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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Component of EC1118A / Component of FX2363 / Component of EC1477A

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nalco Australia Pty Ltd (ABN: 41 000 424 788)
2 Anderson Street
Banksmeadow, NSW, 2019

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
Other Name(s)
CAS Number
Molecular Formula
Molecular Weight
Spectral Data
Methods of Detection and Determination
Degree of Purity
Additives/Adjuvants
Import/Manufacture Volume
Use Details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Vapour Pressure
Dissociation constant
Adsorption/Desorption
Hydrolysis
Inhalation Toxicity
Skin Sensitisation

Surrogate data was provided for other physicochemical and toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None known.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Component of EC1118A / Component of FX2363 / Component of EC1477A

METHODS OF DETECTION AND DETERMINATION

METHOD	UV-Visible and IR Spectroscopy
Remarks	In-house method.

3. COMPOSITION

DEGREE OF PURITY
Not determined. Notified chemical is produced in situ in both hydrocarbon and water based formulations. The purity of the notified chemical is expected to be high but is a complex mixture.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be manufactured as a component of FX2363 and EC1477A at a concentration of up to 20%. The notified chemical will also be imported as a component of the product EC1118A at a concentration of up to 20%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<10	10-20	10-20	10-20	10-20

USE
Pipeline chemical for industrial applications such as oil and gas production.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney, Perth

TRANSPORTATION AND PACKAGING
The product EC1118A containing the notified chemical is not manufactured in Australia. It is imported in 200 L plastic or steel drums to Perth. The product EC1118A containing the notified chemical will be repacked in Western Australia into 1000 or 1500 L Intermediate Bulk Containers (IBC).

The products EC1477A and FX2363 containing the notified chemical will be manufactured in Australia. The products EC1477A and FX2363 containing the notified chemical will be packed into 1000 or 1500 L Intermediate Bulk Containers (IBC) in New South Wales and transported by road to Western Australia.

The IBCs are transported by ship to the floating off-shore oil and gas production facilities in Western Australia.

The notified chemical is not classified as a dangerous good. However, the imported product EC1118A is classified as a dangerous good (Primary Class 3 Secondary Class 8 : Flammable liquid, Corrosive). Manufactured products water-based, EC1477A and FX2363 are also dangerous goods (Primary Class 8 - Corrosive).

5.2. Operation description

Repacking imported product EC1118A (hydrocarbon based):
In the imported final product, the notified chemical is present at up to 20% and will be repackaged into IBCs (1000 or 1500 L) by manually spearing the imported steel drums (200 L) and using manually operated pumping equipment. All workers will wear PPE such as chemical resistant gloves, safety glasses, safety boots, coveralls and respiratory protection as required. Workers will have access to the Material Safety Data Sheet (MSDS). The imported product and solution containing the notified

chemical will be stored at the site(s) in a bunded and dangerous goods approved store.

Manufacture of EC1477A and FX2363 (water-based):
The notified chemical is manufactured by specified addition of the raw materials by manual means into the blending/reaction vessel. Remote manual control of the blending vessel allows control of stirring and heating. After blending, the finished products are packed into IBCs (1000 or 1500L) using a transfer line from the blending vessel into a spear on the top of the IBC using manually operated pumping equipment.

Quality Control
Quality control chemists will undertake sampling and analysis of imported and manufactured products (approximately 200 mL).

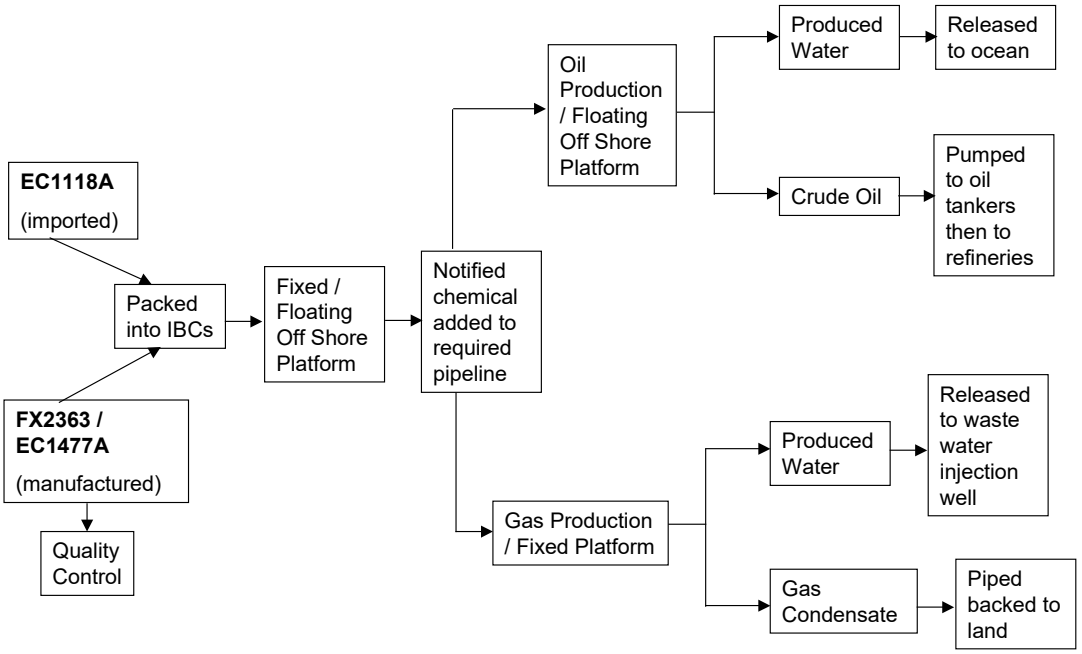
All workers will wear PPE such as chemical resistant gloves, safety glasses, safety boots, coveralls and respiratory protection as required. Workers will have access to the Material Safety Data Sheet (MSDS). All production batch sheets include relevant OH&S information consistent with the chemical nature of the batch ingredients is available to workers.

Salespersons:
Salesperson will handle products containing the notified chemical (up to 20%) while checking dose rates at the end-use sites (approximately 500 mL) and during sampling to determine the concentration in produced water (approximately 500 mL, up to 0.0005% notified chemical). Such workers will be trained in the use of the chemical, have access to the MSDS and wear PPE consistent with the recommendations of the MSDS.

End user operation in Australia – Oil Production:
The notifier advises that products containing the notified chemical (up to 20%) will be dosed to various off-shore flowlines by means of manual attachment (using a camlock) of a transfer line to the bottom valve of the IBC to a dosing pump with a rate measurement cylinder attached. Flowline dosing occurs within a bunded area. The produced oil will flow into a oil/water separator. The notified chemical (up to 20%) is dosed a second time (method identical to that above) to the second stage separator. The production water containing the notified chemical is discharged to the ocean. Produced oil containing trace quantities of the notified chemical 0.0004% is pumped into tankers for transportation to oil refineries within Australia.

End user operation in Australia – Gas Production:
The notifier advises that products containing the notified chemical (up to 20%) will be dosed to various off-shore flowlines by means of manual attachment (using a camlock) of a transfer line to the bottom valve of the IBC to a dosing pump with a rate measurement cylinder attached. Flowline dosing occurs within a bunded area. The produced gas will flow into a gas/water separator. The notified chemical (up to 20%) is dosed a second time (method identical to that above) to the second stage separator. Refined gas is pumped back to mainland and contains trace quantities of the notified chemical (no estimates provided by the notifier). The produced water containing the notified chemical (no estimates provided by the notifier) is disposed of by injection into a water disposal well. Due to its ionic nature and hence low volatility, negligible amounts are expected to partition to the gas phase.

All workers at end-use sites will be trained in the use of the chemical, have access to the MSDS and wear PPE consistent with the recommendations of the MSDS.



Schematic of operations using products containing the notified chemical.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Repacking			
Transport workers	2	2.5 h/day	2-3 days/yr
Storage workers	2	2 h/day	2-3 days/yr
Operators (packing)	2	1-1.5 h/day	12-18 days/yr
Drum cleaning workers	1	3-4 h/day	9 days/yr
Manufacture			
Transport workers (intercompany transfer of IBC)	2	40 h over several days	6-7 times/yr
Operators (manufacture and blending)	2	4 h/day	6-7 days/yr
Operators (packing)	2	2.5 h/day	6-7 days/yr
Operator (cleaning)	1	2 h/day	6-7 days/yr
Storage workers	1	0.1 h/day	12-14 days/yr
Quality control (lab technician)	1	0.5 h/day	6-7 days/yr
Sales Representatives	1	0.25 h/day	4 days/yr
End-Use			
Transport (IBCs to Off-Shore facility)	2	15 h/day	24-36 days/yr
Distribution workers off-shore	2	2 h	24-36 days/yr
Operator (off-shore)	1	0.5 h	48-72days/yr
Cleaning IBCs	1	30-40 min/day	12-18 days/yr

Exposure Details

Import, transport and storage:

Products containing the notified chemical at up to 20% are either imported directly or manufactured as water-based solutions containing the notified chemical at up to 20% and transported by road to the site for repacking and/or distribution. Finished products containing the notified chemical are transported by road and shipped to customers in Western Australia as required. Exposure is not expected during such operations except in unlikely cases of accidental puncture of transport or storage containers.

Repacking imported product EC1118A (hydrocarbon based):

Potential routes of exposure include dermal and accidental ocular exposure as a result of spills and splashes and contact with the spear during transfer of the notified chemical via pump, flexible hose and spear from drums to various pack sizes. Concentration of notified chemical during such operations is no more than 20% and potential exposure will be mitigated by the use of PPE.

Manufacture of EC1477A and FX2363 (water-based):
Potential routes of exposure up to 20% notified chemical include dermal and accidental ocular exposure as a result of spills and splashes during formulation operations and contact with the spear during transfer of the notified chemical via pump, flexible hose and spear from blending vessel to IBCs. Potential exposure will be mitigated by the use of PPE and enclosed blending vessel.

Quality Control
Sampling and analysis of imported and manufactured products containing the notified chemical may result in potential dermal and accidental ocular exposure to up to 20% notified chemical as a result of accidental spills and splashes. Potential exposure will be mitigated by the use of PPE.

Salespersons:
Potential routes of exposure include dermal and accidental ocular exposure as a result manual testing of dose lines (containing up to 20% of the notified chemical).

End user operation in Australia – Oil Production:
Potential routes of exposure include dermal and accidental ocular exposure as a result of manual attaching and detaching transfer lines (containing up to 20% of the notified chemical). Potential exposure will be mitigated by the use of PPE. The dosing process is fully enclosed and as such exposure is expected to be negligible. Appropriate containment procedures (such as catching pans) and engineering controls (local exhaust ventilation) are expected to be in place at the refineries. Workers will wear personal protective equipment such as safety glasses, gloves and overalls. Exposure to the notified polymer in the final blended fuel will be up to 0.0004%.

While the notifier provides no specific details, petrol station workers may be potentially exposed to diluted notified chemical up to 0.0004% in fuel during fuel handling activities and maintenance of automotive fuel systems. Although it expected that the notified chemical would be removed during refining processes.

End user operation in Australia – Gas Production:
Potential routes of exposure include dermal and accidental ocular exposure as a result of manual attaching and detaching transfer lines (containing up to 20% of the notified chemical). Potential exposure will be mitigated by the use of PPE. The dosing process is fully enclosed and as such exposure is expected to be negligible. No exposure is expected during downstream processing/use of gas.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified chemical is used as a pipeline chemical especially in the oil and gas industry. Depending on its application the chemical is either dissolved in water or hydrocarbon based carriers. The hydrocarbon based product is imported into Australia and is not reformulated, but is repacked into intermediate bulk containers (IBCs), whilst the water based product is manufactured in Australia from a precursor chemical. Based on the current usage pattern it is expected that 63.6% of the notified chemical will be hydrocarbon based with the remaining 36.4% being water based. The maximum import value is 20 tonnes of the notified chemical resulting in up to 12.7 tonnes as the hydrocarbon based product being imported and up to 7.3 tonnes as the water based product being manufactured.

Repacking imported product EC1118A (hydrocarbon based):
It is expected that during each operation of filling the 1000L or 1500 L IBC from the 200 L import drums that 0.01 kg will be wasted. The worst case scenario would involve filling the 1000 L IBC. Assuming that the product contains up to 20% w/v of the notified chemical, then each IBC will contain up to 200 kg of the notified chemical. The wastage rate is therefore approximately 0.05%, resulting in approximately 0.64 kg of waste being produced per annum from repackaging.

Residual substance is expected to be 0.1 kg per IBC. As the density of the formulated product is 920 kg/m^3 and the worst case scenario involves only 1000 L IBCs, the amount of formulated product in

each IBC is 920kg. The wastage rate is therefore 0.011% resulting in 1.4 kg per annum of the notified chemical being sent to licensed Dangerous Goods facilities. If any substantial unused amounts of the formulated product remain in the IBCs, this will be tested and recycled back into the filling operation. No waste is expected to be produced from this route.

Imported 200 L plastic drums containing 184 kg of the formulated product are expected to contain less than 0.05 kg of the product as residue. The wastage rate is 0.027% resulting in 3.5 kg per annum being sent to a licensed drum recycling facility.

Manufacture of EC1477A and FX2363 (water-based):
The water based product will be produced in 3000 – 6000 kg batches of product containing up to 20% of the notified chemical. Assuming a worst case scenario of 3000 kg batches, then each batch will contain 600 kg. For the Kwinana operations, it is expected that approximately 0.2 kg per batch will be wasted from rinsing of the blender, whilst 0.01 kg per batch will be wasted from the rinsing of hoses and pumps during the packing operations. A total of 0.21 kg is therefore wasted for every 600 kg of notified chemical formulated into the water based product. At Botany the blender is boiled out and after cooling a solution containing ppm levels of the notified chemical is sent to the effluent plant. Although no precise data are provided to the amount produced at the two plants and the wastage rate at Botany, it is expected that the rate would be similar to that of Kwinana. The overall wastage rate is predicted to be approximately 0.14%, resulting in 2.4 kg per annum being released.

Assuming that each plant produces half of the total then 1.2 kg per annum will be released at the Botany plant, where it is treated with most of the notified chemical adsorbing on the sludge. The sludge will be specially disposed as solid wastes, whilst the waste water is released to sewer where chemical will be treated at Malabar sewage treatment plant with the notified chemical expected to adsorb mainly to the sludge. Traces of the chemical present in the sludge may be used for fertiliser or soil conditioner.

The plant at Kwinana has an intercept pit. The waste water is captured in the intercept pit and is treated and used for irrigation of on - site lawns, with any run – off simply returning to the intercept pit. No contamination of waterways is expected with monitoring at this plant also showing no contamination of bore water.

Spills at both plants are expected to be physically contained with the chemical being recycled to the extent practicable. Due to both plants' designs the chemical is not expected to enter waterways from these sites as a result of a spill.

RELEASE OF CHEMICAL FROM USE
EC1477A and FX2363 (water-based) formulations are expected to be used for gas well operations. The pipelines carrying hot wet gas will require treatment with the notified chemical. The hot wet gas is condensed and separated with the chemical expected to partition to the water phase. Due to its ionic nature and hence low volatility, negligible amounts are expected to partition to the gas phase. The water is then injected into a water disposal well and is not released to the aquatic environment. Consequently none of the 7.3 tonnes of the notified chemical as the active part of the water based product is likely to be released to the marine environment.

EC1118A (hydrocarbon based) is expected to be used for oil well operations. The notified chemical is dosed at two points to treat the pipelines. It is expected that a portion of the chemical will partition to the oil phase and a portion to the water phase at each of these two dosing points. Further the notified chemical is also expected to adsorb to the metal pipeline. The chemical is surface active and dissociates, correspondingly with pH. This will make it difficult to predict its partitioning behaviour between the oil and process water phases of variable acidity. The Chemical Hazard Assessment & Risk Management (CHARM) model further acknowledges that the model is flawed for surfactants. Furthermore the partitioning behaviour is described for a static model and cannot be readily extrapolated to a dynamic situation with likely imperfect separation, two dosing points (in series) and absorption to metal surfaces. The notifier has indicated that 60% is the most likely proportion of the chemical present in overboard line when compared with the total amount of chemical used. The supplied empirical data for the chemical in the overboard line is consistent with this partitioning rate. This results in up to 7.6 tonnes of the notified chemical being released to the marine environment per

annum.

The remaining 5.1 tonnes of the notified chemical will partition to the oil fraction. The chemical will be subjected to the oil refining process and is likely to largely decompose. The chemical has a moderate molecular weight and a boiling point of > 120°C. Any residue is likely to report to the middle fractions such as petrol (distillation temperature of 50 – 190°C) and distillate (distillation temperature of 204 – 288°C) of the distillation process. The chemical is likely to be combusted with the fuel during use.

5.5. Disposal

There is little or no packaging containing formulations containing notified substance that will require disposal. As long as imported drums have not perished (due to effect of hydrocarbons) then they will be cleaned and recycled for other uses. For the few drums that may be unfit for recycling their fate will be puncturing followed by disposal to licensed landfill. The IBCs used for packaging of formulation(s) containing notified substance are never disposed. Residue of notified substance from packaging is expected to be ~2 kg per annum from imported drums and ~10 kg per annum from bulk bins.

5.6. Public exposure

The product EC1118A containing the notified chemical will not be manufactured in Australia. The products EC1477A and FX2363 containing the notified chemical will be manufactured in Australia. The products will not be available for use by the general public.

The products EC 1118A, EC1477A and FX2363 (containing up to 20% notified chemical) will be used industrially in offshore oil and gas production.

The potential for exposure of the general public to EC 1118A, EC1477A and FX2363 during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the new chemical being released from the packaging and the public being exposed or contamination of the environment occurring.

While the notifier provides no specific details, the public may be potentially exposed to diluted notified chemical up to 0.0004% in fuel during fuel handling activities and maintenance of automotive fuel systems. Although it expected that the notified chemical would be removed during refining processes.

No public exposure to the notified chemical is expected from gas production.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Clear amber liquid with amine odour

Melting Point/Freezing Point 3°C (analogue 1)

Remarks Test not conducted on notified chemical. Data taken from MSDS for a complex mixture which contains the notified chemical. Study report not provided. The notified chemical is a complex mixture and expected to have a melting point of approximately 3°C.

Boiling Point > 120°C at 101.3 kPa

METHOD In-house test.

Remarks Study report not provided. Test conducted on product containing notified chemical (up to 20%).

Density 933 kg/m^3 (notified chemical) (temperature unknown)

Remarks Study report not provided. Data taken from the environmental toxicity studies on *Skeletonema costatum* and *Ceriodaphnia dubia.*

TEST FACILITY Asci Corporation (2005a), Asci Corporation (2005b)

Vapour Pressure Not determined.

Remarks The notified chemical as introduced is not isolated from solution. The chemical has high molecular weight and is capable of being ionised. It is likely that the chemical will be of low volatility.

Water Solubility > 100 g/L at 20°C

METHOD In-House Method. 2.00 g of test substance, likely to be FX2363 was diluted to 20.00 g in water and the solution mixed using a magnetic stirrer bar. A clear solution free from solids was obtained with less than 5 minutes stirring. pH (10% aqueous solution) = 5.1

Remarks pH (10% aqueous solution) = 5.1 @ 22°C. The product, likely to be the water based product, which is water soluble in mildly acidic solutions.

Based on data from the MSDS for EC1118A, the hydrocarbon based product is dispersible in water.

TEST FACILITY Nalco Australia (2005)

Hydrolysis as a Function of pH Not determined.

METHOD Test not conducted

Remarks Although the chemical contains hydrolysable groups it is unlikely to undergo hydrolysis at the environmental pH range of 4 – 9. The precursor for the chemical as 100% active liquid has a pH of 11.6 and is stable to hydrolysis. Hydrolysis of the notified chemical may occur at pH > 12 or very low pH values.

Partition Coefficient (n-octanol/water) Log (Weighted average Pow) = 5.4 (analogue 1)

METHOD OECD TG 117 Partition Coefficient HPLC Method (UV at 210 nm) (n-octanol/water). Duplicate analyses were performed on 20 µL aliquots of solutions containing 0.0781 g of an acceptable analogue for the notified chemical in 20 mL of methanol. The mobile phase was 80:20 methanol: water. Reference compounds having Log Pow values of 0.9 – 5.7 were also run.

Remarks The study was conducted as part of the bioaccumulation potential. Only the Log (Weighted average Pow) method was used as the weighted average of Log Pow does not appear valid. All peaks of greater than 1% were included. The first peak had a Pow value of < 0.9 which was outside of the calibration and contributed >

67% of the total peak area. Ascribing 0.9 to this peak resulted in Pow values of 5.40 and 5.45 for runs 1 and 2 respectively.

TEST FACILITY Fawley Aquatic Research Laboratories Ltd (1999a)

Adsorption/Desorption – screening test Not determined

METHOD Test not conducted. The chemical has a high Kow value and likely to bind strongly to the organic components of the sediment. At neutral and acidic pH the compound is likely to be mostly in its ionic form. This will bind to the sediments. In the normal pH of sea water only some of the compound is expected to be in its ionic form.

Dissociation Constant Not determined.
pKa = 4.76 & 6.95

METHOD The chemical will have at least two dissociation constants. These are expected to be typical for this type of chemical.

Particle Size Not Applicable.

Remarks Notified chemical is a liquid.

Flash Point > 100°C (analogue 1)

METHOD Pensky-Martin Closed Cup.
Remarks Test not conducted on notified chemical. Data taken form MSDS for an acceptable analogue. Study report not provided.

Flammability Limits Not Determined.

Remarks The notified chemical as introduced is not isolated from solution. Based on the flash point and unreactivity towards water the notified chemical is not expected to be flammable.

Autoignition Temperature Not Determined.

Remarks Not expected to auto-ignite. The notified chemical as introduced is not isolated from solution.

Explosive Properties Not Determined

Remarks Not expected to be explosive. The notified chemical does not contain functional groups that would impart explosive properties.

Reactivity

Remarks The product containing the notified chemical (up to 20%) is expected to be stable under normal conditions of use.

Viscosity 640SUS at 38°C (notified chemical)

METHOD Unknown
Remarks Study report not provided. Data taken from the environmental toxicity studies on *Skeletonema costatum* and *Ceriodaphnia dubia.*
TEST FACILITY Asci Corporation (2005a), Asci Corporation (2005b)

Fat (or n-octanol) Solubility ≥ 1401.6 mg/100 mL n-octanol at 22°C (analogue 1)

METHOD Farl SOP TS012. Estimating the solubility of test substances in sea water and in

	n-octanol. Ten aliquots of an acceptable analogue for the notified chemical, were added to 100 ml of n-octanol. After each addition the flask was gently swirled.
Remarks	All ten aliquots totalling 1.4016 g of test substance dissolved.
TEST FACILITY	Fawley Aquatic Research Laboratories Ltd. (1999a)

7. TOXICOLOGICAL INVESTIGATIONS

Limited toxicological data have been provided for the notified chemical.

7.1. Toxicological Investigations for the notified chemical

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, acute oral	Notified chemical	LD50 >2000 mg/kg bw low toxicity
Rabbit, skin irritation	Notified chemical	severely irritating/corrosive

7.1.1 Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 92/69/EEC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley CD
Vehicle	Distilled water
Remarks - Method	Statement of GLP. No protocol deviations were reported.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	3 males	2000	0/3
II	3 females	2000	1/3

LD50	>2000 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity commonly noted were diarrhoea, hunched posture, lethargy, pilo-ercetion and pitosis with additional incidents in 1/3 males of ataxia, decreased respiratory rate, laboured respiration and staining around eyes, mouth and snout.
Effects in Organs	Abnormalities noted at necropsy of the female that died during the study were haemorrhagic lungs, dark liver, dark kidneys and sloughing of the gastric mucosa and non-glandular epithelium of the stomach. White foci in one area of the non-glandular epithelium of the stomach were noted in one male at necropsy. No abnormalities were noted at necropsy for any other animals at the end of the study period.
Remarks - Results	There were no remarkable body weight changes during the study period. There was one death. The LD50 cut-off estimated using the flow chart in annex 3 of the EC Directive 92/69/EEC B.1 tris Acute Oral Toxicity would be 2500 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Safepharm (2000a)

7.1.2 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 males

Vehicle	Test substance administered as supplied.
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Statement of GLP. No significant protocol deviations.
	One animal was treated at three sites with patch test removal at 3 minutes, 1 hour and 4 hours after application. The other two animals were treated with two patches which were allowed to remain in contact with the skin for a period of 3 minutes or four hours.

RESULTS

Following 4 hour exposure

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	3.7	2.3	4.0	4	> 72 h < 14 days	0
Oedema	4.0	2.7	2.3	4	> 72 h < 14 days	0

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

Following 1 hour exposure

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1	-	-	1	> 72 h < 7 days	0
Oedema	0.7	-	-	1	> 48 h < 7 days	0

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

Following 3 minute exposure

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.7	1	0.3	1	> 72 h < 7 days	0
Oedema	0	0	0	1	< 24 h	0

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

Remarks - Results

<u>4 hour exposure</u>

Well-defined erythema and moderate to severe oedema were noted at all treated skin sites at the 1-hour observation with moderate to severe erythema and moderate to severe oedema at the 24-hour observation and well-defined to severe erythema and slight to severe oedema at the 48 and 72-hour observations.

Dermal haemorrhage was noted at one treated skin site at the 1-hour observation and at two treated skin sites at the 24, 48, and 72-hour observations.

Blanching of the skin was noted at two treated skin sites at the 24, 48 and 72-hour observations.

Pale green discolouration, possibly superficial dermal necrosis, was scattered over one treated skin site at the 24, 48 and 72-hour observations. A hardened dark brown/black coloured scab or a hardened light brown coloured scab, which prevented an accurate evaluation or erythema and oedema, was noted at all treated skin sites at the 7-day observation.

Glossy skin and/or reduced regrowth of fur were notes at all treated sites at the 14-day observation.

The report stated that no corrosive effects were noted, however, the blanching of the skin, haemorrhage of the dermal capillaries and reduced regrowth of fur are considered to be indicative of full thickness destruction of skin tissue.

No symptoms of systemic toxicity were observed in the animals during the test period and no mortality occurred.

Reduced exposure period
Irritation effects diminished with reduced exposure times with very slight erythema and oedema observed following 1 hour exposure and very slight erythema observed following 3 minute exposure.

CONCLUSION The notified chemical is severely irritating/corrosive to the skin.

TEST FACILITY Safepharm (2000b)

Toxicological data has been provided for two structurally related chemicals. Structural differences may affect the absorption, biotransformation and excretion and hence toxicity of these compounds compared to the notified chemical.

7.2. Toxicological summary for related chemical 3

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rabbit, acute oral	Related chemical 3	LD50 = 1932 ± 417, harmful
Rabbit, acute dermal	Related chemical 3	LD50 >2000 mg/kg bw, low toxicity
Rabbit, eye irritation	Related chemical 3	severely irritating
Rat, repeat dose oral toxicity – 5 days.	Related chemical 3	Insufficient data to determine NOEL/NOAEL/LOAEL
Genotoxicity – bacterial reverse mutation	Related chemical 3	non mutagenic
Genotoxicity – in vitro chromosome aberration	Related chemical 3	non genotoxic

7.2.1. Acute toxicity – oral

TEST SUBSTANCE	Related chemical 3
METHOD	Analogous to OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Test substance administered as supplied
Remarks - Method	Statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	1000	0/5
	5 females		0/5
II	5 males	1750	3/5
	5 females		1/5
III	5 males	3000	4/5
	5 females		5/5

LD50	1932 ± 417 mg/kg bw
Signs of Toxicity	Clinical signs of toxicity commonly noted were anorexia, convulsions, dark material around the eyes and nose, decreased activity, diarrhoea, gasping, hypothermia, laboured breathing, lacrimation, rales, salivation, shallow breathing, an unsteady gate and apparent urinary incontinence. Staining, hair loss and sores. With the exception of staining, hair loss or sores all other signs of toxicity had reversed at the end of the observation period in surviving animals.
Effects in Organs	Abnormalities noted at necropsy of the animals that died during the study included: distentions of the cecum and intestines; red areas on the intestines; a red substance in the intestine and bright red or mottled lungs; and several findings in the stomach inlcuding distention; red areas on the mucosa.serosa; prominent vascularization of the serosa; mucosal rugae absent and sloughing of the mucosa. Abnormalities noted at necropsy for animals sacrificed at the end of the study period included: raised white areas on the stomach mucosa. Abnormalities noted at necropsy in all animals included hair loss and staining of the body.
Remarks - Results	Mean body weights were decreased during days 1-4 but increased for the remainder of the study at does levels with survivors.

CONCLUSION	The test substance is harmful via the oral route.

TEST FACILITY FDRL (1990a)

7.2.2 Acute toxicity – dermal

TEST SUBSTANCE Related chemical 3

METHOD Analogous to OECD TG 402 Acute Dermal Toxicity – Limit Test.
EPA Pesticide Assessment Guidelines, Series 81-2, Revised 1990.

Species/Strain	New Zealand White Rabbits
Vehicle	Test substance administered as supplied.
Type of dressing	Occlusive
Remarks - Method	Statement of GLP.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	There were notified chemical-related severe dermal irritation reactions characterised by oedema and eschar formation.
Signs of Toxicity - Systemic	Observations included anorexia (2/5 males and 2/5 females), soft stools (1/5 males and 1/5 females) and the appearance of gel-like substance in the waste tray of some animals. These symptoms were reversed by day 8.
Effects in Organs	No abnormalities were observed upon macroscopic examination at the end of the study. Macroscopic examination confirmed eschar sloughing.
Remarks - Results	There were no deaths or notified chemical related clinical signs or remarkable body weight changes during the study period.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY FDRL (1990b)

7.2.3 Irritation – eye

TEST SUBSTANCE Related chemical 3

METHOD Analogous to OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	1
Observation Period	24 hours
Remarks - Method	Statement of GLP. No significant protocol deviations. Test conducted in a single animal only. Due to the severe ocular irritation noted, the study was terminated after the 24 hour reading. Test not conducted in additional animals due to the severe irritant effect observed.

RESULTS

Lesion	*Mean Score* Animal No.*	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1			
Conjunctiva: redness	3	3	≥ 24 h	3
Conjunctiva: chemosis	4	4	≥ 24 h	4
Conjunctiva: discharge	3	3	≥ 24 h	3

Corneal opacity	not determined	3	≥ 24 h	not determined
Iridial inflammation	2	2	≥ 24 h	2

*Calculated on the basis of the scores at 24 hour for one animal.

Remarks - Results: The test substance caused severe ocular irritation characterised by corneal opacity, iritis and conjunctival irritation with blistering. 24 hours after administration the treated eye was extremely swollen and the cornea could not be examined. Due to the severity of the reaction the study was terminated at 24 hours.

CONCLUSION: The test substance is severely irritating to the eye.

TEST FACILITY: FDRL (1990c)

7.2.4 Repeat dose toxicity

TEST SUBSTANCE: Related chemical 3

METHOD: Based on OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.

Species/Strain: Rat/Sprague-Dawley

Route of Administration: Oral – gavage

Exposure Information: Total exposure days: 5 days
Dose regimen: 5/5 days per week
Post-exposure observation period: 1 day

Vehicle: One group of animals was administered with the test substance as supplied. The other treatment groups were treated with the test substance in Corn oil.

Remarks - Method: Significant protocol deviations which include:
1. The use of female rats only
2. Only 5 animals per does level
3. Shortened exposure time period 5 days versus either 14 or 28
4. No haematological, clinical biochemistry or urinalysis parameters measured
5. No histopathology or organ weight parameters measured.
6. No reversible time period in the high dose group.
7. Necropsy findings reported only for dose groups 700 mg/kg bw with and without corn oil.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 females	0	0/5
II (low dose)	5 females	50	0/5
III (mid dose)	5 females	100	0/5
IV (mid dose)	5 females	200	0/5
V (high dose)	5 females	700	5/5
VI (high dose – no vehicle)	5 females	700	5/5

Mortality and Time to Death

In the high dose group administered with vehicle, 1 rat died on day 3, and 4 rats died on day 4. In the high dose group administered neat 4 rats died on day 4 and 1 rat died on day 5.

Clinical Observations

In the low dose group salivation was observed in 1/5 animals on day 2. In group III stains on the body were observed in 3/5 animals at day 5 and 2/5 animals on day 4. In group IV animals rales were observed in 1/5 animals on days 3 and 5, stains on the body in 2/5 animals on day 4 and salivation in 1/5 animals on day 1

increasing to 5/5 animals on day 5. In group V and VI clinical signs observed included decreased activity, diarrhea, laboured breathing, salivation stain on body and unsteady gait.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No clinical chemistry, haematological or urinalysis parameters were measured.

Effects in Organs
No histopathology performed.

Remarks – Results

CONCLUSION
Insufficient data to establish a No Observed (Adverse) Effect Level (NO(A)EL). Lethal effects were observed at 700 mg/kg bw/day.

TEST FACILITY FDRL (1990d)

7.2.5 Genotoxicity – bacteria

TEST SUBSTANCE	Related chemical 3
METHOD	Analogous to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Concentration Range in Main Test	Test 1 a) With metabolic activation: Test 1: 1 - 100 µg/plate b) Without metabolic activation: Test 1: 1 - 100 µg/plate Test 2 a) With metabolic activation: Test 1: 10 - 1000 µg/plate
Vehicle	Acetone
Remarks - Method	Statement of GLP. Variations from the standard protocol include: No *E.coli* WP2 or *S. typhimurium* TA102 strain tested. No historical control data supplied. Doses selected based on precipitation and cytotoxicty observed in preliminary test.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 67			
Test 1		100 (all strains)	> 100	Negative
Present	≥ 67			
Test 1		> 100	> 100	Negative
Test 2		≥ 100	> 100	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 in either test. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not mutagenic to *S. typhimurium* bacteria under the conditions of the test.
TEST FACILITY	Microbiological Associates (1990a)

7.2.6 Genotoxicity – in vitro

TEST SUBSTANCE: Related chemical 3

METHOD: Analogous to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Cell Type/Cell Line	CHO-K1 Chinese hamster ovary cells
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Vehicle	Acetone
Remarks - Method	Statement of GLP. The dose range used in the preliminary test was 0.0005 to 5 µL/mL for the six hour exposure group in the absence of metabolic activation and 0.0005 to 5 µL/mL for the 2 hour exposure group in the presence of metabolic activation. Doses for the main test were selected based on the reduction in mitotic index observed. Deviations from protocol: 1. In the presence of activation cells were exposed only for two hours (3-6 hours recommended in the protocol) 2. Triethylenemelamine was used as the positive control in the absence of activation.

Metabolic Activation	*Test Substance Concentration (µL/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.0013*, 0.0025*, 0.005*, 0.01*, 0.02	18	20
Test 2	-	-	-
Present			
Test 1	0.0065*, 0.013*, 0.025*, 0.05*, 0.1	2	20
Test 2	-	-	-

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µL/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥0.05	> 0.005	> 0.02	Negative
Test 2	-	-	-	-
Present				
Test 1	≥ 0.15	≥ 0.025	> 0.1	Negative
Test 2	-	-	-	-

Remarks - Results: The cytotoxicity values provided are the minimum concentration at or after which there were insufficient metaphases for analysis.

No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION: The test substance was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.

TEST FACILITY: Microbiological Associates (1990b)

7.3. Toxicological summary for related chemical 4

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Rat, repeat dose oral toxicity – 91 days.	Related chemical 4	NOAEL, 1000 mg/kg/day
Genotoxicity – in vitro chromosome aberration	Related chemical 4	non genotoxic

7.3.1 Repeat dose toxicity

TEST SUBSTANCE: Related chemical 4

METHOD: Analogous to OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.

Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 91 days Dose regimen: 7/7 days per week Post-exposure observation period: 3 days
Vehicle	Neat (undiluted).
Remarks - Method	Statement of GLP.

Deviations from protocol:

1) Haematological parameters measured did not include platelet count or a measure of blood clotting time/potential.
2) Clinical chemistry parameters measured did not include sodium, potassium, cholesterol, urea, creatinine and albumin.
3) Organ weights were not measured for adrenals, testes, epididymides, uterus, ovaries, thymus, spleen, brain and heart.
4) Histopathological examination was not carried out in the following organs: parathyroid, gall bladder.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration mg/kg bw/day*		*Mortality*
		Nominal	*Actual (mean)*	
I (control)	20/sex	0	0	0
II (low dose)	20/sex	10	9.5 (male), 9.3 (female)	0
III (mid dose)	20/sex	100	94.1 (male), 90.3 (female)	0
IV (high dose)	20/sex	1000	939.4 (male), 863.9 (female)	0

Mortality and Time to Death

All animals survived until scheduled necropsy.

Clinical Observations

No test-item related changes were observed with respect to physical parameters.

Food Consumption

No test-item related change in food consumption were observed in any male treatment group when compared to controls. Increased food consumption in females during weeks 1-6 and 12 in the low dose group and weeks 1-8 and 11-12 in the mid dose group. The observed effects were not dose-related and therefore considered

incidental. There were no test-item related changes in food efficiency for females in any dose group and males in the low dose group when compared with controls. Decreased food efficiency were observed for males in the mid dose group during week 1 and in the high dose group during weeks 1 and 2.

Body Weight
No significant test-item related changes were observed for mean body weights or body weight gains in any treatment group for both males or females when compared to controls. A slight decreased bodyweight was observed in males treated with 100 mg/kg bw/day (3%) and 1000 mg/kg bw/day (5%) at the end of the study period.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry
No significant differences in treatment–related clinical parameters were noted for males treated with 100 mg/kg/day or females treated with 10, 100 and 1000 mg/kg/day. The mean activity of aspartate aminotransferase was increased (5%, not significant) in females treated with 100 mg/kg/day and decreased (8%, not significant) in females treated with 1000 mg/kg/day when compared to controls. The mean activity of alanine aminotransferase was increased in females treated with 100 (14%, not significant) and 1000 (16%, not significant). The mean activity of aspartate aminotransferase was significantly increased ($p<0.05$) in males treated with 10 (15%) or 1000 (18%) mg/kg/day. The mean activity of alanine aminotransferase was significantly increased ($p<0.05$) in males treated with 1000 (46%) mg/kg/day, when compared with controls. The mean protein concentration was significantly increased ($p<0.05$) in males treated with 10 (4%) mg/kg/day and significantly decreased ($p<0.05$) in males treated with 1000 (5%) mg/kg/day.

Haematology
No test-item related changes in parameters of haematology were noted when compared with control animals at the end of the study period.

Urinalysis
No test-item related changes in parameters of urinalyses were noted when compared with controls after four weeks of treatment.

Effects in Organs
A dose related decrease in absolute liver was observed in treated males achieving biological and statistical significance in group IV males (15%, $p <0.05$). The relative liver weight was also statistically significantly decrease in the high dose males (3%). These effects may be due to the decrease in body weight. No macroscopic or microscopic effects were observed in the liver.

Urinary bladder calculus was observed in group IV males (2/5). No urinary bladder calculus was observed in the females or group I-III males. All other macroscopic or microscopic effects observed were considered incidental.

Remarks – Results
Although an increased aspartate aminotransferase were observed in treated males and increased alanine aminotransferase observed in treated males and females, no histopathological findings were observed in the liver and these changes may represent a metabolic adaptation. The decreased relative liver weight observed in high dose males was slight and may be associated with the decreased body weight.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as 94.1 mg/kg bw/day based on the urinary bladder calculus and potential adverse effects in the liver observed at 939 mg/kg bw/day in the males.

TEST FACILITY Hazleton (1983)

7.3.2 Genotoxicity – in vitro

TEST SUBSTANCE Related chemical 4

METHOD	Analogous to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	CHO-WBL Chinese hamster ovary cells
Metabolic Activation System	Aroclor 1254-induced rat liver S9 fraction.
Vehicle	Deionised water
Remarks - Method	Statement of GLP. Doses selected were based on precipitation and cytotoxicity effects observed in the range finding study. Deviations from protocol: 1. In the presence of activation cells were exposed only for two hours (3-6 hours recommended in the protocol)

*Cultures selected for metaphase analysis.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	24.9*, 37.4*, 49.9*, 74.8*	7.25	9.75
Test 2			
Present			
Test 1	49.9*, 99.7*, 150*, 199*	2	9.75
Test 2			

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 49.6	≥ 49.9	≥ 49.9	negative
Test 2				
Present				
Test 1	≥ 165	≥ 99.7	≥ 49.9	negative
Test 2				

Remarks - Results	No statistically or biologically significant increases in the percentage of aberrant cells above the vehicle control levels, were recorded for any cultures treated with the notified chemical in either the presence or absence of metabolic activation. Positive controls confirmed the sensitivity of the test system.
CONCLUSION	The notified chemical was not clastogenic to Chinese hamster ovary cells treated in vitro under the conditions of the test.
TEST FACILITY	Hazleton (1989)

7.4. Other toxicological end-points

7.4.1. Acute toxicity – inhalation

Remarks	The test was not conducted. The notified chemical is a low volatility liquid that is not aerosolised during use. Therefore inhalation is not expected to be a route of exposure. Furthermore, given the potential for severely irritating/corrosive nature of the notified chemical it may not be practical to generate the information.

7.4.2. Skin Sensitisation

Remarks	The test was not conducted. Given the potential for severely irritating/corrosive nature of the notified chemical it may not be practical to generate the information.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Analogue 1. (100% Active)

METHOD: OECD, 1992. OECD Guideline for Testing of Chemicals 306 "Biodegradability in seawater". OECD, Paris France.

Inoculum	Sea Water
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Oxygen meter
Remarks - Method	Sea water was collected from Lat 50° 49.2' N; Long 1° 18.4' W in 25 litre containers. Seawater was aged and stored with gentle agitation in the dark for at least 24 hours. Aged seawater was filtered (10µm) and held at test temperature, with aeration for another 24 hours. Test temperature and salinity of seawater was 19.9°C and 32.2 ‰ (total dissolved solids) respectively. 0.0382 g of test substance was added to 10 L of seawater and the following mineral nutrients were added: KH_2PO_4 85 mg, K_2HPO_4 217.5 mg, $Na_2HPO_4.2H_2O$ 333 mg, NH_4Cl 5.0 mg, $CaCl_2$ 275 mg, $MgSO_4.7H_2O$ 225 mg, $FeCl_3.6H_2O$ 2.5 mg. Sodium acetate 0.00304 g was used as a reference material. A control for inhibitory action of the test substance was run using the test substance 0.00382 g and 0.00304 g of sodium acetate. Concentrations of nitrite and nitrate were measured on the day 28 samples and corrections made to the biological oxygen demand (BOD).

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
0	0	0	0
7	34.84	7	77.6
14	40.72	14	83.08
21	44.4	21	85.61
28	48.5	28	86.03

Day	BOD mg/L Test Substance	BOD mg/L Reference Substance	BOD mg/L Actual mixture Ref + Test	BOD mg/L Theoretical Ref + Test	BOD mg/L Difference Actual less Theoretical
7	2.55	1.84	3.90	4.39	-0.49
14	2.98	1.97	4.43	4.95	-0.52
21	3.25	2.03	4.85	5.28	-0.43
28	3.55	2.04	5.21	5.59	-0.38

Remarks - Results: The Chemical oxygen demand for the test substance was 1916 mg O_2/g. The concentrations of both nitrite and nitrate were lower in the test substance than the control bottles. No correction for nitrification was required. The control for inhibitory action showed that test substance inhibited biodegradation.

CONCLUSION: 48.5% of the chemical degraded after 28 days. The test substance cannot be regarded as readily biodegradable, but is inherently biodegradable.

TEST FACILITY: Fawley Aquatic Research Laboratories (1999b)

8.1.2. Bioaccumulation

TEST SUBSTANCE	Analogue 1. (100% Active)
METHOD	OECD TG 117 Partition Coefficient HPLC Method & Farl SOP TS012. Estimating the solubility of test substances in sea water and in n-octanol as detailed previously.
RESULTS	As detailed previously.
CONCLUSION	The series of chemicals show a wide range of Kow values, but the high average Kow value suggests that the chemical has potential to bioaccumulate, however it is inherently biodegradable, which would limit its bioaccumulation potential.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified Chemical (100% active)
METHOD	OECD TG 203 Fish, Acute Toxicity Test –Turbot/ 96 hr semi-static in seawater
Species	Turbot *(Scophthalmus maximus)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Test substance nominal concentrations were prepared as "water accommodated fractions" (WAF). There was no confirmation of actual dissolved concentrations. Observations for mortality were made daily.
Remarks – Method	Seven were subjected to concentrations of 0.6, 1.2, 2.4, 4.8, 9.6 mg/L of the test substance and a control. Observations for mortality and visible abnormalities were performed at 24, 48, 72 and 96 h. Test solutions were changed at 48 hours. Temperature was maintained at 15°C ± 1.5°C, with a light cycle of 16 hours light and 8 hours dark. Mean Length of turbot 50.1 mm (range 45 – 55 mm) Mean weight of turbot 1.93 g (range 1.4 – 2.9g) pH test solutions 8.1 – 8.2 Dissolved O_2 90 – 101% test solutions Water Salinity 33 – 35 g/L NaCl

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
0		7	0	0	0	0
0.6		7	0	0	0	0
1.2		7	0	0	0	0
2.4		7	0	0	0	0
4.8		7	1	6	7	7
9.6		7	7	7	7	7

LC50	6.1 mg/L at 24 hours. (5.1 – 7.4 with 95% confidence limits) 3.7 mg/L at 48 hours. (5.1 – 7.4 with 95% confidence limits) 3.4 mg/L at 72 hours. (Not possible to establish 95% confidence limits) 3.4 mg/L at 96 hours. (Not possible to establish 95% confidence limits)
NOEC	2.4 mg/L at 96 hours.
LOEC	4.8 mg/L at 96 hours
Remarks – Results	A nominal stock solution of 1000 mg/L was prepared. It was observed to be cloudy and off-white. A homogenised aliquot of the stock solution was added to each test solution. No sub lethal effects were noted.

CONCLUSION	The notified chemical is moderately toxic to fish.
TEST FACILITY	Chemex Environmental International Limited. (2004a)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Chemical (100% active)
METHOD	SOP E207 Based upon ISO TC147/SC5/WG2 protocol by Thompson (1990) - Static Test in sea water.
Species	*Arcatia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	Not Specified
Analytical Monitoring	Test substance nominal concentrations were prepared as WAF. There was no confirmation of actual dissolved concentrations.
Remarks - Method	Four replicates of five copepods were subjected to concentrations of 0.5, 1.0, 2.0, 4.0, 8.0 mg/L of the test substance, 1.0 mg/L of dichlorophenol as a reference substance and a control. Age of copepods at test start 14- 17 days Dissolved Oxygen 95 – 98% Water Temperature 20.5°C. Water Salinity 31 – 35 mg/L

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h [acute]*	*48 h [acute]*
0		20	0	1
0.5		20	0	1
1.0		20	3	7
2.0		20	16	19
4.0		20	20	20
8.0		20	20	20
Reference		20	3	14

LC50	1.5 mg/L at 24 hours (1.2 to 1.7 with 95% confidence limits.) 1.2 mg/L at 48 hours (0.9 to 1.4 with 95% confidence limits.)
LOEC	0.5 mg/L at 48 hours *[acute]*
Remarks - Results	The mortality rate for the reference substance was 70%, which was within the acceptable range of 20- 80%. The mortality rate of the control was 5%, which was considered acceptable.
CONCLUSION	The test substance is considered moderately toxic to *Arcatia Tonsa.*
TEST FACILITY	Chemex Environmental International Limited. (2004b)

8.2.2a. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Chemical (100% active)
METHOD	Annual Book of ASTM Standards, Volume 11.05, Biological Effects and Environmental Fate; Biotechnology; Pesticides, ASTM E1295, 1999 Semi - Static.
Species	*Ceriodaphnia*
Exposure Period	7 days (three brood)

Auxiliary Solvent	Nil
Water Hardness	90 - 96mg $CaCO_3$/L
Analytical Monitoring	Observations for mortality and visible abnormalities were performed daily. Hardness, alkalinity, temperature, dissolved oxygen (DO) specific conductivity and pH were conducted daily.
Remarks - Method	Ten replicates of one daphnid were subjected to concentrations of 0.130, 0.216, 0.360, 0.600, and 1.000 mg/L of the test substance and a control, with the solutions being renewed daily. Test solutions were stirred for 30 minutes prior to test. Temperature 25.4 – 25.5°C DO 7.0 – 8.3 pH 7.8 – 8.2 Specific conductivity (µmhos/cm) 305 – 367 The light intensity was 50 – 100 foot candles with 16 hour light to 8 dark.

RESULTS

Concentration mg/L		*Mean # of young per female*	*Survival Rate*
Nominal	*Actual*		
0		40.3	100
0.130		38.4	100
0.216		36.9	80
0.360		39.8	100
0.600		34.3	100
1.000		0.4	10

NOEC	0.6 mg/L at 7 days
LOEC	1.0 mg/L at 7 days
Growth/ reproduction NOEC	0.6 mg/L at 7 days
Growth/ reproduction NOEC	1.0 mg/L at 7 adys
IC25	0.648 mg/L at 7days (0.566 – 0.689 at 95% confidence limits)
Remarks - Results	A reference concentration of NaCl, which caused 25% inhibition of reproduction, was determined. This concentration was 0.75 g/L. The mean for 20 tests conducted over the period of June 2004 – December 2005 was 0.66 g/L with Standard Deviation of 0.20 g/L. Although 2 daphnids died in the 0.216 g/L test solution, according to the critical Fisher's value, this could not be considered significant.
CONCLUSION	The test substance is considered slightly chronically toxic to *Ceriodaphnia*
TEST FACILITY	Asci Corporation (2005a)

8.2.2b.Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified Substance (100% active)
METHOD	SOP E211 based on Paris Commission Guidelines 1994 "A sediment bioassay using an amphipod". Static.
Species	*Corophium sp.*
Exposure Period	10 days
Auxiliary Solvent	Nil
Water Hardness	Not Specified
Analytical Monitoring	Test substance nominal concentrations were prepared as WAF. There was no confirmation of actual concentrations. Water quality measurements and mortalities observed at the end of the 10 day period.
Remarks - Method	Aerobic layer (5 - 10 cm) of sediment was collected sieved (500 µm) and washed. 1000 mg/L nominal solution of test substance in dilution water was prepared. Test substance and sufficient seawater were added to wet

sediment to obtain required test concentrations. Duplicates of ten *corophium* were subjected to concentrations of 100, 320, 1000, 3200, 10000 mg/L of the test substance and a control.
Temperature 14 - 15°C
DO 90 – 99%
pH of slurry 7.8 – 8.0
Salinity 37 g/L

RESULTS

Concentration mg/L		*Number of Corophium*	*Mortality*	
Nominal Wet Sedmient	*Nominal Dry Sediment*		*Total No dead 10 day*	*Total % Mortality 10 Day*
0	0	20	1	5
100	121	20	3	15
320	387	20	2	10
1000	1199	20	8	40
3200	3815	20	20	100
10000	11934	20	20	100

LC50	1376 mg/kg dry sediment at 10 days
NOEC	387 mg/kg dry sediment at 10 days
LOEC	1199 mg/kg dry sediment at 10 days
Remarks - Results	The test sediment was sieved to determine the number of animals alive. As dead animals may be eaten or decompose any missing animals were counted as dead. The water content of the sediment was determined to be 18%.

CONCLUSION The test substance is considered practically non – toxic to Corophium Sp

TEST FACILITY Chemex Environmental International Limited. (2004c)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified Chemical (100% active)

METHOD	ISO 10253 First Edition, (1995)
Species	*Skeletonema costatum.*
Exposure Period	72 hours
Concentration Range	Nominal: 0.065 – 0.500 mg/L Actual: Not specified
Auxiliary Solvent	Nil
Water Hardness	Not specified
Analytical Monitoring	Cell density, pH and water temperature on a daily basis.

Remarks - Method: Three replicates initially spiked at 5000 cells per mL were subjected to concentrations of 0.065, 0.108, 0.180, 0.300, 0.500 mg/L of the test substance, 1.0 mg/L of dichlorophenol as a reference substance whilst six replicates were used as a control.
Temperature 20.1 – 21.5°C
pH 7.9 – 8.8

RESULTS

Nominal Test Concentration		Total Cell Count at 72 hours
mg/L		X 10^4
Control	Replicate A	42
	Replicate B	56
	Replicate C	29
	Replicate D	42
	Replicate E	36
	Replicate F	28
0.065	Replicate A	28
	Replicate B	34
	Replicate C	27
0.108	Replicate A	0
	Replicate B	0.6
	Replicate C	0.2
0.180	Replicate A	0
	Replicate B	0
	Replicate C	0
0.300	Replicate A	0
	Replicate B	0
	Replicate C	0
0.500	Replicate A	0
	Replicate B	0
	Replicate C	0

EC50: 0.080 mg/L at 72 hours (0.073 – 0.085 at 95% confidence limits)
NOEC Growth: 0.065 mg/L at 72 hours
LOEC: 0.108 mg/L at 72 hours
Remarks - Results: The 72 hour EC50 for dichlorophenol was 1.46 mg/L, this was within the expected range for *Skeletonema costatum*

CONCLUSION: The test substance is highly toxic to *Skeletonema costatum*

TEST FACILITY: Asci Corporation (2005b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

It is expected that the vast majority of the chemical in its hydrocarbon based carrier will be used for its intended use as a pipeline chemical especially in the oil and gas industry. It is expected that 60% of the chemical used in this manner will be released directly to the marine environment, with the remaining 40% being retained in the oil phase. During oil production, 4611 m^3 per day of production water will be disposed of via the overboard line based on current use patterns. Assuming that 7.6 tonnes will be disposed of per annum with 365 working days, then the concentration of the notified chemical will be 4.53 mg/L at the overboard line. According to the CHARM model the dilution at 500 m is approximately 1000 and therefore the predicted environmental concentration (PEC) at 500 m from the discharge line will be up to 4.53 µg/L in the aqueous compartment of the marine environment. At distances closer to the discharge line the PEC will approach the value of the concentration at the discharge line. The concentration of the notified chemical will be mitigated to some extent by adsorption of the notified chemical to dissolved organic carbon (DOC) with subsequent deposition as sediment. However, as the concentration of DOC is low, this process is likely to be slow. Due to the continuous nature of the discharge of the notified chemical it is likely that the concentration will approach the aqueous PEC of 4.53 µg/L, in spite of mitigation by adsorption to DOC.

As indicated previously the notified chemical is expected to bind to the DOC and be deposited as sediment. The binding is expected to be strong as the notified chemical has a high Kow value, which is likely to result in a high Koc value. For this scenario the PEC in the sediments can be calculated from the steady state reached for sediments within a 500 m radius of the overboard line. The daily disposal rate will be up to 20.8 kg. The chemical will also decompose. From the biodegradability data, the slope of the natural log of the amount chemical remaining versus time in days gives a rate constant of -0.02124 day $^{-1}$ with $t_{1/2}$ of approximately 33 days. Assuming a steady state, the amount of chemical may be calculated as Amount = K_1/K_2 where K_1 is the rate of introduction and K_2 is the rate of decomposition. A value of 980 kg is therefore derived. In accordance with the CHARM model it is assumed that the greatest effect of the chemical will occur within 500 m from the discharge line. The total volume of sediment affected is $\pi r^2 d$. If the depth (d) is taken to be 5 cm, the resulting amount of sediment is 39 270 m^3. If the density is approximately 1.2 g/cm^3 (default value) then this results in 47 100 tonnes. The resulting PEC for the benthic system is 20.8 mg/kg of sediment.

During manufacture of EC1477A and FX 2363, approximately 1.2 kg will be released to Malabar Sewage Treatment Plant. Assuming a worst case scenario where no adsorption to sludge occurs then the PEC is calculated from the release from Malabar being 290 ML per day over 260 days in which the chemical is released The resulting PEC at outfall is 0.02 µg/L. The quantities adsorbed to sludge are likely to bio degrade to oxides of nitrogen and carbon; and water vapour.

Any remaining chemical in petrol or distillate is likely to be completely combusted with the fuel.

9.1.2. Environment – effects assessment

The results of the aquatic toxicity tests for the notified chemical are listed below. As alga showed the highest toxic effect for the three trophic levels, the EC50 of 0.080 mg/L acute effects on alga based on the notified chemical will be used as the toxicological endpoint.

Aquatic Organism	Duration	End Point	Toxicity mg/L
Fish	96 hours	LC50	3.4
Arcatia Tonsa	48 hours	LC50	1.2
Ceriodaphnia	7 days	IC25	0.648
Algae	72 hours	EC50	0.080
Benthic Organisms			

Corophium sp	10 Days	LC50	1376 mg/kg

A predicted no effect concentration (PNEC - aquatic ecosystems) of 1.6 µg/L has been derived by dividing the alga end point of 0.080 mg/L by an uncertainty (safety) factor of 50 (as toxicity data are available for three trophic levels and chronic data are available for daphnia.)

A predicted no effect concentration (PNEC – benthic systems) of 13.8 mg/L has been derived by dividing the *Corophium* end point of 1376 mg/kg by an uncertainty (safety) factor of 100. The safety factor reflects that a single semi – chronic test has been performed on a single benthic species and four tests have been performed on aquatic organisms.

9.1.3. Environment – risk characterisation

For the marine aquatic environment the risk quotient (RQ) is calculated as the PEC/PNEC which will be up to 2.83 based on the current usage patterns. Assuming that only one Floating Production Storage and Offloading facility (FPSO) will use the chemical this will pose potential risk to the aquatic marine environment. Based on current use patterns the total amount of chemical should not exceed 4.4 tonnes of chemical used as EC1118A for the RQ to fall to below 1.

For the marine benthic systems the RQ is calculated as the PEC/PNEC which will be up to 1.51 based on the current usage patterns. Assuming that only one FPSO will use the chemical this will pose potential risk to the benthic marine environment. However, as the RQ is lower than that for the aquatic marine environment for the same operation, the limits on the amount of chemical used should be based on the environmental compartment showing the highest risk, namely the aquatic environment.

At the ocean outfall from Malabar the RQ is calculated as 0.01. The discharge of waste at the Botany plant therefore does not pose an unacceptable risk to the marine environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified chemical is imported as a component of a products at a concentration of up to 20%. Exposure during transport and storage would only occur through accidental breaching of the transport containers containing products in which the notified polymer is a component.

Processes involving the notified chemical are largely automated/enclosed which will limit exposure to the notified chemical. However dermal and accidental ocular exposure to the notified chemical (< 20%) could occur during repacking, manufacture, quality control, testing of dose lines and connection and disconnection of dose lines at oil and gas production sites. The use of PPE such as gloves, coveralls, safety eye protection will mitigate exposure to the notified chemical.

Negligible exposure to petrol station workers is expected due to the low predicted concentration of the notified chemical in the fuel (0.0004%) which is expected to be further reduced during fuel refining activities. No exposure is expected during downstream processing/use of gas.

9.2.2. Public health – exposure assessment

The notified chemical is for industrial use only. Public exposure to the products containing the notified chemical is only anticipated in the event of a spill during transport and storage through accidental breaching of the transport containers containing the notified chemical. No public exposure is expected through the use of the chemical in gas production. Negligible exposure to public is expected as a result of fuel handling due to the low predicted concentration of the notified chemical in the fuel (0.0004%) which is expected to be further reduced during fuel refining activities.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified chemical is of low acute toxicity by the oral route. A structurally related chemical is of low dermal toxicity by the oral route. Although these results indicate that low dermal toxicity for the notified chemical harmful effects cannot be ruled out. Acute inhalation toxicity has not been established but this is not considered to be a relevant route of exposure.

Irritation and Sensitisation.
In a skin irritation study the notified chemical was severely irritating with some evidence of corrosive effects. Irritation effects diminished with reduced exposure times with only slight irritation effects observed following 3 minute exposure.

A structurally related chemical was severely irritating to the eye and based on this and the effects observed in the skin irritation study it is considered that the notified chemical would also be severely irritating to the eye. No skin sensitisation study was conducted due to the corrosive effects observed in the skin irritation study. The notified chemical is part of a chemical category which has been shown to have sensitisation effects and as such sensitisation cannot be ruled out for the notified chemical.

Repeated Dose Toxicity
Repeat dose toxicity studies were provided for two structurally related chemicals. For one no NOAEL could be established but lethal effects were observed following 5 day repeat exposure to 700 mg/kg bw/day. A NOAEL of 94.1 mg/kg bw/day was established for the other chemical in a 91-day study based on the urinary bladder calculus and potential adverse effects in the liver observed at 939 mg/kg bw/day in the males. It is not possible to establish a NOAEL for the notified chemical based on this information.

Mutagenicity.
A structurally related chemical was negative in both an Ames test and an *in vitro* chromosome aberration test. Another structurally related chemical was negative in an *in vitro* chromosome aberration test. Based on this information it is considered that the notified chemical would not be mutagenic.

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) and assigned the following risk phrases

C R34 Causes burns
R41 Risk of serious damage to eyes (The risk of severe damage to eyes is considered implicit and the risk phrase R41 is not included on the label).

On the basis of the skin sensitising potential of a structurally related chemicals the notified chemical is classified as R43 (May cause sensitisation by skin contact) as a precautionary measure.

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is severely irritating/corrosive to skin, severely irritating to eyes and has the potential to cause skin sensitisation. These effects may be diminished by the concentration at which it is introduced (20%) although this is not below the cut off concentration for these classifications. Irritation effects in the skin have been shown to be diminished with reduced exposure time (< 1hour).

As contact with the notified chemical cannot be ruled out, there is considered to be a moderate risk to workers involved in repacking, manufacture and quality control of formulations containing the notified chemical, salespersons during the testing of dose lines and oil and gas production workers involved in the connection and disconnection of transfer lines. The risk of corrosive/irritant and potential sensitisation effects would be mitigated by the largely automated processes involved and the use of PPE to limit skin and eye contact. The risk would also be

reduced by reducing skin and eye contact time in the event that contact occurs.

No NOAEL could be established for the notified chemical however the control measures implemented to reduce exposure due to the corrosive nature of the notified chemical would also reduce the risk of adverse systemic effects.

9.2.5. Public health – risk characterisation

Although the notified chemical is hazardous, negligible public exposure to the notified chemical is expected and hence the risk to the public is expected to be low.

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:

C R34 Causes burns
R41 Risk of serious damage to eyes (The risk of severe damage to eyes is considered implicit and the risk phrase R41 is not included on the label).

On the basis of the skin sensitising potential of structurally related chemicals the notified chemical is classified as R43 (May cause sensitisation by skin contact) as a precautionary measure.

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*
Skin corrosion/irritation	1	Causes severe skin burns and eye damage
Serious eye damage	1	Causes serious eye damage
Chronic hazards to the aquatic environment	2	Toxic to aquatic life with long lasting effects.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical may pose a risk to the environment based on the notified use pattern. The following further actions should be considered:

- Limiting the use of the notified chemical in EC1118A to 4.4 tonnes at any FPSO or other oil production facility with direct ocean discharge; and
- FX2363 and EC1477A being water based products should not be used in any applications where there is direct ocean discharge.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Moderate Concern to occupational health and safety due to the corrosive potential of the notified chemical. This concern is mitigated by the largely automated processes described

and the use of PPE to limit skin and eye contact.

10.3.2. Public health

There is No Significant 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 products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are 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 products containing the notified chemical provided by the notifier were 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:
  - R34 Causes burns
  - R41 Risk of serious damage to eyes (The risk of severe damage to eyes is considered implicit and the risk phrase R41 is not included on the label).

- On the basis of the skin sensitising potential of structurally related chemicals, the notifier should also give the notified chemical the following additional health hazard classification:
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - conc≥5%: R34; R43
  - 1%≤conc<5%: R36/37/38; R43
  - 0.5%≤conc<1%: R36/37/38

- The notified chemical should be classified as follows under the ADG Code:
  - Class 8 Corrosive substances

Health Surveillance

- As the notified polymer is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Use of automated processes where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin and eye contact
  - /in case of contact with eyes, rinse immediately with plenty of water
  - After contact with skin, wash immediately.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Coveralls
  - Impervious gloves
  - Eye protection

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

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

- If products and mixtures containing 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.

Disposal

- The notified chemical should be disposed of by licensed hazardous waste treatment.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment such as diking using adsorbent material (diatomaceous earth sand etc.). Prevent entry of the chemical into waterways. Reclaim as far as practicable, and then soak up residue with adsorbent material for 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(1) of the Act; if
  - Greater than 4.4 tonnes of the notified chemical in EC1118A is used at any FPSO or other oil production facility with direct ocean discharge; and
  - FX2363 and EC1477A are used in any FPSO or oil production facility where there is direct ocean discharge.

or

(2) 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.

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