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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Flomin F810

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Flomin F810

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
SNF (Australia) Pty Ltd (ABN 32 050 056 267)
298 Broderick Road
LARA VIC 3212

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name
Structural Formula
Molecular Formula
Molecular Weight
CAS number
Spectral data
Hazardous & Non-Hazardous impurities and additives/adjuvants
Purity
Import volume
Specified use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point
Boiling Point
Vapour Pressure
Hydrolysis as a Function of pH
Partition Coefficient (n-octanol/water)
Dissociation Constant
Flammability Limits
Autoignition Temperature
Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Flomin F810

METHODS OF DETECTION AND DETERMINATION

Remarks	GC and MS data were provided for the major component.
TEST FACILITY	Eastman Kodak Company (1997a)

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Import via sea freight in 1000 L containers.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	300-1000	1000-3000	1000-3000	3000-10000	3000-10000

USE
As a froth generating reagent in the mineral processing industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sea ports closest to end-user sites

IDENTITY OF RECIPIENTS
Coal and mineral processing plants in Queensland and across Australia

TRANSPORTATION AND PACKAGING
The mode of packaging will vary depending on the volume of chemical to be imported, ranging from 200 L drums, 1000 L IBCs (intermediate bulk containers) to 20,000 L iso-tanks and 500 tonnes parcels in mini-bulk chemical ships. Where 200 L, 1000 L or 20,000 L pack sizes are imported, the containers of the notified chemical will be stored in warehouses in the port city and transported to the end-use sites by road in the original containers. Where 500 tonne shipments are received, the chemical will be pumped into a dedicated bunded storage tank at the port of entry, and later transferred to the end-use site in 15 tonne and 38 tonne lots by road tanker.

5.2. Operation description

Once on-site at the mineral processing facility, the notified chemical will be pumped into a fully earthed storage tank, and in some cases to smaller storage tanks closer to the flotation tank. From these tanks the notified chemical is then pumped to the flotation cells through fixed lines, and dosed automatically at predetermined levels. The flotation cells are partially open and may be located inside buildings or in covered areas open to the atmosphere.

The notified chemical will be added to the float cells along with air, water and minerals at a usage rate of typically less than 100 g per tonne of mineral processed. Minerals will partition into the froth in the flotation cell. The minerals are dewatered and then carried by conveyor to an outdoor stockpile before distribution to users throughout Australia. Quality control staff carry out testing when required. Routine cleaning and minor maintenance of the plant is carried out regularly, and shut-downs occur for major maintenance.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehousing Personnel	2	1 hour/day	200 days/year

Production/Operator	6	8 hours/day	260 days/year
Quality Control	1	1 hour/day	260 days/year
End Use	high	8 hours/day	260 days/year

Exposure Details
Transport and Storage
The highest potential for exposure is during the connection and disconnection of hoses when bulk shipments are transferred to tanks at the port of entry, or the packaged material is transferred to holding tanks at the end-use sites. For all other transport and storage activities, workers are not expected to be exposed to the notified chemical except in the case of an accident involving spillage of the notified chemical

Mineral Processing
The reagent dosing system is fully automated minimising the potential for exposure.
Evaporation of the notified chemical during processing will occur, due to the large surface area exposed. Therefore inhalation exposure to the chemical at low concentrations during the flotation process could occur if workers are near the mineral during processing. Inhalation exposure would be substantially reduced in plants that are open to the atmosphere. As most of the control of the process is remote, production workers are not expected to be near the mineral during processing for extended periods of time. Dermal and ocular exposure to the notified chemical (concentration <1%) could occur to splashes from the flotation cells. Skin contact to the notified chemical (concentration <1%) may also occur through deliberate contact with the mineral slurry.

General maintenance is carried out every two weeks. As the flotation cells are not emptied during maintenance, dermal accidental ocular and inhalation exposure to the notified chemical could occur during maintenance activities.

Other procedures that may lead to worker exposure are quality control testing of the notified chemical or of minerals in processing, and cleaning of containers.

All workers transferring the notified chemical (including transport operators pumping the notified chemical from trucks to site storage), washing containers and doing maintenance or handling equipment will be required to wear long sleeved shirts, long trousers, safety glasses with side shields and chemical resistant gloves as a minimum. If they are likely to be in contact with the notified chemical other than through accidental contact, then a chemical resistant apron is required to be worn.

End Use Application- Mineral
Exposure to the notified chemical in the processed mineral is expected to be very low due to low concentration of residual chemical in the mineral (<0.01%). Potential exposure would be further reduced by PPE worn by workers..

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical will be manufactured overseas. Release to the Australian environment is expected to be limited to accidental spills during transportation and storage.

RELEASE OF CHEMICAL FROM USE
The notified chemical will be used as a frothing agent in coal and mineral mines in Queensland and across Australia, and will be added automatically at a concentration of <0.01% to frothing tanks during washing and flotation processing of coal and minerals. Water, to which the notified chemical will be added, is typically recirculated through the processing plant. After frothing, water is separated from the minerals rich phase and sent to settling dams, prior to re-use. It is expected that a large proportion of the total annual import volume of notified chemical will associate with the coal and minerals treated, and will be thermally decomposed during the burning of the coal or further processing of the mineral ore.

The notifier indicates the split of the notified chemical between the tails and concentrate is likely to vary strongly from mine-site to mine-site as the interactions between surface active materials, desired

minerals, tails and water is difficult to predict and near impossible to measure. The expected ranges are 10 to 99% in the tails with the balance in the concentrate. It is likely based on the ratio of tails to minerals being typically >20:1, the size of the tails particles typically being smaller than the concentrate and the preponderance of water follows to the tails end of the process that the ratio will be in the range of 80 to 99% in the tails. The exception to this is in coal where the ratio of tails to coal is much lower, typically <2:1.

All of the concentrates are further processed through smelting in the case of the mineral ores, coking if coking coal or burning if the coal is used for general heating processes. All of these processes will lead to the ultimate conversion of the notified chemical to CO_2 and water.

Settling dam walls are typically constructed using tailings and are designed to permit water to leach. It is, therefore, anticipated that some water will inevitably enter the groundwater. Based on the apparent relatively high water solubility of the notified chemical, it is expected that a proportion of the total annual import volume will be mobile and could enter groundwater. Given the very large quantities used, this release could be significant. Settling dam walls occasionally breach during periods of intense precipitation, releasing the contents of the dam. It is possible, that in such an event, significant quantities of notified chemical may be released, and enter terrestrial waterways.

5.5. Disposal

Residual with used transport containers will be disposed of through a registered cleaning/reconditioning company. Water from the process is contained onsite and all residue is reused, resulting in adsorption onto the coal, then destroyed into the coking process (the product from the coal washery is used to manufacture coke through partial oxidation of the coal to drive off volatile compounds and leave a carbon residue for steel making. In the heating process, gaseous products are burnt as fuel and the liquid condensates are used as industrial solvents or fuel). Notified chemical that leaches into groundwater is expected to eventually degrade via biotic and abiotic means to form simple organic compounds.

5.6. Public exposure

Public exposure during the use of this chemical will be very low due to use only occurring at mineral processing plants, where there is no public access. Public exposure may occur only in the case of a transport accident where the packaging was breached.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear liquid with characteristic alcohol odour

Melting Point/Freezing Point -11.99ºC

METHOD	Calculation method: MPBPWIN v1.40 (Mean or Weighted MP)
Remarks	Based on the major component.
TEST FACILITY	SNF (2005)

Boiling Point 203.4ºC

METHOD	MPBPWIN v1.40 (adapted Stein and Brown method)
Remarks	For the major component.
TEST FACILITY	SNF (2005)

Density 890-950kg/m^3 at 25ºC

Remarks	Report was not provided.

Vapour Pressure 7.8×10^{-3} kPa at 25ºC

METHOD MPBPWIN v1.40 (mean of Antoine & Grain methods)
Remarks For the major component. With respect to the environment the notified chemical is classified as being volatile (Mensink *et al* 1995).
TEST FACILITY SNF (2005)

Water Solubility

<0.100 g/L at 20ºC (Water Solubility Test)
≥0.100 g/L at 19°C (Fish/Daphnid Test)
≥1.000 g/L at 18.4-19.1°C in distilled water (Alga Test)
≥1.000 g/L at 19.0-20.3°C in sea water (Alga Test)
2.024 g/L at 20°C (WSKOW v1.41)

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks In the water solubility test (flask method), an unknown quantity of notified chemical was mixed with an unknown quantity of water and was agitated at 30°C for up to 3 days before equilibrating at 20°C. Analysis by Gas Chromatography (no details) indicated a water solubility of <0.100 g/L. However, this water solubility test is in direct contrast with observations on water solubility made during ecotoxicity testing. The notified chemical was observed to be soluble at 1.000 g/L at 19.0-20.3°C in sea water after 20 hours stirring, as reported in the algal toxicity test report. Since details of the water solubility test are very limited the higher solubility of ≥1.0 g/L will be assumed, which is consistent with the structure.
TEST FACILITY Sharp & Howells (2007)

Hydrolysis as a Function of pH Not determined.

Remarks The notified chemical does not contain functionality that is expected to hydrolyse within the environmental pH range of 4-9.

Partition Coefficient (n-octanol/water) log Pow = 2.55

METHOD QSAR Estimation
Remarks For the main component, as estimated using KOWWIN v1.67.

Adsorption/Desorption

log K_{oc} (1st Signal) = <1.25 (0.72)
log K_{oc} (2nd Signal) = 1.89
log K_{oc} (3rd Signal) = 2.74

METHOD OECD TG 121 Estimation of the Adsorption Coefficient on Soil and on Sewage Sludge Using HPLC.
Remarks The notified chemical was compared against 7 reference substances. 3 distinct signals were observed, with the first (and main component of ~60%) eluting prior to acetanilide (log K_{OC} = 1.25), the second eluting between atrazine (log K_{OC} = 1.81) and monuron (log K_{OC} = 1.99), and the third (minor component ~7.7%) eluting between linuron (log K_{OC} = 2.59) and pyrazophos (log K_{OC} = 3.65). The log K_{OC} of the main component was estimated as 0.72 by extrapolation.
TEST FACILITY Siemans (2006)

Dissociation Constant Not determined

Remarks The notified chemical is not expected to dissociate in the environmental pH range of 4-9.

Particle Size Not applicable
Remarks The chemical is a liquid at room temperature.

Flash Point Varying results

METHOD Closed cup using Miniflash and Setaflash instruments.
Remarks Study performed on two samples of the notified chemical. A handwritten memo

28/10/97 and test sheet with details of the testing were provided.
Sample 1: No flash to 600ºF (315.5ºC) using Miniflash.
Sample 2: On first run there was no flash to 600ºF (315.5ºC) using Setaflash. On a re-test there was a flash at 235ºF (112.8ºC) when the flame was applied 3 times quickly at the test temperature.

Autoignition Temperature

Remarks Not expected to autoignite below boiling point.

Explosive Properties

Remarks Not expected to explode based on its structure.

Reactivity

Remarks Flomin F 810 is expected to be stable under normal conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral (dose range)	LD50 Males = 922 mg/kg ; Females = 707 mg/kg ; Combined = 825 mg/kg, harmful
Rat, acute oral (limit test)	LD50 >500 mg/kg bw, insufficient data to reach a conclusion
Rat, acute dermal	LD50 >2000 mg/kg bw, low toxicity
Rat, acute inhalation	not determined
Rabbit, skin irritation	moderately irritating
Rabbit, eye irritation	severely irritating
Guinea pig, skin sensitisation – adjuvant test	no conclusion made
Rat, repeat dose dermal toxicity – 13 days.	NOAEL 2000 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro	not determined
Genotoxicity – in vivo mouse micronucleus test	non genotoxic

7.1.1 Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley (SAS:VAF(SD))
Vehicle	Test substance administered as supplied
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2000	100%
II	5 per sex	1000	60% male/80% female
III	5 per sex	500	0%

LD50	Males = 922 mg/kg ; Females = 707 mg/kg ; Combined = 825 mg/kg
Signs of Toxicity	Slight to severe weakness, prostration, stumbling, dehydration, gasping, reduced or ceased faeces, inguinal hair coat wet with urine, red urine and red staining of hair on face and forearms. The surviving group II animals appeared clinically normal from day 5 and the group III animals appeared clinically normal from day 3.
Effects in Organs	Treatment-related gross pathological changes were only observed for three of seven group II animals which died on day 1. These changes consisted on oedema of the glandular gastric mucosa (1/5 male rats) and red discolouration of the urinary bladder (2/5 male, 1/5 female). No other treatment related changes were observed in the group I and group III animals.
Remarks - Results	Multistix® tests indicated that red colouring in urine was blood. Blood was also detected in the urine of group II and group III animals not showing red colouration.
CONCLUSION	The notified chemical is harmful via the oral route.
TEST FACILITY	Eastman Kodak Company (1998a)

7.1.2 Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 401 Acute Oral Toxicity. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).
Species/Strain	Rat/Sprague-Dawley (Crl:CD(SD) IGS BR)
Vehicle	Test substance administered as supplied
Remarks - Method	The purpose of the study was to evaluate the acute toxicity in the female-sprague dawley rat and in particular whether this strain of rat would exhibit hematuria. Therefore deviations from the OECD protocol (Maximum dose tested 500 mg/kg bw and testing carried out in one sex only) were not considered to impact the objective of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 female	500	0

LD50	>500 mg/kg bw
Signs of Toxicity	Abnormal clinical signs were limited to reduced activity and stumbling on the day of dosing.
Effects in Organs	No treatment-related changes were observed at necropsy.
Remarks - Results	No red urine or hematuria were observed following treatment in this study however it was not apparent whether microscopic hematuria was tested for.
CONCLUSION	A single oral dose of 500 mg/kg bw/day did not cause gross hematuria in female rats of this strain.
TEST FACILITY	Eastman Kodak Company (1999a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Test substance administered as supplied
Type of dressing	Occlusive
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 Males	2000 mg/kg	0%
2	5 Females	2000 mg/kg	40%

LD50	>2000 mg/kg bw
Signs of Toxicity - Local	Erythema and desquamation of the skin was observed in males and females. Induration (hardening) of the skin was also observed in females. Local effects had not reversed in all animals at the end of the observation period.
Signs of Toxicity - Systemic	One female rat was found dead on day 1 and a second female on day 3. Weakness, prostration, red urine, lack of faeces and stumbling was observed in females only. No systemic effects were observed on and after day 4.

Effects in Organs	No treatment related changes were observed in the treated males. Minor distention of the urinary bladder (1/2) and darker than normal spleens (2/2) was noted in the females that died. Microscopic changes in these rats consisted of focal necrosis and minimal haemorrhage in the glandular gastric mucosa (1/1), moderate or severe atrophy and moderate or severe congestion of the splenic red pulp (2/2) and or minor atrophy (2/2) and a minimal necrosis (1/2) of the splenic white pulp.
Remarks - Results	Multistix® tests indicated that red colouring in urine was blood. Blood was also detected in the urine of some animals not showing red colouration.

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

TEST FACILITY Eastman Kodak Company (1998b)

7.3. Acute toxicity – inhalation

Not determined

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (sex not specified)
Vehicle	None. Test substance administered as received.
Observation Period	72 hours.
Type of Dressing	Occlusive
Remarks - Method	Statement of GLP. All animals were euthanized following the 72-hour examination due to the degree of irritation observed.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	2.3	2.7	3	72 hour	3
Oedema	1.3	2	3	3	72 hour	3

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	The severity of the irritant response either increased or remained the same during the 72-hour observation period. At the 1-hour observation, signs of irritation consisted of very slight to well-defined erythema and very slight to moderate oedema. At the 72 hour observation signs of irritation consisted of well-defined to moderate-severe erythema and slight to moderate oedema and the study terminated due to the degree of irritation observed.

CONCLUSION The notified chemical is moderately irritating to the skin.

TEST FACILITY Eastman Kodak Company (1997b)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Observation Period 22 days for 2 animals and 11 days for one animal
Remarks - Method Statement of GLP

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.3	1.3	2.7	3	<22 days	0
Conjunctiva: chemosis	1	1.3	1.7	3	<22 days	0
Conjunctiva: discharge	0.3	0.7	1	3	<15 days	0
Corneal opacity	0	0	0	1	7-14 days	1
Iridial inflammation	0	0	0.33	1	<48 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results In one animal (no 3) the following effects were observed:

1. corneal opacity (25-50% of the lower two quadrants) was noted on days 15 and 22
2. iridal inflammation at the 24 hour observation
3. green staining from the 24 hour observation through to day 22 (25-95% of the cornea was effected).

The degree of staining and opacity decreased with time and there was evidence of repair (circumcorneal blood vessels), however complete repair did not occur within 21 days. An attending veterinarian confirmed there was most likely permanent damage.
In the other two animals no corneal opacity or iridal inflammation was observed although green staining was visible at the 24 and 72 hour observation.

CONCLUSION The notified chemical is severely irritating to the eye.

TEST FACILITY MPI Research Inc. (2006)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation 1981- <Footpad method>.
Species/Strain Guinea pig/Crl(HA)BR VAF/Plus®
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: not applicable
topical: 10% v/v (acetone, dioxane and guinea pig fat 7:2:1) (maximum dose tested)
MAIN STUDY
Number of Animals Test Group: 10 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal: 1% v/v (in Freund's Complete Adjuvant)
topical: not applicable
Signs of Irritation No signs of irritation were reported
CHALLENGE PHASE
1st challenge intradermal: not applicable
topical: 10% v/v (acetone, dioxane and guinea pig fat 7:2:1)
Remarks - Method Statement of GLP

Deviations from current OECD TG 406 Skin Sensitisation guidelines

1. Absence of a reliability check performed.
2. Only 10 animals in the test group
3. The intradermal induction was performed in the footpad and involved only one injection.
4. No topical induction conducted
5. Only 7 day rest period between induction and challenge
6. No data relating to irritation scores in the main study following intradermal induction was reported.
7. The challenge concentration may not be the maximum non-irritant dose as it was the only one tested in the preliminary study

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	10%	0/10	0/10	-	-
Control Group	10%	0/10	0/10	-	-

Remarks - Results

Intradermal injection:
No data relating to irritation scores following intradermal induction with Freund's Complete Adjuvant (with and without notified chemical) were reported.

Topical challenge:
In the preliminary study no signs of irritation were observed at the only tested concentration of 10% v/v (acetone, dioxane and guinea pig fat 7:2:1) tested in animals previously exposed to Freund's Complete Adjuvant. Following challenge no reactions were observed in the test or control group animals.

Body weight gains were normal.

CONCLUSION

There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test, however, the test conditions employed are inadequate or not sufficiently documented. Therefore, on the basis of inadequate evidence, no conclusion is made.

TEST FACILITY

Eastman Kodak Company (1997c)

7.7. Repeat dose toxicity

TEST SUBSTANCE

Notified chemical

METHOD

In house – no guidelines for a two-week dermal toxicity study

Species/Strain: Rat/Sprague-Dawley

Route of Administration: Dermal –semi-occluded

Exposure Information: Total exposure days: 13
Dose regimen: 13 consecutive days
Duration of exposure (dermal): 6 hours/day
Post-exposure observation period: None

Vehicle: None. Test substance administered as supplied.

Remarks - Method: Deviations from OECD TG 410 Repeated Dose Dermal Toxicity: 21/28-day

1. Exposure period 13 days
2. No recovery groups
3. Only liver, kidney and spleen were weighed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5/sex	0	0/10
II (low dose)	5/sex	100	0/10
III (mid dose)	5/sex	500	0/10
IV (high dose)	5/sex	2000	0/10

Mortality and Time to Death

All animals survived until scheduled necropsy.

Clinical Observations

Local effects: Erythema, desquamation and eschar formation were observed at the application site for animals in all treatment groups.

Systemic effects: Dehydration was observed for one male and two female high-dose rats (dehydration in the male rat was caused by a malfunction in the watering system). A single incidence of hematuria and discoloured (green) urine was observed for one high-dose female. There were considered to be no treatment related effects on feed consumption or body weight.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Clinical Chemistry: A significantly decreased mean serum phosphorous levels was noted in the high dose male group and a significantly increased mean serum triglyceride level was noted in the high dose female group. Decreased mean serum glucose levels (although not statistically significant) were noted in the high dose male and female groups. In addition, trace/slight levels of red blood cell hemolysis were observed in one mid dose male, one low dose, one mid dose and two high dose females. Another high dose female showed moderate hemolysis.

Haematology: All hematologic parameters for male and female rats from all treated groups were comparable with the control groups. A number of abnormalities, primarily of minimal severity, were observed in the red blood morphology of the peripheral blood smears from animals at all dose levels, including the controls. There appeared to be a slight increased in abnormal cell types for the high-dose male and high- and mid- dose female groups, however, there was no consistent effect in any particular cell type.

Urinalysis: No treatment related changes were detected in the urinalysis. When the urine was tested for the presence of blood, a moderate amount was present in one control male and two low-dose males, a small amount was present in one mid-dose male and trace amounts of non-hemolysed blood was detected for one mid-dose female.

Effects in Organs

Organ Weight: An increase (~10%) in relative liver weight was noted in the high dose males and females (the increase was only statistically significant in the high dose females).

Macroscopic findings: Treatment related lesions were limited to the skin at the application site. Lesions consisted of erythema (high-dose females (2/5)) and desquamation (high-dose males (2/5), high-dose females (5/5), mid dose females (2/5), low-dose females (4/5)).

Microscopic findings: The severity of hepatocellular vacuolation in the high dose female was slightly increased in comparison to the female control group. Four of the control group were graded as minimal with one graded as mild for hepatocellular vacuolation, while all five high dose group were graded as mild. There were no abnormal microscopic findings in the spleen.

Remarks – Results

Red blood cell hemolysis observed in the serum for animals from animals was not considered to be treatment related as no adverse effect on hematologic parameters or the spleen.

As the liver weight change and cytoplasmic vacuolation were slight, and serum analytes associated with liver function were comparable among the groups, these changes were not considered toxicologically significant.

CONCLUSION
Based on the dermal irritation observed at all treatment levels, a no-observed-effect level (NOEL) was not determined. However for systemic effects, the No Observed Adverse Effect Level (NOAEL) was established as 2000 mg/kg bw/day in this study, based on the absence of toxicologically significant findings in the treated animals.

TEST FACILITY Eastman Kodak Company (1999b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified Chemical

METHOD EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA (pKM101)
Metabolic Activation System	S9 microsomal fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 100-5000 µg/plate b) Without metabolic activation 100-5000 µg/plate
Vehicle	Dimethylsulphoxide
Remarks - Method	The preliminary test (dose rangefinding study) was conducted using strains TA100 and WP2uvrA (pKM101). Deviations from protocol 2-Aminoanthracene used as the sole indicator of the efficacy of the S9-mix.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	3,300 (both strains)			
Test 1		2500 (TA98, TA100), 5000 (all *S. typhimurium* strains)	>5000	negative
Test 2		2500 (all *S. typhimurium* strains)	>5000	negative
Present	3,300 (TA100), 5000 (WP2uvrA			
Test 1		5000 (TA98, TA100)	>5000	negative
Test 2		5000 (all *S. typhimurium* strains)	>5000	negative

Remarks - Results The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Negative controls were within historical limits. Positive controls confirmed the sensitivity of the test system

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

TEST FACILITY Covance (1997)

7.9. Genotoxicity – in vitro

Not determined

7.10. Genotoxicity – in vivo

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/CD-1
Route of Administration	Oral – gavage
Vehicle	Corn Oil
Remarks - Method	Test item administered twice about 24 hours apart. No significant protocol deviations.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 female	0	24 hours after final dose
II (low dose)	5 female	1000	24 hours after final dose
III (mid dose)	5 female	1250	24 hours after final dose
IV (high dose)	5 female	1500	24 hours after final dose
V (positive control, CP)	5 female	50	24 hours after final dose

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	Signs of toxicity after the first dose were not reported with the exception of one high-dose animal that was euthanised for humane reasons. After the second dose observations in all dose groups included decreased movement, lethargic, uncoordinated movement, tail cold and ventral recumbency.
Genotoxic Effects	The test substance did not induce a statistically significant increase in the frequency of micronucleated polychromatic erythrocyte over the levels observed in the vehicle control.
Remarks - Results	
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo mouse micronucleus test.
TEST FACILITY	ILS (2006)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical.

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
EEC/Annex V C.4

Inoculum	Activated Sludge
Exposure Period	28 d
Auxiliary Solvent	Nil
Analytical Monitoring	Carbon dioxide, Temperature, pH, DOC.
Remarks - Method	Distilled water was used for the preparation of the Basal Salts Medium (BSM) and the other solutions. A test substance stock of 20 mg DOC/L was prepared (27 mg/L purged BSM). The pH of the stock solution was not adjusted because it was within the required range of 3 to 10. A positive control using sodium benzoate was also exposed to validate the test.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	1.5	3	20
8	4	8	51
10	12.5	10	60
16	37.5	16	67
23	48.5	23	71
28	53.5	28	74

Remarks - Results

The notified chemical was found to be ultimately biodegradable. All validation criteria were met.

It was noted that the test substance, as received by the laboratory, is a crude mixture containing several components and impurities including water. If the carbon dioxide evolution was normalized to the amount of the major component, the percent biodegradation calculated would suggest ready biodegradability. However, because some of the impurities contain significant amounts of carbon it is not possible to quantify theoretical CO_2 evolution in terms of major component alone.

Although the test substance could not be classified as readily biodegradable, it is unlikely that the test substance would persist in an aquatic environment as evidenced by the significant carbon dioxide evolution.

CONCLUSION: According to the strict conditions of the test, the notified chemical cannot be classified as readily biodegradable.

TEST FACILITY: Eastman Kodak Company (1997d)

8.1.2. Biochemical oxygen demand (BOD)

TEST SUBSTANCE	Notified chemical
METHOD	OECD Method C.5. "Degradation, Biochemical Oxygen Demand"
Exposure Period	20 d
Auxiliary Solvent	Nil
Remarks – Method	The method and materials can be found in "Determination of Biochemical Oxygen Demand of Solid and Liquid Organic Chemicals". Method No. KPCQ-A-EA-G-M-3-1, Eastman Kodak Company. The density was determined by weighing the test substance contained in a 1 mL volumetric flask on a Mettler AT261 balance. The density was done in triplicate. The mean of the three density results was found to be 0.91 g/mL.

RESULTS

BOD (5 days) g/g	*COD g/g*	*BOD5/COD*
0.070	2.54	0.028

Remarks – Results	The 5 day BOD result was calculated on dilutions that exhibited a dissolved oxygen drop less than the required drop of two milligrams per litre. This was necessary due to the inhibitory effect of this test substance. The dissolved oxygen drop of the dilution water and the seeded dilution water was outside of the method requirements. The reference sample was within the accuracy requirements for the method. Therefore, this will not adversely affect the results of the test. The results of the 20 day BOD for the test substance at 0.0030% was 1.30 g BOD /g of test substance. The test substance exhibited inhibitory effects in the 20-day BOD test, therefore only the most dilute solution was used to calculate the final 20 day BOD. An inhibitory BOD result should be interpreted as an estimated result due to decrease activity of the microorganisms.
CONCLUSION	Not readily biodegradable and inhibitory at the test concentration used (contrast with Ready Biodegradability Test).
TEST FACILITY	Eastman Kodak Company (1997e)

8.1.3. Chemical oxygen demand (COD)

TEST SUBSTANCE	Notified chemical
METHOD	
Remarks – Method	The test was performed in duplicate and 0.500 M potassium dichromate solution was used to standardize the ferrous ammonium sulphate titrant. Mercuric sulphate was added to minimise chloride interferences, if any. The method used was CQS-EQS/CLAS-QOD-0053.
Remarks – Results	The results of the COD analysis for the test substance were 2.48 and 2.60 g COD/g test substance. The average result was 2.54 g COD/g test substance. The Chemical Oxygen Demand result, which is also used in the calculation of the BOD5/COD ratio, was performed in duplicate instead of triplicate. One sample setup used a sample weight that was too large. This had no adverse on the BOD5/COD ratio or the COD result.
TEST FACILITY	Eastman Kodak Company (1997f)

8.1.2. Bioaccumulation

REMARKS Based on the molecular weight, relatively high water solubility and low log P_{OW}, the notified chemical is not expected to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical.

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static Test.
EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static Test.

Species	Fathead minnow (*Pimephales promelas*)
Exposure Period	96 h
Auxiliary Solvent	Nil
Water Hardness	123.0 mg $CaCO_3$/L
Analytical Monitoring	Purity analysis: GC/FID; Structure Confirmation: GC/MS.
Remarks – Method	The concentration of the test substance in the exposure solutions was not analytically verified because the test substance is a crude mixture containing several components. The test substance exposures were prepared by adding the appropriate amount of test substance to cuboidal glass test vessels containing 20 L of dilution water. Prior to the addition of the organisms, the exposure solutions were vigorously stirred with a hand-held mixer for 2-3 minutes to enhance dissolution of the test substance.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		14	0	0	0	0
6.25		14	0	0	0	0
12.5		14	0	0	0	0
25		14	0	0	0	0
50		14	0	2	2	2
100		14	14	14	14	14

LC50	57.4 mg/L at 96 hours. 95% CI: 29.71 – 110.8 mg/L
NOEC	25 mg/L at 96 hours.
Remarks – Results	Values are based on nominal concentrations only. The minnows in the dilution water controls exhibited normal behaviour and appearance throughout the test. The test substance and control exposures appeared clear and colourless throughout the test. There were no apparent particulates, surface slicks or precipitates observed. All test validation criteria were satisfied.

CONCLUSION The notified chemical is harmful to fish.

TEST FACILITY Eastman Kodak Company (1998c)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static Test. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static Test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Nil
Water Hardness	123.0 mg $CaCO_3$/L
Analytical Monitoring	Purity analysis: GC/FID; Structure Confirmation: GC/MS.
Remarks - Method	The concentration of the test substance in the exposure solutions was not analytically verified because the test substance is a crude mixture containing several components. The test substance exposures were prepared by adding the appropriate amount of test substance to cuboidal glass test vessels containing 20 L of dilution water. Prior to the addition of the organisms, the exposure solutions were vigorously stirred with a hand-held mixer for 2-3 minutes to enhance dissolution of the test substance.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
6.25		20	0	0
12.5		20	0	0
25.0		20	0	0
50.0		20	0	0
100.0		20	0	11

LC50	98.1 mg/L at 48 hours 95% CI: 86.4 – 111.3 mg/L
NOEC	50.0 mg/L at 48 hours
Remarks - Results	At 48 h, partial immobility (11 out of 20 daphnids) was observed in the test vessels containing nominally 100 mg/L. The daphnids in the dilution water controls exhibited normal behaviour and appearance throughout the test. Values are based on nominal concentrations only. The test substance and control exposures appeared clear and colourless throughout the test. There were no apparent particulates, surface slicks or precipitates observed. All test validation criteria were satisfied.
CONCLUSION	The notified chemical is harmful to daphnids.
TEST FACILITY	Eastman Kodak Company (1998d)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 201 Alga, Growth Inhibition Test.
Species	*Selenastrum capricornutum*
Exposure Period	72 hours
Concentration Range	Nominal: 10, 18, 32, 56, 101, 320, 1010 mg/L
Auxiliary Solvent	Nil
Analytical Monitoring	Analysis was not conducted
Remarks - Method	Nutrient medium was prepared from distilled water. Immediately prior to testing, the pH of the culture medium was adjusted to pH 8.1 ± 0.2 by the addition of 1M HCl or NaOH. The notified chemical was found to be soluble in sea water at 1000 mg/L after stirring for 20 h. A reference test was conducted concurrently using 3,5-Dichlorophenol at 5.6, 3.2, 1.8, 1.0 and 0.32 mg/L.

RESULTS

Growth	
E_rC50	*NOEC*
mg/L at 72 h	*mg/L*
76.65	32
95% CI: 51.56 - 131.39	

Remarks - Results	The results are based on nominal concentrations. The 3,5-Dichlorophenol EC50 and control growth rate did not meet the recommended guideline criteria, however, this was not thought to have affected the end result.
CONCLUSION	The notified chemical is harmful to freshwater algae.
TEST FACILITY	Opus (2006)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical is manufactured overseas and is imported into Australia. The notified chemical will be used domestically within the mining industry as a frothing agent for the processing of coal and minerals. It is expected that the majority of the total annual import volume will associate with the coal and minerals processed with it, and will be thermally decomposed when the coal is burnt/oxidised or when the minerals are further processed.

During the processing, the notified chemical is added to water. The latter, is sent to settling dams prior to recycling. Due to the low log K_{OC} (estimated to be 0.72 for the main component), it is expected that notified chemical will leach with water from the settling dams and potentially enter groundwater. This quantity could be significant but unquantifiable.

Accidental spills during transportation are expected to be minimal, and will be contained, and disposed of to secure landfill or by incineration. Quantities released during settling dam wall breach, may be significant in the local environment, but also unquantifiable. Intentional release to surface water is not expected. Therefore, it is not possible to calculate a Predicted Environmental Concentration (PEC) with the aquatic environment.

9.1.2. Environment – effects assessment

Based on the results of ecotoxicity testing, the notified chemical was found to be harmful to aquatic organisms, with the most sensitive trophic level being fish. Based on this, the Predicted No-Effect Concentration has been calculated as follows:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	57.40	mg/L
Assessment Factor	100.00	
Mitigation Factor	1.00	
PNEC:	574.00	µg/L

9.1.3. Environment – risk characterisation

The main route of destruction of the notified chemical will arise during oxidative processes associated with the further processing and use of the mineral ores and coal. This will result in the formation of CO_2 and water.

The notified chemical is moderately volatile (Mensink *et al* 1995) from water, based on its estimated Henry's Law Constant of 2.63 X 10^{-4}, and will evaporate from hard surfaces, based on its vapour pressure. Therefore, it is expected that significant losses to air may arise from both tailings dams and from the concentrated coal fines or mineral ore heaps during handling, transport and storage. In air the notified chemical is likely to be non-persistent based on an estimated half-life of 7.7 hours (estimation by AOP Program v1.91).

As described above, some notified chemical may leach in the tailings dam given its relatively high water solubility and its low log K_{OC}, with the potential for notified chemical reaching groundwater. Therefore, proper containment and groundwater recovery infrastructure should be in place when the notified chemical is used.

Direct release to surface waters is not expected under the proposed used patterns, and therefore, no PEC can be calculated. The risk to the environment is expected to be acceptable, provided that the above recommendations for physical containment and groundwater recovery infrastructure are complied with.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Exposure to the neat notified chemical is only expected during the connection and disconnection

of hoses (when bulk shipments are transferred to tanks at the port of entry, or the packaged material is transferred to holding tanks at the end-use sites) and during quality control activities.

The estimated dermal exposure to the notified chemical, based on EASE model using reasonable worst case defaults for particular activity (European Commission, 2003) is as follows:

Activity	*Estimated exposure for activity <mg/day>*	*Estimated exposure for notified chemical <mg/kg bw/day>**
Coupling and decoupling of transfer line	42	0.6
Quality control sampling	21	0.3

* for a 70 kg worker and a 100% dermal absorption factor

Exposure would be limited by the use of PPE.

The potential for worker exposure during mineral processing is limited due to the fully automated systems, however exposure to the notified chemical is likely to be site-dependent, varying with layout and type of plant. Dermal and ocular exposure to splashes from the flotation cells or following deliberate contact with the mineral slurry would be limited by the low concentration of the notified chemical (<1%). Exposure would be further limited by the use of PPE.

Inhalation exposure to the chemical during the flotation process could occur if workers are near the mineral during processing. The atmospheric concentration of the notified chemical is expected to be low due to the low concentration of the notified chemical in the mineral slurry and the relatively low vapour pressure of the notified chemical. Inhalation exposure is expected to be greater where the atmospheric concentration of the notified chemical could build up i.e. when the flotation cells are located inside buildings. Maintenance workers exposure is expected to be more prolonged than production workers.

Exposure to the notified chemical during handling of the processed coal and minerals is expected to be minimal due to the low concentration of the notified chemical (<0.01%).

9.2.2. Public health – exposure assessment

Public exposure during the use of this chemical will be very low due to use only occurring at mineral processing plants, where there is no public access.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified chemical is harmful via the oral route (LD50 825 mg/kg bw) and of low toxicity via the dermal route (LD50 > 2000 mg/kg bw (although mortalities were observed)). The notified chemical was considered to be a gastric irritant at doses of 1000 mg/kg bw and cause gross hematuria at 1000 mg/kg bw (oral) and 2000 mg/kg bw (dermal, females only).

Irritation and Sensitisation.
Based on the results of irritation studies in rabbits, the notified chemical is considered to be moderately irritating to skin and severely irritating to eyes. The effects observed in the eyes were delayed effects. Although there was no evidence of sensitisation in a footpad sensitisation test in guinea pigs, due to the inadequate conditions of the test no conclusion of the sensitisation potential could be made. The notified chemical does not contain a structural alert for sensitisation (Barratt, 1994).

Repeated Dose Toxicity.
In a 13-day dermal repeat dose study in rats, based on the dermal irritation observed at all treatment levels, a no-observed-effect level (NOEL) was not determined. However for systemic effects, the No Observed Adverse Effect Level (NOAEL) was established as 2000 mg/kg bw/day in this study, based on the absence of toxicologically significant findings in the treated animals. However, it is noted that in the acute dermal toxicity that adverse effects (death, gross

hematuria) were noted at this dose and therefore a dermal NOAEL of 1000 mg/kg bw/day is chosen for risk assessment purposes.

Mutagenicity.
The notified chemical was negative in an Ames test and an in vivo mouse micronucleus test. Based on these studies, the notified chemical is not considered to be a potential mutagen.

Hazard classification for health effects.
Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Systemic Effects (dermal exposure)
Dermal exposure to the notified chemical through contact with the neat notified chemical, contact with the mineral slurry (concentration notified chemical <1%) and contact with the processed mineral (concentration notified chemical <0.0l%). Dermal exposure is expected to be greatest where contact with the neat notified chemical could occur. Based on a NOAEL of 1000 mg/kg bw/day, the margin of exposure (MOE) for various activities are as follows:

Activity	*Estimated exposure for notified chemical <mg/kg bw/day>*	*Margin of Exposure*
Coupling and decoupling of transfer line	0.6	250
Quality control sampling	0.3	500

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Therefore, the risk of systemic effects for all workers using modelled worker data is considered to be acceptable.

Local Effects (skin/eye)
The notified chemical is moderately irritating to skin and may cause delayed serious damage to the eyes. The risk of adverse effects would be greatest where dermal and ocular exposure to the neat chemical could occur (i.e. during transfer and quality control operations), however, irritancy effects cannot be ruled out (especially in the eye) where contact with the mineral slurry could occur. The risk of irritancy effects would be ruled out by the use of PPE (gloves and safety glasses).

Respiratory effects
The respiratory effects of the notified chemical are not known, however, as the atmospheric concentration of the notified chemical is expected to be low, there is not expected to be a significant risk of adverse respiratory effects. Where the atmospheric concentration of the notified chemical may build up, the risk of adverse respiratory effects cannot be ruled out, especially in maintenance workers where exposure could be for more prolonged periods of time. The risk would be reduced by the presence of adequate ventilation or the use of respiratory protection where adequate ventilation is not available.

9.2.5. Public health – risk characterisation

The risk to public. health is considered to be negligible based on the negligible exposure expected.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC

Approved Criteria for Classifying Hazardous Substances. The classification and labelling details are:

(Xn) R22 Harmful if swallowed
(Xi) R38 Irritating to skin
(Xi) R41 Risk of serious damage to eyes

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Health		
Acute toxicity (oral)	4	Harmful if swallowed
Acute toxicity (dermal)	5	Maybe harmful in contact with skin
Skin Corrosion/Irritation	2	Causes skin irritation
Serious eye damage/eye irritation	1	Causes severe eye damage
Environment	Acute 3 Chronic 3	Harmful to the aquatic environment. Harmful to the aquatic environment with long lasting effects.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R22 Harmful if swallowed
  - R38 Irritating to skin
  - R41 Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - conc >25%: R22, R38, R41
  - 20% < conc < 25%: R38, R41
  - 10%<conc<20%:R41
  - 5%<conc< 10%:R36
- The following safety phrases should appear on the MSDS and label for the notified chemical:
  - S24: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
  - S37: Wear suitable gloves
  - S39: Wear eye/face protection

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Pumps, couplings and transfer lines should be selected to avoid spillage.

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Ventilation systems where mineral processing occurs inside buildings.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with skin and eyes
  - Minimise time spent near open floatation cells

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Protective clothing
  - Protective gloves
  - Eye protection
  - Respiratory protection when working near the floatation cells where adequate ventilation is not available

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

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

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

Environment

- The following control measures should be implemented to minimise environmental exposure during use of the notified chemical:
  - Physical bunding should be put in place to contain process waters in the event of a settling dam wall breach and groundwater recovery infrastructure should be employed.
  - Tailings dams / settlings pounds should be adequately lined and or be designed to allow ground water recovery.

Disposal

- The notified chemical should be disposed of by incineration or to secure landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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