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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

INTERMEDIATE F-6804 ACTIVE INGREDIENT

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989* (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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

INTERMEDIATE F-6804 ACTIVE INGREDIENT

1. APPLICANT

Nalco/Exxon Energy Chemicals Australia Pty Ltd of 226 York St, SALE, VIC 3850 has submitted a standard notification statement in support of their application for an assessment certificate for Intermediate F-6804 Active Ingredient.

2. IDENTITY OF THE CHEMICAL

The notified chemical is classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (8) in relation to skin and eye irritancy, skin sensitisation and severe effects after repeated or prolonged exposure by the dermal route. However, for commercial reasons, the identity of the notified chemical has been granted exemption from publication in the Full Public Report and the Summary Report. The conditions of this being permitted are:

- A descriptive generic name, Salt of an aliphatic amino acid amide be used to identify the substance in public reports and Material Safety Data Sheets (MSDS),
- The relevant employee unions shall be informed of the conditions of use of the notified chemical,
- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,
- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,
- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,
- Confidentiality will expire after a 3 year period,
- The chemical be identified as a skin and eye irritant, a skin sensitiser and capable of producing reproductive effects in males in the Health Effects section, and that reference to assessment by NICNAS be made on the MSDS,
- These conditions shall be published in the Chemical Gazette.

Trade name: the notified chemical is to be imported as a 47.5% solution containing 50% monoethylene glycol under the name of Intermediate F-6804

Molecular weight: 500 < MW < 1000

Method of detection and determination: a colourimetric method for detection of this class of chemical in brine was provided

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear amber-brown liquid
Odour:	expected to be reminiscent of geraniums
Boiling Point:	197°C
Density:	1108 kg/m^3 at 15°C
Vapour Pressure:	2.29 X 10^{-14} kPa (estimated by ASTER using QSAR for the C_{14} compound)
Henry's Law Constant:	5.95 X 10^{-15} Pa· m^3/mole (presuming vapour pressure and water solubility as calculated)
Water Solubility:	2.4 g/L (estimated by ASTER using QSAR for the C_{14} compound)
Partition Co-efficient (n-octanol/water) log P_{ow}:	2.57 (estimated by ASTER using QSAR for the C_{14} compound)
Hydrolysis as a function of pH:	not determined
Dissociation Constant:	3.16 (estimated by ASTER using QSAR for the C_{14} compound)
Flash Point:	120°C
Flammability Limits:	3.2 vol % (combustible but not flammable)
Autoignition Temperature:	413°C
Explosive Properties:	not considered to be explosive
Reactivity/Stability:	not considered reactive; does not degrade or decompose; hazardous polymerisation will not occur; incompatible with strong oxidising agents

Comments on physico-chemical properties

Several parameters of the notified chemical were obtained by the notifier from the ASTER database which used quantitative structure activity relationships (QSAR). The estimated high water solubility was consistent with the intended use for which this property is essential. ASTER estimated that approximately 95% of the notified chemical would partition to water using the fugacity method. The Henry's Law constant was calculated based on the estimated vapour pressure and water solubility and indicated that the compound is not expected to be volatile from water or moist soil surfaces. The compound will react with strong oxidising agents but is stable otherwise.

4. PURITY OF THE CHEMICAL

Degree of purity: 95%

Toxic or hazardous impurities: None
Non-hazardous impurities (> 1% by weight): A polymer of a simple organic acid is present at 5%.

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a corrosion inhibitor in crude oil pipelines and may also be used for the same purpose in oil wells. It is to be imported in 200 L steel drums at a rate of 10-100 tonnes per year. The formulation to be imported contains 50% monoethylene glycol and 2.5% of a simple organic acid in addition to the notified chemical.

6. OCCUPATIONAL EXPOSURE

The steel drums in which the notified chemical is to be imported are to be removed from the container either at the reformulation site or offsite. Occupational exposure is unlikely except in the case of a transport or unloading accident.

The imported formulation is transferred from the drums into a blend tank using a specially designed air diaphragm pump. Water is added to reduce the concentration of the notified chemical to 25%, and, following blending, a filling spear is inserted into the blend tank through the top man-hole cover for drumming off into either 1000 L bulk containers or 200 L steel drums. Exposure during these operations is possible from spills, drips and splashes and would be expected to occur occasionally.

The 1000 L bulk containers are either stainless steel or polypropylene. They are filled using a filling spear through a man-hole cover and are tested for potential leakage on a regular basis.

After filling, the bulk containers or drums will be transported to oil wells on land or oil rigs offshore. In the latter case, the containers are loaded into sea containers and shipped to the platform by boat. In either case, the containers or drums of the notified chemical formulation are hooked up to a chemical injection pump facility via a flexible connection hose connected to the bottom outlet camlocked valve of the tank which has ball valve isolation. Injection by small dosage chemical pumps at levels of ppm occurs through stainless steel tubing either directly into the pipeline flow or via the process lift gas if being used as a gas lift corrosion inhibitor downhole. Low level exposure may be possible when connecting and disconnecting lines.

7. PUBLIC EXPOSURE

No public exposure to the notified chemical is expected to occur during storage or distribution to blending sites.

No public exposure is expected to occur during reformulation or distribution to oil platforms.

If used in crude oil pipelines the notified chemical will be reclaimed at crude oil processing plants and sent to waste water treatment plants. Effluent from these plants will be sent to sea. If used in oil wells, waste chemical will be disposed directly into the sea. Given that the notified chemical is stated to be readily biodegraded and that significant dilution of any waste will occur on entering the sea, no significant public exposure is expected to occur.

8. ENVIRONMENTAL EXPOSURE

. Release

The material will be imported in 200-L steel drums as a 1:1 mixture of the notified chemical and monoethylene glycol solvent. The drums will be transported in totally sealed containers by road tanker to the blend yards in major cities close to oilfields around Australia where the mixture will be blended with equal volumes of water in batches of 20000 L. The diluted material (approximately 25% notified chemical) will then be repacked into 1000 L bulk containers for transfer to the marine terminal to be shipped to the oil platforms. The notifier expects that the material will initially be used by one customer on 12 platforms in the Bass Strait. At the platform, the containers will be connected by pump to the pipeline and the diluted material continuously fed in at a final concentration of 10 - 20 ppm.

Environmental release of the notified chemical in its intended use as a corrosion inhibitor in oil pipelines will be minimal unless spilt accidentally. The notifier estimates that approximately 500 - 520 kg/year of chemical will be left as residues in "empty" drums after decanting. These drums will be sent to reconditioners where the residues will be incinerated producing oxides of carbon, nitrogen and hydrogen. Releases during normal product transfer operations (discounting accidental spillage) has been estimated at 1250 kg/year and will be collected and incinerated.

A possible future use of the notified chemical will be as a corrosion inhibitor in oil wells on the platforms. In this use, crude oil pumped up from wells would contain the notified chemical in the water phase. The water, containing 100% of the chemical, would be separated from the crude oil and discharged into the sea. The notified chemical is replacing a compound that is currently used in this fashion with 100% disposal to the sea.

. Fate

During use in the oil pipeline, the notifier does not expect release of the notified chemical to the environment will occur under normal operating conditions. On shore, the crude oil will be separated from the water phase which will contain 100% of the notified chemical due to its high water solubility. The notifier estimates that 70 kg/day of the chemical will be treated in the water phase at the Esso Longford Crude and Gas Processing plant which feeds into biodegradation ponds at the Dutson Downs wastewater treatment plant. The outflow mixes with other wastes from the Latrobe valley before discharging 1.2 km offshore. After treatment, the notifier estimated about 18 kg/day of the chemical will be released into the sea from the plant at a concentration of 20 ppm in the receiving waters. However, the rationale for this calculation was not provided and the effluent concentration

was recalculated as 0.45 ppm before dilution by the sea based on an outflow of 4 X 10^7 L/d (1).

A biodegradability test performed according to *OECD Guideline 306 Biodegradability in Seawater* found that 73% of the material biodegraded after 28 days. Transformation was linear for the first 15 days (67% biodegraded) but then slowed until 28 DAT (73% biodegraded). This would classify the notified chemical as readily biodegradable since 60% degraded within the 28 d time frame of the test.

The potential bioaccumulation of the compound was estimated by measuring the log K_{ow} according to OECD Guideline 117 Partition Coefficient (n-octanol/water), HPLC Method. The experiment identified 10 peaks with log K_{ow} ranging from < 0 to 5.7. Based on the molecular structure and estimated water solubility of the notified chemical, however, the expected log K_{ow} is low and the compound would not be expected to bioconcentrate or bioaccumulate to a significant degree. In addition, ASTER (fugacity) estimated that it would not partition into aquatic biota.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity studies on the notified chemical were not available. However, toxicological data on some analogues were provided and are evaluated below. The major difference between the analogues and the notified chemical is that, in the latter, the free amine groups have been neutralised.

9.1 Acute Toxicity

9.1.1 Oral Toxicity

Test article:	**8EHQ-1084-0531S (2)**
Species/strain:	rat, Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage
Clinical observations:	nine animals exhibited decreased activity (5M, 4F), ataxia (4M, 5F) and salivation; all animals exhibited diarrhoea; 2 animals (1M, 1F) displayed dark material around the eyes; 4 animals (1M, 3F) exhibited wet abdomens
Mortality:	4M, 2F
Morphological findings:	no noteworthy findings
Result:	administration of the test chemical at 5000 mg/kg resulted in 60% mortality
Test article:	**MRD-HCP-75-037* (3)**
Species/strain:	rat
Number/sex of animals:	10 males

Observation period: 14 days

Method of administration: gavage

Clinical observations: none
Mortality: none

Morphological findings: not done

Result: no mortality from a single dose of 2000 mg/kg

* the test articles MRD-HCP-75-037 and MRD-HCP-75-039 (see below) contain the same active ingredient except that the former contains 9.5% Aromatic 100 solvent and the latter 33% heavy aromatic naphtha

9.1.2 Dermal Toxicity

Test article: **MRD-HCP-75-039* (4)**

LD_{50}: > 3160 mg/kg

Species/strain: albino rabbits

Number/sex of animals: 4 males

Observation period: 14 days

Method of administration: occluded polyethylene sheet, abdominal skin abraded

Clinical observations: none given

Mortality: no deaths

Morphological findings: no abnormalities

Result: no mortality at dose levels of 200 and 3160 mg/kg

***** this is the same chemical as for the oral toxicity data listed above except that the test article contains 33% heavy aromatic naphtha

9.1.4 Skin Irritation

Test article: **MRD-HCP-75-039* (4)**

Species/strain: albino rabbits

Number/sex of animals: 4 males

Method of administration: occluded polyethylene sheet, abdominal skin abraded

Observations:

Time after decontamination (days)	*Dose*	
	200 mg/kg	*3160 mg/kg*
1	marked erythema	marked erythema
3 or 4	marked desquamation	marked erythema, moderate skin fissures, scabby skin
7	moderate desquamation	moderate erythema, marked desquamation, scabby skin
11	moderate desquamation	marked desquamation, slightly scabby skin
14	slight desquamation	moderate desquamation

* the rabbits used for determination of dermal toxicity in the study shown above were also observed for signs of skin irritation

Result: severe skin irritant in rabbits

Test article: **8EHQ-1084-0531S (5)**

Species/strain: New Zealand White rabbits

Number of animals: 6

Method of administration: 0.5 mL of the test article under an occlusive gauze patch

Result: severe irritant; a Draize score (6) of 4 for erythema (severe) was recorded in each rabbit at 24 and 72 hours after decontamination for intact and abraded skin and a Draize score of 1 for oedema (very slight) was recorded under the same conditions

9.1.5 Eye Irritation

Test article: **MRD-HCP-75-039 (4)**

Species/strain: albino rabbits

Number of animals: 6

Method of administration: 0.1 mL of test substance into one eye

Draize Scores[i] (6):

	Time after instillation													
Animal	***1 hr***		***4 hrs***		***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***
1	1	-	1	-	2	4	2	4	2	3	2	3	2	2
2	1	-	1	-	2	4	2	3	2	2	2	1	1	1
3	1	-	1	-	2	4	2	3	2	2	2	1	1	1
4	1	-	1	-	2	3	2	3	2	3	2	3	2	2
5	1	-	1	-	1	3	1	2	1	2	1	1	1	1
6	1	-	1	-	2	4	2	3	2	2	2	1	2	1
Iris														
1	0		1		1		1		1		1		1	
2	0		1		1		1		1		1		0	
3	0		1		1		1		0		0		0	
4	0		1		1		1		1		1		0	
5	0		1		1		1		1		0		0	
6	0		1		1		1		1		0		0	
Conjunctiva														
	r[c]	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1
2	1	0	2	2	1	2	2	1	3	2	1	2	1	0	1	1	0	0	0	0	0
3	1	0	2	2	1	2	2	1	2	2	1	1	1	1	1	1	1	1	0	0	0
4	1	1	2	2	2	2	2	2	2	2	2	2	2	1	2	1	1	2	1	0	1
5	1	1	1	2	1	2	2	1	2	1	1	1	1	0	1	1	0	0	0	0	0
6	1	0	2	2	1	2	2	1	2	2	1	1	2	0	1	1	0	0	1	0	0

[i] See Attachment 1 for Draize Scales
[a] Opacity [b] Area [c] Redness [d] Chemosis [e] Discharge

Result: the test article is judged to be a moderate eye irritant in rabbits

9.2 Repeated Dose Toxicity

Test article: **MRD-HCP-75-037 (7)**

Species/strain: New Zealand White rabbits

Number/sex: 10 males, 10 females per group

Method of administration, dose and duration: appropriate amounts of the test substance were dissolved in the control solvent and applied at a dose volume of 2 mL/kg to the dorsal surface of each animal once a day for 28 days; all rabbits were fitted with Elizabethan collars to prevent ingestion of the test substance and the backs were wiped with paper towels approximately 6 hours after application to remove excessive test substance, if necessary; the doses used were 2.0% (low dose) and 40% (high dose) (v/v)

Toxicologically Significant Observations:

Mortality

one animal died spontaneously in the control group, one in the low dose group and one in the high dose group; one animal in each dose group was killed as moribund; all animals in the high dose group were terminated on day 8 due to the severe dermal response

Clinical signs

slightly higher ano-genital staining was observed in the low dose group; three males and one female in the control group showed signs of emaciation during one of the four weeks of the study compared to one female in the low dose group; in the high dose group 6 males (2 slight, 3 moderate, 1 extreme) and 9 females (5 slight, 1 moderate, 3 extreme) exhibited signs of emaciation up until termination on day 8

necrotic dorsal surface was not observed in the control group but was observed in the treated groups; in the low dose group 2 males and 4 females exhibited a necrotic dorsal surface and in the high dose group 9 males and 9 females

Skin reactions

Skin reactions are summarised as follows:

Erythema*

Day:		***0***		***2***		***4***		***7***		***10***		***12***		***15***		***17***		***20***		***32***
Dose		***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***
Control	S	1	3	5	9	3	7	6	8	5	4	6	8	5	8	8	8	8	9	7
	M									3	1	3	1	4	1	1	1	1	0	1
	E																			
LD	S	1	1	5	4					7	8			1		3	1			
	M			5	6		3		2	2	1	9	8	4	3	5	7	7	7	2
	E					10	7	10	8			1	1	5	5	2	1	3	2	7
HD	S		2																	
	M			7	8															
	E			3	1	10	10	9	9											

* in this table responses are graded as slight (S), moderate (M) or extreme (E) and the number of animals out of a possible 10 for each sex is shown; for clarity zeros are left out

Oedema

no oedema was observed in control or high dose animals up to sacrifice; for low dose animals, no oedema was observed up to day 10 in females and day 17 in males; for males the responses were 2 slight, 1 medium at day 17; 3 slight at day 20 and 2 slight at terminal sacrifice; for females the responses were 1 slight at day 10; 2 slight, 1 medium at days 12 and 15; 1 slight at days 17 and 20 and no response at terminal sacrifice

Atonia

Day:		***0***		***2***		***4***		***7***		***10***		***12***		***15***		***17***		***20***		***32***
Dose		***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***
Control	S					1		1				4		5		2		4		3
	M											1								
	E																			
LD	S						5			3	2	1		2	2	8	5	1	3	1
	M					5	4	3	3	5	5	5	8	6	5	2	2	7	4	4
	E					5		7	7	2	2	4	1	2	2			2		4
HD	S						3													
	M					4	7	1	4											
	E					6		8	5											

Desquamation

Day:		***0***		***2***		***4***		***7***		***10***		***12***		***15***		***17***		***20***		***32***
Dose		***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***	***F***	***M***
Control	S								4	1	2	1	2		2	3	1	3	3	1
	M																			
	E																			
LD	S			2	4	6	1	6	1		5					1	4	1	3	1
	M					1	9	2	8	7	4			4	3	1	1	3	2	5
	E					1		1		3		10	9	6	6	8	4	6	4	3
HD	S			5	1	3	3	3	1											
	M					1	7	2	2											
	E							4	6											

Fissuring

Day:		0		2		4		7		10		12		15		17		20		32
Dose		**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
Control	S																			
	M																			
	E																			
LD	S							5	3	5	2	3	2	3	6	1	4	1	6	3
	M							2	1	3	1	5	3	3	2	4	4	5	2	3
	E											2	1	2		4	1	2		1
HD	S							4	4											
	M							4	1											
	E																			

Eschar*

Day:		0		2		4		7		10		12		15		17		20		32
Dose		**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
Control																				
LD								1		3	4	10	9	9	9	9	7	8	8	7
HD																				

* the number of animals out of 10 showing a response are given in this table; the high dose animals showed no response up to terminal sacrifice on day 8; zeros are not shown in the table for clarity

Exfoliation*

Day:		0		2		4		7		10		12		15		17		20		32
Dose		**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
Control																				
LD								3		10	7	7	9	5	7	8	6	5	3	1
HD																				

* the number of animals out of 10 showing a response are given in this table; the high dose animals showed no response up to terminal sacrifice on day 8; zeros are not shown in the table for clarity

Clinical Chemistry/Haematology

haemoglobin, haematocrit and erythrocyte counts of the high dose males and females were slightly lower than control values at the time of necropsy; serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase and lactic acid dehydrogenase were elevated in low dose males and females at termination; total and direct bilirubin and cholesterol levels in high dose males and females were also greater than controls

Necropsy Findings/Histopathology

the major findings at necropsy were small testes in males of the low and high dose groups; small epididymes were also observed in the high dose group and the prostate glands in two animals were also small; no significant histopathological changes were reported

Result: the major target organs were identified as the skin in males and females and the testes, epididymes and prostate in males; there is some indication of liver toxicity from the clinical chemistry data

9.4 Overall Assessment of Toxicological Data

Analogues of the notified chemical exhibited low acute oral toxicity (LD_{50} > 2000 mg/kg) in rats and low acute dermal toxicity (LD_{50} > 2000 mg/kg) in rabbits. Skin irritancy in rabbits was severe and eye irritancy was moderate. A 28-day subchronic dermal toxicity study in rabbits demonstrated that the target organs in male animals were the testes, epididymes and prostate. The skin was also a target organ (at the site of application) and there was some indication of liver toxicity in both sexes from clinical chemistry results but this was not supported by histopathology findings.

No skin sensitisation studies were provided on the basis that the analogues could be predicted to be skin sensitisers from chemical structure.

No genotoxicity studies were provided. However, a structure-activity analysis was provided which suggested the notified chemical was unlikely to be genotoxic. This conclusion was accepted on the basis that in the event of a false negative prediction, the likely genetic effects would be overshadowed by the severity of the other hazards.

It can be concluded that the notified chemical can be regarded as a severe skin irritant, a moderate eye irritant, a skin sensitiser and a chemical capable of inducing reproductive effects in males on repeated or prolonged exposure.

On the basis of the analogue data and structure-activity predictions the notified chemical should be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (8) in relation to irritant effects (skin, eye), sensitising effects (skin) and severe effects after repeated or prolonged exposure (dermal route).

It was claimed by the notifier that the primary amine groups on the analogues of the notified chemical were responsible for their hazardous nature and that neutralisation of these by acrylic acid in the case of the notified chemical would mitigate the observed effects. Whether this is true is unknown but may provide an extra margin of safety if the notified chemical is treated as exhibiting the hazards of the analogues.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following studies have been provided:

Ecotoxicology results on selected marine species

Test Organism	*Test Type*	*Duration*	*Parameter and Result*
Mussel (*Abra alba*)	flow-through	5 d	EC_{50} = 86 mg/L
Copepod (*Acartia tonsa*)	unspecified	48 h	LC_{50} = 2.8 (1.2, 4.8) mg/L
Alga (*Skeletonema costatum*)	unspecified	72 h	EC_{50} = 3.5 mg/L

The notifier submitted toxicity data on the marine bivalve mussel *Abra alba* in place of fish. Organisms were placed in five concentrations of the diluted form of the chemical (solution containing 25% of the notified chemical) plus controls for 5 days at 11°C and 33 $^{0}/_{00}$ salinity. The EC_{50} for reduced feeding as assessed by fecal pellet production was 86 mg/L (no confidence limits given).

Ecotoxicological data for the marine calanoid copepod *Acartia tonsa* were submitted in place of the freshwater invertebrate *Daphnia magna*. Organisms were exposed to four nominal concentrations of the notified chemical of 0.5 - 20 mg/L in filtered natural seawater plus a control for 48 h at 19°C. The notifier calculated an LC_{50} of 1.6 (1.2, 3) mg/L but did not reference the method of statistical analysis. The LC_{50} was recalculated by probit analysis as 2.8 (1.2, 4.8) mg/L.

The notifier examined the toxicity of the notified chemical on the marine diatom *Skeletonema costatum* in a 72-h static test. Four concentrations of 1 - 8 mg/L plus a control were run. The calculated EC_{50} value for reduced growth rate was 3.5 mg/L (no confidence limits given).

The results indicate that the notified chemical is moderately toxic to marine algae and copepods and slightly toxic to mussels.

The notifier also provided information obtained from the US EPA's ASTER database which estimated ecotoxicology values for various aquatic organisms using QSAR. A summary of these results is presented below.

Estimated ecotoxicology results from the ASTER database

Test Organism	*Test Type*	*Duration*	*Parameter and Result*
Water flea (*Daphnia magna*)	Static	48 h	LC_{50} = 67 mg/L
Bluegill sunfish (*Lepomis macrochirus*)	Flow-through	96 h	LC_{50} = 98 mg/L
Fathead minnow (*Pimephales promelas*)	Flow-through	96 h	LC_{50} = 125 mg/L
Channel catfish (*Ictalurus punctatus*)	Flow-through	96 h	LC_{50} = 54 mg/L
Rainbow trout (*Oncorhyncus mykiss*)	Flow-through	96 h	LC_{50} = 53 mg/L
Fathead minnow	Flow-through	32 d	MATC = 20 mg/L

In addition, ASTER estimated a bioconcentration factor of 43 for fathead minnows which indicates the notified chemical is not expected to bioconcentrate in fish. These values show that these freshwater organisms are expected to be less sensitive to the notified chemical than the marine organisms tested.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

After treatment of the oil production waters, the estimated concentration in the effluent from the seawater outflow of 0.45 mg/L is an order of magnitude less than the most sensitive species tested. In addition, the dilution effect of the seawater at the outflow has been estimated at 105:1 during the worst-case of no current and slack tide; at more typical conditions, the dilution ranges from 170:1 to 230:1 (reference: Gippsland Water, personal communication). The concentrations of notified chemical resulting from these dilutions ranges from 0.0042 mg/L at the worst case to 0.0019 mg/L. Even at the worst-case dilution, the concentration would be 667X lower than most sensitive LC_{50} to any of the aquatic organisms tested (LC_{50} = 2.8 (1.2, 4.8) mg/L for *Acartia tonsa*). Thus the use of the notified chemical as a corrosion inhibitor in oil pipelines is not expected to cause adverse effects to organisms in the marine environment.

If the notified chemical is used in oil wells, 100% of the amount used will be discharged directly to the sea at an estimated effluent concentration of 20 mg/L. If the dilution conditions of the outflow are also representative of those at the oilwell platforms, then the worst-case dilution would result in a concentration of 0.19 mg/L which is approximately 15 times lower than the LC_{50} of *A. tonsa*. At typical dilutions, the concentration of notified chemical would be 0.087 - 0.12 mg/L. These concentrations would also not be expected to cause adverse effects. The compound is not expected to bioaccumulate or have any significant chronic effects as it is readily biodegradable in seawater.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicological data were available for the notified chemical. However from the analogue data submitted with the notification, the notified chemical should be considered a severe skin and a moderate eye irritant, a skin sensitiser and may cause reproductive effects in males on repeated or prolonged exposure. It is noteworthy that the latter effects were detected during a 28-day subchronic study involving application of the test chemical to the skin, the most likely route of exposure. One mitigating factor may be reaction of

primary amine groups on the notified chemical compared to the analogues. However, in the absence of quantification of this effect the notified chemical would be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (8) with respect to irritant effects (skin, eye), sensitising effects (skin) and severe effects after repeated or prolonged exposure.

Although the genotoxic potential of the notified chemical was not measured, a theoretical structure-activity analysis was presented which suggested that it was not likely to induce effects with a genetic basis. It is considered that the other hazards presented by the notified chemical are of greater concern than the probability of error in the prediction of genotoxicity.

There are no hazards predicted solely on the basis of the physico-chemical properties.

Exposure to the notified chemical is possible during transfer of the imported formulation from 200 L drums to a bulk mix tank for dilution, during drumming off and during transfer by injection of the final solution into the oil pipeline flow or downhole. Exposure to spills, drips and splashes is possible during connection and disconnection of lines and removal of drum spears. It is expected that drips, splashes and spills will occur on a regular, albeit infrequent basis. Thus, there is a potential risk of skin and eye irritation, skin sensitisation and reproductive effects. It should be kept in mind, however, that the reproductive effects seen in the subchronic study in rabbits may have been potentiated by fissuring of the skin allowing greater entry of the chemical. In the work situation such fissuring would only be expected to occur in circumstances of repeated or prolonged exposure of unprotected skin which is unlikely under normal conditions of use.

The risk of adverse public health effects is expected to be negligible on the basis that no public exposure to the notified chemical is likely to occur.

13. RECOMMENDATIONS

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

. Personal protective equipment should be worn during transfer operations - pumping, insertion and removal of spears, coupling and uncoupling lines and opening and closing drums and larger containers - involving the notified chemical and during clean up and maintenance of equipment. It should conform to Australian standards (AS) or Australian/ New Zealand standards (AS/NZS) standards as follows:

    - Chemical-type goggles should be selected and fitted in accordance with AS 1336 (9) and meet the requirements of AS/NZS 1337 (10);

    - Impermeable rubber or PVC coated fabric gloves should conform to AS 2161 (11);

    - A splash suit should conform to AS 3765.1 (12);

    - Protective footwear should conform to AS/NZS 2210 (13).

. Safe work practices, as should be followed when handling any chemical formulation, should be adhered to - these include:

    - Minimising spills and splashes;

    - Practising good personal hygiene; and

- Practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal; when cleaning up spills personal protective equipment as described above should be worn.

. Users of the notified chemical should be aware of the presence of monoethylene glycol in the formulation to be imported and in reformulations; personal protective equipment as outlined above for use when handling the notified chemical will provide adequate protection;

. A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for Intermediate F-6804 was provided in accordance with Worksafe Australia's *National Code of Practice for the Preparation of Material Safety Data Sheets* (14).

This MSDS was provided by Nalco/Exxon Energy Chemicals Australia Pty Ltd as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Nalco/Exxon Energy Chemicals Australia Pty Ltd.

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. Secondary notification will also be required in the event that future uses of the notified chemical significantly increase the environmental exposure or is proposed in oil pipelines and wells where significantly lower dilution effects are likely.

16. REFERENCES

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14. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra.

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