File No: NA/550

2 November 2000

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

# FULL PUBLIC REPORT

## Chemical in CAL 611

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

## Chemical in CAL 611

## 1. APPLICANT

Clariant (Australia) Pty Ltd of 675-685 Warrigal Road CHADSTONE VIC 3148 has submitted a standard notification statement in support of their application for an assessment certificate for Chemical in CAL 611.

## 2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, details of exact import volume, purity and formulation, full identity of structurally related analogue substances (Analogue A – G), specific use and end use customers have been exempted from publication in the Full Public Report and the Summary Report.

| | |
|---|---|
| **Marketing Name:** | CAL 611 (product that contains the notified chemical at 60 – 100%) |
| **Method of Detection and Determination:** | Nuclear magnetic resonance;<br>Infra red (IR);<br>High performance liquid chromatography. |
| **Spectral Data:** | IR spectrometric data were submitted for the identification of the notified chemical |

## 3. PHYSICAL AND CHEMICAL PROPERTIES

Data are not available for the notified chemical. Unless otherwise indicated the following data are for the product CAL 611 or have been estimated by use of ACD software.

| | |
|---|---|
| **Appearance at 20°C at 101.3 kPa:** | Slightly yellow liquid with a characteristic odour |
| **Boiling Point:** | >100°C |
| **Specific Gravity:** | 1.17 |
| **Vapour Pressure:** | 2.4 kPa at 25°C |
| **Water Solubility:** | 100 mg/L at 25°C (estimated) |
| **Partition Co-efficient (n-octanol/water):** | log $P_{ow}$ 3.47 (estimated) |
| **pH:** | 12.5 (100 g/L water) (from Material Safety Data Sheet) |
| **Hydrolysis as a Function of pH:** | Stable over a wide pH range |
| **Adsorption/Desorption:** | $K_{oc}$ 1 851 |
| **Dissociation Constant:** | $pK_a$ 0.5 – 3.0 |
| **Flash Point:** | >100°C |
| **Flammability Limits:** | Not expected to be flammable |
| **Autoignition Temperature:** | Not expected to ignite |
| **Explosive Properties:** | Not expected to be explosive |
| **Reactivity/Stability:** | May release hydrogen sulphide in contact with strong acids |
| **Particle Size:** | Not applicable as imported as a liquid |

### Comments on Physico-Chemical Properties

The vapour pressure of the notified chemical was not determined. The notifier claims that the product CAL 611 has a vapour pressure of 18 mm Hg (2.4 kPa), which is the vapour pressure of the solvent water. For this assessment use was made of ASTER Ecotoxicity Profile (US EPA 1996). Using this software on the free parent acid of the notified chemical determines

the vapour pressure was 3.34 x $10^{-4}$ mm Hg (4.5 x $10^{-5}$ kPa) indicating that the notified chemical can be classified as very slightly volatile (Mensink 1995). The salt of the notified chemical would be expected to have a lower vapour pressure.

The water solubility of the notified chemical was not determined. The notifier claims that CAL 611 is soluble in water in all proportions. The notifier determined the water solubility of the free parent acid of the notified chemical by ACD Software to be 100 mg/L, which is comparable to 46.3 mg/L determined using ASTER Ecotoxicity Profile. The notifiers claim that the water solubility of the salt would be higher is accepted.

The hydrolysis as a function of pH of the notified chemical was not determined. The notifier claims that CAL 611 is stable over a wide pH range and can be used in strongly basic and strongly acidic media. Typically, the notified chemical will be used within the pH range of 8.5 to 12. This assessment notes that ASTER Ecotoxicity Profile hydrolysis half-life data are unavailable for the class of compounds that the notified chemical belongs to but would expect the notified chemical to be stable over a wide pH range.

The partition coefficient log $P_{OW}$ of CAL 611 was not determined. The notifier determined the partition coefficient log $P_{OW}$ of the free parent acid of the notified chemical by ACD Software to be 3.47 which is in close agreement with 3.67 obtained by ASTER Ecotoxicity Profile. The notifier expects that the partition coefficient of the salt form would be lower. This assessment notes that the values above are consistent (Lyman et al 1982) with the free parent acid of the notified chemical being hydrophobic in character. The salt form of the notified chemical, with much higher water solubility, would be expected to be relatively hydrophilic.

The adsorption coefficient log $K_{OC}$ of CAL 611 was not determined. The notifier determined the adsorption coefficient log $K_{OC}$ of the free parent acid of the notified chemical by ACD Software to be 3.3 and expects that the adsorption coefficient of the salt would be lower. This is equivalent to the adsorption coefficient log $K_{OC}$ of the free parent acid of the notified chemical determined from ASTER Ecotoxicity Profile. This is consistent (McCall et al 1980) with the free parent acid of the notified chemical having low mobility in soil.

The notified chemical is expected to be completely dissociated in the environmental pH range based on its high water solubility and the high pH (12.5) of CAL 611.

The notifier also supplied the ACD calculations of an isomer of the free parent acid of the notified chemical and these calculations gave identical properties and aquatic toxicity when compared to the free parent acid of the notified chemical.

## 4. PURITY OF THE CHEMICAL

| | |
|---|---|
| **Degree of Purity:** | Very high |
| **Hazardous Impurities:** | None |
| **Non-hazardous Impurities (> 1% by weight):** | None |
| **Additives/Adjuvants:** | None |

## 5. USE, VOLUME AND FORMULATION

The notified chemical is an industrial surface active agent for use in mining process operations. At present, use at one site has been confirmed, although use at other sites is anticipated.

The notified chemical will be imported in 200 L plastic drums as a component (60 to 100%) of the product CAL611 at greater than 10 tonnes per annum for the first five years. No manufacturing of the notified chemical will take place in Australia.

At the time of this assessment the notified chemical is in use in Australia under a NICNAS Commercial Evaluation permit granted under section 21G of the Act.

In use the notified chemical is either pumped or gravity fed from the 200 L plastic drums to a storage tank. An automatically controlled main system is used to regulate flow, mix reagents and deliver reagents to the addition points in the processing operation. The process is completely automated.

## 6. OCCUPATIONAL EXPOSURE

| *Category & Number of Worker* | *Maximum Potential Exposure Duration & Personal Protective Equipment* |
|---|---|
| Transport and Storage, 10 | 1 hour/day; 20 days/year.<br>Industrial standard overalls. |
| Reagent Handlers, 12 | 1 hour/day; 20 days/year.<br>Industrial standard overalls, rubber gloves & goggles, safety boots and helmets. |
| Plant Operators, 6 | 1 hour/day; 20 days/year.<br>Industrial standard overalls, rubber gloves & goggles, safety boots and helmets. |
| Maintenance workers, 4 | Negligible.<br>Industrial standard overalls. |
| QC/Lab Technicians, 4 | 1 hour/day; 20 days/year.<br>Industrial standard overalls, rubber gloves & goggles. |

*Transport and Storage*
Transport and storage workers may be exposed to the notified chemical in the event of a spill.

*Reagent Handlers*
Reagent handlers are responsible for connecting pump lines between the import containers and the processing operations. This is done by timing the flow rate via a measuring cylinder. For both activities there may be potential for dermal contact to drips and spills.

*Plant Operators*
During regular shift inspections at the mine sites, plant operators may have need to assist reagent handlers in pumping CAL611 and may receive dermal contact from drips and spills as pump equipment is manipulated.

*Maintenance Workers*
Maintenance involves servicing pump equipment used in reagent transfer operations. The notifier indicates that exposure is expected to be negligible during the operations.

*QC & Laboratory Technicians*
Technicians may receive dermal contact from drips and spills as they collect samples and analyse the contents.

*Control of Exposure*
Personal protective clothing compliant with Australian Standards is recommended by the notifier and is listed in the table above against each worker category. Automated pumping equipment is in use to prevent direct worker exposure. The notifier stated that drums of reagents, including CAL611 are stored in ventilated, bunded areas to prevent fumes from entering the workplace.

*Worker Education and Training*
At the mine site, workers receive instruction and training in the handling of all chemicals on site.

*Adverse Effect Reporting*
The notifier advised that no health effects have been reported from the occupational use of the notified chemical.

## 7. PUBLIC EXPOSURE

It is expected that during transport, reformulation, and storage, exposure of the general public to the notified chemical will be minimal, except in the event of an accidental spill. The notified chemical should be prevented from entering drains and watercourses. Spills should be removed by liquid binding materials, for example, sand, soil, and diatomaceous earth, and transferred to sealed containers for incineration. Contaminated areas should be washed with water and detergent.

As the use of the chemical only occurs at mining sites, exposure of the public is expected to be minimal.

## 8. ENVIRONMENTAL EXPOSURE

### *Release*

The notified chemical is to be used in mining.

The notifier claims greater than 99% of the notified chemical is deposited into tailings dams or underground backfill. This assessment considers that this rate of binding is high and that a rate of approximately 70% is more typical.

Using the notifier estimate of less than 1% of reagent disposed of with tailings, then for each tonne of imported CAL 611, less than 10 kg of product or 6 to 10 kg of the notified chemical.

This assessment notes that the reagent disposed of with the underground backfill is assumed to be locked within the cured cement and release to the environment is not expected.

The notified chemical disposed of with the tailings is not expected to be released to the wider environment. Tailings dams are designed to "substantially" reduce the potential for seepage.
Tailing dams are lined soil or geotextile material and the leakage rate depends on the hydraulic

conductivity of the liner. Hydraulic conductivity depends on the size and frequency of defects or discontinuity in the liner and underlying base material, and the length of time the hydraulic head is applied to the liner (US EPA 1995). Older tailings dam floors are usually constructed from soils. The integrity of soil floors depends largely upon the soil type, texture, strength, plasticity and dispersion index. The integrity also depends upon the degree of maintenance and the age of the tailings dam. Regardless of the lining used, there remains a risk of tailings dam seepage, which may ultimately lead to contamination of surface and ground water. This concern is reinforced by various environmental reports on mining operations where seepage from a new tailings dam has contaminated ground water bores, or periodic discharge of process water has occurred when storm events coincide with periods of full water storage capacity (Normandy Mining Limited 1998), (North Limited 1998), (Pasminco 1999). At some of these sites water quality monitoring has been required by the state Environment Protection Authority, with water quality criteria exceeded on a number of occasions.

Release to the environment may also occur as a result of either inappropriate handling or accidental spillage during transport. In such cases where liquid containing the notified chemical is released to the environment, the notifier recommends that the spilt product should be taken up with liquid absorbing material. The waste material from spillages should then be disposed of by either approved incineration or landfill.

## Fate

The notifier claims that greater than 99% of the notified chemical will be incorporated during the process.

Less than 1% of the reagent will be disposed of into the tailings dams. The water in the tailings dams is expected to become very acidic, commonly between pH 1 and 2. The notified chemical is expected to be hydrolytically stable. However, it is likely to degrade slowly in the tailings dam under the very low pH.

The Ready Biodegradability of CAL 611 was not determined. However, the notifier supplied a list of results of between 3 hours and 27 days of an unspecified wastewater biodegradation study ("Stand test") on Analogue A. Analogue A was found to be not readily biodegradable with only 25% degradation after 27 days. However, the ASTER Ecotoxicity Profile indicates that the free parent acid of the notified chemical has a calculated BOD half-life of 2 to 16 days. The notified chemical may, therefore, be considered as not persistent.

In the case of accidental release to waterways, the notified chemical would not be likely to be persistent, either hydrolysing or degrading slowly. Furthermore, Mackay Level 1 Environmental Partitioning calculations from the ASTER Ecotoxicity Profile indicate that approximately 40% of the free parent acid of the notified chemical would partition to soil and sediment and approximately 56% would partition to water. The salt form of the notified chemical would be expected to be relatively mobile and partition to water to a greater extent. The partition and adsorption coefficients of approximately 3.5 and 3.3, respectively, for the free parent acid of the notified chemical indicates that the chemical is relatively hydrophobic with low mobility in soil. As notified chemical is a salt with high water solubility and expected mobility in soil, it is unlikely to bioaccumulate since exposure to natural waters is

expected to be low.

The notifier indicates that product drums in which CAL 611 is imported will retain very little residual notified chemical following pumping to the storage tank. Emptied drums will be rinsed in a washing area with rinse water to be included in processing operations. All drums will then be retained on site in a drum holding area. The notifier indicates that empty drums are often used on site as barriers and markers for mine areas.

## 9. EVALUATION OF TOXICOLOGICAL DATA

The notifier stated that toxicological studies are not available for the notified chemical or the product CAL 611. However, to support their claims for variation to the schedule requirements the notifier has submitted test data on a surrogate substance; Analogue A at 45% in an aqueous formulation. The notifier claims that based on structurally similarities, the notified chemical is expected to share the same toxicological profile as that of Analogue A. Data for analogue A covered three of the eight toxic end points where data is required under Parct C of the Schedule to the Act.

Further supporting toxicity data from the published literature was provided by the notifier or sourced independently by NICNAS on other structurally related analogues identified as:

| **Analogue Substances– Masked Names** | **Approximate Molecular Weight** |
|---|---|
| Analogue B [1] [2] | 160 |
| Analogue C [3] | 190 |
| Analogue D [4] | 210 |
| Analogue E [5] | 215 |
| Analogue F [6] | 355 |
| Analogue G [7] | 775 |

Of the surrogate data submitted, Analogue A and Analogue E are considered for this assessment to be the most closely related analogues to the notified chemical.

The studies provided are summarised and the toxicity end points are compared with the supplementary data obtained from the literature.

[1] (RTECS 1999)
[2] TOXLINE, 1999
[3] RTECS, 1999; HSDB, 1999.

[4] RTECS, 1999; HSDB, 1999.
[5] RTECS, 1999; HSDB, 1999.
[6] RTECS, 1999; HSDB, 1999.
[7] HSDB, 1999, Brooks, 1983, Hewstone 1994.

## 9.1 Acute Toxicity

**Summary of the acute toxicity of Analogue A:**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| Acute oral toxicity | Rat | $LD_{50}$>4 000 mg/kg (males)<br>$LD_{50}$>3 150 mg/kg (females) | (Pharma Research Toxicology and Pathology 1987) |
| Skin irritation | Rabbit | Moderate Irritant | (Pharma Research Toxicology and Pathology 1987) |
| Eye irritation | Rabbit | Severe Irritant | (Pharma Research Toxicology and Pathology 1987) |

### 9.1.1.1 Oral Toxicity (Pharma Research Toxicology and Pathology 1987)

| | |
|---|---|
| *Test Substance:* | Analogue A |
| *Species/strain:* | Rat/Wistar |
| *Number/sex of animals:* | 10/sex |
| *Observation period:* | 14 days |
| *Method of administration:* | Oral gavage of 3 150 and 4 000 mg/kg of body weight in female and male rats, respectively. Both sexes also received a dose of 5 000 mg/kg. |
| *Test method:* | OECD TG 401 |
| *Mortality:* | Three female and two males in the 5 000 mg/kg group died by the first day post-treatment. All females receiving 3 150 mg/kg and all males receiving 4 000 mg/kg survived. |
| *Clinical observations:* | The following clinical symptoms were seen in surviving animals: reduced spontaneous activity; squatting posture; flanks held close; piloerection; locomotor disturbances; abnormal breathing noises and narrowed eye lids. The symptoms were reversible from the second day onwards. |

| | |
|---|---|
| *Morphological findings:* | At necropsy, decedents displayed the following: lung discoloured (bright red); reddened stomach mucosa; stomach filled with a colourless, clear liquid; stomach/intestinal tract filled with reddish brown liquid (blood); small intestine filled with colourless, clear liquid.<br><br>Animals killed at the end of the observation period had no visible macroscopic peculiarities. |
| *Comment:* | Body weight gain of survivors was normal. |
| *$LD_{50}$:* | >3 150 mg/kg for females<br>>4 000 mg/kg for males |
| *Result:* | Analogue A was of very low acute oral toxicity in rats |

*Acute Oral Toxicity in Rats*

| *Test Substance* | *$LD_{50}$* |
|---|---|
| Analogue B | 694 mg/kg |
| Analogue C | 4 510 mg/kg |
| Analogue D | 18 100 mg/kg |
| Analogue E | 1 817 mg/kg |
| Analogue F | 2 140 mg/kg |
| Analogue G | 3 100 mg/kg |

### 9.2.1. Dermal Toxicity in Rabbit

| *Test Substance* | *$LD_{50}$* |
|---|---|
| Analogue F | 1 250 mg/kg |

### 9.2.1. Inhalation Toxicity

| *Test Substance* | *$LC_{50}$ Toxic Effects* |
|---|---|
| Analogue B | 1 700 mg/$m^3$/4 hour;<br>Lacrimation, dyspnoea, changes in structure or function of salivary gland. |
| Analogue C | 1 640 mg/$m^3$/4 hour;<br>Somnolence, dyspnoea, weight loss or decreased weight gain. |

**Skin Irritation (Pharma Research Toxicology and Pathology 1987)**

*Test substance:* Analogue A

*Species/strain:* Rabbit/New Zealand White

*Number of animals:* 3

*Observation period:* 7 days

*Method of administration:* A semi-occlusive application of 0.5 mL undiluted test substance was made on the dorsal skin. After 4 hours, the substance carefully removed with tap water.

*Test method:* OECD TG 404

*Draize scores:*

| ***Time after treatment (days)*** | ***Animal #*** | | |
|---|---|---|---|
| | ***1*** | ***2*** | ***3*** |
| ***Erythema*** | | | |
| 1 | [a]2 | 2 | 3 |
| 2 | 2 | 2 | 2 |
| 3 | 0 | 2 | 2 |
| ***Oedema*** | | | |
| 1 | 1 | 0 | 1 |
| 2 | 1 | 0 | 1 |
| 3 | 0 | 0 | 0 |

[a] see Attachment 1 for Draize scales

| | |
|---|---|
| *Mean Individual Scores (24, 48 & 72 hour observation)* | Erythema and scab formation: 1.3, 2.0, 2.3;<br>Oedema: 0.7, 0.0, 0.7. |
| *Comment:* | By the seventh day post-treatment, all signs of irritation had disappeared except for one animal, which still had dry and brittle skin. |
| *Result:* | Analogue A was moderately irritating to the skin of rabbits |

*Skin Irritation*

| *Test Substance* | *Skin Irritancy* |
|---|---|
| Analogue B | Moderate |
| Analogue C | Mild |
| Analogue F | Severe |
| Analogue G | Severe |

**Eye Irritation (Pharma Research Toxicology and Pathology 1987)**

| | |
|---|---|
| *Test substance* | Analogue A |
| *Species/strain:* | Rabbit/New Zealand White |
| *Number of animals:* | 3 |
| *Observation period:* | 7 days |
| *Method of administration:* | A single dose of 0.1 mL of test substance was applied to the conjunctival sac of the left eye of each animal, with the right untreated eye serving as control. Treated eyes were rinsed thoroughly with saline 24 hours post-treatment. |
| *Test method:* | OECD TG 405 |

*Draize scores of unirrigated eyes:*

| | Time after instillation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| ***Animal*** | ***1hour*** | | ***1 day*** | | ***2 days*** | | ***3 days*** | | ***7 days*** | |
| ***Cornea*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** | ***o*** | ***a*** |
| 1 | [1]2 | - | 3 | 2 | 3 | - | 3 | 3 | 1 | 1 |
| 2 | 3 | - | 1 | 2 | 2 | - | 2 | 3 | 4 | 4 |
| 3 | 3 | - | 2 | 1 | 3 | - | 3 | 3 | 4 | 3 |
| ***Iris*** | | | | | | | | | | |
| 1 | 1 | | 1 | | 1 | | 1 | | 1 | |
| 2 | 1 | | 1 | | 1 | | 1 | | 1 | |
| 3 | 1 | | 1 | | 1 | | 1 | | 1 | |

| ***Conjunctiva*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** | ***r*** | ***c*** | ***d*** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | + | 3 | 3 | + | 3 | 3 | + | 3 | 2 | + | 2 | 2 | - |
| 2 | 2 | 3 | + | 2 | 2 | + | 2 | 2 | + | 3 | 2 | + | 3 | 2 | - |
| 3 | 2 | 2 | + | 2 | 2 | + | 3 | 3 | + | 3 | 2 | + | 3 | 1 | - |

[1] see Attachment 1 for Draize scales
o = opacity. A = area of lightening observed with fluorescein r = redness c = chemosis d = discharge

Individual mean scores (24, 48 & 72 hours)

Corneal opacity: 3.0, 1.7, 2.7;
Iridial lesions: 1.0, 1,0, 1.0;
Conjunctival redness: 3.0, 2.3, 2.7;
Conjunctival chemosis: 2.7, 2.0, 2.3.

*Comment:*

From one hour to 7 days after application, all animals showed slight swelling of the conjunctiva to swelling with half-closed lids as well as diffuse crimson to bright red colouration. The cornea had in parts scattered to mother-of-pearl-like areas of opacity, for two animals the cornea was completely turbid at 7 days after application. Up to 72 hours after application, the irises of all animals were reddened, 7 days after application the iris of two animals could not be assessed due to the opacity.

In addition, up to 72 hours after application the following symptoms were observed in parts: clear, colourless to white slimy discharge and brown discolouration, bleeding and detachment of cornea and nictitating membrane. Seven days after application, the cornea and nictitating membranes of all animals were discoloured white to brown-white. At this assessment time point two animals showed advanced vascularisation of the cornea.

*Result:* Analogue A was severely irritating to the eye of rabbits

*Eye Irritation*

| *Test Substance* | *Eye Irritancy* |
|---|---|
| Analogue B | Severe |
| Analogue C | Severe |
| Analogue D | Moderate |
| Analogue F | Severe |
| Analogue G | Severe |

### 9.2.1. Skin Sensitisation

No data on skin sensitisation were submitted.

The notifier indicates evidence of skin sensitivity was not reported in a dermal repeat dose study in rabbits or rats using analogues (see below).

**Repeated Dose Toxicity**

### 9.2.1. 28 day Repeated Dermal Dose Toxicity (Hewstone 1994)

The following is summarised from the published paper. No results were presented or tabulated. The original data was not provided for assessment.

| | |
|---|---|
| *Test Substance* | Analogue G |
| *Species/Sex* | Phase 1 – Rabbit (male and female);<br>Phase 2 – Rabbits and Rats (young and mature males). |
| *Concentration and Dosing Schedule:* | Phase 1<br>0, 1, 3, 5, 25% solutions applied topically at 2 mL/kg/day,<br>5 days/week for 4 weeks;<br><br>Phase 2<br>25% solution applied topically at 2 mL/kg/day,<br>5 days/week for 4 weeks, followed by a 28 day recovery period. |

*Findings:*
Phase 1 - Rabbits
No toxic effects at 1 or 3% in males or at all doses in females.
In males at 5% and 25%, aspermatogenesis and tubular hyperplasia and skin damage (fissuring and exfoliation) and bodyweight loss (extent of body weight loss was not reported) was observed. No effects were seen in any other organs. The effects in the male reproductive tract were reported to correlate with the degree of body weight loss. The No Observed Adverse Effect Level (NOAEL) is determined at 3% (15.8 mg/kg).

Phase 2 – Rats and Rabbits (investigation into reproductive tract effects observed above)
Rabbits – similar male reproductive tract findings as observed in phase 1. Testicular atrophy was evident in a gross reduction in size and weight of the testes and in a reduced testes to bodyweight ratio. In the epididymides, reduction or absence of spermatozoa was consistent with the testicular effects. Some reversibility of testicular effects occurred during recovery. However the duration of the recovery period was considered insufficient to determine if reversibility was complete.

Rats – no reproductive tract effects reported.

*Comment:*
Hewstone (1994) comments that the reproductive tract effects observed in rabbits are generic to this class of compound. Furthermore, these effects appear to be species specific being demonstrated only in the rabbit. Hewstone (1994) makes reference to investigations where rabbit male reproductive effects may be physiological, a result of reduced food consumption and body weight loss and not as a result of a direct toxic effect.

### 9.2.2. Inhalation Developmental Study - (TOXLINE 1999)

The following is taken from the TOXLINE abstract. The original data were not available for assessment.

| | |
|---|---|
| *Test Substance* | Analogue B |
| *Species* | Rat, Charles River CD (SD) BR (mated) |
| *Concentration and Dosing Schedule:* | 0, 5.8, 51 and 214 mg/m$^3$ 6 hours/day on days 6-15 of gestation. Number of animals per dose was not provided. |

*Findings:*
Three dams at 214 mg/m$^3$ died on gestation days 15 to 17. At 5.8 and 51 mg/m$^3$, clinical signs of maternal toxicity were red staining and encrustation of face and forelimbs. In addition, dams at 214 mg/m$^3$ showed urinary staining, matted fur, vaginal discharge, piloerection, hunched posture, hypoactivity and breathing difficulties. Body weight and weight gain were unaffected in dams at 5.8 mg/m$^3$. Significant body weight decreases occurred on gestation day 10, 13, 16, and 21 in dams at 51 mg/m$^3$ and on gestation day 10, 13, and 16 at 214 mg/m$^3$, relative to control group animals. Significant decreases in weight change were reported on gestation days 6 to 16 in dams at 214 mg/m$^3$.

Post mortem findings in treated and control dams were comparable. Mean implants, corpora lutea, and preimplantation loss in treated groups were comparable to controls. Uterine weights were not reported.

Total number of foetuses, live foetuses, and mean foetal weight (both males and females) decreased significantly while the number of early resorptions, post implantation loses and total number with malformations were increased in animals at 214 mg/m$^3$. Treatment related malformations at 214 mg/m$^3$ (included undescended testes, bent scapulae and/or limb bones and ribs). Foetal variations were similar in treated and control groups.

*Comment:*
Based on the summary data provided the lowest observed effect level (LOEL) for maternal toxicity is determined at 5.8 mg/m$^3$ and the NOAEL for developmental effects is 51 mg/m$^3$.

### 9.3 Genotoxicity

| *Test Substance* | *Mutagenicity* |
|---|---|
| Analogue C<br>(HSDB 1999) | Mutagenic in *Salmonella* strains TA1535 and TA100 in the presence or absence of S9. |
| Analogue D<br>(HSDB 1999) | Non mutagenic in any strain of *Salmonella* in the presence or absence of S9. |
| Analogue G<br>(Brooks 1983) | Non mutagenic to *Salmonella* strains TA1535, TA1537, TA1538, TA98, TA100, at 12.5 to 1 000 μg/plate in the presence or absence of S9.<br>No increased cell transformations in mammalian (BHK21/Cl-13) cells at 500 to 4 000 μg/mL in the presence or absence of S9. |

## 9.4 Overall Assessment of Toxicological Data

In the absence of data on the notified chemical, the notifier provided data on Analogue A. In addition, data on other structurally related analogues (Analogues B-G) were also provided. Full study data were only provided for Analogue A. Data on Analogues B-G are taken, without assessment, from literature abstracts or papers.

Analogue A and Analogues B-G have low acute oral toxicity, typically an oral $LD_{50}$ of greater than 2 000 mg/kg (range: 694 mg/kg to 18 100 mg/kg). Analogue A is closely related to the notified chemical and it is expected that the oral toxicity of the notified chemical would be similar to that of Analogue A. Analogue F was of moderate acute dermal toxicity; the rabbit dermal $LD_{50}$ is reported at 1 250 mg/kg. Analogue B and Analogue C had moderate acute inhalation toxicity, $LC_{50}$ of 1 700 and 1 640 mg/L/4 hours, respectively. It is expected that the acute dermal and inhalation toxicity profile of the notified chemical would be similar to that observed with the analogues. The analogues are severely irritating to eyes and prolonged skin contact results in mild to severe skin irritation. Repeated contact results in severe skin damage characterised by fissuring and exfoliation. By analogy, the notified chemical will share the same degree of skin and eye irritancy.

A 28 day repeat dermal dose study on Analogue G revealed significant systemic effects (aspermatogenesis and tubular hypoplasia) in males at 5% and 25% but not at 1% or 3%. There were reportedly no effects in other organs but experimental details were not provided. Application at 5% and 25% also resulted in skin damage and bodyweight loss. The effects in the male reproductive tract appeared to correlate with the degree of bodyweight loss and may be species dependent as in subsequent investigations in rabbits and rats, reproductive effects were only observed in rabbits. This data is insufficient to determine a repeat dose health effect classification for the chemical.

Teratogenicity was evaluated in rats exposed by inhalation to 5.8, 51 and 214 $mg/m^3$ Analogue B on days 6 to 15 of gestation. The LOEL for maternal toxicity is determined at 5.8 $mg/m^3$. Treatment related malformations were observed in foetuses at 214 $mg/m^3$. The NOAEL for developmental effects was 51 $mg/m^3$.

Analogue C was found to be mutagenic to bacteria, but not the sodium salt of this compound. Blends of Analogue G did not show evidence of genotoxic activity in a bacterial mutation assay or in a mammalian cell transformation assay. In the absence of data no determination can be made on the clastogenic potential of the class of compounds represented by Analogues A - G.

*Hazard Classification*

In the absence of specific data, analogue data with 45% of active chemical, and lack of study reports for assessment this is a conservative health effects classification. Classification of the health hazards of the notified chemical is made by analogy with Analogue A and Analogues B-G. The analogue chemicals meet the criteria for classification as Harmful (Xn) under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999). Based on the findings of significant skin and eye irritation scores, Analogue A meets the criteria for classification as a severe eye irritant (R41 - Risk of Serious Damage to Eyes), and skin irritant (R38 - Irritating to skin). Analogue F is classified as acutely toxic by the dermal route (R21 – Harmful in Contact with Skin) based on the reported acute dermal $LD_{50}$, and

Analogue B and Analogue C are moderately acute by the inhalation route (R20 – Harmful by Inhalation).

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier has supplied ecotoxicity studies on Analogue A (see Fate above), which are summarised in the following table:

| *Test* | *Species* | *Test concentrations (nominal) mg/L* | *Results mg/L* |
|---|---|---|---|
| Acute Toxicity[9] (Static Test) (OECD TG 203) | Zebra Barbel (Brachydanio rerio) | 500 | 96 hour $LC_{50}$ > 500 |
| Respiration Inhibition | Aerobic Waste Water Bacteria | - | 3 hour $EC_{50}$ = 650 |

### 10.1 Acute Toxicity Fish (Pharma Research Toxicology and Pathology 1987)

The Acute Toxicity fish test was performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

The acute toxicity of Analogue A to Zebra Barbel was determined in a 96 hour static test at a single nominal concentration of 500 mg/L. The notifier states that there were no mortalities during the entire trial period and that no changes in the appearance and behaviour of the fish were observed when compared with the control group. The 96 hour $LC_{50}$ of the notified chemical was determined by the notifier to be greater than 500 mg/L and the highest concentration tested without toxic effects was 500 mg/L. Measured concentrations of the test samples were not determined.

### 10.2 Microorganisms (Hoechst 1986)

The notifier supplied a very brief summary of two unspecified 24 hour waste water biological tests (said to be a Fermentation and a Consumption Inhibition test) carried out on Analogue A. Nominal test concentration ranges were not supplied and measured concentrations of the test samples were not determined. The 24 hour $EC_{50}$ values of Analogue A are claimed by the notifier to be 650 and 1 500 mg/L, respectively.

The ASTER Ecotoxicity Profile calculated for this assessment on the free parent acid of the notified chemical is summarised in the following tables:

**Acute Toxicity**

| ***Species*** | ***Duration days*** | ***Endpoint*** | ***Concentration mg/L*** |
|---|---|---|---|
| Water flea *Daphnia magna* | 2 | $LC_{50}$ | 3.8 |
| Bluegill *Lepomis macrochirus* | 4 | $LC_{50}$ | 5.2 |
| Flathead minnow *Pimephales promelas* | 4 | $LC_{50}$ | 6.3 |
| Channel catfish *Ictalurus punctatus* | 4 | $LC_{50}$ | 2.7 |
| Rainbow trout *Oncorhynchus mykiss* | 4 | $LC_{50}$ | 2.5 |

**Chronic Toxicity**

| *Species* | *Duration days* | *Endpoint* | *Concentration mg/L* |
|---|---|---|---|
| Flathead minnow *Pimephales promelas* | 32 | MATC | 1.0 |

The notifier also provided calculated ecotoxicity data of isomers of the free parent acid of the notified chemical from ACD software. The data reported was identical for both isomers and indicated that they are moderately toxic to fish, daphnia and algae with either an $EC_{50}$ or $LC_{50}$ range of 6 to 17 mg/L.

### 10.3 Conclusion

The ecotoxicity data supplied by the notifier for Analogue A indicates that the notified chemical is practically non-toxic to fish and sewage microorganisms. The ecotoxicity data calculated in the ASTER Ecotoxicity Profile for the free parent acid of the notified chemical indicates that it is moderately toxic to fish and daphnia. This is confirmed by the notifiers calculations indicating isomers of the free parent acid of the notified chemical are moderately toxic to fish, daphnia and algae.

The data indicates that the salt form of the notified chemical has higher solubility in water and a lower toxicity to aquatic organisms when compared to the free parent acid.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical disposed of in the tailings is expected to be contained within the tailings dam with minimal release to the environment.

The notified chemical disposed of with the underground backfill will be locked within the cured cement and release to the environment is not expected.

Based on an annual maximum import volume of 100 tonnes of CAL 611, 600 to 1 000 kg of the notified chemical will be released to tailings dams and underground backfill per annum. The notifier claims that the proposed mine produces approximately 2 400 000 tonnes of tailings per year and that the tailings are approximately 50% solids in water. Therefore, 1 200 ML of water will be consigned to tailings dams. If it is assumed that at the single proposed mine site all of the released notified chemical is released to tailings dams and not to underground backfill, then based on maximum import volumes of CAL 611 the final concentration of the notified chemical in the process effluent would be 0.5 to 0.8 mg/L.

The environmental safety margin for exposure of the most sensitive aquatic organism, Rainbow trout 96 hour $LC_{50}$ = 2.5 mg/L from calculated ecotoxicity data for the free parent acid of the notified chemical, would be equal to 3 to 5. However, this assessment notes that it is unlikely that the notified chemical will exist as the free parent acid within the tailings dam, which although expected to be very acidic, will contain relatively high concentrations of dissolved metals. Therefore, the environmental safety margin for exposure of the most sensitive aquatic organism, Zebra Barbel 96 hour $LC_{50}$ greater than 500 mg/L from ecotoxicity data for structurally related analogue A would be 625 to 1 000.

Tailings storage dams are designed to reduce "substantially" the potential for seepage as well as cope with a one in a hundred-year flood. However, regardless of the type of floor employed there remains some risk of tailings dam seepage which may lead to contamination of surface and ground water. Also, periodic discharge of process water at the mine site has been known to occur when storm events coincide with periods of full water storage capacity.

It is assumed that a high evaporation rate from dams of large surface area would result in a constant volume of the dam water. However, the concentration of the notified chemical would not be expected to increase, as some adsorption to sediment and hydrolytic degradation are likely to occur in the highly acidic dam effluent. In the event of a dam breach due to heavy rainfall, high dilution of the dam contents would be expected. Also, the major environmental concern of liberated dam water from a breach would likely be the high acidity of the water as well as any dissolved metals contained within the water.

Given the above, environmental exposure and the overall environmental hazard of the notified chemical is assessed as acceptable.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicology studies on the notified chemical or the product CAL 611 containing it were submitted. Analogues of the notified chemical were of low acute oral toxicity and moderate dermal and inhalation toxicity. Analogues are severe eye irritants and mild to severe skin irritants in rabbits. Data on skin sensitisation were not submitted. In a limited summary of a repeat dose 28 day dermal exposure study in rabbits, an analogue caused severe skin effects, bodyweight loss and effects on the male reproductive tract in males only. The reproductive tract effects were correlated with the degree of bodyweight loss. An inhalation developmental study on another analogue in rats caused developmental effects at maternally toxic doses. One cited study indicated that a related compound was mutagenic to bacteria, however, studies on other related compounds did not indicate this.

In the absence of toxicological data on the notified chemical, classification of the health hazards of the notified chemical is made by analogy with analogues. The overall hazard classification is Harmful (Xn) with risk phrases: R20/21 Harmful by Inhalation and in Contact with Skin; R41 – Risk of Serious Damage to Eyes; and R38 – Irritating to Skin.

*Occupational Health and Safety*
In the occupational environment skin and eye irritancy and systemic toxicity are the hazards of concern for the notified chemical. Transport and storage of the 200 L import containers should not result in worker exposure except in the event of accidental spillage.

Worker exposure during normal use of the notified chemical is most likely to occur from drips and spills when connecting or disconnecting lines or cleaning pumps and ancillary equipment. The notifier states that plant workers involved in transferring the notified chemical during the processing phase are required to wear rubber gloves, safety goggles and overalls. It is critical that employers ensure that workers wear the protective clothing as specified, to minimise the potential for exposure to the 60-100% solution of chemical and the adverse effects of irritancy and toxicity. At the commencement of the processing phase, the notified chemical is contained within an automated process at an initial concentration of less than 0.1%. The subsequent processes also require little worker intervention. Chemical incorporated during process operations is ultimately destroyed during subsequent off-site metal processing.

*Public Health*
As the notified chemical will only be used in the mining industry, there will be minimal public exposure. Based on the information provided, the notified chemical is unlikely to pose a significant hazard to public health when used in the proposed manner due to limited potential for exposure.

## 13. RECOMMENDATIONS

*Occupational Health and Safety*
To minimise occupational exposure to CAL 611 the following guidelines and precautions should be observed:

- Development and implementation of a skin and eye exposure management system: the workplace, equipment and work tasks should be structured to minimise skin and eye exposure and any resultant damage to health;

- Workers should be advised of the potential for skin and eye effects upon contact with CAL 611 and to promptly report any adverse effects to the occupational health and safety officer at their workplace. If an adverse effect occurs, the employer should review work practices and opportunities for contact with the substance and instigate preventive measures to ensure other workers do not develop the same condition;

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia 1987) and AS 3765.1 (Standards Australia 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand 1994);

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

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

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

*Public Health*
If the conditions of use are varied and greater exposure of the public may occur further information may be required to assess the hazards to public health.

*Environment*
To minimise the potential for environmental impact it is recommended that as much as possible of the notified chemical be disposed of to underground backfill.

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for CAL 611 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.

## 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. No other specific conditions are prescribed.

## 16. REFERENCES

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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 |