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October 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

AM2

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

AM2

1. APPLICANT

Ausmelt Ltd of 12 Kitchen Road Dandenong VIC 3175 (ABN 72 005 884 355), Clariant (Australia) Pty Ltd of 100 Heales Road Lara VIC 3212 (ABN 30 069 435 552) and Megachem Pty Ltd of 49 Nicholas Drive Dandenong South VIC 3175 (ACN 007 076 477) have submitted a limited notification statement in support of their application for an assessment certificate for AM2.

2. IDENTITY OF THE CHEMICAL

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

3. PHYSICAL AND CHEMICAL PROPERTIES

The physico-chemical properties tabulated below are for the notified chemical unless otherwise stated.

Appearance at 20°C & 101.3 kPa:	White paste
Melting Point:	>90°C (with some decomposition)
Density:	>1 g/cm^3
Vapour Pressure:	Not determined. The notified chemical is likely to have low vapour pressure considering its high molecular weight.
Water Solubility:	Not determined. The notifier indicates the notified chemical is completely soluble in neutral to alkaline solution. Sparingly soluble in acidic solution.
Partition Co-efficient (n-octanol/water):	Not determined. The notified chemical has surfactant properties. Based on ACD calculations, the log P_{ow} for the free acid component is 2.3.
Hydrolysis as a Function of pH:	Not determined. Experimental data suggest that

	hydroxamic acids are susceptible to acid and base catalysed hydrolysis (Bauer et al, 1974). In the environmental pH range of 4 to 9, significant hydrolysis of the notified chemical is unlikely to occur.
Adsorption/Desorption:	Not determined. The notified chemical is expected to have low affinity for organic matter in soil. It is expected to adsorbed to soil and sediment due to its anionic nature and ion chelating ability.
Dissociation Constant:	Not determined. The notified chemical is expected to be dissociated in alkaline solution. Hydroxamic acids have pKas of approximately 9.
Flash Point:	Not determined. The notified chemical is not flammable.
Flammability Limits:	Not determined. The notified chemical is not flammable.
Autoignition Temperature:	Not determined. The notified chemical is not expected to undergo auto-ignition.
Explosive Properties:	Not determined. The notified chemical is not explosive.
Reactivity/Stability:	Not determined. The notified chemical forms strong complexes with oxidised transition metals almost instantaneously.

3.1 Comments on Physico-Chemical Properties

The notifier indicates that the notified chemical is completely soluble in neutral to alkaline solutions and sparingly soluble in acidic solutions. In fish and daphnia toxicity studies, the authors experienced difficulties preparing stock solutions of the notified polymer in water. This was from 10 mg/L (pH 7.5-7.9) in the fish study to less than 10 mg/L in synthetic softwater for the daphnia study. The literature indicates partitioning of 16:1 and 1:1 between water and carbon tetrachloride for hydroxamic acids of chain length similar to the notified chemical (Addison and Côté 1973).

4. PURITY OF THE CHEMICAL

Degree of Purity: >85%

Hazardous Impurities: none

Additives/Adjuvants:

Chemical name:	Water
CAS No.:	7732-18-5
Weight percentage:	Approximately 14%

5. USE, VOLUME AND FORMULATION

The notified chemical is a mineral processing reagent used during the processing of ores by flotation. This process involves addition of the reagent to aqueous slurries of crushed and finely ground ore contained in flotation tanks. During the use of the notified chemical in the flotation process, the mineral particles become separated as froth and float to the surface while the tailings settle at the bottom of the flotation tank.

The notified chemical, AM2, will be manufactured in Australia. The formulation containing >85% notified chemical will be transferred into 180 kg drums, ready for distribution to customers.

It is estimated that less than 3000 tonnes per year will be manufactured each year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Manufacture
AM2 is manufactured in a closed reaction vessel at approximately 50°C. All materials are weight and dispensed from the original packaging into the reaction vessel. After completion of the chemical reaction, the formulated product is pumped from the reaction vessel to the filtration and packaging area. Weighing, chemical transfer and mixing are carried out under local exhaust ventilation. Fumes are removed by a two stage caustic jet scrubber system prior to release to the atmosphere.

The number and category of workers potentially exposed to the notified chemical during manufacture are as follows:

Category of workers	*Exposure duration*	*Number of workers exposed*
Storemen/forklift operators/truckdrivers	1 hour/day; 50 days/year	3
Plant operators	6 hours/day; 100 days/year	7
QC/chemists/Laboratory staff	0.5 hour/day; 100 days/year	6
Maintenance personnel	<10 hours/year	2
Chemical engineer	Incidental	1
Production staff	Incidental	1

Plant operators may experience skin contamination to the notified chemical during transfer and filling drum processes, particularly if spillage occurs. These workers and maintenance personnel may also be exposed dermally to the notified chemical during cleaning and maintenance of plant equipment. Gloves, safety glasses, helmets, boots and overalls are worn during routine handling of the notified chemical.

Laboratory workers may experience skin contamination when sampling and testing the notified chemical. However, exposure is likely to be mainly from small quantities of the notified chemical.

Mineral Processing
At the customer site, AM2 will be quantitatively transferred from 180 kg drums to a storage tank using metered pumping equipment. The chemical may be transferred to a mixing tank for dilution prior to delivery to the flotation tanks. An automatically controlled ring main system will be used to regulate the flow, mix the reagents and deliver reagents into the addition points in the flotation circuits. The delivery process is completely automated. Plant operators will have intermittent dermal exposure to the notified chemical when connecting, disconnecting and cleaning the pumping equipment. Plant operators work in 12 hour shifts, 24 hours/day for 365 days/year. Plant operators will wear overalls, gloves and safety glasses or goggles.

Transport
Exposure to the notified chemical during transport of sealed drums should not result in exposure except in the event of accidental spillage.

7. PUBLIC EXPOSURE

Public exposure may occur in the event of a transport accident or flooding causing overflow of tailings dams or effluent systems. Following transport spillages the AM2 paste will be shovelled into labelled containers for reclamation. The dissemination of the paste form of the chemical will be readily contained and its entry into sewers, waterways or low-lying areas should be easily avoided. The notified chemical is not volatile and is unlikely to be inhaled. Exposure, if it occurs, is most likely to occur as dermal contact. In the case of flooding, the notified chemical may be spread from smashed storage drums or from tailings dams. It is likely to be diluted over the flood area. Drinking water contaminated in this way is likely to have only very low concentrations of AM2.

Since these events are infrequent and since the notified chemical is manufactured and used in well controlled (and in many cases remote) situations, the potential for public contact with the notified chemical is minimal.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notified chemical will be manufacture at one site in Victoria. All water borne effluent will be passed through a triple interceptor pit followed by treatment by Dissolved Air Flotation and pH neutralisation prior to release to the sewerage system. Up to 90 % of the notified chemical will be removed from the wastewater stream prior to release into the sewer and approximately 10 kg of the notified chemical will be released from the manufacturing facility per year.

At the mine site, the chemical functions as a flotation reagent, and approximately 98% remains bound to the mineral surfaces, and consequently become incorporated in the metal concentrates. These concentrates are smelted for recovery of the metal and the high temperature of the furnaces will destroy the compound, producing water vapour and oxides of carbon and nitrogen.

Some of the remaining reagent becomes attached to the surface of the gangue (waste) minerals, and these are deposited into the tailings dams. The notifier indicates that up to 2% of the notified chemical may be disposed of with the tailings. Based on use at 5 mine sites in Australia, this equates to approximately 30 tonnes of the notified chemical being released to tailings dams per annum.

The reagent disposed of with the tailings is not be expected to be released to the wider environment as tailings dams are designed to substantially reduce the potential for seepage.

8.2 Fate

Approximately 98% of the notified chemical will be exported with the metal concentrates and destroyed during smelting, with the production of water vapour and oxides of carbon and nitrogen.

Approximately 2% of the reagent will be disposed of into tailings dams. The notifier has supplied a full test report which confirms that the affinity of the flotation agent to oxidised base metal sulphides is such that the notified chemical will be present in tailings dam water in very low concentrations. The distribution of the notified chemical in a mineral flotation system was assessed on a sample of North Parkes oxidised copper/gold ore. The flotation agent was added to the ore slurry at a dosing rate of 100 g/tonne in a Denver Flotation Cell, giving an initial test concentration of 50 mg/L. Samples of the slurry were taken at 15 seconds and 2 and 19 minutes and of the float or concentrate at 5 and 7 minutes. These samples were filtered through a 0.7 μm glass fibre filter paper to remove solid material and the concentration of the flotation agent in the filtrate was determined by electrospray-mass spectrometry. The concentration of the notified chemical in the filtrate after 15 sec, 2 and 19

min is 3.5, 0.8 and 0.005 mg/L (ppm), respectively. The filtrate obtained from the float contained the notified chemical at a concentration of 0.4 and 0.3 mg/L (ppm), respectively. Therefore, after 19 minutes the concentration of unbound notified chemical has been reduced by 99.99%. The dosing rate used in this test was 10 times greater than the recommended dosing rate for mining operations. Therefore, the concentration of the notified chemical present in tailing dam water is expected to be at or below 0.5 μg/L (ppb). The notifier also supplied an earlier report for the distribution of the notified chemical in a mineral flotation system which relied on a colorimetric technique to determine the concentration of flotation agent in tailings water. No colouration was observed in any of the test samples. This technique was not suitable because it has a limit of detection in the ppm range which is at least an order of magnitude above the toxicity of the notified chemical to algae.

It is a characteristic of most sulphide metal mines that pyrite and other gangue metal sulphides will slowly oxidise when exposed to air with production of sulphuric acid and solutions of metal sulphates. Consequently, the water in the tailings dams becomes very acidic (pH 1-2). The acid or based catalysed hydrolysis of hydroxamates to carboxylic acid and hydroxylamine derivatives proceeds readily and the hydrolysis mechanism is said to resemble that of amides (Bauer and Exner 1974). Therefore, decomposition of the notified chemical in tailings dams as a result of hydrolysis is likely. In this case this would result in the formation of the alkyl acid and hydroxylamine derivatives. These products are further expected to slowly degrade to simpler compounds through chemical and physical processes.

In the case of accidental release, if discharged to waterways, the notified chemical would be likely to persist, hydrolysing only slowly. The studies of distribution in a mineral flotation systems described above indicate the notified chemical will be rapidly removed from the aquatic compartment through strong adsorption to soil and sediments. The physico-chemical data and the low molecular weight indicate that the notified chemical has the potential to bioaccumulate (Connell 1990). This is further supported by unpublished data that is claimed to show that a hydroxamic acid of similar chain length is accumulated from water by trout and distributed widely throughout their tissues (Darrow *et al.* 1978). However, exposure to natural waters is expected to be low.

The notifier indicates that up to 10 kg of the notified chemical may be released into the sewer from the manufacturing facility per year. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified chemical to very low concentration levels. Therefore, the environmental exposure and overall environmental hazard from the notified chemical is expected to be low.

9. EVALUATION OF TOXICOLOGICAL DATA

Test data on the notified chemical, AM2, are not available. In support for Variation to the Schedule Requirements, data on acute oral and dermal toxicity, repeat dose toxicity, genotoxicity, carcinogenicity and reproductive studies for caprylohydroxamic acid (CHA) were submitted by the notifier as read across data for the assessment of the potential acute and long term effects of the notified chemical. A BIBRA report for n-decanoic acid was also submitted, including acute toxicity, repeat dose toxicity, genotoxicity and reproductive study (BIBRA, 1996).

9.1 Acute Toxicity

Summary of the acute toxicity

Test	*Species*	*Outcome*
acute oral toxicity	Rat	10700 mg/kg[#]; >10 g/kg[*]
	Mouse	8820 mg/kg[#]
acute dermal toxicity	rabbit	> 5 g/kg[*]
skin irritation	human and rabbit	irritant[*]
eye irritation	rabbit	irritant[*]
skin sensitisation	human	non-sensitiser[*]

[#]caprylohydroxamic acid (CHA)
*n-decanoic acid

9.1.1 Oral Toxicity

Test Substance:	CHA
Species:	Rat and Mouse (unspecified strain, number and sex of animals)
LD_{50}:	10700 mg/kg in rat and 8820 mg/kg in mice (RTECS, 2000)
Comment:	Details of toxic effects were not reported.
Result:	CHA was of very low acute oral toxicity in rats

Test Substance:	n-decanoic acid
Species:	Rat (unspecified strain, number and sex of animals)
Clinical/Morphological observations:	At 10 g/kg/bw (the highest dose tested), discharge from eyes and nose, and some reduction of neuromuscular control and central nervous system depression were also observed. No gross abnormalities were seen in the lungs, kidneys, digestive tact and adrenal tissues examined.
LD_{50}:	>10 g/kg (BIBRA, 1996)
Result:	n-decanoic acid was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

Test substance:	n-decanoic acid
Species:	Rabbit (unspecified strain, number and sex of animals)
Method of administration:	Presumed 24-hour covered contact
LD_{50}:	>5 g/kg; 1.5 g/kg (mixed isomers) (BIBRA, 1996)
Result:	n-decanoic acid was of low dermal toxicity in rats

9.1.3 Inhalation Toxicity

Test substance: n-decanoic acid

Exposure to concentrated vapour (not further defined) of decanoic acid for 8 hours caused no death within 2 weeks in 6 rats of unspecified strain and sex (BIBRA, 1996).

9.1.4 Skin Irritation

Test substance: n-decanoic acid

A human patch test for the identification and classification of skin irritation potential was evaluated for the purpose of obtaining a more relevant assessment of chemical irritation potential by human skin irritation test. The test involved exposing 30 volunteers to 29 test materials including decanoic acid. An occlusive, 4 hour application of 0.2 mL (or 0.2 g for solids) test substance is applied on to a 25 mm Plain Hill Top Chamber containing a Webril pad (Hill Top patch system) at the upper outer arm of 30 volunteers. Test materials were applied progressively at 15 and 30 min, 1, 2, 3 and 4 hours. Decanoic acid caused skin irritation in >80% of the volunteers (York et al, 1996).

No irritant reactions were observed in 10 subjects treated with a 17.2% solution of decanoic acid in propanol for 24 hours (contact) and with 1% decanoic acid in petrolatum for 48 hours (covered) to unspecified number of subjects (BIBRA, 1996).

Daily applications of 8.6% decanoic acid in propanol for 24 hours (covered) to 10 subjects caused irritation with reddening in three subjects after 2 days and in 7 subjects after 8 days (BIBRA, 1996).

Contact with neat decanoic acid for 4-24 hours produced moderate to severe irritation to intact and abraded rabbit skin (BIBRA, 1996).

In repeated contact (uncovered) with the ears of rabbits for 5 days/week for 2 weeks, 10% decanoic acid in ethyl ether or acetone caused diffuse scaling (BIBRA, 1996).

Test substance: Sodium and potassium salts of decanoic acid

Contact with 0.5% solutions of the sodium and potassium salts of decanoic acid for 4 hours (covered) caused irritation in 3-40% of an unspecified number of volunteers. Similarly, contact (covered) with 0.25% aqueous sodium decanoate caused weak irritant reactions in 2/25 volunteers. Similar tests with 0.1% elicited no irritant responses (BIBRA, 1996).

Test substance: decanoic acid (mixed isomers)

Decanoic acid described as mixed isomers produced moderate irritation when applied neat to uncovered rabbit skin (BIBRA, 1996).

9.1.5 Eye Irritation

Test substance: n-decanoic acid

Instillation of 0.1 mL neat decanoic acid caused eye irritation in rabbits. Application of "an excess of" 1% decanoic acid mixed isomers in propylene glycol caused severe corneal damage in rabbits (BIBRA, 1996).

9.1.6 Skin Sensitisation

Test substance:	n-decanoic acid
Species:	human
Number of subjects:	28 volunteers
Induction procedure:	Induction phase of five consecutive 48 hour covered patch test of 1% decanoic acid in petrolatum, sometimes separated by 24 hour periods of treatment with a mild irritant.
Challenge procedure:	After 10-14 days, the same concentration of test material is used for a 48 hour closed patch test
Result:	No skin sensitisation was induced in volunteers treated with a dilute solution (BIBRA, 1998).

9.2 13-week Repeat Dose Toxicity

Test substance:	10% CHA (Taselin) (Sugiyama, 1974)
Species/strain:	Rat/Wistar
Number/sex of animals:	10/sex
Method of administration:	Oral (gavage)
Dose/Study duration:	
Test Group	Control: 0 mg/kg/day Low dose: 100 mg/kg/day

Mid dose: 500 mg/kg/day
High dose: 2500 mg/kg/day

(vehicle: gum arabic)

Test method: Similar to OECD TG 407

Clinical observations:
Two of the females in mid-dose groups died due to technical error in dose administration.

No abnormal clinical signs manifested from treated animals, except for activity in behaviour seen in high dose group.

Haematology:
Increase in the leucocyte count and significant decreases in erythrocyte, haematocrit and haemoglobin counts was seen in all animals in high dose group.

Clinical Chemistry:
No significant changes were observed.

Pathology:
Spleen weights were raised in the high-dose group.

Histopathology:
A slight atrophy in the epithelial cells of the glomeruli, and some blood-coloured sediment in the spleen were found in high dose group. In some animals, liver cells showed a slight tendency to atrophy and loss of tissue clarity.

Comment:
The decrease in erythrocyte count, increase of leucocyte count and the increase in absolute and relative weight of spleen suggest that administration of large doses of CHA affects the haematogenous functions.

Result:
Based on the abnormalities seen in blood cell counts and in the liver, spleen and kidney in the high dose group, the NOAEL is considered to be 500 mg/kg/day.

Test substance: n-decanoic acid

In humans, no overt toxicity has been reported from dermal use of 5% decanoic acid in aqueous ethanol for the treatment of skin disorders (BIBRA, 1996).

Ten rats fed with 10% dietary decanoic acid (5 g/kg bw/day) for 150 days did not develop gross changes of the forestomach or glandular stomach (BIBRA, 1996).

Normal growth, organ weights, and cellular structure of the liver and intestine were observed in a group of 15 rats of each sex fed with dietary 2.5 g decanoic acid/kg bw/day (as triglyceride) for 47 weeks. No mortality occurred during the study (BIBRA, 1996).

Dietary levels of 8% (approximately 4 g/kg bw/day) decanoic acid for 6 weeks, caused reduced body weight gain, increased plasma triglycerides and cholesterol levels, and a marginal reduction in clotting time in 12 male rats. Some indication of thrombogenic capacity was also identified (BIBRA, 1996).

Dogs (unspecified number) fed up to 4.4 g decanoic acid/kg bw/day for 102 days showed no changes in organ weights, structure or function of liver or kidney, or electrical activity of the heart (BIBRA, 1996).

No overt toxicity was seen when 400 mg/kg bw decanoic acid was injected into the body cavities of six mice on 5 consecutive days (BIBRA, 1996).

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay

Test substance:	CHA
Strains:	*S typhimurium*: TA1535, TA100, TA1537, TA1538 and TA98 *E. coli* WP2 *hcr trp*
Metabolic activation:	Liver S9 fraction from rats pre-treated with Aroclor 1254
Concentration range:	0 – 30000 μg/plate
Test method:	Similar to OECD TG 471 and 472
Result:	Caprylohydroxamic acid showed very weak mutagenicity in WP2 *hcr* with and without metabolic activation under the conditions of the test (Ohta, 1980).
Test substance:	decanoic acid

In another study, decanoic acid gave no evidence of mutagenicity in *S. typhimurium* in the presence and absence of metabolic activation (S9), and in *E coli* in the absence of S9 (BIBRA, 1996).

9.3.2 *Bacillus subtilis* "rec assay"

Test substance:	CHA
Strains:	*B subtilis* H17Rec$^+$ and M45Rec$^-$
Metabolic activation:	Liver S9 fraction from rats pre-treated with Aroclor 1254
Concentration range:	0 – 1000 μg/disk (Repair Test)

Result:	CHA was negative in rec assay under the conditions of the test (Ohta, 1980).

9.4 Reproductive Toxicity

Test substance:	10% CHA (Taselin)
Species/strain:	Rat/Wistar
Number/sex of animals:	18/female
Method of administration:	Oral (gavage) from days 9 to 14 of gestation
Dose/Study duration:	
Test Group	Control: 0 mg/kg/day Low dose: 50 mg/kg/day Mid dose: 250 mg/kg/day High dose: 500 mg/kg/day (vehicle: gum arabic) Most of the dams were sacrificed on day 20 of gestation. The remaining dams were allowed to litter naturally.

Observations
No changes in behaviour and appearance were observed in treated dams. Body weight gains and food intakes of the dam, and foetal weights at the mid and high dose groups were lower compared to control. The retardation of ossifications was observed with foetal weight decrease. The body weight of the neonates at mid dose group was significantly lower at both birth and weaning. However, no morphological or functional differentiation of the neonates was observed. Growth retardation of foetuses and neonates observed at higher doses may be due to slight suppression of body weight gains and food consumption in their dams (Suzuki Y et al, 1975). No skeletal abnormalities were observed.

Result
Based on the absence of adverse effects on neonates (foetal mortality and effects on morphological or functional differentiation of neonates), CHA was not teratogenic under the conditions of the study.

Test substance: decanoic acid

A diet containing 2.5 g/kg bw/day decanoic acid and 7.4 g/kg bw/day octanoic acid (as triglycedires) was fed to an unspecified number of male and female rats from 3 weeks prior to mating, throughout pregnancy and lactation, and to the weaned offspring for 15 week prior to their mating. No effects on pup birth weight or litter size in either generation was reported. Females of the second generation had less milk and of lower nutritional quality. The authors of the study suggested that this was also responsible for the increased mortality of their offspring (BIBRA, 1996).

9.5 Carcinogenicity

Test substance: CHA

A total of 1184 male and female ICR mice were divided into 10 groups to determine whether CHA had tumour-causing properties. Treatment of 0.06% and 1% of CHA was administered orally and intravenously within 24 hours after birth. The mice were switched to basic feed at 2, 4 and 6 months after the administration of CHA. Autopsies were performed at the third and six months, and histological examinations were conducted on the livers, lungs, spleens and kidneys. Either no tumours were found at all, or if tumours were found, the rate of occurrence was within the range for spontaneous occurrence and was not significantly different. When internal organs of the mice treated with CHA were compared to those treated with known carcinogens, it was concluded that CHA had no tumour causing properties in relation to the organs examined (Nishio, 1972).

Test substance: decanoic acid

No abnormalities in the cellular structure of the liver or intestine were observed from thirty (15/sex) rats fed with a diet containing 2.5 g/kg bw/day decanoic acid (as the triglyceride) for 47 weeks. Similarly, a group of ten rats fed with a diet containing 5 g/kg bw/day decanoic acid for 150 days did not develop forestomach tumours (BIBRA, 1996).

9.6 Toxicokinetics & Metabolism

Acetohydroxamic acid (AHA)
A study in mice investigated the absorption, distribution and metabolism of ^{14}C-AHA. Measurements of radioactivity in blood showed that AHA is rapidly absorbed, with radioactivity peaking at one hour after intraperitoneal administration, compared with a peak of 30 minutes for urea, which is known to be rapidly absorbed, distributed and excreted. The biological half-life of urea was determined as 1.3 hours, compared to 4 hours for AHA. An examination of radioactivity levels in tissue revealed no significant tissue binding. AHA is rapidly excreted in the urine mostly unchanged (60%), but also as amide (15-20%) or acetate (10% with a further 7% as CO_2 derived from the acetate). When acid/acetate is formed directly from the hydroxamate, hydroxylamine is formed as a transient species and is rapidly reduced to ammonia by haemoglobin, which is itself oxidised to methaemoglobin (Fishbein et al, 1973).

By analogy, the notified chemical is expected to undergo a similar metabolic conversion.

n-decanoic acid
Studies in man and other mammals have shown that decanoic acid is readily absorbed from the intestine and that it is metabolised through the metabolic pathways of the dietary fatty acids.

9.7 Overall Assessment of Toxicological Data

In toxicokinetic studies with hydroxamates, absorption is rapid and the chemical is excreted in the urine largely unchanged. Metabolism occurs to the amide or the acid, where further breakdown to CO_2 may occur. Hydroxylamine is produced with breakdown to the acid, however, this is rapidly converted to ammonia.

No toxicological data were provided for the notified chemical. However, data on a similar chemical, caprylohydroxamic acid, and n-decanoic acid were submitted. These serve to build conclusions regarding the toxicological profile of the notified chemical, AM2.

CHA
CHA was of very low acute oral in rats and mice and low acute dermal toxicity in rats. In a 13-week repeated dose oral toxicity study in rats, Taselin, containing 10% CHA affected the haematogenous functions when administered at high dose. Based on the abnormalities found in blood cell counts, the liver, the spleen and the kidney at 2500 mg/kg/day, the NOAEL was 500 mg/kg/day.

CHA showed very weak mutagenicity in *E coli* and was non-genotoxic in *Salmonella* and *Bacillus* strains. In a rat study, CHA was not considered a teratogen. In a carcinogenicity study in mice, CHA had no tumour causing properties in relation to the tissues examined.

n-decanoic acid
n-decanoic acid exhibited very low acute oral toxicity in rats. Exposure to concentrated vapour of decanoic acid for 8 hours caused no death in rats. It was irritant to the skin of humans and to the skin and eyes of rabbits. The sodium and potassium salts were also irritant to human skin. Evidence of skin sensitisation potential was not observed in volunteers treated with dilute solution.

Limited studies in humans, rats and dogs suggested a low toxicity upon repeated oral administration. When a mixture of decanoic acid and octanoic acid (as triglycerides) was fed to rats through successive generations, an increased mortality rate, related to nutritional factors, was seen among the offspring comprising the third generation.

Decanoic acid gave no evidence of carcinogenicity in very limited oral studies in rats.

AM2
By analogy, the notified chemical is likely to be rapidly absorbed and excreted, with some metabolism to the corresponding amide and acid. Consequently, AM2 is likely to be of low acute toxicity, but may be irritating to the skin and eyes. On repeated exposure, it may affect the haematogenous functions at high doses. Based on the limited data available, it is unlikely to be genotoxic.
On the basis of the data supplied, AM2 is classified as a hazardous substances in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). It warrants the risk phrases: Irritating to eyes and skin (R36/38).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Full test reports on the ecotoxicity studies for AM2 were provided by the notifier.

Test	*Species*	*Results*
Sub-lethal fish imbalance toxicity test	Eastern Rainbow Fish *Melanotaenia duboulayi*	EC_{50} (96 h) = 4.97 mg/L NOEC (96 h) = 3 mg/L
Acute Immobilisation	Water Flea *Ceriodaphnia dubia*	EC_{50} (48 h) = 0.78 mg/L NOEC (48 h) = 0.22 mg/L
Growth Inhibition	Algae *Selenastrum capricornutum*	EC_{50} (72 h) = 0.085 mg/L NOEC (72 h) = 0.01 mg/L

- EC_{50} – median effective concentration
- NOEC - no observable effect concentration

The test on fish (Ecotoxicology Unit, UTS, 2001) was performed under static conditions using five specimen fish per loading rate in the temperature range of 23-25 ºC. The test was conducted at nominal concentrations of 0.03, 0.1, 1, 3 and 10 mg/L. The test substance was found to be relatively insoluble in the dilutant water so ethanol was used as a co-solvent. The results of the definitive study showed that, after 96 h, no sublethal effects were observed in the test vessels containing less than 1 mg/L of the notified chemical, however, 5% of fish exhibited sublethal effects in the solvent control. After 96 h, 15% of the fish at the nominal concentration of 3 mg/L showed signs of imbalance while at a concentration of 10 mg/L, 95% of fish exhibited sublethal effects. NOEC and LOEC values were calculated using ANOVA and Dunnetts test while the EC_{50} value was determined using the trimmed Spearman-Karber Method. The 96-hour EC_{50} for the notified chemical to *Melanotaenia duboulayi* is 4.97 mg/L and the 96-hour NOEC is 3 mg/L. The LOEC (10 mg/L) was deemed to be invalid because the estimated value is greater than the LC_{50} value for the notified chemical.

The immobilisation test with *Ceriodaphnia dubia* (CSIRO Centre for Advanced Analytical Chemistry, 2001) was also performed under static conditions with observations performed at 24 and 48 hours. The test was performed in quadruplicate using 5 daphnids per flask at a temperature of 25 ºC. A 2 mg/L stock solution of the notified chemical was prepared and diluted to give concentrations of 0.008, 0.025, 0.074, 0.22, 0.67 and 2 mg/L. After 48 h, no immobilised daphnids were observed in the test vessels containing less than 0.22 mg/L of the notified chemical while 10% immobilisation was exhibited in the control. At the nominal concentrations of 0.67 and 2 mg/L of the notified chemical, 66% and 100% immobilisation were observed, respectively. The 48-hour EC_{50} for the notified chemical to *Ceriodaphnia dubia* is 0.78 mg/L as determined by the trimmed Spearman-Karber Method.

Algae were exposed to the test substance at concentrations of 0.05, 0.1, 0.25, 0.5 and 1 mg/L for 72 h at 24˚C under constant illumination and shaking (CSIRO Centre for Advanced Analytical Chemistry, 2000). Three replicate test flasks were prepared for the test substance and three controls. At the test substance concentrations of 0.05, 0.1, 0.25, 0.5 and 1 mg/L the algae exhibited 32, 58, 98, 99 and 100% inhibition, respectively. Therefore, the growth rate of *Selenastrum capricornutum* was adversely affected by the test substance, giving a 96 h EC_{50} of 0.085 mg/L and NOEC of 0.01 mg/L.

In addition to the toxicity studies described above, the notifier also supplied a literature report (Addison and Côté, 1973) concerned with the variation of chain length on the toxicity of alkylhydroxamic acid to salmon (*Salmo Solar*). This study showed that the toxicity increases with chain length and gave 24 h EC_{50} values for the alkylhydroxamic acid to salmon of 13.3 and 0.53 mg/L. While not conducted according to present guidelines, these are in reasonable agreement to the above, considering the 1:1 mixture.

The ecotoxicity data indicates that the notified chemical is moderately toxic to fish, highly toxic to daphnia and very highly toxic to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notifier estimates that approximately 98% of the notified chemical will be exported with the metal concentrates and destroyed during smelting, with the production of water vapour, and oxides of carbon and nitrogen.

Approximately 2% of the reagent may be disposed of into tailings dams. The notifier has shown that after 19 minutes the initial concentration of unbound notified chemical in the water under test condition was reduced by 99.99%. Therefore, the concentration of the notified chemical present in tailings dam water is expected to be at or below 0.5 µg/L. The ecotoxicity data indicate that the notified chemical is moderately toxic to fish, highly toxic to daphnia and very highly toxic to algae. However, the concentration of the notified chemical present in the tailings dam water will be two orders of magnitude below the EC_{50} for the most sensitive species (algae).

It is a characteristic of most sulphide metal mines that pyrite and other gangue metal sulphides will slowly oxidise when exposed to air with production of sulphuric acid and solutions of metal sulphates. Consequently, the water in the tailings dams becomes very acidic (pH 1-2). The acid or based catalysed hydrolysis of hydroxamates to carboxylic acid and hydroxylamine derivatives proceeds readily and the hydrolysis mechanism is said to resemble that of amides (Bauer and Exner, 1974). Therefore, decomposition of the notified chemical in tailings dams as a result of hydrolysis is likely. In this case this would result in the formation of fatty acids and hydroxylamine derivatives. These products are further expected to slowly degrade to simpler compounds through chemical and physical processes. Release to the wider environment is not expected as tailings dams are designed to reduce the potential for seepage. Therefore, exposure to natural waters is expected to be low.

In the case of accidental release, if discharged to waterways, the notified chemical would be likely to persist, hydrolysing only slowly. The studies of distribution in a mineral flotation system described above indicate the notified chemical will be rapidly removed from the aquatic compartment through strong adsorption to soil and sediments. The physico-chemical data and the low molecular weight (313 and 343 g/mol) indicate that the notified chemical has the potential to bioaccumulate (Connell, 1990). This is further supported by unpublished data that claims the alkyl hydroxamic acid is accumulated from water by trout and distributed widely throughout their tissues (Darrow et al, 1978). However, exposure to natural waters is expected to be low.

Up to 10 kg of the notified chemical will be released into the sewer from the manufacturing

facility per year. Subsequent treatment at local sewage treatment plants would further dilute and remove the notified chemical to very low concentration levels.

Therefore, the environmental exposure and overall environmental hazard from the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
By analogy, the toxicity of the notified chemical is not expected to differ substantially from that of CHA and n-decanoic acid. AM2 is expected to have very low acute oral, dermal and inhalation toxicity. It is irritating to skin and eyes but is not expected to be sensitising to skin. Upon repeated exposure to high dose, haematogenous functions, the liver, the spleen and the kidney may be affected. It is unlikely to have teratogenic, genotoxic or tumour causing properties. On the basis of the data supplied, AM2 would be classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) and warrants the risk phrases: Irritating to eyes and skin (R36/38).

Occupational Health and Safety
The notified chemical will be manufactured in Australia, hence worker exposure to the notified chemical may occur during manufacture and drumming off the chemical for distribution to mining operators. The manufacturing process is largely automated and enclosed, therefore exposure is limited to intermittent dermal exposure when connecting and disconnecting pipes during transfer and filling operations. Dermal exposure of maintenance workers to the notified chemical is possible during routine maintenance but is expected to be low. Therefore, as skin and eye irritation effects may occur, gloves, safety glasses, boots and protective clothing are required during handling of the notified chemical.

Similarly, during end-use of the notified chemical as ore flotation agent, the reagent storage, mixing and flotation processes are automated and continuous, thus minimising worker exposure. Plant operators and maintenance personnel will have intermittent exposure to the notified chemical when connecting, disconnecting and cleaning the pumping equipment. As the notified chemical has skin and eye irritation potential, precautions should be taken during handling of the chemical. Therefore, flotation plant operators are required to wear protective clothing, gloves and safety glasses when carrying out their tasks.

Conclusion
Overall, it is concluded that there is a risk of skin and eye irritation during manufacture, use and disposal of the notified chemical and precautions are required to minimise exposure. The risk of systemic health effects is low, as is the risk of adverse health effects during transport.

Public Health
AM2 is manufactured and used with well engineered protective processes on sites not available to the public, therefore, the likelihood of members of the public being exposed to it is very low. Any exposure that does occur is most likely to be by dermal contact. Because AM2 has low toxicity, the consequences of such contact are unlikely to be significant.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - R36/38: Irritating to eyes and skin

- The NOHSC Chemicals Standards Sub-committee should also consider the appropriate environmental hazard classification of the notified chemical.

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosed and automated manufacturing process
  - Exhaust ventilation during manufacture and filling processes

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid spills and splashing during weighing and transfer operations

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - chemical resistant gloves
  - protective clothing which protects the body, arms and legs
  - eye protection

  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 AM2 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.

Secondary notification

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

Under subsection 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.

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* (NOHSC, 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.

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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