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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Grace Proprietary Acetate Salt

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Grace Australia Pty Ltd (ABN 41 080 660 117)
1126-1134 Sydney Rd
Fawkner VIC 3060

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Spectral Data
Manufacture/Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a Function of pH
Adsorption/Desorption
Dissociation Constant
Flammability Limits
Explosive Properties
Reactivity
Acute Inhalation Toxicity
Induction of Germ Cell Damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Notified in accordance with NSN regulations: Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Proprietary Acetate Salt
CBA 1115 (and other products)

MOLECULAR WEIGHT
251.06

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Separation by HPLC with detection by mass spectrometry or ^{1}H nmr spectroscopy
Remarks	A reference nmr spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 76.4 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	ethanol, 2,2′-iminobis-		
CAS No.	111-42-2	*Weight %*	0.6 %
Hazardous Properties	R36/38 – Irritating to skin and eyes (NOHSC, 1999a) NOHSC exposure standard 13 mg/m^3 TWA (NOHSC, 1995)		

Chemical Name	ethanol, 2-amino-		
CAS No.	141-43-5	*Weight %*	0.03 %
Hazardous Properties	R20 – Harmful by inhalation R36/37/38 – Irritating to eyes, respiratory system and skin (NOHSC, 1999a) NOHSC exposure standard 7.5 mg/m^3 TWA, 15 mg/m^3 STEL (NOHSC, 1995)		

NON HAZARDOUS IMPURITIES (> 1% by weight)

Chemical Name	ethanol, 2,2′-iminobis-, acetate (salt)		
CAS No.	23251-72-1	*Weight %*	21.7 %

Chemical Name	ethanol, 2-amino-, acetate (salt)		
CAS No.	54300-24-2	*Weight %*	1.4 %

ADDITIVES/ADJUVANTS
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Local manufacture.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Up to 100 tonnes per annum

USE
The notified chemical will be used in aqueous solution (13 – 31 % notified chemical) as a grinding aid and/or pack set inhibitor for Portland cement and other hydraulic cements.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Local manufacture at a number of sites.

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be manufactured at the notifier's sites, possibly in all mainland states, and transferred in aqueous solution to cement production sites throughout Australia.

TRANSPORTATION AND PACKAGING
The aqueous products containing the notified chemical will be transported from the site of manufacture to the site of use in totes, isotanks or bulk tankers. Transport will be by road.

5.2. Operation Description

The notified chemical will be prepared at the notifier's site by mixing the raw materials in a tank, together with the other ingredients which comprise the cement additive mixture. The finished cement additive will contain up to 31 % notified chemical in aqueous solution. The finished additive mixtures will be pumped to storage tanks, then dispensed into bulk tankers or large volume liquid containers for transport to the cement production plants.

At the production plants, the cement additive will be added to the production process at the grinding stage. Addition is automated through an additive dispensing unit, due to the large volumes of materials involved in the cement production process. The notified chemical will be incorporated in the finished cement at low levels (< 0.02 %). Finished cement will mostly be transferred by bulk transport (road, rail or sea) for transfer to concrete production facilities, while a small proportion (~ 10 %) will be bagged for transfer to industrial customers, who will prepare pre-mixed products for sale to small volume users including public sale.

Concrete will contain a maximum concentration of 0.002 % notified chemical. Concrete use will be predominantly industrial, although there may be a small proportion used by the public.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Concentration of Notified Chemical*	*Exposure Duration*	*Exposure Frequency*
Notifier's sites				
Plant Operator	10	≤ 31 %	2 hr/day	daily
Truck Driver	10	≤ 31 %	2 hr/day	daily
Quality Control	5	≤ 31 %	1 hr/day	daily
Supervisor	5	≤ 31 %	1 hr/day	daily
Salesman	1	≤ 31 %	4 hr/day	daily
Cement Producer				
Storemen	10	≤ 31 %	1 hr/day	daily
Process Engineer	20	≤ 31 %	2 hr/day	daily
Laboratory Technician	20	≤ 31 %	1 hr/day	daily
Maintenance Fitter	10	≤ 31 %	1 hr/day	daily
Mill Worker	140	< 0.02 %	8 hr/day	daily
Concrete Producer				
Quality Control	25	< 0.02 %	4 hr/day	daily
Labourer	100	< 0.002 %	4 hr/day	daily
Truck Driver	400	< 0.002 %	4 hr/day	daily
Concrete Contractor				
Placing and Finishing Crew	1000	< 0.002 %	8 hr/day	daily
Concrete Testing Laboratory				
Jobsite Technician	100	< 0.002 %	6 hr/day	daily

Exposure Details

Exposure to concentrated solutions of the notified chemical may occur for workers at the manufacture sites and in addition of the solutions to the cement production process. These processes will generally be automated, and exposure is likely to be limited to dermal contact with the aqueous cement additive, containing up to 31 % notified chemical, during connection and disconnection of transfer hoses during container or tanker filling and transfer of the additive to storage tanks, and during set up and maintenance of dosing and filling equipment. Laboratory staff sampling and handling the additives during routine quality control operations may also be exposed to small amounts of the additive mixtures, predominantly dermally.

All personnel handling cement additives, cement, or concrete containing additives at the notifier's site will wear safety glasses, impervious gloves and rubber boots. The Material Safety Data Sheet (MSDS) for the additive CBA 1115 recommends that workers handling the additive use overalls, safety glasses, goggles or face shield, PVC or rubber gloves, and boots, and that adequate ventilation, including local exhaust ventilation, be used.

Dermal and inhalation exposure to the cement dust containing < 0.02 % notified chemical may occur during transfer and bagging of cement, preparation of concrete and during mixing of concrete premixes. Widespread exposure to wet concrete containing the notified chemical at < 0.002 % may occur during use of the concrete in construction and other industries. After the concrete has set, the notified chemical is expected to be contained within the hardened matrix and will not be available for exposure.

The notifier states that workers handling fresh concrete routinely wear rubber boots and impervious gloves for protection against the irritant effects due to the high pH.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notifier indicates that release during the manufacture and formulation processes and transportation will only occur during cleaning and transfer of the additive containing the notified chemical. The notifier indicates that storage containers and mixing vessels will be rinsed with water (50-200 L) and the rinseate will either be used in the formulation of the next batch of additive or processed by licences waste disposal contractors. At the additive manufacturing sites the process equipment will either be air or water purged. The resultant washwater is recycled back into the process.

RELEASE OF CHEMICAL FROM USE

Any spills of the product either during manufacture or transport to customer sites would be cleaned up with an absorbent and disposed of to landfill. Spills during the manufacture are likely to be collected and recycled back into the process if possible.

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. Generally 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.

Release at concrete contractor sites and during use by the public, where workers will shovel and rake, consolidate and trowel finish is expected to be minimal. Any unused concrete will be disposed in landfill, as too will product packaging and old concrete in builder's rubble. Once the additive is incorporated into the powdered cement, potential release is low as it bonds strongly with the clay, which will limit aquatic exposure during the cleaning of equipment and trucks.

Although the notifier has not indicated expected releases of the notified chemical from formulation, transport and use, it is reasonable to assume that these will be in the order of 1 % of the manufactured volume. This equates up to 1000 kg of the notified chemical released each year.

5.5. Disposal

The notified chemical will ultimately be disposed of in landfill.

5.6. Public exposure

The notified chemical will be manufactured at several Grace cement additive manufacturing sites. Raw materials will be mixed in a tank and the resulting aqueous solution will be automatically pumped to storage tanks and dispensed into bulk tankers or large volume liquid containers for road transport to warehouses or cement production plants. Cement additive will enter the cement production process at the grinding stage, via an automated process. Around 90 % of the finished cement containing < 0.02 % notified chemical will be transferred by bulk transport to concrete production facilities, and around 10 % is bagged for repackaging into ready-mix products for use by the building industry and for public sale at retail outlets. Final concrete mixes will contain < 0.002 % of the notified chemical. All Grace sites are fully bunded to prevent releases to the environment. Tankers are flushed with water, which is recycled into the next product batch or collected in a pit and extracted and processed by waste removal with excess to the sewer.

It is expected that during transport, storage and industrial use, exposure of the general public to the

notified polymer will be low, except in the event of an accidental spill of the aqueous solution cement additive. Care should be taken as this will render surfaces slippery. Spills should not be allowed to enter water courses. They should be contained and absorbed with non-flammable liquid-binding material (eg. sand) and placed into appropriate labelled containers. Waste should be disposed of in accordance with state land waste management authorities.

Public exposure to the notified chemical will occur from contact with finished concrete structures containing the notified chemical and when using ready-mix preparations containing the notified chemical for domestic repair/maintenance/building purposes. There will be dermal exposure to finished concrete structures and dermal, inhalation, ocular and possibly oral exposure from the mixing and use of ready-mix preparations.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa White crystalline solid

Melting Point 61 - 63°C

METHOD OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Melting was determined visually.
TEST FACILITY RCC Umweltchemie AG (1997a)

Boiling Point 358°C at 101.3 kPa

METHOD OECD TG 103 Boiling Point.
EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks Apparent boiling at 177 – 195°C was observed using thermal analysis; based on the boiling point of the constituents of the salt, this was considered to be likely to be due to decomposition, and a calculated boiling point (Meissner's method) was determined for use in vapour pressure calculations.
TEST FACILITY RCC Umweltchemie AG (1997b)

Density 1040.3 kg/m^3 at 70°C

METHOD OECD TG 109 Density of Liquids and Solids.
EC Directive 92/69/EEC A.3 Relative Density.
Remarks Oscillating densitometer; liquid density measured at 70°C.
TEST FACILITY RCC Umweltchemie AG (1997c)

Vapour Pressure 2.1×10^{-10} kPa at 25°C

METHOD OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Calculated using the Modified Watson Correlation.
TEST FACILITY RCC Umweltchemie AG (1997d)

Water Solubility > 1000 g/L at 20°C

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The water solubility of the notified chemical was determined by visual observation. The notified chemical (25.3 g) was added stepwise to water (25 mL). The notifier indicates that the substance was immediately dissolved and that complete saturation was not achieved at the maximum amount added. The test was not continued. On the basis of these preliminary results the notifier indicates the water solubility of the notified chemical is > 1000 g/L. However, the notifier indicated in the partition coefficient calculation that the water solubility of the notified chemical is approximately 1980 g/L.

TEST FACILITY RCC Umweltchemie AG (1997e)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	$t_{½}$
4	50	> 1 Year
7	50	> 1 Year
9	50	312 h

Remarks The notified chemical exhibited less than 10 % degradation after 5 days at pH 4 and 7 at 50°C, which indicates a half-life of greater than one year at 25°C. At pH 9 the notified chemical exhibited approximately 50 % degradation, indicating a half-life of approximately 312 h at 50°C. As the notified chemical does not contain any groups capable of hydrolysis and the results could not be replicated at 80 and 90°C, the losses observed during this test could be attributed to experimental error and decomposition.
TEST FACILITY RCC Umweltchemie AG (1997f)

Partition Coefficient (n-octanol/water) log Pow at 20°C = -2.3

METHOD ECC Directive 92/69
Remarks The partition coefficient was calculated from the ratio of the solubilities of the notified chemical in n-octanol and water. The notifier indicates that the solubilities in n-octanol and water are 10.43 and 1980 g/L, respectively.
TEST FACILITY RCC Umweltchemie AG (1997g)

Adsorption/Desorption Log K_{oc} ~0.13

Remarks The notifier has provided an estimation of the adsorption/desorption coefficient based on the notified chemical's octanol-water partition coefficient using the equation log K_{oc} = 0.544(log Pow) + 1.377. This indicates the notified chemical has a low potential for adsorption onto soils. However, given the cationic nature of the notified chemical, it is likely to associate with clay fraction of soils.

Dissociation Constant Not determined

Remarks The notifier indicates that the dissociation constants for the notified chemical are predicted to be ~ 8.5 (NH) and ~ 4.8 (OH) based on calculations using ACD/pKa Predictor 3.0 (ACD, 1998).

Particle Size

Remarks The notified chemical is never isolated from aqueous solution.

Flash Point > 145°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup. Test performed until decomposition was observed at 145°C.
TEST FACILITY RCC Umweltchemie AG (1997h)

Flammability Limits not flammable

Remarks The solid notified chemical could not be ignited with a gas flame in a preliminary test, and, due to its low vapour pressure, explosive vapour/air mixtures are not expected to be formed under any conditions.

TEST FACILITY RCC Umweltchemie AG (1997i)

Autoignition Temperature > 400ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks The guideline used is not appropriate for liquids or gases, and strictly only the range below 60ºC, where the notified chemical is solid, was examined in this test; however the lack of any effects at higher temperatures is indicative that the autoignition temperature is higher than the maximum temperature achieved in the test.
TEST FACILITY RCC Umweltchemie AG (1997j)

Explosive Properties Not explosive.

Remarks No groups likely to contribute to explosive properties are present in the notified chemical.

Reactivity

Remarks Stable under normal environmental conditions; may react with nitrosating materials (eg nitrites) to form hazardous nitrosamine compounds.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 ~ 7500 mg/kg bw	low toxicity
Rat, acute dermal LD50 > 2000 mg/kg bw	low toxicity
Rat, acute inhalation	test not conducted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test.	no evidence of sensitisation.
Rat, oral repeat dose toxicity - 28 days.	NOEL = 200 mg/kg bw/day
Genotoxicity - bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration test	non genotoxic
Genotoxicity – in vivo	test not conducted

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/Sprague-Dawley
Vehicle Water (dose volume 2 mL/kg bw)
Remarks - Method A limit test at 7.5 g/kg bw was specified by the study sponsor.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	7500	5/10

LD50 ~ 7500 mg/kg bw
Signs of Toxicity Eight animals showed clinical signs of toxicity in the first four day of the study; five of these animals died during this time. Signs included nasal discharge, lethargy, tremors, toe walking, lacrimation and piloerection.
Effects in Organs No abnormalities were seen at necropsy in the animals that survived the study period. In the animals that died, red, swollen stomach and reddened kidneys with loss of distinction between cortex and medulla were

observed.

Remarks - Results	All surviving animals gained weight during the study. The limit dose chosen is higher than the level at which the notified chemical would be considered to be of low toxicity (2000 mg/kg bw).

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY Toxikon Corporation (1996a)

7.2. Acute toxicity - dermal

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.

Species/Strain	Rabbit/New Zealand White
Vehicle	None.
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	0/10

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	No oedema or erythema were observed at 30-60 minutes after bandage removal..
Signs of Toxicity - Systemic	No clinical signs of toxicity were observed.
Effects in Organs	No gross abnormalities were seen at necropsy.
Remarks - Results	All animals gained weight during the study.

CONCLUSION The notified chemical is of low toxicity via the dermal route.

TEST FACILITY Toxikon Corporation (1996b)

7.3. Acute toxicity - inhalation

Test not conducted.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	None
Observation Period	3 days
Type of Dressing	Not stated.
Remarks - Method	No significant protocol deviations.

RESULTS

Remarks - Results	All Draize scores at 4, 24, 48 and 72 hours for oedema and erythema were zero.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY	Toxikon Corporation (1996c)

7.5. Irritation - eye

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Observation Period	3 days
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	All draize scores for conjunctival, iris and corneal effects were zero at 24, 48 and 72 hours after instillation. At 1 hour after instillation, all animals showed conjunctival redness, chemosis and discharge (Draize score 1 in all cases). Blistering of the nictitating membrane persisting beyond the 24 hour observation was seen in two animals.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Toxikon Corporation (1996d)

7.6. Skin sensitisation

TEST SUBSTANCE	
METHOD	OECD TG 406 Skin Sensitisation – Buehler Test.
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: 100 %
MAIN STUDY	
Number of Animals	Test Group: 10 per sex Control Group: 5 per sex
induction phase	Induction Concentration: 100 %
Signs of Irritation	No signs of erythema or oedema were observed.
CHALLENGE PHASE	topical application: 100 %
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No dermal reactions were seen at challenge in either the test or control groups.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Toxikon Corporation (1996e)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week.

Vehicle	Water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 per sex	0	0/10
II (low dose)	5 per sex	50	0/10
III (mid dose)	5 per sex	200	0/10
IV (high dose)	5 per sex	1000	0/10

Mortality and Time to Death
All animals survived to scheduled sacrifice.

Clinical Observations
No clinical signs of toxicity were observed; body weights and food consumption were not affected by treatment.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Several small but statistically significant differences were observed between the high dose animals and controls were observed. These were decreased glucose and increased urea in the high dose females and decreased albumin and total protein in the males.

Increased urine pH was observed for both sexes at the high dose; the increase was statistically significant for the females. Differences in haemoglobin levels among the males appear to be related to a comparatively high haemoglobin level in the control males.

Effects in Organs
No significant differences in organ weights between groups were observed. All macroscopic and microscopic lesions observed at necropsy were either scattered occurrences without dose relationship, or were found at similar incidence in all groups.

Remarks – Results
The changes in clinical biochemistry were within the range of common variation of the parameters, and were considered by the study authors to be a reflection of metabolic adaptation.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on clinical biochemistry changes observed at 1000 mg/kg bw/day.

TEST FACILITY RCC Umweltchemie AG (1997k)

7.8. Genotoxicity - bacteria

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100.
Metabolic Activation System	10 % S9 liver fraction from rats pretreated with Aroclor 1254.
Concentration Range in Main Test	a) With metabolic activation: 0.1 - 10000 µg/plate. b) Without metabolic activation: 0.1 - 10000 µg/plate.
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	Two independent experiments were performed in triplicate.

RESULTS

Remarks - Results	No signs of precipitation of test substance or of cytotoxicity were observed under any conditions. No increase in the numbers of revertant

colonies were seen in any strain either in the presence or absence of metabolic activation.
Appropriate positive controls were used and resulted in large increases in numbers of revertant colonies in all cases, confirming the sensitivity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Toxikon Corporation (1996f)

7.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 473 In vitro Mammalian Chromosomal Aberration Test.
Cell Type/Cell Line Chinese Hamster V79 cells
Metabolic Activation System S9 liver fraction from rats pretreated with phenobarbital and β-naphthoflavone; final protein concentration 0.75 mg/mL.
Vehicle Water
Remarks - Method No significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	300, 500*, 1000, 2000*, 3000, 4000*	18 hr	18 hr
Test 2	250, 500*, 1000, 2000*, 4000*, 5000	18 hr	18 hr
	1000, 2000*, 4000, 5000	28 hr	28 hr
Present			
Test 1	100, 300, 500*, 1000, 3000*, 5000*	4 hr	18 hr
Test 2	100, 300, 500*, 1000, 3000*, 5000*	4 hr	18 hr
	500, 1000, 3000, 5000*	4 hr	28 hr

*Cultures selected for metaphase analysis.

RESULTS
Remarks - Results No test substance precipitation was observed. In the presence of metabolic activation, no clear indications of cytotoxicity were seen at any concentration used; in the absence of metabolic activation, cytotoxicity indicated by reduction in cell numbers below 50 % of control was seen at and above 3000 μg/mL. Significant reduction in mitotic index was also observed only under these conditions.
No significant increases in the frequency of chromosome aberrations or polyploidy was seen under any test conditions, either in the presence or absence of metabolic activation.
Appropriate positive controls were used and resulted in large increases in numbers of cells with chromosome aberrations in all cases, confirming the sensitivity of the test system.

CONCLUSION The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY Cytotest Cell Research GmbH & Co. KG (1997)

7.10. Genotoxicity – in vivo

Test not conducted.

7.11. Developmental toxicity

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 414 Teratogenicity.
Species/Strain	Rat/Crl:CR®BR VAF/Plus (Sprague-Dawley)
Route of Administration	Oral – gavage.
Exposure Information	Exposure period: days 6 to 19 of gestation
Vehicle	Water
Remarks - Method	The animals were sacrificed on gestational day 20 and the uterine contents examined.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	25 female	0	0/25
II	25 female	500	0/25
III	25 female	1000	0/25
IV	25 female	2000	0/25

Mortality and Time to Death
All animals survived to scheduled sacrifice.

Effects on Dams
In the 1000 and 2000 mg/kg bw/day groups, red perioral substance, excess salivation and red substance on the fur were observed. Two animals in the 2000 mg/kg bw/day group showed urine stained abdominal fur and red perivaginal substance.

The 2000 mg/kg bw/day group showed significantly reduced body weight gains for the entire dosage period and for the entire gestational period. Reductions in absolute body weights were seen for both the 1000 and 2000 mg/kg bw/day groups on gestational days 8 to 11, and also on gestational day 20 (sacrifice) for the 2000 mg/kg bw group. Food consumption was also decreased for these groups during all or part of the treatment period.

Effects on Foetus
Foetal body weights were significantly reduced in the 2000 mg/kg bw/day group; other litter parameters were unaffected by treatment.
Delays in skeletal ossification were observed for the 1000 and 2000 mg/kg bw/day groups. The incidences of incomplete ossification of ischia, pubes, lumbar arches, sternal centres (2000 mg/kg bw/day only) and hydoids were increased in these groups relative to controls.

Remarks - Results
Maternal toxicity, manifested in reduced body weight gains and clinical signs of toxicity, and foetal toxicity, manifested in incomplete ossification, were both observed at 1000 mg/kg bw and above. Reduced foetal body weights were also seen at 2000 mg/kg bw/day.

CONCLUSION
For both maternal toxicity and developmental effects, a NOEL of 500 mg/kg bw/day was established in this study.

TEST FACILITY Argus Research Laboratories, Inc. (1999)

7.12. Summary of Toxicity Data on Analogue Chemicals

Parent Amine
The parent amine is an eye and skin irritant, but these properties are likely to be due to the pH, and therefore not be relevant to a salt of the amine. It was found to not induce mutations in four *S. typhimurium* strains and to be relatively non-toxic to rats in two subchronic oral studies. In an experiment where the parent amine was

continuously dosed with 2 % amine (conditions not stated, assumed to be in drinking water) and also up to 0.3 % $NaNO_2$ (a nitrosating agent) for 104 weeks, no indications of pre-neoplastic changes in the liver were observed (National Library of Medicine, 2002). A number of LD50 results for acute oral treatment of mammal species have been published, ranging from 1580 mg/kg bw in guinea pigs to 11 g/kg in rabbits; observed signs of toxicity included depressed activity, muscle contraction and gastrointestinal changes (NIOSH, 2002).

The parent amine is expected to relate closely to the notified chemical in cases where the dosage does not exceed the buffering capacity of the medium, in which cases the effective treatment is the same regardless of the initial protonation state of the amine, particularly for repeat dose toxicity (non-gastric effects) and mutagenicity.

Analogue Amine
The analogue amine was similarly found to be a skin and eye irritant. It had low acute oral toxicity in a variety of mammalian species. On subchronic administration, effects on the liver, kidney and optic nerve were observed at concentrations of $\geq$ 170 mg/kg bw/day (oral) for 90 days in rats and guinea pigs. Liver and kidney effects were also seen on repeat dermal treatment. No indications of skin sensitisation or genotoxicity (except in the presence of the nitrosating agent, $NaNO_2$) were observed in animals. A number of patch test results from human trials included several tests where a slight degree of sensitisation was observed. The analogue amine was found to be safe for use in cosmetic products under certain conditions (Cosmetics Ingredients Review, 1983). An OECD SIDS program report indicates that the most reliable result for repeated oral exposure gives a No Observed Adverse Effect Level (NOAEL) of around 1000 mg/kg bw/day for up to 90 days, with liver and kidney changes at higher exposure levels. For systemic effects on dermal exposure, the NOAEL is around 2000 mg/kg bw/day in rats (OECD, 1997).

A 2-year dermal carcinogenicity study on the analogue amine in rats and mice was conducted under the National Toxicology Program (NTP). In a preliminary 13-week toxicity study, the major effects observed were increased kidney and liver weights in both species, as well as local effects. The results of the carcinogenicity study indicated equivocal evidence of carcinogenicity in male rats (renal tubule cell adenoma), no evidence of carcinogenicity in female rats, and some evidence of carcinogenicity in female mice (hepatocellular neoplasms at 1000 mg/kg bw/day). No conclusions could be drawn from the study on male mice, due to a confounding infection (NTP, 1998). The study also included genotoxicity testing, which showed uniformly negative results, including testing for germ cell damage in *Drosophila melanogaster*.

The results form the analogue amine cannot be directly used for assessment of the notified chemical, as, even for endpoints where the initial protonation state is not important, the differences in metabolites may result in significantly different toxicity profiles. However the analogue amine bears sufficient similarity to the parent amine of the notified chemical that indications of high toxicity would be cause for concern about the notified chemical.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test.
Inoculum	Activated sludge
Exposure Period	28 Days
Remarks - Method	The notified chemical was incubated in duplicate for 28 days at a test substance concentrations of 45.0 and 45.7 mg/L (18.3 and 21.9 mg/L DOC, respectively).

RESULTS

Test substance		*Aniline*	
Day	*% degradation*	*Day*	*% degradation*
28	11	28	99

Remarks - Results	The biodegradation of the reference substance, aniline, was 99 % after 28 days, indicating the test conditions were valid. After 28 days, the test substance exhibited 11 % biodegradation, which indicates the notified chemical is not readily biodegradable in aerobic environments.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	RCC Umweltchemie AG (1997l)

8.1.2. Bioaccumulation

Remarks	Data regarding the bioaccumulation potential of the notified chemical were not provided for this notification. The high water solubility of the notified chemical suggests that it is unlikely to cross biological membranes and bioaccumulate (Connell, 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test, 96 h semi-static
Species	Rainbow trout (*Oncorhynchus mykiss*)
Exposure Period	96 h

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*3h*	*24h*	*48h*	*72h*	*96h*
0			0	0	0	0	0
120	113		0	0	0	0	0

LC50	> 120 mg/L at 96 hours.
LOEC	> 120 mg/L at 96 hours.
Remarks – Results	The results of the limit study showed that no mortalities or sub-lethal effects were observed in any of the test vessels. The 96-hour EC_{50} for the

notified chemical to *Oncorhynchus mykiss* is greater than 120 mg/L.

CONCLUSION The ecotoxicity data indicates the notified chemical is practically non-toxic to fish.

TEST FACILITY RCC Umweltchemie AG (1997m)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 202 *Daphnia* sp. Acute Immobilisation Test
Species *Daphnia magna*
Exposure Period 48 hours

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	-	20	0	0
6.25	-	20	0	0
12.5	-	20	0	0
25	-	20	0	0
50	-	20	0	0
100	94	20	0	0

LC50 > 100 mg/L at 48 hours
LOEC > 100 mg/L at 48 hours
Remarks - Results The immobilisation tests with *Daphnia* were performed using 20 daphnids per concentration with observations performed at 24 and 48 hours. After 48 h, no immobilised daphnids were observed at any test substance concentration. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is greater than 100 mg/L.

CONCLUSION The ecotoxicity data indicates the notified chemical is practically non-toxic to daphnia.

TEST FACILITY RCC Umweltchemie AG (1997n)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 201 Alga, Growth Inhibition Test.
Species *Scenedesmus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal 4.3, 9.4, 20.8, 45.5 and 100 mg/L
Concentration Range Actual 97% of nominal

RESULTS

Biomass	*Growth*	*LOEC*

E_bC50 (mg/L at 72 h)	E_rC50 (mg/L at 72 h)	(mg/L at 72 h)
> 100	> 100	> 100

Remarks - Results

Algae were exposed to the test substance at the nominal concentrations of 4.3, 9.4, 20.8, 45.5 and 100 mg/L for 72 h at 24˚C under constant illumination and shaking. Analysis of the test substance concentration (100 mg/L) after 72 h showed mean measured concentration of 97.3 mg/L. Neither the biomass nor the growth rate of *Scenedesmus subspicatus* were adversely affected by the test substance.

CONCLUSION

The ecotoxicity data indicates the notified chemical is practically non-toxic to daphnia.

TEST FACILITY

RCC Umweltchemie AG (1997o)

8.2.4. Inhibition of microbial activity

Not inhibitory to activated sludge as the toxicity control in the ready biodegradation test was greater than 35 % within 14 days.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The majority of the notified chemical will be incorporated into the matrix of the concrete. Once the concrete has solidified, the notified chemical is expected to pose minimal 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. Up to 1000 kg of notified chemical may be released to the environment annually via spills and waste cement/concrete. 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 new chemical will be used as an ingredient of concrete formulations, and most will eventually be incorporated into the matrix of the concrete and as such pose minimum risk to the environment. The compound is not readily biodegradable (11 % over 28 days), and has a low n-octanol/water partition coefficient of –2.3 and a high water solubility (> 1000 g/L), all indicating that any material released would eventually partition to water. However, given the cationic nature of the notified chemical, it is expected to rapidly associate with soil and sediments.

9.1.2. Environment – effects assessment

The notified chemical is practically non-toxic to fish, daphnia and algae. In addition, bioaccumulation is not expected as the high water solubility of the notified chemical suggests that it is unlikely to cross biological membranes (Connell, 1990).

9.1.3. Environment – risk characterisation

The new chemical will pose little risk to the environment once incorporated in set concrete. The notified chemical is practically non-toxic to aquatic organism and there will be limited aquatic exposure, with much less than 1 % likely to reach waterways.

The above considerations indicate minimal hazard to the environment when the notified chemical is used as a component of cement in the manner and at the levels indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

During manufacture of the cement additives containing the notified chemical, and during addition of the additives to the cement production process, there may be dermal contact with the notified chemical at up to 31 % in solution. There may be dermal or inhalation exposure to cement dust containing < 0.02 % notified chemical during handling of the cement containing the notified chemical. Wet concrete will contain < 0.002 % notified chemical, and protective equipment worn to prevent exposure to the concrete will prevent significant exposure to the notified chemical.

Workers handling cement additives, cement, or concrete containing additives at the notifier's site will wear safety glasses, impervious gloves and rubber boots. For workers handling the cement powder, an exposure standard of 10 mg/m^3 for dusts in general will apply (NOHSC, 1995), and inhalation exposure to the notified chemical is therefore expected to be negligible. Dermal exposure is also expected to be low as protective equipment will be used to prevent exposure to the irritant effects of the cement.

9.2.2. Public health – exposure assessment

Public exposure to the notified chemical will arise from dermal contact with finished concrete structures containing < 0.002 % of the notified chemical, and from dermal, inhalation, ocular and possibly oral exposure from the mixing and use of ready-mix cement preparations containing the notified chemical. There is expected to be no migration of the notified chemical from the concrete matrix in finished structures.

9.2.3. Human health - effects assessment

The notified chemical is of low acute oral toxicity in rats; a limit test was conducted at 7500 mg/kg bw with five out of 10 animals dying; no signs of toxicity were seen in the surviving animals at the end of the observation period. It was of low acute dermal toxicity in rabbits. It is not irritating to rabbit skin, and is a minimal irritant to rabbit eyes. It was found to be non-sensitising to guinea pig skin in a non-adjuvant test. The MSDS for the notified chemical indicates that it has also been tested at 75 % in an adjuvant test with similarly negative results. No results for acute inhalation toxicity of the notified chemical were presented.

In a repeat dose study, minor adaptive changes in clinical biochemistry and a difference in urine pH were observed at 1000 mg/kg bw/day. No organ changes indicative of systemic toxicity were observed, and a NOEL of 200 mg/kg bw/day was established.

The notified chemical was found to be non-genotoxic in a bacterial reverse mutation test and a mammalian cell chromosome aberration test, and this is supported by published data showing a lack of genotoxicity for the parent amine.

Developmental toxicity testing was performed on the notified chemical, and effects on maternal health (clinical observations and body weights) and foetal health (delayed skeletal ossification) were seen at 1000 mg/kg bw/day. A NOEL of 500 mg/kg bw/day was established in this study.

The notifier stated that there is no evidence concerning adverse effects in humans exposed to the notified chemical.

A number of published sources of toxicological data for the parent amine and for an analogue of the parent amine indicated that the long term health effects of the notified chemical are not expected to be highly injurious, although the analogue showed some indications of carcinogenicity at high dose levels in rats and mice.

Based on the data supplied by the notifier, the notified chemical would not be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical has low hazard, and will be used in occupational settings where little exposure is expected. Cement additives will contain the notified chemical in concentrated (up to

31 %) aqueous solution. Dermal exposure to the additives will be reduced by the use of personal protective equipment including overalls, safety glasses, goggles or face shield, PVC or rubber gloves and boots, and use of adequate ventilation, including local exhaust ventilation. For workers handling cement powder and concrete, the risk due to the notified chemical will be low due to the low concentrations of notified chemical and the low hazard it poses; also protective measures taken to prevent exposure to the cement or concrete will reduce exposure to the notified chemical to negligible levels.

After the concrete containing the notified chemical has hardened, the notified chemical will not be available for exposure.

9.2.5. Public health – risk characterisation

Negligible public exposure is expected from contact with hardened concrete containing the notified chemical. The notified chemical is likely to only be available for public exposure through handling of ready mix cement preparations. The notified chemical is of low toxicity and is present at < 0.02 % in ready-mix cement preparations, consequently the hazard from public exposure to the notified chemical throughout all phases of its life-cycle is considered to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

10.2. Environmental risk assessment

On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used as a cement additive under the conditions described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical and a product containing the chemical (CBA 1115) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical and a product containing the chemical (CBA 1115) provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in cement additives:
  - overalls, safety glasses, goggles or face shield, PVC or rubber gloves and boots

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of into landfill.

Emergency procedures

Spills/release of the notified chemical should be contained as described in the MSDS (ie. Contain with absorbent material and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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