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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Ancamine 2168

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Facsimile:	(61) (02) 9577 9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Ancamine 2168

1. APPLICANT

Anchor Chemical Australia Pty Ltd of 2/20 Hunter Street PARRAMATTA NSW 2124 has submitted a standard notification statement in support of their application for an assessment certificate for Ancamine 2168.

2. IDENTITY OF THE CHEMICAL

Trade Name:	Ancamine 2168 (containing > 90% notified chemical)
Method of Detection and Determination:	the notified chemical was identified by infrared (IR) spectroscopy and gas chromatography

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	brown liquid with amine-like odour
Boiling Point:	> 225°C
Specific Gravity:	1.01
Vapour Pressure:	1.3×10^{-3} kPa at 25°C
Water Solubility:	< 100 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	log P_{ow} = 2.68 at 21°C and pH 12.5 (shake flask method)
Hydrolysis as a Function of pH:	stable (see comments below)

Adsorption/Desorption:	K_{oc}=831-16 007 (see comments below)
Dissociation Constant:	K_a=2.19 x 10^{-11}
Flash Point:	> 205°C
Flammability Limits:	combustible; very low vapour pressure
Autoignition Temperature:	not determined
Explosive Properties:	stable
Reactivity/Stability:	stable under normal conditions

Comments on Physico-Chemical Properties

The notifier claims that the water solubility is less than 100 mg/L. However, the partition coefficient calculated the aqueous phase concentration more precisely as 4.51 to 5.04 mg/L.

Hydrolysis testing determined the pH 7 and 9 half-lives to be greater than one year at 25°C and the pH 4 half-life to be 81.2 days. This is as expected as the chemical does not contain any groups likely to be hydrolysable in the environmental pH range.

The partition coefficient (mean value) was determined by the shake flask method, with the aqueous phase concentrations ranging from 4.5081-5.0391 mg/L (with pH values of 12.11-12.48) and the organic phase concentrations ranging from 2249.2 to 2281.4 mg/L.

The notified chemical, mixed with methanol, was introduced to the HPLC column in 20 µL injections. Calculations using the retention times resulted in log Ks (log P_{OW}) in the range -0.03382 to 1.1267. These are lower than the value of 2.68 determined by the shake flask method. The log Ks were used to determine its log K_{OC}, according to the regression equation Log K_{OC} = (log K - I)/S, where I the intercept and S is slope, were derived from linear regression of the reference compound (a thiourea solution). The subsequent log K_{OC} values were 2.9194, 4.0169, 4.0145 and 4.2043, giving K_{OC} values of 830.52, 10 397, 12 720 and 16 007, respectively. Based on these results, the notified chemical can be expected to be generally immobile in soils (1).

The value supplied for the dissociation constant was not supported by a test method or report. It is claimed to be based on structure-activity relationships. The K_a value is identical to that for cyclohexylamine in an aqueous solution (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Toxic or Hazardous Impurities:

Chemical name:	Cyclohexanamine,4,4'-methylenebis-
Synonyms:	PACM
CAS No.:	1761-71-3
Weight percentage:	< 3%
Toxic properties:	oral LD_{50}=625 mg/kg (rat) dermal LD_{50}=2110 mg/kg (rabbit) severe eye irritant (rabbits) severe skin irritant (rabbits)

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported and used in epoxy resin formulations. Applications for epoxy systems containing the chemical include industrial flooring, chemically resistant tank linings (where the tank walls require protection from corrosive material) and mortars. The epoxy coating containing the notified chemical will also be applied to steel structures exposed to corrosive environments such as marine piers and boat hulls. The epoxy resin formulation is made up of two parts. One part, the hardner, contains the notified chemical at 50 to 95%. Prior to use it is mixed with the second part, resulting in an overall notified chemical level of 20 to 40%.

It is estimated that more than one tonne per annum of the notified chemical will be imported in the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported in 205 L steel drums and transported from the docks by road to the notifier's warehouse. At the warehouse the drums will be stored until transported to customer sites. The product containing the notified chemical is expected to be sold to about 10 customers, but initially a single customer will incorporate the notified chemical into epoxy industrial coating formulations. About 10 to 20 workers (waterside workers, drivers and warehouse workers) will be involved in transport and handling of the notified chemical from the wharf to the warehouse and another 10 to 15 workers from the warehouse to customer sites. As no repackaging or formulation will be carried out by these

workers, exposure to the notified chemical is not expected except, in the event of a spill.

Formulation
At the notifier's site, four process operators will transfer the notified chemical from the 205 L drums into enclosed stirred formulating tanks via drum pumps. Other ingredients required to formulate the paint product will be added at this stage. The final paint product is drained from the formulating vessel and packaged into 2 L pails or 250 L drums. The notifier states that the formulation process is of short duration but has not stated the time or frequency of handling. Workers connecting and disconnecting hoses and pumps may receive skin and eye exposure from drips and splashes. Inhalation exposure to the notified chemical is expected to be minimal, as the notified chemical is not volatile and the system enclosed. The notifier states workers are required to wear appropriate eye protection, gloves, safety boots and overalls.

End use
The coating mixture is prepared by emptying 2 L pails of hardener (containing the notified chemical) into a mixing station, adding other components and stirring. This is most likely via an open mixing process. The final paint mixture may contain between 20 to 40% of the notified substance and this may be carried in the original hardener pails, to the spray applicator. The notifier states that there may be 100 to 200 professional spray applicators apply the coating mixture to steel surfaces by pumping the mixture from a pail to a spray gun. The paint normally cures in about 3 hours. The notifier has not described this process, but it is highly likely that substantial dermal exposure will occur. Considerable quantities of coating mix will be lost as a result of overspray during spray applications, notifier's estimate being 10 to 15%. However, as the majority of application will occur outdoors, overspray will be captured in protective sheets. The notifier estimates that approximately 80% of the overspray will be captured by this technique and up to 20% may escape into the surrounding environment. Dermal and ocular exposure to the notified chemical during the spray application is expected. At these sites applictors will be attired with suitable personal protective equipment, including gloves and overalls.

7. PUBLIC EXPOSURE

There will be negligible public exposure from transport, storage, epoxy formulation and disposal. Exposure to the notified chemical during transport and handling would occur only in the event of an accidental spill. Spills may generate carbon monoxide, toxic oxides of nitrogen, ammonia and toxic, irritating or flammable combustion products if ignited. Containment include reution of vapour with water spray, extinguishing and/or removal of ignition sources and dyke construction to prevent speading. If recovery is unfeasible, spillage should be mixed with dry soil, sand or non-reactive absorbent (eg. Sodium bisulphate) and disposed according to local and national requirements. Clean-up personnel must wear self-contained breathing apparatus and butyl rubber protective clothing.

Exposure to the chemical will be limited to workers involved in the formulation and application of coating in their uncured state. The notifier estimates 20% of the spray paint to

escape to the surrounding environment. The paint normally cures in approximately 3 hours, during which time poly(methylenecyclo-hexanamine) is fully reacted into a polymer, contained within a coating, which limits its public and environmental exposure in its end-use state.

8. ENVIRONMENTAL EXPOSURE

Release

Emptied chemical drums may be rinsed with other ingredients being added to the paint. However, estimates by the notifier quote drum residues as approximately 0.5 kg. Drums will typically be reconditioned or recycled.

The new product will be applied to steel structures by spray applicators. In some instances, the hardener pails are used as containers for transporting and delivering the paint to the spray applicator. Otherwise, hardener containers are rinsed with solvent before being disposed of to landfill. Typically, approximately 0.5% of paint would remain unused in any application pail disposed of to landfill.

When applied to marine structures, floating boom devices will be employed to capture overspray. However, up to 20% of the overspray could escape and potentially enter aquatic environments.

Fate

Material disposed of to landfill will be incorporated in a solid polymer matrix where it will be immobilised. A similar fate is predicted for the cured material associated with the articles to which it is applied.

Any uncured material released as a result of accidents is likely to become associated with soil/sediment and be slowly broken down by natural biological and abiotic processes. Similarly, it is likely that any particles of cured material, e.g. from abraded dust, etc., released into stormwater or sewage systems would deposit onto sediments, and be slowly destroyed through these processes.

No data on biodegradation specific to the notified chemical accompanied the notification. The results of the hydrolysis study suggest that the notified chemical is resistant to hydrolysis. The notifier claims that a biodegradation study on methylenedianiline (MDA) reports that it does not degrade. MDA is the starting material for the notified chemical and shares some structural similarity. As a result, they further claim that the notified chemical would not be expected to exhibit significant biodegradation based on this structural similarity. However, aliphatic monocyclic compounds, in particular cyclohexylamine, are understood to be easily degradable (3).

Whilst it is unclear how biodegradable the notified chemical is, most organic material is eventually degraded through the agency of biological and abiotic processes. It could be expected that the notified chemical would be degraded in an aerobic environment to water, and

oxides of carbon and nitrogen.

The log P_{OW} of the notified chemical was determined to be 2.68, indicating that this chemical has potentially to bioaccumulate (4) indicates that chemicals with a log P_{OW} < 2 should not bioaccumulate. However, this log P_{OW} is a mean value determined by the shake flask method, with the partition coefficient determined by the HPLC method (in the adsorption/desorption test) to be in the range -0.033820 to 1.1267.

The notifier argues that the potential for bioaccumulation is very low. The notified chemical is a mixture of amines, containing both cycloaliphatic and aromatic amine functionality. Firstly, it is claimed that there are no examples of amine-compounds which have been confirmed to bioaccumulate on a high level. Secondly, many amines, especially the lower aliphatic amines and cycloaliphatic amines, biodegrade. Thirdly, the bioaccumulation factors (BCF) for amines which do not degrade are typically less than 100, with some exceptions that contain chlorine (which would result in an elevated log P_{OW}). The notified chemical does not contain chlorine.

In support, the notifier presents examples where molecules with structural similarities have low BCF values, for example. an -NH_2 group bonded to an aromatic ring and an -OH group bonded to a cyclohexyl group.

In summary, the notifier claims that many amine-containing chemical compounds with log P_{OW} values less than 3 and structurally similar to the components of the notified chemical have been shown not to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Ancamine 2168

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	Rat	LD_{50} = 367 mg/kg	(5)
acute dermal toxicity	Rat	LD_{50} >1 000 mg/kg	(7)
skin irritation	Rabbit	corrosive to skin	(7)
eye irritation	Rabbit	study not done	-
skin sensitisation	Guinea pig	study not done	-

9.1.1 Oral Toxicity (5)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	preliminary study: 5/sex main study: 5 males in low and high dose groups 5 females in mid dose group
Observation period:	15 days
Method of administration:	preliminary study: 400 mg/kg administered by gavage; vehicle was 50% (v/v) polyethylene glycol 300 (PEG 300). In the preliminary study males were slightly more sensitive to the test substance than females. Accordingly males were used in the main study to obtain a dose response curve and calculate the median lethal dose. main study: 0, 126 and 800 mg/kg administered by gavage; vehicle was 50% (v/v) PEG 300.
Mortality (combined results from preliminary study and main study):	3 males and 2 males at 400 mg/kg and all males at 800 mg/kg; death occurred between 30 minutes to 2 hours of dosing
Clinical observations:	piloerection and pallor of the extremities were observed within 5 minutes of dosing in all rats at all doses including controls; abnormal gait and increased salivation were observed in rats dosed at 400 and 800 mg/kg; lethargy, decreased respiratory rate, partially closed eyelids, gasping, walking on toes, unsteadiness, body tremors, bluish colour to skin/extremites, cold body surfaces and prostration were observed in rats dosed at 400 mg/kg; all surviving rats recovered by day 4
Morphological findings:	decedents-males and females dosed at 400 mg/kg: congestion (characterised by darkened tissue) in the heart, liver, spleen and kidneys; congestion, fluid contents, thickening and congestion of blood vessels in the stomach; congestion (defined by gaseous distension, fluid contents and prominent blood vessels) along the alimentary tract, with red fluid contents; congested blood vessels in the brain;

	animals euthanised at day 15 – no abnormalities detected.
Test Method:	similar to OECD guidelines (6)
LD_{50}:	367 (range: 250 to 540) mg/kg
Result:	the notified chemical was of moderate acute oral toxicity in rats

9.1.2 Dermal Toxicity (7)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	1 000 mg/kg of test material dissolved in tetrahydrofuran was applied to an area of clipped intact skin site; the site was covered with semi-occlusive dressing; after 24 hours the dressing and residual test material were removed
Mortality:	one female was found dead on day 8
Clinical observations:	males: necrotic skin and severe oedema were noted after 24 hours and throughout the 14 day observation period; females: peeling skin was noted in one animal on days 13 and 14
Morphological findings:	males: damage to the muscle under the test site was noted in 3/5 animals and damage to the muscle under the test site and increased vascularisation of the underlining muscle was noted in 1/5 animals; females: damage to the muscle under the test site was noted in 2/5 animals; signs of coccidiosis (protozoan infection; causes destruction of the intestinal mucosa), gas in the stomach, fluid in the intestinal tract and hemorrhaging in thelarge intestine and caecum were noted in 1/5 animals. It is not clear in the study report if the gastrointestinal effects seen in this rat are solely

	due to the protozoan infection
Test method:	40 CFR Part 158, series 81-2 (8) (procedure similar to OECD guidelines)
LD_{50}:	> 1 000 mg/kg
Result:	the notified chemical was of moderate acute dermal toxicity in rabbits; the notified chemical was corrosive to rabbit skin

9.1.3 Inhalation Toxicity

No inhalation studies were conducted for the notified chemical.

9.1.4 Skin and Eye Irritation and Skin Sensitisation

Based on the findings of the acute dermal toxicity study the notified chemical is considered corrosive to rabbit skin. Therefore, consistent with animal welfare considerations and OECD test guideline recommendations on corrosive substances, skin sensitisation and skin and eye irritation studies have not been conducted. The notifier states that one of the low molecular weight species of the notified chemical is reported to be a skin sensitiser.

9.2 28 Day-Repeated Dose Toxicity (9)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex: control, distilled water; 10/sex: vehicle control, PEG; 5/sex: low and mid dose animals; 10/sex: high dose animals;
Method of administration:	gavage; 10 mL/kg/day in 50% (v/v) aqueous PEG 300
Dose/Study duration::	test material administered daily for 28 consecutive days: Control water (group 1) 0 mg/kg/day Control PEG 300 (group 2) 0 mg/kg/day Low dose 15 mg/kg/day Mid dose 150 mg/kg/day High dose 300 mg/kg/day all animals were sacrificed at the end of the treatment period, with the exception of 16 animals from the control and high dose groups, which were

	maintained for an additional 2 week recovery period before sacrifice
Mortality:	three male and two female rats from the high dose group died during treatment; clinical signs and macroscopic findings were similar to those recorded for high dose group rats (see Clinical Observations below)
Clinical observations:	treatment phase: high dose - clinical signs included hunched posture, paddling of forepaws, unsteady gait, thin appearance, lethargy, soft faeces, wet urogenital region, distended stomach, partially closed eyes, noisy respiration and ungroomed appearance; body weight gain was markedly reduced mid and high doses – most animals demonstrated increased salivation and associated wet fur, occasionally accompanied by red/brown staining; low dose – intermittent cases of increased salivation; food and water consumption were unremarkable across all treated groups recovery phase: ungroomed appearance persisted in all rats from the high dose group for five days into the recovery period; subsequently hair loss was the only clinical sign noted
Clinical chemistry/Haematology:	the following statistically significant changes were recorded at the end of the treatment period: high dose group- increased glutamic-pyruvic transaminase (GPT) increased urea and triglycerides and low cholesterol (females) and glutamic-oxaloacetic transaminase (GOT); increased GOT and triglycerides levels mid dose group females no significant treatment related changes were observed in haematological parameters
Urinalysis:	lower urinary volumes were recorded for the high dose group, higher specific gravity was recorded for high and mid dose males at the end of the treatment period; higher urinary protein was recorded for female rats

Macroscopic pathology:	treatment phase: pale and mottled kidneys, minimal adipose tissue were noted in the majority of high dose group rats and watery contents of the small intestines were observed in high dose animals; Recovery phase: pale kidneys were noted in one high dose female
Histopathology treatment related findings:	treatment phase: kidney- vacuolation of the cortical tubular epithelium in high and mid-dose males and females; basophilia and vacuolation of the cortical tubular epithelium and eosinophilic casts of cortical tubules in high dose males; tubular dilation in mid and high dose males; adrenal- diffuse cortical hypertrophy in high dose males and females; liver- centrilobular hepatomegaly (hypertrophy) in mid and high dose males; spleen- occasional lymphocytolysis observed in mid and high dose males recovery phase: kidney-vacuolation of the cortical tubular epithelium in both sexes and basophilia and tubular dilation in males; adrenal- diffuse cortical hypertrophy in both sexes; liver- centrilobular hypertrophy in males; spleen- lymphocytolysis in males
Organ Weights:	treatment phase: increased liver weights in high and mid dose males; increased adrenal weights in high dose males and females; increased kidney weights in both sexes of mid and high dose groups recovery phase; high adrenal weights in high dose males
Other findings:	group 2 control animals receiving PEG 300 (vehicle), in comparison to group 1 control animals receiving distilled water, exhibited lower bodyweight gains for females, higher water consumption for males, higher urinary specific gravity in males and females, lower urinary volume in females and lower urinary pH in males; all other differences from vehicle control rats in comparison to distilled water controls were considered incidental; these findings were not considered to have affected the evaluation of findings related to treatment with the test substance

Test method:	similar to OECD guidelines (6)
Result:	treatment related effects were observed in the kidneys, adrenals, liver and spleen at mid and high doses; target organs for toxicity at the high dose level were the kidney, liver and adrenals; There was no evidence of recovery following the two week recovery period; the treatment related effects seen at high and mid doses, in particular in the kidney, were considered to be severe and irreversible during this period; a no-observed-effect-level (NOEL) of 15 mg/kg/day dosage, was established.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (10)

Strains:	*Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* WP2*uvrA*
Concentration range:	78 – 5 000 µg/plate
Test method:	similar to OECD test guidelines (6)
Result:	the notified chemical was not considered to be mutagenic in bacterial strains tested, in the absence or presence of metabolic activation by rat liver S9 fraction

9.3.2 Analysis of Metaphase Chromosomes from Chinese Hamster Lung Cells (11)

Cells/strain:	Chinese hamster lung (CHL) cells, strain JCRB0030
Concentration:	three concentration ranges: 1.25 – 5 µg/mL 5 – 20 µg/mL 10 – 40 µg/mL
Test method:	according to OECD guidelines (6)
Comment:	there was an increase in the proportion of polyploid cells in two concentration ranges; at 10 – 40 µg/mL with metabolic activa`tion, the increase was within the historical control range; 5 – 20

	µg/mL without metabolic activation, the increase was considered to be treatment related
Result:	the notified chemical was not considered to be clastogenic in CHL cells in the presence or absence of metabolic activation by rat liver S9 fraction; the notified chemical exhibited polyploidy inducing activity in the absence of metabolic activation and to a lesser extent with metabolic activation

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited moderate acute oral toxicity (LD_{50} = 367 mg/kg) and moderate dermal toxicity (LD_{50} >1 000 mg/kg) in rats and rabbits, respectively. The notified chemical was corrosive to rabbit skin in the acute dermal toxicity test. Based on these findings further irritation and justification studies were not carried out and the notified chemical is considered to be corrosive to skin and eye. Because of its corrosive properties the notified chemical was not tested for skin sensitisation potential, but it is considered as a sensitiser because the notifier states that one of the low molecular weight species of the notified chemical is a skin sensitising agent.

In a 28-day repeat oral dose study in rats, five animals died during treatment at the highest dose of 300 mg/kg. Target organs for toxicity were the kidney, adrenals and liver. Treatment related effects seen at the mid (150 mg/kg) and high dose levels were considered severe and were considered irreversible for the high dose group over a two-week recovery period.

The notified chemical was not found to be mutagenic in a bacterial reverse mutation assay. The notified chemical did not show evidence of clastogenic activity in an *in vitro* cytogenic test system. However polypoidy-inducing activity was demonstrated with or without metabolic activation. No *in vivo* genotoxic studies were performed.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (12), the notified chemical would be classified as hazardous on the basis of acute oral and dermal toxicity (R21/22), severe effects in liver, kidney and adrenals after repeated oral exposure (R48/22), and corrosive properties, namely causes burns (R34). It may also warrant R43, may cause sensitisation by skin contact.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided for the notified chemical. A variation was sought, on the basis of the degree of exposure to the aquatic environment of the notified chemical. Generally, environmental exposure will be limited to the cured epoxy paint system.

However, the notifier provided the results of structure activity relationships (SAR), estimated by techniques described by (13), which base aquatic toxicity on the water octanol partition coefficient (log P_{OW}) of a chemical.

This technique requires selection of a chemical class for which a SAR has been determined to represent the chemical of interest. The notified chemical consists of a mixture of chemical species, primarily cyclohexylamino functionality. Aromatic amine functionality is also present. This led the notifier to select the SAR class of *Amines, aliphatic* for the notified chemical. The results of an estimate based on the SAR class *Anilines* was included for comparison.

SAR Model: Aliphatic Amines

Fish	Log 96 hr LC_{50} mM/L = 0.72 to 0.64(log P_{OW})
Daphnid	Log 48 hr LC_{50} mM/L = -0.524 to 0.584(log P_{OW})
Algae	Log 96 hr LC_{50} mM/L = -0.548 to 0.434(log P_{OW})

SAR Model: Anilines

Fish	Log 96 hr LC_{50} mM/L = 0.956 to 0.739(log P_{OW})
Daphnid	Log 48 hr LC_{50} mM/L = -1.623 to 0.271(log P_{OW})
Algae	not reported

LC_{50} Estimates based on SAR Models for log P_{OW} of 2.68

	Aliphatic Amine SAR Model		Aniline SAR Model	
Species	Log LC_{50} (mM/L)	LC_{50} (mg/L)	Log LC_{50} (mML)	LC_{50} (mg/L)
Fish (96 h)	-0.995	33.9	-1.025	31.7
Daphnid (48 h)	-2.089	2.7	-2.349	1.5
Algae (96 h)	-1.711	6.5	—	—

For comparison, *Environment Australia* calculated the LC_{50}s, based on the supplied SAR models (13), for the log P_{OW}s in the range -0.033820 to 1.1267, as determined by HPLC. These calculations indicate that the toxicity of the notified chemical decreases with decreasing log P_{OW}.

The SAR results for both aliphatic amines and aniline are generally in agreement. They seem to indicate that the chemical is expected to be non-toxic to fish up to the level of its water solubility (5.04 mg/L). It can be expected that the chemical is moderately to highly toxic to daphnids. However, the toxicity to algae is unclear as the estimated LC_{50} is only just higher than the water solubility. Therefore, the notified chemical should be classed as moderately toxic in the absence of further data.

The US EPA notes that aliphatic amines can be highly toxic to all groups of freshwater organisms, that is fish, aquatic invertebrates and green algae. However, toxicity is related to the length of the hydrophobic carbon chain: the longer the chain (or greater the number of carbons), the more toxic to aquatic organisms when the number of amines is constant; and the greater the number of amines, the greater the toxicity given a constant carbon chain length. Small aliphatic amines are more toxic to algae than to fish and invertebrates; higher molecular weight amines are equally toxic to all aquatic organisms (14).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Although the material may be (at worst) highly toxic to aquatic organisms if released into the environment in the uncross-linked state, this is likely only in the case of a serious accident. Most release will be as an epoxy resin as part of a semi-solid, highly cross-linked mass that should immobilise the notified chemical.

Considerable loss of the coating mix will occur as a result of overspray during application. This is estimated at 10-15%, and consequently 15 tonnes (15% of 100 tonnes) of the notified chemical will be lost per year at maximum import rates. However, the majority (80%) is expected to be captured in protective sheets, allowing the coating to cure into a polymeric mass with disposal to landfill. The remaining 20% (or 3 tonnes) will be lost and is expected to be deposited onto the factory floor or surrounding soil. The paint should cross-link into a water insoluble mass that should partition to soil and remain immobile.

Some material will also be used in coatings for marine structures. The notifier indicates that when applying the coating to marine structures, floating boom devices are employed to collect the lost material (overspray). However, it is anticipated that only 80% of the overspray is captured. A large project that may require application of 2 500 L of epoxy coating (containing 40% of the new chemical) and assuming 20% loss, approximately 30 kg of the new chemical could potentially be released into the marine environment.

A worst case scenario calculated for 30 kg of the notified chemical released into a **static** body of water, assuming that the marine structures (e.g. wharf piers) are surrounded by a 10 megalitre (i.e. 10 m x10 m x100 m), results in a Predicted Environmental Concentration of 3 mg/L. This identifies a potential toxicity concern for daphnids. However, the volume of water into which the chemical would be released is likely to be undergoing continuous dilution through the agency of tides and other dynamic processes. It should also be appreciated that even if released shortly after preparation of the coating mix, it is likely that a good deal of crosslinking of the components of the notified chemical to the major resin component will have taken place. The notifier has also indicated that the coating will continue to cure under the water. This should decrease the solubility and mobility of the amines, and consequently decrease the intrinsic toxicity.

The environmental hazard from the notified chemical is expected to be low when it is handled and used in the indicated manner. However, operators of spraying equipment should be aware of the toxicity of the material to aquatic organisms, and take all precautions to minimise release to the water compartment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical has certain physio-chemical characteristics that may promote dermal absorpion or irritation. Firstly, it has a molecular weight of less than 500 low enough to facilitate transmission across biological membranes. It also has low water solubility and moderately high log partition coefficient indicating high affinity for lipids

The notified chemical has moderate acute toxicity via the oral and dermal routes. It is predicted to be corrosive to skin and eyes. Oral administration of the notified chemical for 28 days resulted in liver, kidney and adrenal gland toxicity. No inhalation studies were conducted on the notified chemical. The notified chemical is not likely to be genotoxic. Based on the toxicological data provided the notified chemical would be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (12) and warrant risk phrases. The notifier states that the product containing the notified chemical also contains an ingredient which is a skin sensitiser.

Occupational Health and Safety

Exposure of transport and storehouse workers to the notified chemical is not likely to occur except in the event of a spill. The occupational health and safety risk posed to these workers while the drums remain intact is low. Specialised procedures and equipment would be needed to clean up spills as indicated in the Material Safety Data Sheet (MSDS).

During formulation of the product containing the notified chemical splashes and spills are likely to occur as hoses are connected/ disconnected and drums are filled. During these activities eye and dermal contact are expected to be the main routes of exposure to the notified chemical. The notifier's MSDS stresses the corrosive nature of the chemical. It recommends the use of chemical goggles and gloves (neoprine rubber, impervious, cuffed butyl rubber and nitrile rubber gloves), clothing and footwear during formulation which will serve to control the risk of adverse health effects from dermal and eye contact with the notified chemical. Formulation occurs predominantly within closed systems. This prevents the build up of chemical vapour in the workplace air. The notified chemical is not used as an aerosol or mist and has a low vapour pressure. Consequently, there is little chance for inhalation exposure and the risk of adverse effects on the respiratory tract is expected to be low.

There is exposure to the notified chemical during mixing of the paint products containing the notified chemical with other components and during spray applications. At these two exposure sources the notifier has not indicated that there will be any engineering controls in place. Therefore, the use of adequate eye and skin protection (see Recommendations)) will be required. These workers also need to observe the glove types listed in the MSDS. Since there is also the possibility of inhalation of spray mist, use of suitable respiratory protection during spray application is recommended.

Public Health
No significant public exposure to the notified chemical as a formulated hardner is anticipted during transport, storage or reformulation/mixing. Dermal contact will occur once the notified chemical is in a reacted cured polymer state. This incorporation within a paint coating will preclude its bioavailability and therefore public exposure will be negligible. Based on the use pattern of poly (methylenecyclohexanamine), it is considered that the notified chemical will not pose a significant hazard to public health.

13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (15) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (16);
- Industrial clothing should conform to the specifications detailed in AS 2919 (17) and AS 3765.1 (18);
- During spray applications respiratory protection should be selected and worn in accordance with (AS/NZS) 1715 (19) to comply with (AS/NZS) 1716 (20).
- Impermeable gloves or mittens should conform to AS 2161 (21);
- All occupational footwear should conform to AS/NZS 2210 (22);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then 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. It specifies specific glove types for handling of Ancamine 2168.

The notified chemical is potentially highly toxic to certain aquatic organisms. Operators of spraying equipment should be aware of the toxicity of the material and take all precautions to minimise release to the water compartment.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the product containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (23).

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 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise and if the method of use change in such a manner as to greatly increase the environmental exposure of the notified chemical, or if additional information becomes available on adverse environmental effects.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe