard could arise from release of untreated chemical-contaminated water into the aquatic compartment. This risk is controlled because truck wash water is discharged into concrete setting basins then recycled into subsequent batches of cement.

The low expected environmental exposure of the notified chemical when integrated into concrete and the estimate worst case PEC, suggest the overall environmental hazard should be minimal.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Assessment of Toxicological Hazard

TEA exhibited low acute oral and dermal toxicity in rats. It was slightly irritant to the skin of rabbits but was irritating to intact human skin. Studies in rabbits, although conflicting, suggest it is an eye irritant. Although not shown to be sensitising in animal studies, TEA was shown to cause allergic contact dermatitis and occupational asthma in humans. TEA was not genotoxic in *in vitro* assays and did not cause severe systemic effects in repeated dose studies. Based on this profile, salts of TEA, including the notified chemical, are classified as hazardous substances in terms of skin and eye irritation and skin and respiratory sensitisation according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999). The overall classification is Irritant (Xi) and the risk phrases R38 – Irritating to Skin, R42 – May Cause Sensitisation by Inhalation and R43 - May Cause Sensitisation by Skin Contact, are assigned.

Occupational Health and Safety

Cement additive production
The notified chemical is a cement additive formed in a reaction vessel by reaction of TEA with an organic acid and present at up to 20% in the final product. The system is closed and exposure will most likely occur during transfer of the product to storage tanks or flushing of storage or mix tanks with water. The notifier has stated that special equipment is used to flush lines with compressed air and the process is designed to minimise exposure. Plant operators may be dermally exposed to residues on couplings or from accidental spillage. Similar exposure may occur when the cement additive is transferred from the bulk storage

tanks to containers for transportation. Mainly dermal exposure is also possible for quality control workers who sample the batch during production. It can be assumed that opportunities for exposure are limited. The main health risks appear to be skin irritation and skin sensitisation. These risks will need to be further controlled through the use of protective clothing and gloves. The risk of respiratory sensitisation is low given the low vapour pressure of TEA and the fact that aerosols should not be generated during transfer of the notified chemical. The risk of eye irritation is expected to be low but will need to be controlled through the wearing of eye protection.

Transport of cement additive is in 1 000 L totes, iso-tanks or 20 000 L tanker trucks. Transport workers are required to hook up the sealed delivery system that dispenses the cement additive to customers' storage tanks. The health risks to these workers are as described above and protective clothing, gloves and goggles will need to be worn.

Cement production, concrete production, testing or use
Once the cement additive is transferred to storage tanks by transport workers, it is added to the cement mill via a sealed, automatic delivery system to a final low concentration (0.03%). Workers involved in cleaning or maintenance of this system and exposed to high concentrations of cement additives should wear personal protective equipment to minimise the risk of skin and eye irritation and skin sensitisation. Once the cement additive is mixed with the cement dust at a concentration of 0.03%, the risk of adverse health effects from the additive itself should be negligible since this level is well below the concentration cut-offs for irritation (20%) or sensitisation (1%). Similarly, workers involved in concrete production, testing or use are unlikely to be at risk of skin or eye irritation or skin sensitisation from exposure to the notified chemical in either cement or concrete.

Public Health and Safety
During manufacture, transport, use or disposal of the notified chemical or products containing it, exposure of the general public is such that the risk to public health and safety is assessed as low.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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